#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

AMENDMENT NO. 1 TO FORM F-1 **REGISTRATION STATEMENT** UNDER THE SECURITIES ACT OF 1933

#### **GH Research PLC**

(Exact Name of Registrant as Specified in Its Charter)

Ireland

(State or Other Jurisdiction of Incorporation or Organization)

Davis Polk

New York.

2834

Not applicable

(I.R.S. Employer Identification Number)

(Primary Standard Industrial Classification Code Number) **GH Research PLC** 28 Baggot Street Lower Dublin 2

D02 NX43 Ireland Tel: +353 1 437 8443

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Cogency Global Inc. 122 East 42nd Street, 18th Floor

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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $\Box$ 

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company.

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act.  $\Box$ 

#### CALCULATION OF REGISTRATION FEE

Title Of Each Class Of Securities To Be Registered	Amount to be Registered <sup>(1)</sup>	Proposed Maximum Offering Price Per Share <sup>(2)</sup>	Proposed Maximum Aggregate Offering Price <sup>(1)(2)</sup>	Amount Of Registration Fee <sup>(3)</sup>
Ordinary shares, nominal value \$0.025 per share	9,583,333	\$16.00	\$153,333,328	\$16,728.67

(1) Includes ordinary shares that the underwriters may purchase pursuant to the option to purchase additional shares, if any, See "Underwriting."

(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.

(3) \$10,910 of such fee was previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), shall determine

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

#### SUBJECT TO COMPLETION, DATED JUNE 21, 2021

#### 8,333,333 Ordinary Shares



This is an initial public offering of 8,333,333 ordinary shares of GH Research PLC, nominal value \$0.025 per ordinary share. Prior to this offering, there has been no public market for our ordinary shares.

We have applied to list our ordinary shares on the Nasdaq Global Market, or Nasdaq, under the symbol "GHRS." We expect that the initial public offering price will be between \$14.00 and \$16.00 per share.

We are an "emerging growth company" under the applicable Securities and Exchange Commission rules and have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Our business and investment in our ordinary shares involve significant risks. These risks are described under the caption "Risk Factors" beginning on page  $\underline{13}$  of this prospectus.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds, before expenses to GH Research PLC	\$	\$

(1) See the section titled "Underwriting" for additional information regarding compensation payable to the underwriters. We have agreed to reimburse the underwriters for certain expenses in connection with the offering.

We have granted the underwriters an option for a period of 30 days to purchase up to 1,250,000 additional ordinary shares from us at the public offering price, less the underwriting discounts and commissions.

The underwriters expect to deliver the ordinary shares against payment in New York, New York on 2021.

#### Cowen

Stifel

**Canaccord Genuity** 

**JMP Securities** 

Prospectus dated , 2021

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No dealer, salesperson or other person is authorized to give any information or to represent as to anything not contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell, and we are seeking offers to buy, only the ordinary shares offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date, regardless of the time of delivery of this prospectus or any sale of the ordinary shares.

Neither we nor the underwriters have done anything that would permit this offering or the possession or distribution of this prospectus or any filed free writing prospectus in any jurisdiction where other action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus or any free writing prospectus filed with the U.S. Securities and Exchange Commission, or SEC, must inform themselves about, and observe any restrictions relating to, the offering of the ordinary shares and the distribution of this prospectus or any filed free writing prospectus or any filed free writing prospectus or any filed free writing to,

Until , 2021 (the 25th day after the date of this prospectus), all dealers that buy, sell or trade ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

This prospectus is not a prospectus for the purposes of the Irish Companies Act 2014, the European Union (Prospectus) Regulations 2019 of Ireland (as amended) or the Prospectus Rules issued by the Central Bank of Ireland and the Central Bank of Ireland has not approved this prospectus.

#### ABOUT THIS PROSPECTUS

Prior to the completion of this offering, we will undertake a corporate reorganization described under the section titled "Corporate Reorganization and Share Consolidation," whereby, (i) pursuant to the terms of a share for share exchange agreement dated May 27, 2021, all shareholders of GH Research Ireland Limited exchanged each of the shares held by them for ordinary shares of GH Research PLC of the same share classes with the same shareholder rights as the shares held by them in GH Research Ireland Limited and, as a result, GH Research Ireland Limited became a wholly owned subsidiary of GH Research PLC, which we refer to as our Corporate Reorganization, and (ii) immediately and conditional upon the SEC declaring this registration statement effective, (a) all of our outstanding preferred shares will be converted on a one to one basis and when aggregated with the existing ordinary shares there will be 101,302,126 issued ordinary shares and (b) we will undertake a 2.50-for-one share consolidation of all of our ordinary shares of nominal value \$0.01 each into ordinary shares of nominal value \$0.025 each, which we refer to as our Share Consolidation.

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms "the company," "we", "us" and "our" refer to (i) GH Research Ireland Limited prior to the completion of our Corporate Reorganization (as defined herein) and (ii) GH Research PLC (and, where the context requires, its subsidiary) following the completion of the Corporate Reorganization.

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#### PRESENTATION OF FINANCIAL AND OTHER INFORMATION

#### **Financial Statements**

We maintain our books and records in euro, our results are subsequently converted to U.S. dollars and we prepare our financial statements in accordance with generally accepted accounting principles in the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. The terms "dollar," "USD" or "\$" refer to U.S. dollars and all references to "€" are to Euro.

We have historically conducted our business through GH Research Ireland Limited, and therefore our historical financial statements present the results of operations of GH Research Ireland Limited. Following the completion of this offering, and after the completion of the transactions described under the section titled "Corporate Reorganization and Share Consolidation," our financial statements will be prepared on a consolidated basis and will present the consolidated results of operations of GH Research PLC and its subsidiary GH Research Ireland Limited.

This financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

#### Market and Industry Data

This prospectus contains industry, market and competitive position data that are based on general and industry publications, surveys and studies conducted by third parties, some of which may not be publicly available, and our own internal estimates and research. Third-party publications, surveys and studies generally state that they have obtained information from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. These data involve a number of assumptions and limitations and contain projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions or estimates.

#### Rounding

We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

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#### **PROSPECTUS SUMMARY**

This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our ordinary shares, you should carefully read this entire prospectus, including our financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described in the sections entitled "Risk Factors," "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case appearing elsewhere in this prospectus.

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms "the Company," "we", "us" and "our" refer to (i) GH Research Ireland Limited prior to the completion of the share exchange as part of our Corporate Reorganization (as defined herein) and (ii) GH Research PLC (and, where the context requires, its subsidiary) following the completion of the Corporate Reorganization. See "Corporate Reorganization and Share Consolidation" for more information.

#### Overview

We are a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. Our initial focus is on developing our novel and proprietary 5-Methoxy-N,N-Dimethyltryptamine, or 5-MeO-DMT, therapies for the treatment of patients with Treatment-Resistant Depression, or TRD. Our portfolio currently includes GH001, our proprietary inhalable 5-MeO-DMT product candidate which is delivered via a vaporization device produced by a third party, and GH002, our proprietary injectable 5-MeO-DMT product candidate. We have completed a Phase 1 healthy volunteer clinical trial, in which administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in an individualized dosing regimen with intra-subject dose escalation within a single day. GH001 is currently being investigated in the Phase 2 part of an ongoing Phase 1/2 clinical trial in patients with TRD. Based on observed clinical activity, we believe that administration of a single dose of GH001 has the potential to induce ultra-rapid remissions as measured by the Montgomery-Asberg Depression Rating Scale, or MADRS, in certain patients, driven by the ultrarapid onset of psychoactive effects (commonly within seconds) and an intense and short-lived (commonly five to 30 minutes) initial psychoactive experience. The goal of the ongoing Phase 2 part of the trial is to assess whether an individualized dosing regimen with intra-subject dose escalation within a single day can further increase the MADRS remission rate as compared to a single GH001 dose.

#### **Our Pipeline**

We are developing our 5-MeO-DMT product candidates, GH001 and GH002, in our focus area of psychiatric and neurological disorders. Our lead program, GH001, is currently in the Phase 2 part of an ongoing Phase 1/2 clinical trial in patients with TRD. In light of our completed Phase 1 clinical trial of GH001 in healthy volunteers, we plan to request clearance from European regulatory authorities to begin two additional Phase 2 clinical trials in patients with psychiatric or neurological disorders.

#### **Our Market Opportunity**

Patients with Major Depressive Disorder, or MDD, who have not adequately responded to adequate therapy clearly have harder-to-treat depression, generally referred to as TRD. There is no consensus definition for TRD, but in the context of clinical trials, failure of at least one pharmacotherapy, one pharmacotherapy and one psychotherapy, or two pharmacotherapies have been used, the latter having been referred to by regulatory authorities as patients with TRD. The Sequenced Treatment Alternatives to Relieve Depression, or STAR\*D study, a collaborative study funded by the U.S. National Institute of Mental Health, demonstrated that approximately 37% of patients with MDD did not achieve a response despite two treatment steps. Based on this result and based on an estimated number of approximately 48 million MDD patients in the United States and Europe according to the National Institute of Mental Health, about 50% receive treatment with pharmacotherapy or pharmacotherapy and psychotherapy, we estimate that there are approximately nine million TRD patients in the United States and Europe according to the National Institute of Mental Health, about 50% receive treatment with pharmacotherapy or pharmacotherapy and psychotherapy, we estimate that there are approximately nine million TRD patients in the United States and Europe according to the Mental Health and provide the States and Europe according to the National Institute of Mental Health, about 50% receive treatment with pharmacotherapy or pharmacotherapy and psychotherapy, we estimate that there are approximately nine million TRD patients in the United States and Europe according to the Mental Health and provide the States and Europe who would be candidates for treatment.

#### 5-MeO-DMT Mechanism of Action in Psychiatric and Neurological Disorders

5-MeO-DMT is a serotonergic psychedelic, a class of psychoactive drugs that act primarily through an agonist action on serotonin receptors and cause an altered state of consciousness. *In vivo* and *in vitro* research from academic studies suggest that 5-MeO-DMT acts primarily as a serotonin agonist, active at both the 5-HT1A and 5-HT2A receptors, which are expressed in neurons in different areas of the central nervous system. 5-MeO-DMT appears to have a higher affinity for the 5-HT1A receptor subtype and a more selective pattern of distribution across various neurotransmitter receptor types compared to other tryptamines, such as psilocin and N,N-Dimethyltryptamine, or DMT, both of which have stronger affinity for the 5-HT2A receptor subtype and a less selective receptor binding profile.

Further academic research suggests that 5-MeO-DMT may also act as regulator of inflammation and immune homeostasis through the sigma-1 receptor, and that it may affect structural neuroplasticity, meaning that it may induce proliferation, survivability and accelerate maturation of specific neurons in the brain. Such mechanisms have the potential to address some of the hypothesized root causes of depression, including reduced neural connectivity and a proinflammatory state. However, it is not known whether these mechanisms have any clinical relevance in the context of single day administration of 5-MeO-DMT as tested in the current development program.

We believe that the intensity of the acute psychoactive effects after administration of 5-MeO-DMT may correlate with short- and long-term clinical improvement across various psychiatric and neurological disorders. Such a correlation has been shown for other serotonergic psychedelics in various academic studies. We have defined an intense psychoactive effect as a Peak Experience, or PE. We assess the occurrence of PEs using a proprietary visual analogue scale, or PE scale, which averages answers scored by the patient from 0 to 100 for three parameters of the experience: intensity, feelings of loss of control and profoundness. A PE is determined to have been achieved if the patient's average score across these three parameters is at least 75 on this scale. We use the occurrence or non-occurrence of a PE for dose selection of our product candidates in our individualized dosing regimen.

We believe that the mechanism of action of our product candidates, as well as the correlation between the intensity of the psychoactive effects and therapeutic outcomes, can be explained by recent observations regarding human brain functional connectivity, or FC, via so-called resting-state networks, or RSNs. These RSNs have been shown in academic studies to be responsible for various aspects of complex cognitive function, and it has been found that patients with mental disorders can have disturbed RSN connectivity. It has further been found that the administration of serotonergic psychedelics can lead to decreased connectivity within those RSNs. In addition, depending on the intensity of the short-term psychoactive effects, an increased reorganization of RSN activity can be observed following the experience, and we believe this reorganization could correlate with treatment response.

We believe that administration of our product candidates has the potential to result in:

- acute decreased functional connectivity within the relevant RSNs;
- subsequent reintegration and resumption of normal functional connectivity, or a "re-set", of the relevant RSNs; and
- resolution of depressive thought patterns and improvement in other symptoms of mental disorders.

We believe that the occurrence of PEs as assessed by our proprietary PE scale is predictive of the "re-set" and may be indicative of therapeutic activity. Our lead product candidate, GH001, is designed to produce an ultra-rapid onset of psychoactive effects (commonly within seconds) and an intense and short-lived (commonly five to 30 minutes) initial psychoactive experience. Although the initial psychoactive effects are short-lived, we believe the ensuing "re-set" of normal functional connectivity has the potential to create durable therapeutic benefits. Our approach of quantifying PEs allows for a simple assessment of psychoactive effects, and our PE-guided individualized dosing regimen aims to optimize the therapeutic outcome. GH002 and potential additional products candidates will follow a similar treatment paradigm.



#### Our 5-MeO-DMT Therapies: GH001 and GH002

We believe that GH001 has a high propensity to induce PEs. This is important because we believe that the occurrence of PEs may be correlated with rapid induction of durable remission in patients with TRD, and thereby we believe may potentially act as a marker for therapeutic effects.

We believe that there is no clinically relevant tolerance development to 5-MeO-DMT when the drug is re-administered within hours, or in other words, no diminished psychoactive effects. Together with the ultra-rapid onset and short duration of psychoactive effects, this aspect allows re-administration of GH001 in an individualized dosing regimen where GH001 can be administered several times within one day. We are currently investigating whether this individualized dosing regimen can increase the rate of occurrence of PEs in patients with TRD compared with administration of a single dose and whether this results in an increased rate of ultra-rapid remission, while at the same time avoiding unnecessarily high doses. We believe that treatment optimization within the same day is important, not only because of the direct patient benefit, but also because patients with insufficient response can be identified early, without the need for lengthy trial-and-error approaches, during which time the patient is often exposed to potential side effects of ineffective treatments.

We believe that the ultra-rapid onset and short duration of psychoactive effects may confer a significant convenience and feasibility advantage compared to other serotonergic psychoactive agents studied for the treatment of mental disorders, where the initial psychoactive effects have a slower onset and can last for several hours. We further believe that those features and the type of psychoactive effects induced by GH001 allow for dosing without the need for lengthy and complex patient preparation prior to treatment, with only limited required support from a healthcare provider during the experience and without the need for frequent psychological integration work after the experience. This reduces training requirements for healthcare providers and creates a convenient and efficient potential therapeutic paradigm overall.

We have completed a Phase 1 clinical trial with seven days of follow-up of GH001 in healthy volunteers, where administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in an individualized dosing regimen with intra-subject dose escalation within a single day. We are currently conducting a Phase 1/2 clinical trial with seven days of follow-up of GH001 in patients with TRD, who in their current depressive episode have failed at least two adequate courses of pharmacological therapy or one adequate course of pharmacological therapy and at least one adequate course of evidence-based psychotherapy, as assessed by the Antidepressant Treatment History Form – Short Form, or ATHF-SF. The trial is designed in two parts: a completed Part A (n=8), which is an open-label, single-arm, single-dose Phase 1 trial with two dose levels (12 mg, 18 mg) of GH001 being investigated and an ongoing Part B (n=8), which is an open-label, single-arm phase 2 trial applying our individualized dosing regimen with intra-patient dose escalation with GH001. In Part B, patients will receive at least one and up to three doses of GH001 in a single day; the three dose steps applied are 6 mg, 12 mg and 18 mg. The administration of a higher dose level will be guided by an evaluation of whether the patient achieves a PE at the previously administered dose. Patients of 18 to 64 years of age (inclusive) will be enrolled in the trial.

The primary endpoint of the Phase 1 Part A is to assess the safety and tolerability of single dosing of GH001 in patients with TRD. The primary endpoint of the Phase 2 Part B is to assess the effects on the severity of depression, as assessed by the proportion of patients in remission on day seven after dosing, defined as a MADRS total score of less than or equal to 10. The MADRS is a widely accepted scale for depression that ranges from zero to 60 that has been used as a primary endpoint in pivotal trials of other depression treatments. Participants are monitored on the dosing day, with additional follow-up visits on day one and on day seven after dosing. A study safety group, or SSG, which included external experts, was established to evaluate the safety and efficacy data from all patients after completion of each dose level of Part A and after the completion of Part B.

We completed patient dosing of GH001 in the Phase 1 Part A of the trial; the Phase 2 Part B is ongoing.

Eight patients were recruited into Part A. The median age was 29 years. The median baseline severity of depression by MADRS was 33. Four patients received 12 mg and four patients received 18 mg of GH001.

All patients completed all planned visits. No serious adverse events, or SAEs, were reported. 3 of 4 patients (75%) in the 12 mg group and 3 of 4 patients (75%) in the 18 mg group experienced at least one Adverse Drug Reaction, or ADR. All ADRs were mild and resolved spontaneously. The ADRs reported were: headache (3 patients), feeling abnormal, flashback (each in 2 patients), dizziness and muscle spasms (each in 1 patient). Based on the available data from Part A, the SSG concluded that, in Part A, no unexpected or severe adverse effects and no clinically significant changes were observed in any of the safety laboratory analyses, vital signs, psychiatric safety assessments or measures of cognitive function.

As a secondary objective in Part A, we also evaluated clinical activity, including MADRS remission, defined as a MADRS total score of less than or equal to 10, and MADRS clinical response, defined as a reduction of 50% or more from baseline in the MADRS total score. Two patients in the 12 mg group and one patient in the 18 mg group of Part A had a MADRS remission on day seven after dosing, as well as a MADRS clinical response, and one further patient in the 18 mg group had a MADRS clinical response on day seven after dosing. The other four patients also exhibited improvement on the basis of the MADRS scale on day seven compared to baseline, but did not achieve a MADRS remission or MADRS clinical response. The mean MADRS reduction at day seven was 65% in the 12 mg group and 41% in the 18 mg group. The mean PE total score was 58.2 in the 12 mg group and 59.1 in the 18 mg group. Two of four patients achieved a PE in the 12 mg group, both of which achieved a MADRS remission.

The ongoing Phase 2 Part B of this clinical trial will include the potential for up to three doses of GH001 on the same administration day, in the event a PE was not met with the initial or second dose. The goal of this individualized dosing regimen is to increase the rate of occurrence of PEs and the clinical remission rate compared to a single GH001 dose in patients with TRD.

To date, our clinical trials have been conducted in the Netherlands. With regard to planned regulatory interactions, we intend to request a pre-Investigational New Drug application, or pre-IND, meeting with the U.S. Food and Drug Administration, or the FDA, and a Scientific Advice meeting with the European Medicines Agency, or the EMA. We intend to discuss the adequacy of the following:

- the data from our completed clinical trial in healthy volunteers and ongoing clinical trial in patients with TRD;
- the design of our planned Phase 2b trial of GH001 in TRD;
- the current status and plans for our nonclinical studies;
- the current status and plans for the pharmaceutical manufacturing of our active pharmaceutical ingredient, or API, and GH001 drug product;
- the current status and plans for the device required to administer GH001; and
- any additional topics as requested by the regulatory agencies.

We plan to conduct the following trials with GH001:

- A multi-center, randomized, controlled Phase 2b trial evaluating safety and efficacy in TRD patients, including a long-term, open-label follow-up study;
- Phase 2a trials evaluating safety and efficacy in two or more additional psychiatric or neurological disorders; and
- A clinical pharmacology trial in healthy volunteers, designed to further elucidate the pharmacokinetic profile of GH001.

The outcomes of these trials will help inform our future clinical development plans and shape the most efficient path to market for GH001. Subject to completing clinical development, we plan to seek regulatory approval of GH001 in both the United States and Europe.

Given GH001's proposed mechanisms of resetting functional connectivity and serotonergic agonism, we believe that it represents a compelling therapeutic option for multiple psychiatric and neurological disorders other than TRD. Through collaborations with academic institutions and commercial contract research organizations, or CROs, we intend to explore the benefits of GH001 in additional psychiatric or neurological indications. We plan to initiate proof-of-concept Phase 2a trials in two or more psychiatric or neurological disorders.

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. We believe GH002 has the potential to be an attractive therapeutic option, e.g., in patients with underlying airway or pulmonary disease or in situations where it is difficult to assure that the GH001 inhalation is performed adequately, such as in acute psychiatric emergency care situations where a patient may be unable to use an inhalation device. GH002 is currently in preclinical development and we anticipate developing GH002 in indications within our focus area of psychiatric and neurological disorders.

#### **Our Strategy**

Our mission is to develop novel proprietary 5-MeO-DMT therapies to induce ultra-rapid and durable remissions in patients with psychiatric and neurological disorders. In order to achieve this mission, key elements of our strategy include:

- advancing GH001, our inhalable 5-MeO-DMT product candidate, for the treatment of TRD through clinical development, regulatory approval and commercialization, if approved;
- advancing GH001 into clinical development in additional psychiatric and neurological disorders beyond TRD;
- advancing GH002, our injectable 5-MeO-DMT product candidate, into clinical development;
- investigating additional delivery systems and additional routes of administration for 5-MeO-DMT;
- expanding our intellectual property portfolio around 5-MeO-DMT; and
- maximizing the value of our product portfolio by building internal commercialization infrastructure and entering selective partnerships.

#### **Corporate Information**

GH Research PLC was incorporated as a public limited company under the laws of Ireland on March 29, 2021 to become a holding company for GH Research Ireland Limited. GH Research Ireland Limited was originally incorporated under the laws of Ireland on October 16, 2018 as GH Research Limited. GH Research Limited was re-registered as GH Research Ireland Limited on March 29, 2021. Our registered office is located at 28 Baggot Street Lower, Dublin 2, D02 NX43, Ireland, and our telephone number is + 353 1 437 8443. Our website address is www.ghres.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

#### **Corporate Reorganization and Share Consolidation**

Pursuant to the terms of a share for share exchange agreement dated May 27, 2021, all shareholders of GH Research Ireland Limited exchanged each of the shares held by them for ordinary shares of GH Research PLC of the same share classes with the same shareholder rights as the shares held by them in GH Research Ireland Limited and, as a result, GH Research Ireland Limited became a wholly owned subsidiary of GH Research PLC. In addition, we will undertake a 2.50-for-one share consolidation of all of our ordinary shares of nominal value \$0.01 each into ordinary shares of nominal value \$0.025 each, which shall take effect immediately upon the SEC declaring this registration statement effective. Please see "Corporate Reorganization and Share Consolidation" beginning on page <u>103</u> for more information.



#### **Recent Developments**

On April 8, 2021, we entered into a subscription agreement, pursuant to which we sold 25,379,047 of our Series B preferred shares (which will be redesignated into 10,151,618 ordinary shares prior to the closing of this offering) to certain investors for a total of \$125.2 million in gross proceeds (before deducting offering expenses of \$6.4 million), which we refer to as the Series B Financing. See "Related Party Transactions." As of March 31, 2021, after giving pro forma effect to the Series B Financing and our receipt of the net proceeds in the amount of \$118.8 million therefrom, we had cash of \$123.4 million.

#### **Risk Factors**

Our business is subject to a number of risks of which you should be aware before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth in the section titled "Risk Factors" before deciding whether to invest in our ordinary shares. Among these important risks are, but not limited to, the following:

- We are a clinical-stage biopharmaceutical company and we have incurred significant losses since our inception. We expect that we will continue to incur significant losses for the foreseeable future;
- We will need substantial additional funding, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts;
- Drug and drug-device combination product development is a highly uncertain undertaking and involves a substantial degree of risk;
- GH001 and GH002 are investigational 5-MeO-DMT therapies based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. To our knowledge, no such therapies have been approved in the United States nor the European Union for commercialization;
- Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome. The outcome of nonclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials, which to date have only been conducted in the Netherlands, may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities;
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following regulatory approval, if obtained;
- GH001 and GH002, and any future product candidates we may develop, are subject to controlled substance laws and regulations in the territories where the product will be marketed, such as the United States, the European Union, the United Kingdom and the rest of Europe, as well as the UN international drug control treaties, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post-approval, and our financial condition. In addition, during the review process of GH001 and GH002, and prior to approval, the FDA, EMA and/or other comparable foreign regulatory authorities may require additional data, including with respect to whether GH001 or GH002 has abuse potential. This may delay approval and any potential rescheduling process;
- 5-MeO-DMT is currently classified as a Schedule I drug in the United States and any product containing this substance, such as GH001 and GH002, must be rescheduled to be marketed. There can be no assurance that the Drug Enforcement Administration, or DEA will make a favorable scheduling decision. Even assuming categorization as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V) at the federal level, such substances would also require scheduling determinations under state laws and regulations;
- The potential reclassification of 5-MeO-DMT in the United States could create additional regulatory burdens on our operations and negatively affect our results of operations;



- Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors and other members of the medical community;
- We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue;
- Our business and commercialization strategy depends on our ability to identify, qualify, prepare, certify, and support third-party clinics or treatment centers offering any of our product candidates, if approved. If we are unable to do so, our commercialization prospects would be limited and our business, financial condition, and results of operations would be harmed.
- We rely on applications for patents and other intellectual property rights to protect our GH001 and GH002 product candidates, the prosecution, enforcement, defense and maintenance of which may be challenging and costly. Failure to adequately prosecute, maintain, enforce or protect these rights could harm our ability to compete and impair our business;
- We rely on third parties to assist in conducting our nonclinical studies and clinical trials. If they do not perform satisfactorily, we may not be able to initiate new clinical trials, successfully complete clinical trials, obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed;
- The development and manufacture of our active pharmaceutical ingredients, product candidates and medical devices required to deliver such product candidates is complex, and we may encounter difficulties during further development or in production. We currently rely completely on third parties to develop, formulate and manufacture our nonclinical study and clinical trial supplies. The development and commercialization of any of our active pharmaceutical ingredients, product candidates and medical devices required to deliver such product candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of such drug supplies or fail to do so at acceptable quality levels, including in accordance with rigorously enforced regulatory requirements or contractual obligations, and our operations could be harmed as a result;
- A pandemic, epidemic or outbreak of an infectious disease in Ireland or worldwide may adversely affect our business;
- We depend heavily on our executive officers, principal consultants and others, and the loss of their services would materially harm our business; and
- We have identified material weaknesses in our internal control over financial reporting in connection with the audit of our financial statements for the years ended December 31, 2019 and 2020, and we may identify additional material weaknesses. If our remediation of these material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, our ability to accurately or timely report our financial condition or results of operations may be adversely affected.

#### Implications of Being an Emerging Growth Company and a Foreign Private Issuer

As a company with less than \$1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. An emerging growth company may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include, but are not limited to:

 an option to present only two years of audited financial statements in addition to any required interim financial statements and correspondingly specified reduced Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in this prospectus; and  an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. See "Management's Discussion and Analysis of Financial Condition and Results of Operations— Emerging Growth Company Status."

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earlier to occur of: (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.07 billion or more; (ii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three-year period; (iii) the date on which we are deemed to be a large accelerated filer under the rules of the SEC; or (iv) the last day of the fiscal year following the fifth anniversary of this offering. We may choose to take advantage of some but not all of these exemptions.

Upon the completion of the offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with "foreign private issuer" status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations with respect to a security registered under the Exchange Act;
- the requirement to comply with Regulation FD, which requires selective disclosure of material information;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer. As a result, we do not know whether some investors will find our ordinary shares less attractive, which may result in a less active trading market for our ordinary shares or more volatility in the price of our ordinary shares.

#### THE OFFERING

Ordinary shares offered by us	8,333,333 ordinary shares (or 9,583,333 ordinary shares if the underwriters exercise their over- allotment option in full).
Ordinary shares outstanding immediately after this offering	48,854,183 ordinary shares (or 50,104,183 ordinary shares if the underwriters exercise their over-allotment option in full).
Over-allotment option	We have granted to the underwriters an option, exercisable within 30 days from the date of this prospectus, to purchase up to an aggregate of 1,250,000 additional ordinary shares.
Use of proceeds	We estimate that the net proceeds to us from the offering will be approximately \$112.8 million, or \$129.7 million if the underwriters exercise their option to purchase additional ordinary shares in full, based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.
	We currently intend to use the net proceeds from this offering, together with our existing cash, as follows:
	<ul> <li>to fund clinical trials, and other activities to support the development of our product candidate GH001 through completion of all ongoing trials, the planned Phase 2a trials in at least two new indications and the planned multi-center, randomized, controlled Phase 2b trial in TRD;</li> </ul>
	<ul> <li>to fund clinical trials with our product candidate GH002 and one additional potential product candidate through completion of Phase 2a trials;</li> </ul>
	<ul> <li>to fund the technical development of our active pharmaceutical ingredients, product candidates, and the medical devices used for the administration of our product candidates, as well as the expansion of our external manufacturing capabilities, and to fund the nonclinical development activities related to our product candidates; and</li> </ul>
	<ul> <li>the remainder to fund general and administrative expenses, working capital and other general corporate purposes, including business development activities.</li> </ul>

	See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering.
Dividend policy	We do not anticipate paying any cash dividends in the foreseeable future. See "Dividend Policy" for more information.
Lock-Up Agreements	We, our officers and directors and substantially all of our existing shareholders have agreed with the underwriters not to sell, transfer or dispose of any ordinary shares or similar securities for a period of 180 days after the date of this prospectus, subject to certain exceptions. See "Shares Eligible for Future Sale" and "Underwriting."
Risk factors	See "Risk Factors" and other information included in this prospectus for a discussion of the risks relating to investing in our ordinary shares. You should carefully consider these risks before deciding to invest in our ordinary shares.
Listing	We have applied to have the ordinary shares listed on the Nasdaq Global Market. The ordinary shares will not be listed on any other stock exchange or traded on any automated quotation system.
Nasdaq Global Market Symbol	"GHRS"
Payment and Settlement	The underwriters expect to deliver the ordinary shares against payment therefor through the facilities of the Depositary Trust Company on , 2021.

Unless otherwise stated in this prospectus, the number of our ordinary shares outstanding after this offering is based on 40,520,850 shares outstanding as of March 31, 2021, after giving effect to the issuance of an aggregate of 10,151,618 shares in April 2021 pursuant to the Series B Financing (taking into account the Share Consolidation), and the Corporate Reorganization, and excludes:

- 1,202,734 ordinary shares that will be made available for future issuance under our Share Option Plan, which will become effective in connection with this offering; and
- 50,487 ordinary shares issuable upon the exercise of options to purchase our ordinary shares granted on June 4, 2021, with an exercise price of \$12.32 per share.

Unless otherwise indicated, all information contained in this prospectus also reflects and assumes:

- the valid adoption of our amended and restated constitution, or the Constitution, prior to the completion of this offering;
- the Share Consolidation to be effected immediately and conditional upon the SEC declaring this registration statement effective;
- an initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus;
- no exercise by the underwriters of their option to purchase up to 1,250,000 additional ordinary shares in this offering; and
- no exercise of outstanding options.

#### SUMMARY FINANCIAL DATA

The following summary financial data should be read in conjunction with "Selected Financial Data," "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus. The summary historical financial data for the years ended December 31, 2020 and 2019 and as of December 31, 2020 and 2019 are derived from our audited financial statements included elsewhere in this prospectus and, other than pro forma amounts do not reflect the Corporate Reorganization and the Share Consolidation to be effected immediately and conditional upon the SEC declaring this registration statement effective. We derived the summary historical financial data for the three months ended March 31, 2021 and 2020 and as of March 31, 2021 from the unaudited condensed interim financial statements included elsewhere in this prospectus, which have been prepared on the same basis as the audited financial statements and, other than pro forma amounts, do not reflect the Corporate Reorganization, and the Share Consolidation to be effected immediately and conditional upon the SEC declaring this registration statement effective. Our historical results are not necessarily indicative of the results that may be expected in the future and the results for the three months ended March 31, 2021 are not necessarily indicative of the results to be expected for the full year ending December 31, 2021 or any other interim period.

Our audited financial statements are prepared in accordance with IFRS and presented in U.S. dollars.

Our functional currency is the euro. For financial reporting purposes, our financial statements, which are prepared using the functional currency, have been translated into U.S. dollars. Our assets and liabilities are translated at the exchange rates at the balance sheet date, our revenue and expenses are translated at average exchange rates and shareholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net loss for the period but are included in foreign exchange translation adjustment to other comprehensive loss, a component of total equity.

	Three Months Ended March 31,				Year Ended December 31			
	2021			2020	2020		2019	
	(in USD thousands, except share and per share data)							
Income Statement Data:								
Operating Expenses:								
Research and development	\$	(692)	\$	(11)	\$	(338)	\$	(296)
General and administrative		(448)		<u>(8)</u>		(108)		(14)
Loss from operations		(1,140)		(19)		(446)		(310)
Foreign currency translation differences		(9)				_		_
Loss for the period	\$	(1,149)	\$	(19)	\$	(446)	\$	(310)
Basic and diluted loss per share		(0.015)		(0.000)		(0.006)		(0.004)
Weighted average number of shares outstanding - basic and diluted	75	,923,079	70,	000,000	70,	898,420	70	,000,000
Pro forma basic and diluted loss per share <sup>(1)</sup>		(0.038)		(0.001)		(0.016)		(0.011)
Pro forma weighted average ordinary shares outstanding - basic and diluted <sup>(1)</sup>	30	,369,232	28,	000,000	28,	359,368	28	,000,000

(1) Pro forma basic and diluted loss per share and pro forma weighted average ordinary shares outstanding - basic and diluted gives effect to (i) our Corporate Reorganization and (ii) the Share Consolidation as if such transactions had occurred on January 1, 2019.

		As of March 31, 2021			
	Actual	Pro Forma <sup>(1)</sup>	Pro Forma as Adjusted <sup>(2)</sup>		
		(in USD thousands)			
Balance Sheet Data:					
Cash	\$4,576	\$123,404	\$236,154		
Total assets	5,556	124,384	237,134		
Share capital	871	1,013	1,221		
Total equity	\$4,315	\$123,143	\$235,893		

<sup>(1)</sup> The pro forma information gives effect to (i) the consummation of the Series B Financing and our receipt of net proceeds therefrom, (ii) our Corporate Reorganization and (iii) our Share Consolidation.

(2) The pro forma as adjusted information gives further effect to the issuance and sale of 8,333,333 ordinary shares in this offering by us at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, as set forth under "Use of Proceeds." Each \$1.00 increase or decrease in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash, total assets and total equity by \$7.8 million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 1,000,000 in the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash, total assets and total equity by \$14.0 million, assuming the assumed initial public offering price per share remains the same, and after deducting estimated underwriting discounts and commissions.

#### **RISK FACTORS**

Investing in our ordinary shares involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this prospectus, including our financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our ordinary shares. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our ordinary shares could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of your investment. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business and the market price of our ordinary shares. Certain statements below are forward-looking statements. See the section titled "Cautionary Statement Regarding Forward-Looking Statements" appearing elsewhere in this prospectus.

#### Risks Related to Our Financial Position and Need for Additional Capital

## We are a clinical-stage biopharmaceutical company and we have incurred significant losses since our inception. We expect that we will continue to incur significant losses for the foreseeable future.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable. We have no products approved for commercial sale and have not generated any revenue to date, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Since our inception, we have devoted substantially all of our financial resources and efforts to research and development, including nonclinical studies and our clinical trials. Our financial condition and operating results, including net losses, may fluctuate significantly from guarter to guarter and year to year. Accordingly, you should not rely upon the results of any guarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' (deficit)/equity and working capital. Our net losses were \$1,149 thousand, \$446 thousand and \$310 thousand for the three months ended March 31, 2021 and the years ended December 31, 2020 and 2019, respectively. As of March 31, 2021, we had an accumulated deficit of \$2 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates in our initial and potential additional indications as well as for other product candidates.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials, including in expanded geographies such as the United States, for our GH001 and GH002 product candidates for our initial and potential additional indications;
- continue both the technical development and expansion of our external manufacturing capabilities for our current product candidates GH001 and GH002 and of the medical devices required to deliver these product candidates;
- initiate and continue research and development, including nonclinical, clinical, and discovery efforts for any future product candidates;
- seek to identify additional product candidates;
- seek regulatory approvals for our product candidates GH001 and GH002, including the medical devices required to deliver these product candidates, or any other product candidates that successfully complete clinical development;
- add operational, financial and management information systems and personnel, including
  personnel to support our product candidate and device development and help us comply with
  our obligations as a public company;



- hire and retain additional personnel, such as clinical, quality control, scientific, commercial and administrative personnel;
- continue to prepare, file, prosecute, maintain, protect and enforce our intellectual property rights and claims;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval;
- comply with ongoing regulatory requirements for products approved for commercial sale, if ever;
- acquire or in-license other product candidates, medical devices to deliver our product candidates, and other technologies; and
- incur increased costs as a result of operating as a public company.

Our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or the FDA, or other comparable foreign regulatory authorities, to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for our product candidates or for the medical devices required to deliver our product candidates, or if there are any delays in completing our clinical trials or the development of any of our product candidates or of the medical devices required to deliver.

#### We will need substantial additional funding, which may not be available on acceptable terms, or at all. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts.

We expect to spend substantial amounts to continue the nonclinical and clinical development of our current and future programs. Even if this offering is successful, if we are able to gain marketing approval for product candidates that we develop, including any indication for which we are developing or may develop our GH001 and GH002 product candidates, we may require additional amounts of cash in order to launch and commercialize such product candidates and the medical devices required to deliver such product candidates to the extent that such launch and commercialization is not the responsibility of a future collaborator that we may contract with in the future. In addition, other unanticipated costs may arise in the course of our development efforts. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidates we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our GH001 and GH002 product candidates, additional 5-MeO-DMT delivery approaches and the medical devices required to deliver these therapies for our initial and potential additional indications, as well as other product candidates we may develop;
- the timing and uncertainty of, and the costs involved in, obtaining marketing approvals for our GH001 and GH002 product candidates including the medical devices required to deliver these therapies for our initial and potential additional indications, and other product candidates we may develop and pursue;
- the number of future product candidates that we may pursue and their development requirements;
- the number of jurisdictions in which we plan to seek regulatory approvals;
- if approved, the costs of commercialization activities for GH001 and GH002 for any approved indications, or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities;

- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of GH001 and GH002 and the respective medical devices for any approved indications or any other product candidates;
- the extent to which we may in-license or acquire rights to other products, product candidates, medical devices or technologies;
- our headcount growth and associated costs as we expand our research and development, increase our office space, and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property-related claims;
- the effect of competing product and market developments; and
- the ongoing costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Any of our current or future license agreements may be terminated if we are unable to meet the payment or other obligations under the agreements.

## Raising additional capital may cause dilution to holders of our ordinary shares or purchasers of ordinary shares in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect our expenses to increase in connection with our planned operations. Until such time, if ever, that we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, convertible debt financings, strategic collaborations and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a shareholder. Debt financing, if available, may result in fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through strategic collaborations or marketing, distribution, licensing and royalty arrangements with third parties, we may have to relinquish valuable rights to our intellectual property or technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us or issue and sell our shares, which may result in dilution to our shareholders. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.



We are in the early stages of clinical drug development and have a very limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability. Since the number of patients included in our clinical trials is small and the follow-up is short, the results from such clinical trials may be less reliable than results achieved in larger clinical trials with longer follow-up, which may hinder our efforts to obtain regulatory approval for GH001 or any future product candidates.

We are a clinical-stage biopharmaceutical company with a very limited operating history, focused on novel therapies which may be able to induce ultra-rapid and durable remissions in patients with depression and in other indications within our focus area of psychiatric and neurological disorders. We commenced operations in 2018, have no products approved for commercial sale, and have not generated any revenue from product sales. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We are conducting a Phase 1/2 clinical trial for GH001 and have not initiated clinical trials for any other product candidates. The results of clinical trials with smaller sample sizes and shorter follow-up, such as our completed Phase 1 clinical trial in 22 healthy volunteers and our ongoing Phase 1/2 clinical trial in 16 planned patients with TRD, both with seven days follow-up, can be disproportionately influenced by various biases associated with the conduct of small short-term clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, and the potential failure of shorter studies to accurately depict long-term safety and efficacy results, which limits the ability to generalize the results, thus making the clinical trial results less reliable than clinical trials with a larger number of patients and longer follow-up. As a result, there may be less certainty that such product candidate would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of GH001, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our initial Phase 1 and Phase 1/2 clinical trials. To date, our clinical trials have been conducted only in the Netherlands, and we have not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we must prioritize development of certain product candidates. Moreover, we may expend our limited resources on programs that do not yield a successful product candidate or fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We currently have one product candidate in clinical development and one product candidate in preclinical development. The development of these programs and product candidates, of the medical devices required to deliver these product candidates and of any potential future programs and product candidates require significant capital investment. Due to the significant resources required for the development of our programs and product candidates, we must focus our programs and product candidates on specific diseases and disease pathways and decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our drug development strategy is to clinically test and seek regulatory approval for our product candidates in indications in which we believe there is the most evidence that we will be able to efficiently generate proof-of-concept data. We then intend to expand to clinical testing and seek regulatory approvals in other psychiatric and neurological disorders. However, even if our product candidates are able to gain regulatory approval in one indication, there is no guarantee that we will be able to expand to other indications, and we may expend significant resources in seeking such approvals.

In addition, we may focus resources on pursuing indications outside of psychiatric and neurological disorders based on the same strategic approach (e.g., mechanistic rationale, the availability of translational tools, clinical development path, commercial opportunity) we utilize in determining on which

of our discovery programs to focus. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or particular medical devices to deliver those product candidates, or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Additionally, we may reprioritize product candidate development plans and activities at any time and delay or terminate development of any product candidates we identify. Similarly, our potential decisions to delay, terminate, or collaborate with third parties in respect of certain programs, product candidates, or medical devices to deliver those product candidates may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the biopharmaceutical industry, in particular for psychiatric and neurological disorders, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

### Exchange rate fluctuations may materially affect our results of operations and financial condition.

Due to the international scope of our operations, our assets, earnings and cash flows are influenced by movements in exchange rates of several currencies, particularly the pound sterling, and going forward, by the U.S. dollar, as we expand our operations. Our reporting currency is denominated in U.S. dollars and our functional currency is the euro and the majority of our operating expenses are paid in euro and pound sterling. We also regularly acquire services, consumables and materials in euro and pound sterling. Further potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and the price of our ordinary shares may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which may also have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place. See Note 3 in the notes to our annual financial statements appearing elsewhere in this prospectus for a description of foreign exchange risks.

In addition, the possible abandonment of the euro by one or more members of the European Union could materially affect our business in the future. Despite measures taken by the European Union to provide funding to certain EU member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the reintroduction of individual currencies in one or more EU member states, or in more extreme circumstances, the dissolution of the European Union. The effects on our business of a potential dissolution of the European Union, the exit of one or more EU member states from the European Union or the abandonment of the euro as a currency, are impossible to predict with certainty and any such events could have a material adverse effect on our business, financial condition and results of operations.

#### Risks Related to Research and Development and the Biopharmaceutical Industry

### Drug and drug-device combination product development is a highly uncertain undertaking and involves a substantial degree of risk.

We have no products approved for commercial sale. To generate revenues from the sales of any approved products that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing, and marketing therapies with significant commercial success. Our ability to generate revenue and achieve profitability depends on many factors, including:

 completing research and technical, nonclinical and clinical development of our product candidates and the medical devices required to deliver these product candidates;

- obtaining regulatory approvals and marketing authorizations for product candidates, including the medical devices required to deliver these product candidates for which we successfully complete clinical development and clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates and the medical devices required to deliver these product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and commercial demand of our product candidates and medical devices;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we
  may enter;
- successfully getting our product candidates rescheduled under the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act, or CSA, and comparable state laws by the U.S. Drug Enforcement Administration, or DEA, and other applicable regulatory agencies inside and outside the United States;
- launching and successfully commercializing product candidates and the medical devices required to deliver these product candidates for which we obtain regulatory approval, either by collaborating with a partner or, if launched independently, by establishing a sales, marketing and distribution infrastructure;
- obtaining and maintaining an adequate price for our product candidates and devices in the countries where our products are commercialized;
- obtaining adequate reimbursement for our product candidates and medical devices from payors;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- receiving milestone and other payments under any future collaboration arrangements;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- attracting, hiring and retaining qualified personnel; and
- complying with laws and regulations, including laws applicable to controlled substances.

Because of the numerous risks and uncertainties associated with drug and drug-device combination product development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever.

# GH001 and GH002 are investigational 5-MeO-DMT therapies based on a novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. To our knowledge, no such therapies have been approved in the United States nor the European Union for commercialization.

We have concentrated our research and development efforts on GH001 and GH002 for the treatment of psychiatric or neurological disorders and our future success depends on our successful development of these product candidates. Our risk of failure is high. We may experience problems or delays in developing GH001 and GH002. Any such problems or delays would cause unanticipated costs, and any development problems may not be solved. For example, we or another party may uncover a previously unknown risk associated with GH001 and GH002 that may be more problematic than we currently believe, and this may prolong the period of observation required for obtaining, or result in the failure to obtain, regulatory approval or may necessitate additional clinical testing.

In addition, the product specifications and the clinical trial requirements of the FDA, the European Commission, the EMA, and other regulatory authorities and the criteria these regulators use to determine

the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidate. The regulatory approval process for novel product candidate such as ours is unclear and can be more expensive and take longer than for other. better known or more extensively studied therapies. For example, because our GH001 and GH002 product candidates contain 5-MeO-DMT, which is categorized as a Schedule I controlled substance under the CSA, a Schedule 1 drug under the United Kingdom's Misuse of Drugs Regulations 2001 and is similarly categorized by most states, foreign governments and the UN Convention on Psychotropic Substances, 1971, the development towards regulatory approval of GH001 and GH002 is especially challenging and uncertain. The high technical complexity of the development of drug-device combination products further increases risks and uncertainties towards regulatory approval of our product candidates. This risk and uncertainty is particularly high in the area of drug-device combination products for inhaled delivery of the drug component, such as with GH001. In the past, drug-device combination products have experienced significant delays due to technical challenges faced in achieving the tight technical performance specifications required for regulatory approval, or due to specific adverse events associated with inhaled delivery. We anticipate that GH001 and the device required to deliver GH001 will require significant additional technical development work before it achieves adequate technical performance specifications to allow regulatory approval. It is uncertain whether this development work will be successful. To our knowledge, no 5-MeO-DMT therapies have received FDA approval nor received marketing authorization from the European Commission. As a result, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for GH001 and GH002 in either the United States or the European Union. Approvals by the European Commission may not be indicative of what the FDA may require for approval and vice versa.

# Our business substantially depends upon the successful development of our GH001 and GH002 product candidates. Failure to successfully develop GH001 and/or GH002 would prevent us from obtaining regulatory approval for, and successful commercialization of, GH001 and/or GH002 and our business may be materially harmed.

We currently have no products approved for sale and invest the majority of our efforts and financial resources in the development of our lead product candidates, GH001 and GH002, for the treatment of psychiatric or neurological disorders. Successful continued development and ultimate regulatory approval of GH001 and GH002 for our initial and potential additional indications is critical to the future success of our business. We will need to raise sufficient funds for, and successfully enroll and complete, our clinical development programs of our GH001 and GH002 product candidates for the treatment of TRD and potentially other psychiatric and neurological disorders.

Before we can generate any revenue from sales of GH001, GH002 or any other approved product, we must undertake additional technical, nonclinical and clinical development, regulatory review and approval in one or more jurisdictions for the product candidates and the medical devices required to deliver these product candidates. To date, our clinical trials have been conducted exclusively in the Netherlands. We plan to pursue clinical trials in multiple European countries, Canada, and the United States for all of our clinical programs. We have not submitted Investigational New Drug applications, or INDs, or other comparable applications, for any of our product candidates, including the medical devices to deliver our product candidates, with the FDA, EMA, or other comparable foreign regulatory authorities, outside of the Netherlands. We do not expect that we need to submit separate Investigational Device Exemption applications, or IDEs, or other comparable applications, with the FDA, EMA or other comparable foreign regulatory authorities for the medical devices to deliver our product candidates, and we have not done so, though there can be no assurance that IDEs or comparable applications will not be necessary in the future. In addition, if one or more of our product candidates are approved, we must ensure access to sufficient commercial manufacturing capacity for the product candidates and the medical devices required to deliver these product candidates and conduct significant marketing efforts in connection with any commercial launch, as well as obtaining pricing and reimbursement authorizations in individual European and other countries. These efforts will require substantial investment, and we may not have the financial resources to continue development of our product candidates or commercialization of any products.

We may experience setbacks that could delay or prevent regulatory approval of our product candidates, including the medical devices to deliver our product candidates or our ability to commercialize any products, including:

- delay or failure in establishing acceptable performance characteristics, quality manufacturing standards and manufacturing capabilities for our product candidates or for the medical devices required to deliver our product candidates;
- negative or inconclusive results from our nonclinical studies or clinical trials or the clinical trials of
  others for product candidates similar to ours, leading to a decision or requirement to conduct
  additional nonclinical testing or clinical trials or abandon a program;
- product or device-related side effects experienced by subjects in our clinical trials or by individuals using drugs or therapeutics similar to our product candidates;
- delays in submitting INDs (or IDEs, if applicable) in the United States or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators or institutional review boards to commence a clinical trial, including Schedule I research protocols required by the DEA, or a suspension or termination of a clinical trial once commenced;
- if the FDA, EMA or other comparable foreign regulatory authorities do not find the earlier technical, nonclinical and clinical trial work sufficient, then we may need to conduct additional technical development work or nonclinical or clinical trials beyond what we currently have planned, before we can initiate further clinical studies. Any significant technical development or nonclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates and medical devices or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates and medical devices and may harm our business and results of operations;
- conditions imposed by the FDA, EMA or other comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our clinical trial design, including with respect to dosing levels administered in our planned clinical trials, or the medical devices used to deliver our product candidates in the clinical trials, which may delay or prevent us from initiating our clinical trials with our originally intended trial design and the originally planned medical devices;
- delays in contracting with clinical sites or enrolling subjects in clinical trials, including, due to the COVID-19 pandemic, the inability to identify clinical sites willing to host our clinical trials and the required scheduled drug DEA researcher registration and Schedule I research protocol in the United States and similar licenses in other jurisdictions to be obtained and maintained by our clinical investigators;
- delays or interruptions in the supply of materials necessary for the conduct of our clinical trials;
- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the FDA, the EMA or other comparable foreign regulatory authorities may require us to submit additional data such as long-term toxicology studies or additional data for the medical devices required to deliver our product candidates;
- delays in reaching, or failure to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;



- our third-party contractors for nonclinical studies or clinical trials may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or take actions that could cause clinical sites or clinical investigators to drop out of the trial, which may require that we add new clinical trial sites or investigators;
- due to the impact of the COVID-19 pandemic, we may experience some delays and interruptions to our technical development efforts, nonclinical studies and clinical trials, we may experience delays or interruptions to our manufacturing supply chain, or we could suffer delays in reaching, or we may fail to reach, agreement on acceptable terms with third-party service providers on whom we rely;
- greater-than-anticipated clinical trial costs, including as a result of delays or interruptions that could increase the overall costs to finish our clinical trials as our fixed costs are not substantially reduced during delays;
- we may elect to, or regulators, IRBs, Data Safety Monitoring Boards, or DSMBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including non-compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates, medical devices required to deliver our product candidates, or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate to initiate or complete a given clinical trial;
- inability to compete with other therapies;
- poor efficacy of our product candidates during clinical trials;
- failure to demonstrate an acceptable benefit/risk profile for our product candidates;
- inability to provide sufficient design, testing, manufacturing and quality information for the medical devices required to deliver our product candidates, including information to support their use and compatibility with the drug constituent of our product candidates;
- unfavorable FDA, EMA or other comparable foreign regulatory authority inspection and review of clinical trial sites or manufacturing facilities;
- if the DEA, or any state or other jurisdiction, delays rescheduling or fails to reschedule 5-MeO-DMT to Schedule II, III, IV or V, or delays classifying or fails to classify our product candidates to Schedule II, III, IV or V;
- unfavorable product labeling associated with any product approvals and any requirements for a Risk Evaluation and Mitigation Strategy, or REMS, that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of an individual product outweigh its risks;
- unfavorable acceptance of our product candidates or clinical trial data by the patient or medical communities or third-party payors;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays related to the impact or the spread of COVID-19 or other pandemics, including the impact of COVID-19 on the FDA's, EMA's or other comparable foreign regulatory authority's ability to continue its normal operations;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or

 varying interpretations of data by the FDA, EMA or other comparable foreign regulatory authorities.

We do not have complete control over many of these factors, including certain aspects of technical drug product and device development, clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator.

GH001 is designed to deliver 5-MeO-DMT to the patient via inhalation of an aerosol into the lungs. This aerosol is defined by specific properties to be pharmaceutically acceptable, such as its purity, and to achieve efficient uptake of 5-MeO-DMT into the systemic circulation, such as its particle size distribution. The generation of this 5-MeO-DMT aerosol requires a drug product and a device with specific performance characteristics and properties and it is therefore anticipated that GH001 and the specific device will be considered a drug-device combination product by the FDA, EMA or other comparable foreign regulatory authorities. Products that are considered to be drug-device combination products will require review and coordination by the drug and device centers within the FDA, EMA or other comparable foreign regulatory authorities prior to initiation of clinical trials and prior to marketing approval, which may delay such trials or marketing approval. Under FDA regulations, combination products are subject to current good manufacturing practice, or cGMP, requirements applicable to both drugs and medical devices, including the Quality System, or OS, and regulations applicable to medical devices. Combination products are also subject to the Medical Device Directives and Standards in Europe, which, beginning on May 26, 2021, will be known as the Medical Device Regulation 2017/745, or MDR, and which require coordination between the drug and the device regulatory laws and regulators. Problems associated with the drug product or device component of the combination product candidate may delay or prevent initiation of clinical trials or marketing approval. In current and previous clinical trials, GH001 has been vaporized using a device we purchased on the market from a single third party manufacturer, Storz & Bickel, Tuttlingen. We do not have a commercial supply agreement with this third party, nor have we established licensing or development agreements with any alternative provider of a device which would be suitable to generate a pharmaceutically acceptable aerosol from GH001. If the FDA, EMA or other comparable foreign regulatory authorities refuse to accept the use of this third-party device in our planned clinical trials then initiation of additional clinical trials could be significantly delayed or prevented. If we fail to develop, manufacture, license, or acquire an alternative device which would be suitable to generate a pharmaceutically acceptable aerosol from GH001, which achieves sufficient uptake of 5-MeO-DMT into the systemic circulation, or if we fail to get sufficient supplies of this third-party device or any alternative device or if the device is unavailable to us for any reason then initiation of additional clinical trials or receipt of marketing approval could be significantly delayed or prevented. If the manufacturer of the thirdparty device makes modifications, or if we elect to change a device component or develop our own proprietary device component, e.g., through a development agreement with a contract manufacturing organization, or CMO, or license an alternative device component, we will need to perform validation testing and obtain FDA, EMA or other comparable foreign regulatory approval prior to using the modified or alternative device component. If the FDA, EMA or other comparable foreign regulatory body fails to approve use of those modified or alternative medical devices or take significant enforcement action against the manufacturer, we would not be able to continue or initiate clinical trials, receive marketing approval or we may have to suspend marketing our products in certain jurisdictions.

In addition, of the large number of drugs in development in the biopharmaceutical industry, only a small percentage result in the submission of a marketing application, such as a new drug application, or NDA, to the FDA, EMA or other comparable foreign regulatory authority, and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval for GH001 or GH002, including the medical devices required for their administration, for any indication, any such approval may be subject to limitations on the indications or uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure that we will successfully develop or commercialize GH001 or GH002 including the medical devices required for their administration, for any indication. Our failure to demonstrate positive results in our clinical trials in any indication for which we are developing GH001 and GH002 could adversely affect our development efforts for GH001 and GH002 in other indications.

Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome. The outcome of nonclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials, which to date have only been conducted in the Netherlands, may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

To obtain the requisite regulatory approvals to commercialize any product candidates and medical devices required for their administration, we must demonstrate through extensive nonclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, in the United States where we hope to advance our product development efforts in the future, the general approach for FDA approval of a new drug is dispositive data from two well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population, using the relevant device. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signs of activity in earlier nonclinical studies or clinical trials. The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with the conduct of small clinical trials, making the clinical trial results less reliable than clinical trials with a larger number of patients. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or emergence of unacceptable safety issues, notwithstanding promising results in earlier studies and trials. Also, a number of companies developing drug-device combination products, especially in the area of inhaled delivery of the drug component, have historically suffered significant setbacks due to technical, performance or manufacturing issues of the device component in their combination product. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of GH001, GH002 or any other product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- nonclinical studies or clinical trials may show the product candidates to be ineffective or less
  effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have
  unacceptable side effects or toxicities;
- failure to reflect similarly efficacious activity in subsequent clinical trials with larger patient populations;
- failure to use clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- manufacturing issues or formulation issues with the product candidate or device that cannot be resolved;
- failure to receive the necessary regulatory approvals;
- manufacturing issues, formulation issues, pricing or reimbursement issues or other factors that make a product candidate or device uneconomical; and
- intellectual property and proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In particular, we have relied upon public nonclinical literature containing limited data thus far, and have not conducted our own nonclinical toxicity studies, and nonclinical studies or clinical trials may show that our product candidates have unacceptable side effects or toxicities.

We assess indications for intensity of psychoactive effect using a metric we devised, Peak Experience, or PE. We believe PE may correlate with clinical outcomes, but PE is a subjective metric and can be inherently difficult to evaluate. In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials.

Moreover, our completed Phase 1 clinical trial in healthy volunteers and our ongoing Phase 1/2 clinical trial in patients with TRD are open-label studies, where both the patient and investigator know whether the patient is receiving the product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. For example, prior MDD studies have exhibited a high placebo effect. In addition, open-label clinical trials may be subject to an "investigator bias," where those assessing and reviewing the psychological and physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled or active-controlled trials. Additionally, the trial design differences and placebo effects that may be possible in clinical research for the indications we are studying may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials or to interpret the clinical data in any of our trials. Furthermore, even in a placebo-controlled or active-controlled trial, it is possible that patients and/or investigators will be able to discern if the administered dose is our product candidate or a placebo or the active control due to the psychoactive effects of 5-MeO-DMT. Therefore, placebo-controlled or activecontrolled trials with our GH001 and GH002 product candidates may be subject to similar limitations as open-label trials. Finally, our clinical trials to date have been short in duration, and our results may not be predictive of long-term safety and efficacy.

The standards that the FDA, EMA and other comparable foreign regulatory authorities use when regulating us require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although we are initially focusing our efforts on development of small molecule drug products and the medical devices required for delivery of these products, we may pursue development of other products, e.g., biological products, each of which could make us subject to additional regulatory requirements. Any analysis we perform of data from technical development, nonclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent initiation of clinical studies or regulatory approval. Our clinical trials have only been conducted in the Netherlands. The FDA's acceptance of data from clinical trials outside of the United States is subject to certain conditions. If the FDA or other comparable foreign regulatory authorities do not accept earlier technical, nonclinical or clinical data, we may need to conduct additional technical development, nonclinical trials.

We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in policy by the FDA, EMA or other comparable foreign regulatory authority during the period of product development and regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether regulations, guidance or interpretations of the FDA, EMA or other comparable foreign regulatory authority will be changed, or what the impact of such changes, if any, may be. In particular, in the United States, where we plan to develop our candidates in the future, the FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding on the FDA, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA or other comparable foreign regulatory authorities, for each product candidate and any relevant device required to deliver such product candidate, and, consequently, the ultimate approval and commercial marketing of any product candidates and medical devices. We may experience negative or

inconclusive results, or regulators may be unwilling to accept nonclinical or clinical data obtained in foreign jurisdictions, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which would have a material adverse effect on our business.

# Our product candidates or use of our product candidates through participation in our clinical trials, may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable side effects that could potentially be caused by GH001, GH002 or any future product candidate, such as hypertension, tachycardia, nausea, headache or flashbacks, referred to as the re-experiencing of some of the effects induced by 5-MeO-DMT intake at some point after the drug's acute effects have worn off, could cause us or regulatory authorities to not initiate, interrupt, delay or halt clinical trials and could result in more restrictive labeling than anticipated, a requirement that we implement a REMS to ensure that the benefits outweigh the risks or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, even death. There can be no assurance that serious side effects, including deaths, will not occur even in the controlled setting of a clinical trial. In addition, many compounds that have initially shown promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Additionally, the composition of our product candidates or learnings in nonclinical studies or clinical trials may result in contraindications or warnings, including Boxed Warnings, for any product candidates for which we may obtain regulatory approval.

If unacceptable side effects arise in the development of our product candidates, foreign regulatory authorities, or, in the future, the FDA, EMA, the IRBs, DSMBs or independent ethics committees at the institutions in which our trials are conducted could refuse to allow us to initiate, or may suspend or terminate our nonclinical studies or clinical trials, or the FDA, EMA or other comparable foreign regulatory authorities could order us to cease nonclinical studies or clinical trials or deny approval of our product candidates for any or all targeted indications.

Treatment-emergent side effects that are deemed to be drug-related could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Undesirable side effects in one of our clinical trials for our product candidates in one indication could adversely affect enrollment in clinical trials, regulatory approval and commercialization of our product candidates in other indications. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of healthy volunteers and patients who have agreed to be enrolled in clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may fail to identify undesirable side effects. Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients' use of the product candidate. If our product candidates, including the medical devices to deliver such product candidates, receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates or medical devices;
- regulatory authorities may require the addition of labeling statements, such as a Boxed Warning or contraindications;
- we may be required to change the way such product candidates are distributed or administered, or change the labeling of the product candidates or medical devices;



- the FDA may require a REMS to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools, and regulatory authorities in other jurisdictions may require comparable risk mitigation plans;
- we may be subject to regulatory investigations and government enforcement actions;
- the FDA, EMA or a comparable foreign regulatory authority may require us to conduct additional technical development work or clinical trials or costly post-marketing testing and surveillance to establish and monitor the safety and efficacy of the product;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates or operating our medical devices; and
- our reputation may suffer.

In addition, patients who participate in our trials may take antidepressants or other medications to treat depression and/or mood disorders, or other medications that may interact with our product candidates, and participation in our clinical trials requires patients to suspend any such existing medication or treatment for the duration of the trial. If a patient chooses to resume his or her existing medications, there is no guarantee such medications will produce the same therapeutic effect, if any, as may have been experienced prior to suspending such medication. Further, the impact of cycling off and/or back on to existing medications could have undesirable side effects or lead to severe mental health trauma. Any such negative reactions of a patient participating in one of our clinical trials may decrease the willingness of patients to participate in our trials, affect the timing or outcome of our clinical trials, product candidates, which in turn may significantly impact our ability to successfully commercialize our product candidates.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates, could negatively impact the perception of our other product candidates, could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

### If we encounter difficulties enrolling patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

Patient enrollment is affected by many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- in the case of clinical trials focused on rare disease, the small size of the patient population and the potential of a patient being undiagnosed or misdiagnosed;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- reluctance of physicians to encourage patient participation in clinical trials;

- the impacts of the COVID-19 pandemic on clinical trial sites, personnel and patient travel;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, including product candidates studying N-methyl-D-aspartate antagonists, neurosteroids, and other serotonergic psychedelics such psilocybin and N,N-Dimethyltryptamine. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause the value of our company to decline and limit our ability to obtain additional financing if needed.

We are also required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, such as www.ClinicalTrials.gov in the United States and a similar system in the European Union, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

## Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available, and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials, including the data we have disclosed for our current clinical trials. These interim updates are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim or topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. This difference may be more pronounced because of the small sample size and short duration of our clinical trials. Interim or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously reported. As a result, interim or topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Additional disclosure of interim data by us or by our competitors could result in volatility in the price of our ordinary shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the ability to initiate further clinical studies, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical



trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, preliminary or topline data that we report differ from late, final or actual results, or if others, including the FDA, EMA or other comparable foreign regulatory authorities, disagree with the conclusions reached, our ability to initiate further clinical studies or obtain approval for, and commercialize our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

### The markets for GH001 and GH002 for TRD and any other product candidates we may develop may be smaller than we expect.

Our estimates of the potential market opportunity for GH001 and GH002 for the treatment of TRD as well as any other product candidates, include several key assumptions based on our industry knowledge, industry publications and third-party research reports. There can be no assurance that any of these assumptions are, or will remain, accurate. If the actual market for GH001 and GH002 for these or other indications, or for any other product candidate we may develop, is smaller than we expect, our revenue, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

### We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for a number of reasons, including:

- our inability to design such product candidates with the pharmacological or pharmacokinetic properties that we desire; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for nonclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact the market price of our publicly traded ordinary shares.

## We may conduct clinical trials for our product candidates in the United States, Europe or other jurisdictions, and the FDA, EMA and applicable foreign regulatory authorities may not accept data from trials conducted outside those respective jurisdictions.

We may choose to conduct one or more of our clinical trials in the United States, Europe or in other foreign jurisdictions outside of the Netherlands where our trials currently are being conducted for GH001 and GH002. The acceptance of study data from nonclinical studies and clinical trials conducted outside those jurisdictions may be subject to certain conditions for acceptance. For example, in cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practices, or GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies, such as the EMA, have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of the

United States or the applicable jurisdiction. The FDA may not accept our data given the limited sample size in our completed and existing trials. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

## A Breakthrough Therapy Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have a Breakthrough Therapy Designation for any of our product candidates, but we may seek a Breakthrough Therapy Designation for any product candidate that we plan to develop in the United States if we believe the qualifying criteria for such a designation can be met. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA has discretion to determine whether the criteria for a Breakthrough Therapy has been met and whether to grant a Breakthrough Therapy Designation to a product candidate. Accordingly, even if we believe a product candidate, we develop meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even after granting Breakthrough Therapy Designation to our product candidates, the FDA may later decide that the drugs no longer meet the conditions for qualification and withdraw the designation.

# A Fast Track Designation by the FDA (or its equivalent in the European Union, an accelerated assessment), even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have Fast Track Designation or acceptance of an accelerated assessment in the EU for any of our product candidates, but we may seek such a designation for the product candidates we plan to develop in the United States and the European Union, if we believe the qualifying criteria for such a designation/ assessment have been met. If a product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation or accelerated assessment. The FDA and the EMA each have broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation/assessment, we cannot assure that the FDA or EMA would decide to grant it. Even if we do receive Fast Track Designation and or an accelerated assessment, we may not experience a faster development process, review or approval compared to conventional FDA or EMA procedures. The FDA or EMA may withdraw the Fast Track Designation or pathway is no longer supported by data from our clinical development program. Many drugs that have received Fast Track Designation and/or accelerated assessment have failed to obtain regulatory approval.

# We may seek orphan drug designation for one or more of our product candidates in the United States, but we may be unable to obtain or maintain such a designation or the benefits associated with orphan drug status, including marketing exclusivity, which may cause our revenue, if any, to be reduced.

Because we are considering developing GH001 and/or GH002 for indications we believe to be rare, we may elect to pursue orphan designations for our candidates as applicable in the jurisdictions where development activities are planned.

In the United States, under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested and granted by the FDA before a new NDA is submitted. In the United States, orphan drug designation entitles a party to financial incentives such as tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, it will disclose publicly the generic identity of the drug and its potential orphan use. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Such a designation may also be revoked by the FDA in certain circumstances, such as if the agency finds that the applicant's request for designation request omitted material information required under the Orphan Drug Act and its implementing regulations.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity. This means that the FDA may not approve any other marketing applications for the same drug and the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the drug was designated. Furthermore, the FDA can waive orphan exclusivity if the applicant is unable to manufacture sufficient supply of the product subject to a period of orphan drug marketing exclusivity.

#### We may seek orphan drug designation for one or more of our product candidates in the European Union, but we may be unable to obtain or maintain such a designation or the benefits associated with orphan drug status, including marketing exclusivity, which may cause our revenue, if any, to be reduced.

In the European Union, orphan designation might be granted by the EMA for a medicine that (i) is intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) with a prevalence in the European Union of not more than five in 10 thousand or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the European Union, orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The benefit of orphan designation in the European Union is scientific advice, and extended market exclusivity, or an additional two years on top of the eight years of market exclusivity for an innovative product. Such a designation may also be revoked by the EMA in certain circumstances, such as if the criteria are no longer met, which might for example occur by a competitor product becoming available in the market. Our inability to obtain or maintain such a designation or the benefits associated with orphan drug status, which could adversely affect our ability to achieve or sustain profitability.



# Obtaining and maintaining regulatory approval of our product candidates and medical devices required to deliver such product candidates in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval of our product candidates and medical devices required to deliver such product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates and medical devices required to deliver such product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants approval of a product candidate and device required to deliver such product candidate, comparable regulatory authorities in other jurisdictions, including Europe, must also approve the manufacturing, marketing and sale of the product candidate and device required to deliver such product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate and device must also be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to governmental approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any partner we work with fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

#### Even if we, or any future collaborators, obtain regulatory approvals for our product candidates and medical devices to deliver such product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could impair our ability to generate revenue.

Once regulatory approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain regulatory approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we and any future collaborators will not be able to promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive regulatory requirements, including under FDA authorities ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by regulatory authorities to monitor and ensure compliance with cGMPs. Despite our efforts to inspect and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection to be not in compliance with cGMP requirements, which may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our drug products.

Accordingly, assuming we, or any future collaborators, receive regulatory approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and guality control.

If we, or any future collaborators, are not able to comply with post-approval regulatory requirements, we, or any future collaborators, could have the regulatory approvals for our products withdrawn by regulatory authorities and our, or any future collaborators', ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

# Changes in regulatory requirements or regulatory guidance or unanticipated events during our nonclinical studies and clinical trials of our product candidates may occur, which may result in changes to nonclinical studies and clinical trial protocols or the need for additional nonclinical studies and clinical trials, which could result in increased costs to us and could delay our development timelines.

Changes in regulatory requirements or regulatory guidance or unanticipated events during our nonclinical studies and clinical trials may force us to amend nonclinical studies and clinical trial protocols or the applicable regulatory authority may impose additional nonclinical studies and clinical trial requirements. Amendments or changes to our clinical trial protocols would generally require resubmission to the applicable regulatory authority and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of clinical trials. These decisions may increase costs, and cause us not to meet expected timelines and, correspondingly, our business and financial prospects could be adversely affected. Similarly, amendments to our nonclinical studies may adversely impact the cost, timing or successful completion of those nonclinical studies. If we experience delays completing, or if we terminate, any of our nonclinical studies or clinical trials, or if we are required to conduct additional nonclinical studies or clinical trials, the development pathway, and ultimately the commercial prospects, for our product candidates may be harmed and our ability to generate product revenue from resulting products, if any, will be delayed.

# We could be subject to product liability lawsuits based on the use of our product candidates in clinical testing or, if obtained, following our products' marketing approval and commercialization. Product liability lawsuits brought against us or any of our future collaborators could divert our resources and attention, require us to cease clinical testing, cause us to incur substantial liabilities or limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. Currently, we have no products that have been approved for commercial sale: however, the use of our product candidates and medical devices to deliver such product candidates by us and any collaborators in clinical trials may expose us to liability claims. We will face an even greater risk if product candidates and medical devices to deliver such product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our partners if any product candidate or medical devices to deliver such product candidates we develop allegedly causes injury or are found to be otherwise unsuitable for human use during product testing, manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. Such claims could be made by participants enrolled in our clinical trials, patients, healthcare providers, biopharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which any approved drug products may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from physicians' or patients' use or misuse of our products or any similar products distributed by other companies.

We maintain product liability insurance coverage limited to clinical trial liability, and this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could harm our business, financial condition, results of operations and prospects.

#### We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.

The development and commercialization of new drug products is highly competitive. We may face competition with respect to any product candidates that we seek to develop or commercialize from biopharmaceutical companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, we face competition from 501(c)(3) non-profit medical research organizations, including the Usona Institute. Such non-profits may be willing to provide treatment at cost or for free, undermining our potential market for GH001, GH002 and any other product candidates we may develop. In addition, a number of for-profit biotechnology companies or institutions are specifically pursuing the development of



5-MeO-DMT or other tryptamines, such as psilocybin and N,N-Dimethyltryptamine, to treat mental health illnesses, including TRD. These competitors include Beckley Psytech, COMPASS Pathways, Cybin, Entheon, Mindmed, Small Pharma, and Viridia Life Sciences. In addition, an increasing number of companies are stepping up their efforts in discovery of new psychoactive compounds. It is also probable that the number of companies seeking to develop psychoactive products and therapies for the treatment of mental health illnesses, such as depression, will increase. If any of our competitors are granted an NDA for their therapies before us and manages to obtain approval for a broader indication, and thus access a wider patient population, we may face more intensified competition from such potential therapies and increased difficulties in winning market acceptance of our GH001 and GH002 product candidates or any future product candidates. All of these risks are heightened because 5-MeO-DMT, which is a naturally occurring substance and therefore not subject to patent protection, may be deemed an appropriate substitute for GH001 and GH002.

We also face competition from larger and smaller pharmaceutical, biopharmaceutical and biotechnology companies who have developed or are developing therapies for the treatment of MDD and TRD, including Axsome Therapeutics, Praxis Precision Medicines, Relmada Therapeutics and Sage Therapeutics, and will face future competition for any other indications we may seek to treat with our GH001 and GH002 product candidates. There are a number of companies that currently market and sell products or therapies, or are pursuing the development of products or therapies, for the treatment of depression, including antidepressants such as SSRIs and serotonergic norepinephrine reuptake inhibitors, or SNRIs, antipsychotics, cognitive behavioral therapy, or CBT, esketamine and ketamine, repeat transcranial magnetic stimulation, or rTMS, electroconvulsive therapy, or ECT, vagus nerve stimulation, or VNS, deep brain stimulation, or DBS, N-methyl-D-aspartate antagonists, neurosteroids, and other serotonergic psychedelics such as psilocybin and N.N-Dimethyltryptamine, among others. Many of these pharmaceutical, biopharmaceutical and biotechnology competitors have established markets for their therapies and have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market superior products or therapies. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new therapeutic substances and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA, EMA or other comparable foreign regulatory authority approval for alternative or superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

If any of these competitors or competitors for our other product candidates receive FDA, EMA or other comparable foreign regulatory authority approval before we do, our product candidates would not be the first treatment on the market, and our market share may be limited. In addition to competition from other companies targeting our target indications, any products we may develop may also face competition from other types of therapies.

Many of our current or potential competitors, either alone or with their strategic partners, have:

- greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products;
- more extensive experience in nonclinical studies, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling drug products;
- more developed intellectual property portfolios;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also

prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of our targeted disease indications or similar indications, which could give such products significant regulatory and market timing advantages over our product candidates. Our competitors also may obtain FDA, EMA or other comparable foreign regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications that we are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete and we may not be successful in marketing any product candidates we may develop against competitors.

In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity and/or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize.

# Our inhalable GH001 5-MeO-DMT product candidate is delivered via inhalation of aerosols produced by a vaporization device which is subject to device regulations in the United States and other jurisdictions. The FDA, EMA or other comparable foreign regulatory authorities, may not accept this device for clinical trials.

In current and previous clinical trials, GH001 has been vaporized using a device we have purchased on the market from a third party. This device has been used in previous trials in the United States. However, there can be no assurance that the FDA or other comparable foreign regulatory authorities will allow it to be used with GH001. In addition, we may decide in future clinical trials to use a different device than the one we have used previously. In either case, we would need to do additional development work and conduct additional studies, including bridging studies to bridge our prior device to any new device we may decide to use, prior to using the new device in future clinical trials. Any delays as a result of changing medical devices to deliver our product candidates would have a material adverse effect on our business.

We do not have a commercial supply agreement with the third-party manufacturer of the device we currently use in clinical trials, nor have we established license or development agreements with any alternative provider of a device, which would be suitable to generate a pharmaceutically acceptable aerosol from GH001. If FDA, EMA or other comparable foreign regulatory authorities refuse to accept the use of the current third-party device in our planned clinical trials and if we fail to develop, manufacture, license, or acquire an alternative device which would be suitable to generate a pharmaceutically acceptable acceptable aerosol from GH001, or if we fail to get sufficient supplies of the current third-party device or any alternative device, then initiation of additional clinical trials or marketing approval could be significantly delayed or prevented.

### Additional time may be required to obtain regulatory approval for GH001 because it is administered as a combination product.

GH001 is administered via inhalation of an aerosol produced by a vaporization device. This device is necessary to produce the aerosol and it is therefore a drug and device combination product that requires coordination within the FDA or other comparable foreign regulatory authorities for review of their device and drug components. Medical products containing a combination of new drugs, biological products or medical devices may be regulated as "combination products" in the United States and Europe. A combination product generally is defined as a product comprised of components from two or more

regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate pre-market review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process. The EMA has a parallel review process in place for combination products, the potential effects of which in terms of approval and timing could independently affect our ability to market our combination products in Europe.

#### **Risks Related to Controlled Substances**

GH001 and GH002, and any future product candidates we may develop, are subject to controlled substance laws and regulations in the territories where the product will be marketed, such as the United States, the European Union, the United Kingdom and the rest of Europe, as well as the UN international drug control treaties, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post-approval, and our financial condition. In addition, during the review process of GH001 and GH002, and prior to approval, the FDA, EMA and/or other comparable foreign regulatory authorities may require additional data, including with respect to whether GH001 or GH002 has abuse potential. This may delay approval and any potential rescheduling process.

In the United States, 5-MeO-DMT is listed by the DEA as a controlled substance or scheduled substance, under the CSA, specifically as a Schedule I substance. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have no currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for medical use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and import/export restrictions. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription and may have a black box warning. Further, most, if not all, state laws in the United States classify 5-MeO-DMT as a Schedule I controlled substance. For any product containing 5-MeO-DMT to be available for commercial marketing in the United States, 5-MeO-DMT must be rescheduled to Schedule II, III, IV or V, or the DEA must reschedule a specific dosage form or product containing 5-MeO-DMT to Schedule II, III, IV or V. Similar rescheduling would be required in the various states and jurisdictions through scheduling-related legislative or administrative action.

Scheduling determinations by the DEA are dependent on FDA approval of a substance or a specific formulation of a substance. Therefore, while 5-MeO-DMT is a Schedule I controlled substance, products approved by the FDA for medical use in the United States that contain 5-MeO-DMT would meet the statutory criteria to be placed in Schedule II, or another schedule, since approval by the FDA satisfies the "accepted medical use" requirement. If and when GH001 or GH002 receives FDA approval, the DEA will need to make a scheduling determination and place 5-MeO-DMT in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. This scheduling determination will be dependent on FDA approval and the FDA's recommendation as to the appropriate schedule. During the review process, and prior to approval, the FDA may determine that it requires additional data, either from nonclinical or clinical studies, including with respect to whether, or to what extent, the substance has the potential for abuse. This may introduce a delay into the approval and any potential rescheduling process. That delay would be dependent on the quantity of additional data required by the FDA. This scheduling determination will be subject to public comment and requests for an administrative hearing which could affect the timing and scheduling of these substances.

5-MeO-DMT is currently classified as a Schedule I drug in the United States and any product containing this substance, such as GH001 and GH002, must be rescheduled to be marketed. There can be no assurance that the DEA will make a favorable scheduling decision. Even assuming categorization as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V) at the federal level, such substances would also require scheduling determinations under state laws and regulations.

If approved by the FDA, and if the finished dosage form of GH001 or GH002 is listed by the DEA as a Schedule II, III, or IV controlled substance, its manufacture, importation, exportation, domestic distribution, storage, sale, prescribing, and dispensing will continue to be subject to a significant degree of regulation by the DEA. In addition, the scheduling process may take significantly longer than the 90-day deadline set forth in the CSA, thereby delaying the launch of our GH001 or GH002 product candidates in the United States. Furthermore, the FDA, DEA, or any comparable foreign regulatory authority could require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of GH001, GH002 and any future product candidates containing controlled substances. In addition, product candidates containing controlled substances are subject to regulations relating to manufacturing, storage, distribution, prescribing, and dispensing, including:

- DEA registration and inspection of facilities. Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, record keeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of GH001 or GH002. Furthermore, importation of controlled substances is subject to additional permits or approvals, which must be obtained prior to each importation. Failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that would have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.
- State-controlled substances laws. Individual U.S. states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they will need to separately reschedule GH001 or GH002. While some states automatically schedule or reschedule a drug based on federal action, other states schedule drugs through rule making or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling would have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.
- Clinical trials. Because our GH001 and GH002 product candidates contain 5-MeO-DMT, to conduct clinical trials with GH001 and GH002 in the United States prior to approval, each of our research sites must submit a research protocol to the DEA and obtain and maintain a DEA Schedule I researcher registration that will allow those sites to handle and dispense GH001 and GH002 and to obtain the product from our importer. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and we could lose clinical trial sites. The importer for the clinical trials must also obtain



a Schedule I importer registration and an import permit for each import. We do not currently conduct any manufacturing or repackaging/relabeling of either GH001, GH002 or their active ingredients (i.e., 5-MeO-DMT) in the United States.

- Post-Approval Importation. If GH001 or GH002 is approved and classified as a Schedule II, III or IV substance, an importer can import it for commercial purposes if it obtains an importer registration and files an application for an import permit (Schedule II) or files an import declaration (Schedule III or IV) for each import shipment. The DEA provides annual assessments/estimates to the UN International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of GH001 or GH002 and have a material adverse effect on our business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a notice and comment period to receive public comments. It is always possible that adverse comments may delay the grant of an importer registration. If GH001 or GH002 is approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If GH001 or GH002 is listed as a Schedule II substance, we will not be allowed to import the drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. Moreover, Schedule I controlled substances, including 5-MeO-DMT, have never been registered with the DEA for importation for commercial purposes, only for scientific and research needs. Therefore, if neither GH001, GH002 nor its drug substance could be imported, GH001 and GH002 would have to be wholly manufactured in the United States, and we would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.
- Manufacture in the United States. If, because of a Schedule II classification or voluntarily, we were to conduct manufacturing or repackaging/relabeling in the United States for commercial purposes, our contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of GH001 or GH002, the active ingredient in the final dosage form is currently a Schedule I controlled substance and would be subject to such quotas as this substance could remain listed on Schedule I during the clinical trials. The annual quota allocated to us or our contract manufacturers for the active ingredient in GH001 or GH002 may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which would have a material adverse effect on our business, financial position and results of operations.
- Distribution in the United States and the United Kingdom. If GH001 or GH002 is scheduled as Schedule II, III or IV, we would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute GH001, GH002 and any future product candidates. These distributors would need to maintain Schedule II, III or IV distribution registrations. This limitation in the ability to distribute GH001 or GH002 more broadly may limit commercial uptake and could negatively impact our prospects. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If GH001 or GH002 is a Schedule II drug, participants in our supply chain may have to maintain enhanced security including specially constructed vaults at manufacturing and distribution facilities. This additional security may also discourage some pharmacies from carrying the product. In addition, GH001 and GH002 will likely be required to be administered at our trial sites or other certified healthcare settings, which could limit commercial uptake. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the tracking of prescribing and dispensing of controlled substances through a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, certain controlled substances, especially Schedule II products. Similarly, the MHRA considers that all Schedule 1 drugs under the United Kingdom's Misuse of

Drugs Regulations 2001 (which Schedule includes 5-MeO-DMT) have no therapeutic benefit, and can only be imported, exported, produced, supplied and the like under a license issued by the UK government's Home Office. 5-MeO-DMT may never be rescheduled under the Misuse of Drugs Regulations 2001, or reclassified under the United Kingdom's Misuse of Drugs Act 1971 (under which it is a Class A controlled substance).

### The potential reclassification of 5-MeO-DMT in the United States could create additional regulatory burdens on our operations and negatively affect our results of operations.

If 5-MeO-DMT, rather than just a specific FDA-approved formulation, is rescheduled under the CSA as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), the ability to conduct research on 5-MeO-DMT would most likely be improved. However, rescheduling 5-MeO-DMT may materially alter enforcement policies across many federal and state agencies, primarily the FDA and DEA. The FDA is responsible for ensuring public health and safety through regulation of food, drugs, supplements, and cosmetics, among other products, through its enforcement authority pursuant to the Federal Food, Drug, and Cosmetic Act, or FDCA. The FDA's responsibilities include regulating the ingredients as well as the marketing and labeling of drugs sold in interstate commerce. Because it is currently illegal under federal law to produce and sell 5-MeO-DMT, and because there are no federally recognized medical uses, the FDA has historically deferred enforcement related to 5-MeO-DMT to the DEA. If 5-MeO-DMT were to be rescheduled to a federally controlled, yet legal, substance, the FDA would likely play a more active regulatory role. The DEA would continue to be active in regulating manufacturing, distribution and dispensing of such substances. The potential for multi-agency enforcement post-rescheduling, including state agencies, e.g., Boards of Pharmacy, could threaten or have a materially adverse effect on our business.

# GH001 and GH002 contain controlled substances, the use of which may generate public controversy. Adverse publicity or public perception regarding 5-MeO-DMT and psychedelics generally or our current or future product candidates using 5-MeO-DMT may negatively influence the success of these therapies.

Therapies containing controlled substances may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, GH001, GH002 and any future product candidates we may develop. Opponents of these therapies may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these therapies. For example, we may face media-communicated criticism directed at our clinical development program. Adverse publicity from 5-MeO-DMT misuse may adversely affect the commercial success or market penetration achievable by our GH001 and GH002 product candidates. Anti-psychedelic protests have historically occurred and may occur and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of, GH001, GH002 or any future product candidates.

If GH001, GH002 or any future product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of the safety and quality of our therapies. We may face limited adoption if third-party therapy sites, therapists, and patients are unwilling to try such a novel treatment. Even if therapies containing controlled substances become widely accepted by physicians and patients, our success will depend in large part on our ability to educate and train physicians and patients, and to successfully demonstrate the safety, tolerability, ease of use, efficacy, cost effectiveness and other advantages of therapies containing controlled substances. There has been a history of negative media coverage regarding psychedelic substances, including 5-MeO-DMT, which may affect the public's perception of our therapies. In addition, 5-MeO-DMT elicits intense psychological experiences, and this could deter patients from choosing this course of treatment. We could be adversely affected if we were subject to negative publicity or if any of our therapies or any similar therapies distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perception, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of our therapies or any similar therapies distributed by other companies could have a material adverse impact on our business, prospects, financial condition and results of operations.

Future adverse events in research into depression and mental health diseases on which we focus our research efforts, or the pharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our therapies. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for GH001, GH002 or any future product candidates.

#### 5-MeO-DMT is listed as a Schedule I controlled substance under the CSA in the United States, and comparable controlled substance legislation in other countries and the UN Convention on Psychotropic Substances, 1971, and any significant breaches in our compliance with these laws and regulations, or changes in the laws and regulations may result in interruptions to our development activity or business continuity.

5-MeO-DMT is categorized as a Schedule I controlled substance under the CSA, a Schedule 1 drug under the United Kingdom's Misuse of Drugs Regulations 2001 and is similarly categorized by most states, foreign governments and the UN Convention on Psychotropic Substances, 1971. Even assuming that GH001, GH002 or any future product candidates containing 5-MeO-DMT in specific formulations or dosage forms are approved and scheduled by regulatory authorities to allow their commercial marketing, the ingredients in such product candidates would likely continue to be Schedule I, or the state or foreign equivalent. Violations of any federal, state or foreign laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges and penalties, including, but not limited to, disgorgement of profits, cessation of business activities, divestiture, or prison time. This would have a material adverse effect on us, including on our reputation and ability to conduct business, the potential listing of our ordinary shares, our financial position, operating results, profitability or liquidity or the market price of our ordinary shares. In addition, it is difficult for us to estimate the time or resources that would be needed for the investigation or defense of any such matters or our final resolution because, in part, the time and resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial. It is also illegal to aid or abet such activities or to conspire or attempt to engage in such activities. An investor's contribution to and involvement in such activities may result in federal civil and/or criminal prosecution, including, but not limited to, forfeiture of his, her or its entire investment, fines and/or imprisonment.

Various federal, state, provincial and local laws govern our business in the jurisdictions in which we operate or currently plan to operate, and to which we export or currently plan to export our products, including laws relating to health and safety, the conduct of our operations, and the production, storage, sale and distribution of our products. Complying with these laws requires that we comply concurrently with complex federal, state, provincial and/or local laws. These laws change frequently and may be difficult to interpret and apply. To ensure our compliance with these laws, we will need to invest significant financial and managerial resources. It is impossible for us to predict the cost of such laws or the effect they may have on our future operations. A failure to comply with these laws could negatively affect our business and harm our reputation. Changes to these laws could negatively affect our competitive position and the markets in which we operate, and there is no assurance that various levels of government in the jurisdictions in which we operate will not pass legislation or regulation that adversely impacts our business.

In addition, even if we or third parties were to conduct activities in compliance with U.S. state or local laws or the laws of other countries and regions in which we conduct activities, potential enforcement proceedings could involve significant restrictions being imposed upon us or third parties, while diverting the attention of key executives. Such proceedings could have a material adverse effect on our business, revenue, operating results and financial condition as well as on our reputation and prospects, even if such proceedings conclude successfully in our favor. In the extreme case, such proceedings could ultimately involve the criminal prosecution of our key executives, the seizure of corporate assets, and consequently, our inability to continue business operations. Strict compliance with state and local laws with respect to

5-MeO-DMT does not absolve us of potential liability under U.S. federal law, the laws of EU member states or of the United Kingdom, nor provide a defense to any proceeding which may be brought against us. Any such proceedings brought against us may adversely affect our operations and financial performance.

Despite the current status of 5-MeO-DMT as a Schedule I controlled substance in the United States, there may be changes in the status of 5-MeO-DMT under the laws of certain U.S. cities or states. The legalization of 5-MeO-DMT without regulatory oversight may lead to the setup of clinics without proper therapeutic infrastructure or adequate clinical research, which could put patients at risk and bring reputational and regulatory risk to the entire industry, making it harder for us to achieve regulatory approval. Furthermore, the legalization of 5-MeO-DMT could also impact our commercial sales if we receive regulatory approval as it would reduce the barrier to entry and could increase competition.

#### **Risks Related to the Commercialization of our Product Candidates**

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Even if the FDA or a comparable foreign regulatory authority approves any of our product candidates and the medical devices required to deliver such product candidates, we will be subject to ongoing regulatory requirements in the applicable jurisdictions for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information. In addition, we will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and their facilities are required to comply with extensive regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates and the medical devices required to deliver such product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. In the United States, the FDA may also require a REMS as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

In the United States, the FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information or other restrictions; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the manufacturing of our products, the approved manufacturers or the manufacturing process;
- withdrawal of the product from the market or voluntary product recalls;
- requirements to conduct post-marketing studies or clinical trials;
- fines, restitution or disgorgement of profits or revenues;
- warning or untitled letters from the FDA or comparable notice of violations from comparable foreign regulatory authorities;
- suspensions of any of our ongoing clinical trials;
- refusal by the FDA or other comparable foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of marketing approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

Regulatory authorities strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, in the United States, companies may share truthful and not misleading information that is not inconsistent with the labeling. The FDA and other comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Violations of the FDCA relating to the promotion of prescription drugs may also lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. Accordingly, to the extent we receive marketing approval for one or more of our product candidates, we and our third-party partners will continue to expend time, money and effort in all areas of regulatory compliance, including promotional and labeling compliance, manufacturing, production, product surveillance and quality control.

The policies of the FDA or other comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow to, or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

## Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors and other members of the medical community.

Even if any of the product candidates we develop receives marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, such as Medicare and Medicaid programs and managed care organizations in the United States, and others in the medical community. In addition, the availability of coverage by third-party payors may be affected by existing and future healthcare reform measures designed to reduce the cost of health care. If the product

candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- the ability to offer our products, if approved, for sale at competitive prices;
- relative convenience and ease of administration compared to alternative treatments;
- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of our products and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the size of the market for such product candidate, based on the size of the patient subsets that we are targeting, in the territories for which we gain regulatory approval;
- the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates;
- the strength of sales, marketing and distribution support;
- the timing of any such marketing approval in relation to other product approvals;
- any restrictions on concomitant use of other medications;
- support from patient advocacy groups;
- media coverage regarding psychedelic substances;
- the ability to obtain sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

If government and other third-party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced.

The successful commercialization of our product candidates in the United States will depend in part on the extent to which third-party payors, including governmental authorities and private health insurers, provide coverage and adequate reimbursement levels, as well as implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government healthcare programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations is essential for most patients to be able to afford medical services and biopharmaceutical products such as our product candidates. Third-party payors decide which medications they will pay for and establish reimbursement levels.

In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for our products and related treatments will be available from third-party payors. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

In the United States, no uniform policy for coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates.

A decision by a third-party payor not to cover or not to separately reimburse for our medical products or therapies using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or therapies using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require copayments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost effectiveness of our products, in addition to the costs required to obtain FDA, EMA or other comparable foreign regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.



# Our business and commercialization strategy depends on our ability to identify, qualify, prepare, certify, and support third-party clinics or treatment centers offering any of our product candidates, if approved. If we are unable to do so, our commercialization prospects would be limited and our business, financial condition, and results of operations would be harmed.

Our commercial success with GH001, GH002 or any future product candidates, if approved, will be dependent upon our ability to identify, qualify, prepare, certify, and support third-party clinics or treatment centers that administer our product candidates. We expect that GH001, GH002 and any future product candidates will be administered in qualified third-party clinics or treatment centers by certified healthcare providers. Because we intend to work with third-party centers and providers who agree to adhere to our treatment protocols, possibly under an FDA REMS or a Risk Management Program, or RMP, in Europe with restricted distribution methods, we may face limitations on the number of sites available to administer GH001, GH002 or future product candidates. Moreover, sites may have difficulty satisfying the requirements of any REMS or RMP. Any limitations on the sites available to administer GH001, GH002 or future product candidates could make it impracticable or impossible for some potential patients to access our product candidates, if approved, which could limit the overall size of our potential patient population and harm our future results of operations.

If we are unable to establish or collaborate with a sufficient network of third-party clinics or treatment centers certified under applicable standards, including regional, national, state or other applicable standards as needed to administer GH001, GH002 or any future product candidate, including the certifications that such third-party clinics or treatment centers may require under a potential REMS in the United States or RMP in Europe, it would have a material adverse effect on our business and ability to grow and would adversely affect our results of operations and commercialization efforts.

Given the novel nature and scheduled drug aspect of our treatment, third-party clinics or treatment centers may face additional financial and administrative burdens in order to deliver any approved therapy, including adhering to a REMS in the United States or an RMP in Europe. The process for a third-party clinic or treatment center to comply with a REMS can be costly and time-consuming, which could delay a third-party clinic or treatment centers' ability to administer our product candidates and materially adversely affect our commercialization trajectory. Furthermore, third-party clinics or treatment centers will need to ensure that they have the necessary infrastructure and equipment in order to deliver GH001, GH002 or any future product candidates, such as adequate ancillary equipment and sufficient treatment rooms. This may deter third-party clinics or treatment centers from providing GH001, GH002 or any future product candidates and reduce our ability to expand our network and generate revenue.

### Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Some countries have a separate decision-making process in addition to whether the government or state insurers will reimburse the price for the product. The requirements governing drug pricing vary widely from country to country. For example, in the European Union, member states can restrict the range of medicinal products for which their national health insurance systems provide reimbursement and they can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product. In the United Kingdom, it instead adopts a system of direct or indirect controls on the profitability of the innovator company placing the medicinal product on the market. Approaches between member states are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement

and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower and may be insufficient to generate commercially reasonable revenues and profits.

## Even if we obtain approval of any of our product candidates in the United States or Europe, we may never obtain approval or commercialize such products in other countries, which would limit our ability to realize their full market potential.

In order to market any products in the United States or European Union, we must establish and comply with numerous and varying regulatory requirements regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals outside of where our clinical trials currently have been conducted could result in significant delays, difficulties and costs for us and may require additional nonclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed.

#### We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties. we may not be able to generate any future product revenue and we would incur significant additional losses.

#### **Risks Related to Ongoing Regulatory and Legal Compliance**

### Changes and uncertainties in the tax system in the countries in which we have operations could materially adversely affect our financial condition and results of operations, and reduce net returns to our shareholders.

We plan to conduct business globally and may file income tax returns in multiple jurisdictions in the future. Our consolidated effective income tax rate could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms under consideration (such as those related to the Organization for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS, Project, the OECD's Pillar One and Pillar Two initiatives and other initiatives); the practices of tax authorities in jurisdictions in which we operate; the resolution of issues arising from tax audits or examinations and any related interest or penalties. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid.

We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices in jurisdictions in which we operate, could increase the estimated tax liability that we have expensed to date and paid or accrued on our balance sheets, and otherwise affect our financial position, future results of operations, cash flows in a particular period and overall our effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders and increase the complexity, burden and cost of tax compliance.

## Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken or will take, which could result in increased tax liabilities. For example, The Office of the Revenue Commissioners of Ireland, or Revenue, or another tax authority could challenge our potential future allocation of income by tax jurisdiction and the amounts paid between potential future affiliated companies pursuant to potential future intercompany arrangements and transfer pricing policies, including amounts to be paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. Additionally, a tax authority could assert that we are tax resident in a jurisdiction where we believe we are not. A change of tax residency could subject us to a higher tax rate or an exit tax.

A tax authority may take the position that material tax liabilities, interest and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, in which case we expect that we might contest such assessment. High-profile companies can be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

We exercise significant judgment when determining tax filing positions. The tax rules and regulations are very complex and there can be no assurance that management's interpretation and application of these rules and regulations to determine tax filing positions will be accepted by the tax authorities. If the tax authorities reject a tax filing position taken by the Company, it could have a material adverse effect on our financial position and operating results. There is a risk that the tax authorities could impose additional taxable income or disallow the deductibility of expenses on intercompany transactions resulting in higher tax obligations in one or more tax jurisdictions. Management's experience has been that the tax authorities can be aggressive in taking positions that would increase taxable income and/or disallow

deductible expenses. If the tax authorities are successful in increasing taxable income and/or disallowing deductible expenses in one or more jurisdictions, it could result in the Company experiencing a higher effective tax rate that could be material. Management regularly consults with professional tax advisors when establishing tax filing positions and believes that the tax filing positions taken are in accordance with tax regulations; however, there is always a risk that the tax authorities could disagree with the tax filing positions taken resulting in additional taxes, interest and penalty becoming due and such amount could be material.

### We may be unable to use net operating loss and tax credit carry-forwards and certain built-in losses to reduce future tax payments or benefit from favorable Irish tax legislation.

As an Irish incorporated and tax resident company, we are subject to Irish corporate taxation on our worldwide profits. Due to the nature of our business, we have generated losses since inception and therefore have not paid any Irish corporation tax. As of March 31, 2021, we had unused net operating losses of \$2 million. Subject to any relevant utilization criteria and restrictions (including those that can restrict the use of carried forward losses where there is a change of ownership of more than half of our ordinary shares and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry-forward and utilization against future operating profits.

As a company that carries out extensive research and development activities, we seek to benefit from the Irish research and development tax credit for certain expenditure on research and development activities, plant and machinery and buildings as set out in the Taxes Consolidation Act 1997 of Ireland, or the TCA, and the Taxes Consolidation Act 1997 (Prescribed Research and Development Activities Regulations) 2004. Credit is given at 25% of allowable expenditure subject to satisfying the applicable conditions.

We may benefit from Ireland's Knowledge Development Box regime in the future, under which an eligible company will be entitled to a corporate tax deduction equal to 50% of its qualifying profits. Qualifying profits are profits directly attributable to the exploitation of certain types of IP (patents, copyrighted computer software) that have been developed by the Irish company through qualifying R&D activities undertaken by the Irish company. In effect, such qualifying profits are taxed at 6.25% where the conditions of the regime are met. The availability of the relief is fact dependent and we will consider the applicability of this relief as our activities progress.

When taken in combination with the research and development tax credit, we expect a long-term rate of Irish corporation tax lower than the statutory rate to apply to us. If, however, there are unexpected adverse changes to the Irish research and development tax credit regime or the Knowledge Development Box regime, or for any reason we are unable to qualify for such regimes, or we are unable to use net operating loss and tax credit carry-forwards and certain built-in losses to reduce future tax payments then our business, results of operations and financial condition may be adversely affected. This may impact our ongoing requirement for investment and the timeframes within which additional investment is required.

### We may become subject to U.S. federal and state forfeiture laws which could negatively impact our business operations.

Violations of any U.S. federal laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges, including, but not limited to, seizure of assets, disgorgement of profits, cessation of business activities or divestiture. As an entity that conducts business involving 5-MeO-DMT, we are potentially subject to federal and state forfeiture laws (criminal and civil) that permit the government to seize the proceeds of criminal activity. Civil forfeiture laws could provide an alternative for the federal government or any state (or local police force) that wants to discourage residents from conducting transactions with 5-MeO-DMT- related businesses but believes criminal liability is too difficult to prove beyond a reasonable doubt. Also, an individual can be required to forfeit property considered to be the proceeds of a crime even if the individual is not convicted of the crime, and the standard of proof in a civil forfeiture matter is lower than the standard in a criminal matter. Depending on the applicable law, whether federal or state, rather than having to establish liability beyond a reasonable

doubt, the federal government or the state, as applicable, may be required to prove that the money or property at issue is proceeds of a crime only by either clear and convincing evidence or a mere preponderance of the evidence.

Investors located in jurisdictions where 5-MeO-DMT remains illegal may be at risk of prosecution under conspiracy, aiding and abetting, and money laundering statutes, and be at further risk of losing their investments or proceeds under forfeiture statutes. Many jurisdictions remain fully able to take action to prevent the proceeds of 5-MeO-DMT businesses from entering their state. Our investors and prospective investors should be aware of these potentially relevant laws in considering whether to invest in us.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from manufacturing GH001 and GH002 and developing and selling GH001, GH002 or any future product candidates outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition. Our directors and managers might also be subject to criminal penalties, including jail time.

Our operations are subject to anti-corruption laws, including the Criminal Justice (Corruption Offences) Act 2018 of Ireland, or Criminal Justice Act, the U.S. Foreign Corrupt Practices Act, or FCPA, the UK Bribery Act 2010, or UK Bribery Act, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Criminal Justice Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage.

The Criminal Justice Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, a financial or other advantage to government officials or other persons to induce them to improperly perform a relevant function or activity (or reward them for such behavior).

Under the Criminal Justice Act and under the UK Bribery Act we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We, along with those acting on our behalf and our commercial partners, operate in a number of jurisdictions that pose a high risk of potential Criminal Justice Act or FCPA or UK Bribery Act violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Criminal Justice Act, FCPA, UK Bribery Act or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

Compliance with the FCPA and the UK Bribery Act in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA and the UK Bribery Act present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

In the future, we may operate in jurisdictions that pose a high risk of potential Criminal Justice Act, FCPA or UK Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Criminal Justice Act, FCPA, UK Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in member states of the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from manufacturing GH001 or GH002 and developing and selling GH001, GH002 or any future product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Criminal Justice Act, the FCPA, the UK Bribery Act or other legal requirements, including Trade Control laws. If we are not in compliance with the Criminal Justice Act, the FCPA, the UK Bribery Act and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which would have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Criminal Justice Act, the FCPA, other anti-corruption laws or Trade Control laws by Irish, U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

## Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of our product candidates, if approved, we will be subject to additional healthcare statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors, customers and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business or financial arrangements.

The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The term remuneration has been interpreted broadly to include anything of value. Further, courts have found that if "one purpose"

of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment and exclusion from government healthcare programs. In addition, a claim submitted for payment to any federal healthcare program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor;

- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery or settlement. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be

additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians will extend to include transfers of value made in the previous year to certain non-physician providers including physician assistants and nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous U.S. state, local and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of biopharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health and other personal information, some of which may be more stringent than those in the United States (such as the European Union's General Data Protection Regulation, or GDPR, which became effective in May 2018) in certain circumstances, and may differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of biopharmaceutical products is subject to additional requirements and regulations, including extensive record keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of biopharmaceutical products.

If the FDA, EMA or a comparable foreign regulatory authority approves any of our product candidates, we will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom may receive stock options as compensation for services provided, may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm,

exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar penalties. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of the business. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. All of these could harm our ability to operate our business and our financial results.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

#### Our actual or perceived failure to comply with applicable health information and data protection laws and regulations, standards and other requirements could lead to governmental enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to U.S. and foreign federal, state and local laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health and personal information privacy laws, and federal and state consumer protection laws, govern the collection, use, processing, storage, transmission, disclosure, destruction and protection of health-related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, which are subject to privacy and security requirements under HIPAA, as amended by HITECH. To the extent that we act as a business associate we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of certain standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Additionally, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018, or CCPA, which came into effect on January 1, 2020 and provides new data privacy rights for California consumers (as that term is defined in the legislation) and new operational requirements for companies that process information of California residents, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action and statutory damages for data breaches that is expected to increase data breach litigation. While there is currently an exception under the CCPA for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may nevertheless impact certain of our business to the evolving regulatory environment related to personal information. In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, which goes into effect on January 1, 2023. Unless amended, the CPRA will impose additional obligations on companies covered by

the legislation and significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and CPRA. Some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase our potential liability and adversely affect our business. Other states and the U.S. federal government are considering comprehensive privacy laws, and on March 2, 2021, the Virginia Consumer Data Protection Act, or CDPA, was signed into law. The CDPA becomes effective January 1, 2023 and contains provisions that require businesses subject to the legislation to conduct data protection assessments in certain circumstances and that require opt-in consent from Virginia consumers to process certain sensitive personal information.

The collection, use, storage, disclosure, transfer, or other processing of personal data (including health data processed in the context of clinical trials) regarding EU data subjects in the European Economic Area, or EEA, and/or carried out in the context of the activities of our establishment in any EEA member state, is subject to the GDPR, which became effective on May 25, 2018.

The GDPR is wide-ranging in scope and imposes numerous additional requirements on companies that process personal data of individuals residing in Europe, including imposing special requirements in respect of the processing of health and other sensitive data, requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring additional disclosures to individuals regarding data processing activities, requiring that appropriate safeguards are implemented to protect the security and confidentiality of personal data, creating mandatory data breach notification requirements in certain circumstances, and requiring that certain measures (including contractual requirements) are put in place when engaging third-party data processors. The GDPR permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenue, whichever is greater. The GDPR also provides individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection, and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information.

The GDPR and the Irish Data Protection Act 2018 also impose strict rules on the transfer of personal data to countries outside the European Economic Area, including the United States, unless the parties to the transfer have implemented safeguards to protect the transferred personal information. The Court of Justice of the European Union, or CJEU, recently raised questions about whether the European Commission's Standard Contractual Clauses, one of the primary mechanisms used by companies to import personal information from Europe, complies with the GDPR. While the CJEU upheld the validity of the Standard Contractual Clauses, the CJEU ruled that the underlying data transfers must be assessed on a case-by-case basis by the data controller to determine whether the personal information will be adequately protected. Further, the European Commission recently proposed updates to the Standard Contractual Clauses. At present, there are few if any viable alternatives to the Standard Contractual Clauses and there is uncertainty regarding how to ensure that transfers of personal information from Europe to the United States might be adequately protected so as to comply with the GDPR. As such, any transfers by us, or our vendors, of personal information from Europe may not comply with European data protection laws and may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions. Loss of our ability to transfer personal information from the European Economic Area may also require us to increase our data processing capabilities in those jurisdictions at significant expense.

Further, the United Kingdom's withdrawal from the European Union and European Economic Area on January 31, 2020 has created uncertainty with regard to data protection regulation in the United Kingdom. As of January 1, 2021, we are also subject to the UK GDPR and UK Data Protection Act of 2018, which retains the EU GDPR in the United Kingdom's national law. In particular, the collection, use, storage,

disclosure, transfer, or other processing of personal data (including health data processed in the context of clinical trials) regarding data subjects in the United Kingdom and/or carried out in the context of the activities of our establishment in the United Kingdom is subject to the UK GDPR and the UK Data Protection Act of 2018. However, it is still unclear whether the transfer of personal information from the European Economic Area to the United Kingdom will remain lawful under the GDPR in the longer term, although this is currently subject to a bridge, allowing for lawful transfers until June 30, 2021 while awaiting an adequacy decision from the European Data Protection Board. If adequacy is granted, this will last for a period of four years before being reconsidered.

In addition, Europe and other foreign jurisdictions have enacted laws, regulations, standards and common practices that relate to the privacy of clinical trial data, including as a condition to approve clinical trials. These requirements are evolving and uncertain and they may result in delays to our ability to launch clinical trials or limit the jurisdictions in which we may conduct clinical trials.

The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR. While we have taken steps to comply with the GDPR and implementing legislation in applicable EEA member states, including by seeking to establish appropriate lawful bases for the various processing activities we carry out as a controller or joint controller, reviewing our security procedures and those of our vendors and collaborators, and entering into data processing agreements with relevant vendors and collaborators, we cannot be certain that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful.

The regulatory framework for data privacy and security issues in the United States and abroad is rapidly evolving and likely to remain uncertain for the foreseeable future. Compliance with applicable privacy and data protection laws and regulations is a rigorous and time-intensive process and could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose certain data, or in some cases, impact our ability to operate in certain jurisdictions. Despite our efforts to bring our practices into compliance with these laws and regulations, we may not be successful in our efforts to achieve compliance due to internal or external factors, such as resource allocation limitations or a lack of vendor cooperation. In addition, because the interpretation and application of privacy and data protection laws are still uncertain, it is possible that these laws and other actual or alleged legal obligations, such as contractual or self-regulatory obligations, may be interpreted and applied in a manner inconsistent with our data management practices. Our failure or perceived failure to comply with these laws, regulations and obligations could result in government investigations, proceedings and enforcement actions (which could include civil, criminal and administrative penalties). public statements against us by government entities, private parties, consumer advocacy groups or others, private litigation, contractual penalties, monetary damages and/or adverse publicity, and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

### Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in U.S. and foreign regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative initiatives and regulatory changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering

the cost of healthcare. For example, in March 2010, the ACA was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, expands the types of entities eligible for the 340B drug discount program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; established annual fees and taxes on manufacturers of certain branded prescription drugs; and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70%) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive and legislative challenges to certain aspects of the ACA. Various portions of the ACA are currently undergoing legal and constitutional challenges in the U.S. Supreme Court; the Trump Administration issued several executive orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers. health insurers or manufacturers of pharmaceuticals or medical devices; and Congress considered several pieces of legislation aimed at significantly revising or repealing the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction. tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, unless additional Congressional action is taken. However, pursuant to Congressional action, these Medicare sequester reductions were suspended through December 31, 2021 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the BBA, among other things, amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount (from 50% under the ACA to 70%) that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other

things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Although a number of these and other measures may require additional authorization to become effective, Congress and the Biden administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level in the United States, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidate, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Legislation changes may also affect the legal requirements under which we perform our technical, nonclinical and clinical development of our product candidates and the medical devices required to deliver such product candidates, and they may affect how the FDA, EMA and comparable foreign regulatory agencies review and approve new drug products, drug-device combination products or medical devices.

For example, on April 5, 2017, the European Parliament passed the MDR, which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the European Economic Area for medical devices and ensure a high level of safety and health while supporting innovation.

The MDR is currently scheduled to become applicable on May 26, 2021. Once applicable, the new regulations will, among other things:

- strengthen the rules on placing medical devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of medical devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union;
- strengthened rules for the assessment of certain high-risk medical devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have a significant effect on the way we can develop our product candidates and the medical devices required to deliver such product candidates, and may delay our development significantly.

In the United Kingdom, medical devices will continue to be regulated by laws equivalent to the EU directives and the government is consulting on new laws which are planned to take effect from the end of December 2022. These new laws will impose an additional regulatory burden for any products we intend to market in Great Britain, as Northern Ireland will remain subject to EU law.

In addition, the European Union has adopted the Clinical Trials Regulation, or Regulation 536/2014, or CTR, in April 2014, which is expected to come into application in 2022. The CTR will be directly applicable in all the EU member states, repealing the current Clinical Trials Directive. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new CTR becomes applicable. The extent to which ongoing clinical trials will be governed by the CTR will depend on when the CTR becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the CTR becomes applicable the CTR will at that time begin to apply to the clinical trial. The CTR harmonizes the assessment and supervision processes for clinical trials throughout the European Union via a Clinical Trials Information System, which will notably contain a centralized EU portal and database.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States or in any other jurisdictions. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

#### In the United States, inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. federal government has shut down several times and certain regulatory agencies, such as the FDA have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to temporarily postpone most inspections of foreign manufacturing facilities along with routine surveillance inspections of domestic manufacturing facilities. On July 10, 2020, the FDA announced its goal of restarting domestic onsite inspections during the week of July 20, but such activities would depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. In April 2020, the FDA stated that its New Drug Program was continuing to meet program user fee performance goals, but due to many agency staff working on COVID-19 activities, it was possible that the FDA would not be able to sustain that level of performance indefinitely. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

#### EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states.

We ultimately intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU member states, and in respect of the United Kingdom (which is no longer a member of the European Union), the UK Bribery Act of 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In addition, in most foreign countries, including those in the European Union, the United Kingdom and the European Economic Area, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

# Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the United Kingdom and pose additional risks to our business, revenue, financial condition, and results of operations.

On June 23, 2016, the United Kingdom held a referendum in which a majority of the eligible members of the electorate voted to leave the European Union, commonly referred to as Brexit. Pursuant to Article 50 of the Treaty on European Union, the United Kingdom ceased being a member state of the European Union on January 31, 2020. The implementation period began February 1, 2020 and continued until December 31, 2020, during which the United Kingdom continued to follow all of the European Union's rules, the European Union's pharmaceutical law remained applicable to the United Kingdom and the United Kingdom's trading relationship remained the same. The United Kingdom and the European Union have signed an EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and will become formally applicable once ratified by both the United Kingdom and the European Union. This agreement provides details on how some aspects of the United Kingdom and European Union's relationship will operate going forward, however there are still many uncertainties and how the TCA will take effect in practice is still largely unknown. The lack of clarity with future UK laws and regulations and their interaction with the EU laws and regulations may negatively impact foreign direct investment in the United Kingdom, increase costs, depress economic activity and restrict access to capital.

The uncertainty concerning the United Kingdom's legal, political and economic relationship with the European Union after Brexit may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise) beyond the date of Brexit.

These developments may have a significant adverse effect on global economic conditions and the stability of global financial markets and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the UK financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

In addition, if other EU member states pursue withdrawal, barrier-free access in the European Economic Area could be diminished or eliminated. The long-term effects of Brexit will depend on how the terms of the TCA take effect in practice and any further agreements (or lack thereof) between the United Kingdom and the European Union.

Such a withdrawal from the European Union is unprecedented, and it is unclear how the restrictions on the United Kingdom's access to the European single market for goods, capital, services and labor within the European Union, or single market, and the wider commercial, legal and regulatory environment, will impact our current and future operations (including business activities conducted by third parties and contract manufacturers on our behalf) and clinical activities in the United Kingdom. In addition to the foregoing, our UK operations support our current and future operations and clinical activities in the European Union and European Economic Area, and these operations and clinical activities could be disrupted by Brexit.

We may also face new regulatory costs and challenges that could have an adverse effect on our operations. The United Kingdom will lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers that could make our doing business in the United Kingdom more difficult. Since the regulatory framework in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime with respect to the approval of our product candidates in the United Kingdom now that the UK legislation can diverge from EU legislation.

For instance, Great Britain will now no longer be covered by the centralized procedures for obtaining EEA-wide marketing and manufacturing authorizations from the EMA (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland) and a separate process for authorization of drug products will be required in Great Britain, resulting in an authorization covering the United Kingdom or Great Britain only. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and restrict our ability to generate revenue and achieve and sustain profitability. The majority of our nonclinical and manufacturing work is done by CMOs, in the United Kingdom. In particular, the United Kingdom no longer being a part of the EU customs union may result in delays in importation and exportation of our clinical trial materials product candidates, and disruption of the supply chain for our clinical trial materials and product candidates. If any of these outcomes occurs, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business. Even prior to any change to the United Kingdom's relationship with the European Union, the announcement of Brexit has created economic uncertainty surrounding the terms of Brexit, and its consequences could adversely impact customer confidence resulting in customers reducing their spending budgets on our product candidates, if approved, which could adversely affect our business, financial condition, results of operations and could adversely affect the market price of our ordinary shares.

## If we or any third parties working with 5-MeO-DMT whom we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We, and third parties working on our behalf, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use,

storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations and the operations of third parties operating on our behalf may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In particular, there is limited toxicology data on 5-MeO-DMT, and the risk of contamination and injury is higher as we and third parties working on our behalf work with 5-MeO-DMT in its aerosolized form. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain employer's liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

#### **Risks Related to Intellectual Property**

We rely on applications for patents and other intellectual property rights to protect our GH001 and GH002 product candidates, the prosecution, enforcement, defense and maintenance of which may be challenging and costly. Failure to adequately prosecute, maintain, enforce or protect these rights could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights relating to GH001 and GH002, any future product candidates, methods used to manufacture the underlying therapeutic substances, compositions and methods for treating patients using those substances and therapies and medical devices used to deliver such substances and therapies, or licensing such rights from third parties. Failure to obtain, maintain, protect, enforce or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market GH001, GH002 and any future product candidates, and medical devices to deliver such product candidates. We also rely on trade secrets and know-how to develop and maintain our proprietary and intellectual property position. Any failure to protect our trade secrets and know-how could similarly adversely affect our operations and prospects.

We do not currently own or exclusively license any issued patents, and we cannot be certain that patents will be issued or granted with respect to our or any of our future licensors' pending and future patent applications, or that issued or granted patents will not later be found to be invalid or unenforceable. The patent position of companies like ours is generally uncertain because it involves complex legal and factual considerations and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights is highly uncertain. The standards applied by the European Patent Office, the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in pharmaceutical patents. Consequently, patents may not issue from our pending patent applications, and even if they do issue, such patents may not issue in a form that effectively prevents others from developing or commercializing competing therapies. As such, we do not know the degree of future protection that we will have on our proprietary therapies. This risk is further heightened with respect to our GH001 and GH002 product candidates given that 5-MeO-DMT is a naturally occurring substance and therefore is not subject to patent protection.

The patent prosecution process is expensive, complex and time-consuming, and we and any of our third-party licensors, licensees, or collaboration partners may not be able to prepare, file and prosecute all

necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaboration partners will fail to identify patentable aspects of inventions made in the course of research, development or commercialization activities before it is too late to pursue patent protection on them. In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not published until and unless granted. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that for any in-licensed patents or pending patent applications, the named applicant(s) were the first to make the inventions claimed in such patents or pending patent applications or that the named applicant(s) were the first to file for patent protection for such inventions.

Moreover, in some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering technology that we license from or license to third parties, and may be reliant on our licensors, licensees or collaboration partners to do so. Therefore, these patents and applications may not be prepared, filed, prosecuted, maintained, enforced or defended in a manner consistent with the best interests of our business. If any of our current or future licensors, licensees or collaboration partners fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any of our licensors, licensees or collaboration partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patents and other intellectual property rights, such rights could be compromised and our right to develop and commercialize our product candidates that are subject to such license rights could be adversely affected.

The patent examination process may also require us or our licensors, licensees or collaboration partners to narrow the scope of the claims of our or our licensors', licensees' or collaboration partners' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our or any of our licensors', licensees' or collaboration partners' patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our or any of our licensors', licensees' or collaboration partners' patents may be challenged in the courts or patent offices in the United States and abroad. Even if patents do successfully issue and even if such patents cover GH001, GH002 and any future product candidates, third parties may initiate an opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation proceedings in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and therapies, or limit the duration of patent protection of our technology and product candidates.

Our and our licensors', licensees' or collaboration partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. In addition, patents and other intellectual property rights will not protect our technology, GH001, GH002 or any future product candidates or medical devices to deliver such product candidates if third parties, including our competitors, design around our protected technology, GH001, GH002 or any future product candidates to deliver such product candidates without infringing, misappropriating or

otherwise violating our owned or in-licensed patents or other intellectual property rights. Moreover, some of our patents and patent applications may be co-owned with third parties in the future. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing therapies and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors, licensees or collaborators were or will be the first to file any patent application related to a product candidate. Furthermore, if patent applications of third parties have an effective filing date before March 16, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If patent applications of third parties have an effective filing date on or after March 16, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, we may be subject to third-party challenges regarding our exclusive ownership of our intellectual property. If a third party were successful in challenging our exclusive ownership of any of our intellectual property, we may lose our right to use such intellectual property, such third party may be able to license such intellectual property to other third parties, including our competitors, and our competitors could market competing therapies and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, we may develop, acquire or license intellectual property rights that have been generated through the use of U.S. government funding. As a result, the U.S. government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive, worldwide, irrevocable license authorizing the U.S. government to use the inventions for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our technology. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

#### We may be involved in lawsuits or administrative proceedings to protect or enforce our patents or other intellectual property rights, and issued patents covering one or more of our product candidates could be found invalid or unenforceable if challenged in court.

Competitors or other third parties may infringe, misappropriate or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To protect our competitive position, we may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of our or our licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to

prosecuting these legal actions and better sustain the costs of such actions than we or our licensors or collaboration partners can. Accordingly, despite our or our licensors' or collaboration partners' efforts, we or our licensors or collaboration partners may not prevent third parties from infringing upon, misappropriating or otherwise violating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United Kingdom, European Union and the United States. We may also fail in enforcing our rights, in which case our competitors and other third parties may be permitted to use our therapies or other technologies without payment to us.

In addition, litigation involving our patents carries the risk that one or more of our patents will be narrowed, held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our therapies or other technologies, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States or in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the European Patent Office or the USPTO or made a misleading statement during prosecution. Third parties may also raise challenges to the validity of our patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (i.e., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover GH001, GH002 or any future product candidates or medical devices to deliver such product candidates. The outcome following legal assertions of invalidity and unenforceability during patent litigation or other proceedings is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant or third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on GH001, GH002 or one or more of any future product candidates or medical devices to deliver such product candidates. Such a loss of patent protection could have a material adverse impact on our business financial condition, results of operations, and prospects. Further, litigation could result in substantial costs and diversion of management resources, regardless of the outcome, and this could harm our business and financial results.

We may also be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. It is possible that we do not perfect our ownership of all patents, patent applications and other intellectual property. This possibility includes the risk that we do not identify all inventors, or identify incorrect inventors, which may lead to claims disputing inventorship or ownership of our patents, patent applications and other intellectual property by former employees or other third parties. There is also a risk that we do not establish an unbroken chain of title from inventors to us. Errors in inventorship or ownership can sometimes also impact priority claims. If we were to lose the ability to claim priority for certain patent filings, intervening art or other events may preclude us from issuing patents. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to monetary damages, we may lose valuable intellectual property rights. Such an outcome could significantly harm our business and financial results.

# Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal, annuity and various other governmental fees on any issued or applied-for patents are due to be paid to the European Patent Office, the USPTO and foreign patent

agencies in several stages over the lifetime of a patent. The European Patent Office, the USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we may rely on our collaboration partners, law firms or other professionals to pay these fees due to the USPTO and comparable foreign patent agencies and to take the necessary action to comply with such requirements with respect to our intellectual property. While instances of inadvertent non-compliance can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of a patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our service providers, licensors or collaboration partners fail to maintain the patents and patent applications covering our product candidates, our patent protection could be reduced or eliminated and third parties, including our competitors, might be able to enter the market with similar or identical therapies or technologies, which would have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, if we fail to apply for or otherwise fail to obtain applicable patent term extensions or adjustments as a result of such non-compliance, we will have a more limited time during which we can enforce our granted patent rights. Further, if we are responsible for patent prosecution and maintenance of patent rights in-licensed to us, any of the foregoing could expose us to liability to the applicable patent owner.

## If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

In the United States, if all maintenance fees are paid on time, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but there can be no assurance that any such extensions will be obtained, and the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture or use are obtained, once the patent life has expired, we may be open to competition from competitive therapies or technologies. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates and concomitant therapies might expire before or shortly after such candidates and concomitant therapies are commercialized. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing therapies similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of GH001, GH002 and any of our future product candidates and medical devices to deliver such product candidates, one or more U.S. patents that we may own or license in the future may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the normal expiration for a patent covering an approved product as compensation for effective patent term loss during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, is limited to the approved indication (or any additional indications approved during the period of extension) and only one patent per approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method of manufacturing it may be extended. Patent term extension may also be available in certain foreign jurisdictions, including the European Union, upon regulatory approval of any product candidates we develop. However, we may not receive an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will not be lengthened and third parties, including our competitors, may obtain approval to market competing

therapies sooner than we expect. As a result, our revenue from applicable therapies could be materially reduced and our business, financial condition, results of operations, and prospects could be materially harmed.

### Intellectual property rights do not necessarily address all potential threats to our business and competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make compositions that are the same as or similar to GH001, GH002, and any future product candidate compositions, or may be able to make medical devices to deliver such compositions, that are not covered by the claims of the patents that we own or license;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or collaboration partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or license;
- we or our licensors or collaboration partners might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that current and future pending patent applications we own or in-license will not lead to issued patents;
- issued patents that we own or in-license may not provide us with any competitive advantage, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- issued patents that we own or in-license may not have sufficient term or geographic scope to provide meaningful protection;
- our competitors might conduct research and development activities in countries that provide a safe harbor from patent infringement claims for certain research and development activities or in countries where we do not have patent rights and then use the information learned from such activities to develop competitive therapies for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our therapies or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional technologies that are patentable; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property, or otherwise develop similar know-how.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

## We may be subject to claims by third parties asserting that we or our employees, consultants or advisors have misappropriated their intellectual property, including trade secrets, or claiming ownership of what we regard as our own intellectual property.

Many of our consultants, advisors and employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors and potential competitors. Some of these individuals executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we intend that our consultants,

advisors and employees do not use proprietary information or know-how of their former employers while working for us, we may be subject to claims that we or these individuals have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. Litigation may be necessary to defend against these claims, regardless of their merit, and we cannot predict whether we would prevail in any such actions. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages, our development and commercialization efforts may be prevented or delayed, and we could be required to obtain a license from such third party to commercialize our therapies or other technologies. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract our management from its day-to-day activities, and may cause negative publicity.

In addition, we may be subject to claims by our current or former employees or contractors asserting an ownership right in our intellectual property as a result of the work they performed on our behalf. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, for which we may not have an adequate remedy, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

# Intellectual property rights of third parties could adversely affect our ability to compete or commercialize our product candidates. Third parties may allege that we are infringing, misappropriating or otherwise violating their intellectual property rights such that we could be required to litigate or obtain licenses from third parties in order to develop or market our product candidates, which could be costly and have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability and the ability of our future collaborators to develop, manufacture, market, and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In the future, we may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to GH001, GH002 or any future product candidates or medical devices to deliver such product candidates. If the outcome of any such proceeding or litigation is adverse to us, it may affect our ability to compete effectively.

Additionally, our competitive position may suffer if patents issued to third parties, or other third-party intellectual property rights, cover our therapies or elements thereof, our manufacture or uses relevant to our development plans, the targets of GH001, GH002 or any future product candidates, or medical devices to deliver such product candidates, or other attributes of GH001, GH002 or any future product candidates. In such cases, we may not be in a position to develop or commercialize such product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms or at all. In the event that a patent has not expired at the time of approval of such product candidate(s) and the patent owner were to bring an infringement action against us, we may have to argue that our product candidates or the manufacture or use of the underlying therapeutic substances do not infringe a valid claim of the patent in question. Alternatively, if we were to challenge the validity of any issued U.S. patent. This means that in order to prevail, we would need to present clear and convincing evidence as to the invalidity of the patent's

claims. The same applies to certain other jurisdictions. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. In the event that a third party successfully asserts its patent against us such that such third party's patent is found to be valid and enforceable and infringed by our product candidates, unless we obtain a license to such patent, under which we would most likely be required to pay various types of fees, milestones, royalties or other amounts, and which may not be available on commercially reasonable terms or at all, we could be prevented from continuing to develop or commercialize our product candidates.

It is possible that we have failed, and in the future may fail, to identify relevant patents or applications that may be asserted against us. For example, certain U.S. patent applications filed after November 29, 2000 can remain confidential until and unless issued as patents, provided that inventions disclosed in the applications have not and will not be the subject of a corresponding application filed outside the United States. In general, patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our therapies could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our therapies or the use of our therapies.

Third-party intellectual property right holders, including our competitors, may actively bring infringement, misappropriation or violation claims against us based on existing or future intellectual property rights, regardless of their merit. We may not be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our therapies. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect.

If we are unsuccessful in defending any such claim, in addition to being forced to pay damages, we or our licensees may be temporarily or permanently prohibited from commercializing any of our product candidates that were held to be infringing. If possible, we might be forced to redesign GH001, GH002 or any future product candidates or medical devices to deliver such product candidates so that we no longer infringe the intellectual property rights of third parties, or we may be required to seek a license to any such technology that we are found to infringe, which license may not be available on commercially reasonable terms or at all. Even if we or our licensors or collaboration partners obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors or collaboration partners and it could require us to make significant licensing and royalty payments. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. We could also be required to indemnify collaborators or contractors against such claims. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

In addition, if the breadth or strength of protection provided by our or our licensors' or collaboration partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

## Intellectual property litigation could cause us to spend substantial resources, distract our personnel from their normal responsibilities, harming our reputation and our business operations.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development and commercialization activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property proceedings could have a material adverse effect on our ability to compete in the marketplace.

## We may not be successful in obtaining or maintaining necessary rights to GH001, GH002 or any future product candidates or any medical devices to deliver such product candidates through acquisitions and in-licenses.

In the future, our programs may require the use of intellectual property or proprietary rights held by third parties, and the growth of our business will likely depend in part on our ability to acquire, in-license, maintain and use these intellectual property and proprietary rights.

For our GH001 inhaled product candidate, we currently acquire the device used to create the inhaled aerosol from a third party. The device and our uses thereof may be covered by one or more patents issued to such third party or other third parties, or other intellectual property rights of such third party or other third party a commercial supply agreement with this third party, nor have we established license or development agreements with any alternative provider of a suitable device. It is our intention, for GH001 and for any future delivery platforms that include the use of a device, to either in-license technology or work with a contract development and manufacturing organization, or CDMO, to develop in-house delivery. However, we may not be able to develop an alternative in-house delivery device suitable for GH001, and our competitive position may suffer if we are unable to obtain necessary commercial supply agreements, licenses, or development agreements with this third party or other third parties to use a suitable device in our GH001 inhaled product candidate or future product.

In addition, with respect to any patents we may co-own with third parties, we may require licenses to such co-owners' interest in such patents. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for GH001, GH002 or any future product candidates or medical devices to deliver such product candidates on commercially reasonable terms or at all. For example, we may collaborate with U.S. and foreign academic institutions to accelerate our nonclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable investigational therapy or program.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a

competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully acquire or obtain a license to third-party intellectual property rights necessary for the development of an investigational therapy or program, or maintain the existing intellectual property rights we have, we may have to abandon development of that investigational therapy or program, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Furthermore, even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments.

## Changes in patent laws or patent jurisprudence could diminish the value of patents in general or prevent us from obtaining adequate patent protection, and thereby impair our ability to protect our product candidates.

As is the case with other companies in our industry, our success is heavily dependent on obtaining, maintaining, protecting and enforcing our intellectual property rights, particularly patents. Obtaining and enforcing patent rights in the pharmaceutical industry involves technological and legal complexity, and is costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For example, the America Invents Act, or the AIA, enacted in the United States in 2012 and 2013, has resulted in significant changes to the U.S. patent system.

Prior to the enactment of the AIA, assuming that other requirements for patentability are met, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 16, 2013, under the AIA, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention regardless of whether a third party was the first to invent the claimed invention. Under this regime, a third party that files a patent application in the USPTO before us could be awarded a patent covering an invention of ours even if we made the invention before the third party. The AIA requires us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other significant changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide additional opportunities for third parties to challenge any pending patent application or issued patent in the USPTO. Such opportunities include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim in any of our future U.S. patents invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use USPTO procedures to invalidate patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of any of our future U.S. patent applications and the enforcement or defense of any patents that may issue from such patent applications.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the

USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If we fail to comply with our obligations under the agreements pursuant to which we license intellectual property rights to or from third parties, or otherwise experience disruptions to our business relationships with our licensors, licensees or collaborators, we could lose the rights to intellectual property that is important to our business and lose the ability to continue the development and/or commercialization of our product candidates.

We are party to development agreements with CDMOs under which we grant such CDMOs nonexclusive rights to use certain of our intellectual property as necessary for such CDMOs to perform their obligations under such agreements, and under which we are granted non-exclusive rights to use certain of such CDMOs' intellectual property as necessary in order to use and exploit such CDMOs' deliverables under such agreements. We expect that we may need to enter into additional license or collaboration agreements in the future that may be important to our business. We expect that future license agreements may impose various financial and other obligations on us related to, among other things, therapeutic development and payment of royalties and fees based on achieving certain milestones. In addition, under such future license agreements, we may be prohibited from developing and commercializing therapies that would compete with the therapies licensed under such agreements. If we fail to comply with our obligations under these agreements, our licensor or collaboration partner may have the right to terminate the agreement, including any licenses included in such agreement, and we may face other liabilities for breach of such agreement.

The termination of any license or collaboration agreements or failure to adequately protect our or our collaborators' rights under such license or collaboration agreements could prevent us from further developing or commercializing GH001, GH002 or any future product candidates or medical devices to deliver such product candidates covered by the agreement or intellectual property licensed thereunder. For example, we may rely on license agreements which grant us rights to certain intellectual property and proprietary materials that we use in connection with the development of our therapies. If such agreements were to terminate, we may be unable to timely license similar intellectual property and proprietary materials from an alternate source, on commercially reasonable terms or at all, and may be required to conduct additional bridging studies on GH001, GH002 or any future product candidates, or medical devices, or the methods for manufacturing them, which could delay or otherwise have a material adverse effect on the development and commercialization of GH001, GH002 or any future product candidates or medical devices to deliver such product candidates.

Our existing and future license agreements may also contain sublicenses from third parties which are not the original licensor of the intellectual property at issue. Under these agreements, we must rely on our licensor to comply with its obligations under the primary license agreements under which such third party obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate the sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property and, in the case of a sublicense, if we were not able to secure our own direct license with the owner of the relevant rights, which we may not be able to do at a reasonable cost or on reasonable terms, it may adversely affect our ability to continue to develop and commercialize GH001, GH002 or any future product candidates or medical devices to deliver such product candidates incorporating the relevant intellectual property.

Disputes may arise regarding intellectual property subject to a license or collaboration agreement, including the following:

the scope of rights granted under the agreement and other interpretation-related issues;

- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor or collaboration partner that is not subject to the agreement;
- the sublicensing of patents and other rights under any current or future collaboration relationships;
- our diligence obligations under the agreement and what activities satisfy those diligence obligations;
- our rights to transfer or assign the agreement;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaboration partners; and
- the priority of invention of patented technology.

In addition, third-party license and collaboration agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

## Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and protect other proprietary information.

We consider our trade secrets and proprietary confidential and unpatented know-how to be important to our business. We rely on trade secrets and confidential know-how to protect our proprietary technology, especially where patent protection is believed to be of limited value. However, trade secrets and knowhow are difficult to maintain as confidential and we may, at times, have to share our trade secrets and confidential know-how with third parties with whom we collaborate for the development, manufacturing or commercialization of our current or future product candidates or under joint research and development programs.

To protect this type of information against disclosure or misappropriation by third parties and our competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or confidential knowhow. Also, current or former employees, consultants, contractors and advisors may unintentionally or willfully disclose our trade secrets and confidential know-how to our competitors and other third parties or breach such agreements, and we may not be able to obtain an adequate remedy for such breaches. Monitoring unauthorized uses and disclosures is difficult, and enforcing a claim that a third party illegally obtained and is using our trade secrets or confidential know-how is difficult, expensive, time-consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction and courts outside the United States are sometimes less willing to protect trade secrets. Furthermore, if a competitor or other third party lawfully obtained or independently developed any of our trade secrets or confidential know-how, we would have no right to prevent such competitor or other third party from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating such trade secrets. If any of our trade secrets were to be disclosed to, or independently developed by a competitor or other third party, or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be materially and adversely harmed.

Failure to obtain or maintain trade secret protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets or confidential know-how.

## If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks in the future as a means to distinguish our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for GH001, GH002 or any future product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks, in which case we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Accordingly, we may not be able to adequately protect our rights to these trademarks and trade names, which we need to build name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our trademarks throughout the world.

# We may not be able to protect our intellectual property rights throughout the world and may face difficulties in certain jurisdictions, which may diminish the value of intellectual property rights in those jurisdictions and negatively impact our business.

We or our licensors have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products, if approved. Filing, prosecuting and defending patents covering product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive and our licensors' or collaboration partners' intellectual property rights in some countries outside of, for instance, the member states of the European Patent Convention and the United States, could be less extensive than those in the member states of the European Patent Convention and the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling therapies or importing therapeutic compositions made using our inventions in and into, for instance, the member states of the European Patent Convention and the United States, or other jurisdictions. In addition, we may decide to abandon national and regional patent applications before grant. Furthermore, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

Competitors may use our and our licensors' or collaboration partners' technologies in jurisdictions where we have not obtained patent protection to develop their own therapies and, further, may export otherwise infringing therapies to territories where we and our licensors or collaboration partners have patent protection, but where enforcement is not as strong as in other jurisdictions. These therapies may compete with GH001, GH002 or any future product candidates, and our and our licensors' or collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in, for instance, the member states of the European Patent Convention and the United States, and companies have encountered significant difficulties in protecting and defending such rights in such

jurisdictions. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors or collaboration partners is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

Proceedings to enforce our and our licensors' or collaboration partners' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaboration partners' efforts and attention from other aspects of our business, regardless of whether we or our licensors or collaboration partners are successful, and could put our and our licensors' or collaboration partners' patents at risk of being invalidated or interpreted narrowly. In addition, such proceedings could put our and our licensors' or collaboration partners' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaboration partners. We or our licensors or collaboration partners may not prevail in any lawsuits that we or our licensors or collaboration partners initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and prospects.

#### **Risks Related to Our Dependence on Third Parties**

We rely on third parties to assist in conducting our nonclinical studies and clinical trials. If they do not perform satisfactorily, we may not be able to initiate new clinical trials, successfully complete clinical trials, obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, such as laboratories, CROs, clinical data management organizations, medical institutions, clinical investigators and consultants, to organize, support or conduct our nonclinical studies and clinical trials and expect to rely on these third parties to conduct nonclinical studies and clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Although our reliance on these third parties for nonclinical and clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our nonclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Moreover, human clinical research must comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the regulatory authorities may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, a regulatory authority will determine that any of our clinical trials comply with GCPs.

The third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These outside

contractors may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

If our relationships with any third parties conducting our studies are terminated, we may be unable to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Switching or adding third parties to conduct our studies involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired nonclinical and clinical development timelines. Although we carefully manage our relationships with third parties conducting our studies, we cannot assure that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material and adverse effect on our business, financial condition and results of operations.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

The development and manufacture of our active pharmaceutical ingredients, product candidates and medical devices required to deliver such product candidates is complex, and we may encounter difficulties during further development or in production. We currently rely completely on third parties to develop, formulate and manufacture our nonclinical study and clinical trial supplies. The development and commercialization of any of our active pharmaceutical ingredients, product candidates and medical devices required to deliver such product candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of such drug supplies or fail to do so at acceptable quality levels, including in accordance with rigorously enforced regulatory requirements or contractual obligations, and our operations could be harmed as a result.

The processes involved in developing and manufacturing our drug substance, product candidates and medical devices required to deliver such product candidates are complex, expensive, highly regulated and subject to multiple risks. Further, as drug substance, product candidates and medical devices required to deliver such product candidates are developed through nonclinical studies, from earlystage clinical trials to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the drug substance, product candidates and medical devices required to deliver such product candidates, such as technical specifications, design, features and manufacturing methods, are altered along the way in an effort to optimize performance, processes and results and to fulfill regulatory requirements, which are stricter for late-stage clinical trials and commercial manufacture than for earlystage trials. We are currently implementing such changes, which carries the risk that they will not achieve the intended objectives, or could lead to delays, and any of these changes could require the conduct of bridging studies and could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. Additionally, the manner in which we currently manufacture our drug substance and product candidates and medical devices required to deliver such product candidates may not fulfill regulatory requirements for late-stage clinical trials and for commercial use, and there can be no assurance that we will be able to manufacture our drug substance and product candidates in a manner that would fulfill such regulatory requirements in a timely manner, or at all. We

have limited experience in drug formulation or manufacturing. Currently, we rely on an extensive network of consultants and contract manufacturers, and in some cases sole source suppliers, for the production of our drug substance, product candidates and medical devices required to deliver such product candidates for current and planned clinical trials.

In order to conduct clinical trials of our product candidates, or supply commercial products, if approved, we will need to manufacture them and the drug substance contained in our product candidates in large quantities. Our CDMOs may be unable to successfully increase the manufacturing capacity for our drug substance and any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If our CDMOs are unable to successfully scale up the manufacture of our drug substance or product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risk would apply to our internal manufacturing facilities, should we decide to build internal manufacturing capacity in the future. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner, and the resources associated with ensuring the ongoing regulatory compliance of such manufacturing facilities would be significant.

In addition, the manufacturing process for any products that we may develop is subject to FDA, EMA, and comparable foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and foreign regulatory authority requirements, including complying with cGMPs on an ongoing basis. Although our agreements with our CDMOs require them to perform according to certain cGMP requirements such as those relating to quality control, quality assurance and qualified personnel, we cannot control the ability of our CDMOs to implement and maintain these standards. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA, EMA or other comparable foreign regulatory authorities or maintain a compliance status acceptable to the FDA, EMA, or other comparable foreign regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CDMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA, or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and prospects.

# If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates, and/or increase the product yield of its manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates that we may develop, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the quality of the product, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operation.

# We depend on third-party suppliers for key raw materials used in our manufacturing processes, as well as for the vaporization device used to administer GH001, some of which are our sole source of supply, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials or medical devices could harm our business.

We rely on our CDMOs to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. We do not have, nor do we expect to enter into, any agreements for the commercial production of these raw materials, and we do not expect to have any control over the process or timing of our CDMOs' acquisition of raw materials needed to produce our product candidates. Furthermore, we currently purchase the vaporization device with which we administer GH001 from a single third-party manufacturer, Storz & Bickel, Tuttlingen. We do not have a commercial supply agreement with such third-party manufacturer. Any significant delay in the supply of a product candidate, the raw material components thereof or any device necessary to administer our products for an ongoing clinical trial due to a manufacturer's need to replace a third-party supplier of raw materials or medical devices could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. Additionally, if our future manufacturers or we are unable to purchase these raw materials to commercially produce any of our product candidates that gains regulatory approvals, or if we are unable to purchase or manufacture medical devices with which we administer any of our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Furthermore, for those third-party suppliers who are our sole source of supply of certain materials, we may not have arrangements in place for a redundant or second-source supply of any such materials or medical devices in the event any of our current suppliers cease their operations for any reason. Establishing additional or replacement suppliers for the raw materials used in our product candidates or medical devices used to administer our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay.

# We expect to depend on collaborations with third parties for the research, development and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to realize the market potential of those product candidates.

We are currently seeking and may continue to seek third-party collaborators for the research, development and commercialization of certain of the product candidates we may develop. Our likely collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, biotechnology companies and academic institutions. If we enter into any such arrangements with any third parties, we will likely have shared or limited control over the amount and timing of resources that our collaborators dedicate to the development or potential commercialization of any product candidates we may seek to develop with them. Our ability to generate revenue from these arrangements with commercial entities will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs, or any product candidates we may develop, pose the following risks to us:

- collaborators generally have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not properly obtain, maintain, enforce or defend intellectual property or proprietary rights relating to our product candidates or research programs, or may use our proprietary information in such a way as to expose us to potential litigation or other intellectual property-related proceedings, including proceedings challenging the scope, ownership, validity and enforceability of our intellectual property;



- collaborators may own or co-own intellectual property covering our product candidates or research programs that results from our collaboration with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property or such product candidates or research programs;
- we may need the cooperation of our collaborators to enforce or defend any intellectual property we contribute to or that arises out of our collaborations, which may not be provided to us;
- collaborators may control certain interactions with regulatory authorities, which may impact our ability to obtain and maintain regulatory approval of our product candidates;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or research programs or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborators may decide to not pursue development and commercialization of any product candidates we develop or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or research programs if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may restrict us from researching, developing or commercializing certain products or technologies without their involvement;
- collaborators with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of such product candidates;
- we may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control;
- collaborators may grant sublicenses to our technology or product candidates or undergo a change of control and the sublicensees or new owners may decide to take the collaboration in a direction which is not in our best interest;
- collaborators may become bankrupt, which may significantly delay our research or development programs, or may cause us to lose access to valuable technology, know-how or intellectual property of the collaborator relating to our products, product candidates or research programs;
- key personnel at our collaborators may leave, which could negatively impact our ability to productively work with our collaborators;
- collaborations may require us to incur short and long-term expenditures, issue securities that dilute our shareholders or disrupt our management and business;
- if our collaborators do not satisfy their obligations under our agreements with them, or if they terminate our collaborations with them, we may not be able to develop or commercialize product candidates as planned;
- collaborations may require us to share in development and commercialization costs pursuant to budgets that we do not fully control and our failure to share in such costs could have a detrimental impact on the collaboration or our ability to share in revenue generated under the collaboration;



- collaborations may be terminated in their entirety or with respect to certain product candidates or technologies and, if so terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates or technologies; and
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our development or commercialization program under such collaboration could be delayed, diminished or terminated.

We may face significant competition in seeking appropriate collaborations. Recent business combinations among biotechnology and pharmaceutical companies have resulted in a reduced number of potential collaborators. In addition, the negotiation process is time-consuming and complex, and we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop product candidates or bring them to market and generate product revenue.

If we enter into collaborations to develop and potentially commercialize any product candidates, we may not be able to realize the benefit of such transactions if we or our collaborator elects not to exercise the rights granted under the agreement or if we or our collaborator are unable to successfully integrate a product candidate into existing operations and company culture. The failure to develop and commercialize a product candidate pursuant to our agreements with our current or future collaborators could prevent us from receiving future payments under such agreements, which could negatively impact our revenues. In addition, if our agreement with any of our collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely. We may also find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. Many of the risks relating to product development, regulatory approval, and commercialization described in this "Risk Factors" section also apply to the activities of our collaborators and any negative impact on our collaborators may adversely affect us.

### We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

#### Risks Related to Employee Matters, Managing Our Business and Operations

## A pandemic, epidemic or outbreak of an infectious disease in Ireland or worldwide may adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in Ireland or worldwide our business may be adversely affected. In December 2019, a novel strain of coronavirus named SARS-CoV-2 was

identified in Wuhan, China. This virus continues to spread globally, including in Ireland and the disease it causes, COVID-19, has been declared a pandemic by the World Health Organization, or WHO. The COVID-19 pandemic has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities, regulatory reviews and our supply chain. For example, the COVID-19 pandemic may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, EMA or other comparable foreign regulatory authorities, which may delay the development or approval process for our product candidates.

The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations. For example, due to local restrictions in the Netherlands, we were forced take a three-month break in patient recruitment in our ongoing clinical trial in patients with TRD in 2020. We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the novel coronavirus and the actions to contain the coronavirus or treat its impact, among others. At present, we are not experiencing significant impact or delays from the COVID-19 pandemic on our business, operations and, if approved, commercialization plans. In addition, we have taken steps to mitigate against COVID-19 pandemic-related delays, and may take additional measures, intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. In particular, our remote work arrangements for employees, coupled with stay-at-home orders and guarantines, pose challenges for those employees and our IT systems, and extended periods of remote work arrangements could strain our business continuity plans, introduce operational risk, including cybersecurity and IT systems management risks. Finally, an ongoing pandemic may also cause the risks associated with our industry and business described herein and in our public filings to become more significant.

A significant outbreak of other infectious diseases in the future also could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

## We depend heavily on our executive officers, principal consultants and others, and the loss of their services would materially harm our business.

Our success depends, and will likely continue to depend, upon our ability to hire, retain the services of our current executive officers, principal consultants and others. The loss of their services might impede the achievement of our research, development and commercialization objectives. We do not maintain "key person" insurance for any of our executives or other employees.

Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. Replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategies. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

#### We only have a limited number of employees to manage and operate our business. If we are unable to hire or to retain adequate personnel, then we may not be able to meet our operational goals.

As of May 31, 2021, we had eight employees and a large part of our development efforts remains outsourced to consultants, CMOs and CROs, aiming to optimize cash utilization and to manage and operate our business in a highly efficient manner. We cannot ensure that we will be able to hire and/or retain adequate staffing levels to develop GH001 and GH002 or other potential product candidates, or to run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

## Our employees, independent contractors, consultants, collaborators and CROs may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and CROs may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates:

- regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities; and
- laws that require the accurate reporting of financial information or data.

Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our nonclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this kind of activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, integrity oversight and reporting obligations, possible exclusion from participation in the United States in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.



## We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of regulatory affairs and sales, marketing and distribution, as well as to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional gualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Moreover, our expected growth could require us to relocate to a different geographic area of Ireland. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

## Our business is subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular in foreign economies and markets;
- differing and changing regulatory requirements, price controls and reimbursement regimes;
- potentially reduced protection for our intellectual property rights;
- difficulties in compliance with different, complex and changing laws, regulations and court systems of multiple jurisdictions and compliance with a wide variety of foreign laws, treaties and regulations;
- changes in regulations and customs, tariffs and trade barriers;
- changes in currency exchange rates and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by governments;
- negative consequences from changes in, including the interpretation of, tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States and European Economic Area;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, or health epidemics such as COVID-19; and
- cyber-attacks, which are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect.



These and other risks associated with our planned international operations may materially adversely affect our ability to attain profitable operations.

# Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third-party logistics or other service providers, distributors, suppliers or other contractors or consultants, could result in information theft, data corruption and significant disruption or unavailability of our business operations.

We, our collaborators, our CROs, third-party logistics and service providers, distributors, suppliers and other contractors and consultants utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. If our privacy, data protection, or information security measures (or those of any third parties that handle our sensitive information) are inadequate or are breached as a result of third-party action, employee or contractor error, malfeasance, malware, system error, software bugs or defects in our products, trickery, process failure or otherwise, third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, and, as a result, there is improper disclosure of, or someone obtains unauthorized access to sensitive information, including personally identifiable information or protected health information, or if we suffer a ransomware or advanced persistent threat attack, or if any of the foregoing is reported or perceived to have occurred, our reputation and business could be damaged, we could incur significant costs associated with remediation and the implementation of additional security measures, we may incur significant liability and financial loss, and be subject to regulatory scrutiny, investigations, proceedings, lawsuits and penalties. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. These threats pose a risk to the security of our, our collaborators', our CROs' third-party logistics and service providers', distributors', suppliers' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack, data breach, inaccessibility or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws, and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed; and could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

#### Risks Related to the Offering and Ownership of Our Ordinary Shares

#### There has been no prior active trading market for our ordinary shares and an active and liquid market for our ordinary shares may fail to develop, which could harm the market price of our ordinary shares and you may not be able to resell your ordinary shares at or above the initial public offering price.

This offering constitutes our initial public offering of ordinary shares, and no public market has previously existed for our ordinary shares. We have applied to list our ordinary shares on Nasdaq, and we expect our ordinary shares to be quoted on Nasdaq, subject to completion of customary procedures in the United States. Any delay in the commencement of trading of our ordinary shares on Nasdaq would impair the liquidity of the market for our ordinary shares and make it more difficult for holders to sell their ordinary shares.

Even if our ordinary shares are listed and quoted on Nasdaq, there is a risk that an active trading market for our ordinary shares may not develop or be sustained after this offering is completed. The initial offering price was determined by negotiations among the lead underwriters and us. Among the factors considered in determining the initial offering price will be the following:

- our financial information;
- the history of, and the future prospects for, our company and the industry in which we compete;
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenue;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

Following the offering, our ordinary shares may not trade at a price equal to or greater than the initial offering price. The initial offering price may not be indicative of the market price of our ordinary shares after the offering. In the absence of an active trading market for our ordinary shares, investors may not be able to sell their ordinary shares at or above the initial offering price or at the time that they would like to sell.

## The market price of our ordinary shares may be volatile and you could lose all or part of your investment.

The price of the securities of publicly traded emerging pharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. As a result of this volatility, you may not be able to sell your ordinary shares at or above the initial public offering price. The market price of our ordinary shares may fluctuate significantly due to a variety of factors, including the following:

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in entering into strategic relationships with respect to development or commercialization of our GH001 and GH002 product candidates or any future product candidates;
- entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial therapeutic introductions by competitors;
- changes in government regulations and healthcare payment systems;
- developments concerning proprietary rights, including patent and litigation matters;
- public concern relating to the commercial value or safety of any of our GH001 and GH002 product candidates or any future product candidates;
- negative publicity or public perception of the use of 5-MeO-DMT as a medical treatment;
- financing or other corporate transactions, or the failure to obtain financing or enter into other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- the trading volume of our ordinary shares on Nasdaq;
- sales of our ordinary shares by us, members of our senior management and directors or our shareholders or the anticipation that such sales may occur in the future;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- general economic, political, and market conditions and overall market volatility in the United States, the United Kingdom or the European Union as a result of the COVID-19 pandemic or other pandemics or similar events; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ordinary shares and may otherwise negatively affect the liquidity of our ordinary shares. In addition, the stock market in general, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including as a result of the COVID-19 pandemic.

# Our executive officers, directors and certain significant shareholders will continue to own a substantial number of our ordinary shares and, as a result, may be able to exercise control over us, including the outcome of shareholder votes. Certain of our directors and officers hold interests in one of these shareholders and these shareholders may have different interests from us or your interests.

Upon the completion of this offering, our officers, directors, 5% holders and their affiliates will represent beneficial ownership, in the aggregate, of approximately 62% of our total outstanding ordinary shares, including 31% held by Florian Schönharting, the chairman of our board of directors (exclusive of any potential shares that may be purchased as part of this offering). As a result, these parties may be able to determine all matters requiring shareholder approval. For example, these shareholders may be able to exert control over our business, including significant corporate actions such as mergers, schemes of arrangement, sales of substantially all of our assets, and election, re-election and removal of directors. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares, or other such changes in control, that you may feel are in your best interest. The interests of this group of shareholders may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those who purchase ordinary shares in this offering, including seeking a premium value for their ordinary shares, and might affect the prevailing market price for our ordinary shares.

For more information regarding our principal shareholders and their affiliated entities, see "Related Party Transactions" and "Principal Shareholders."

### Participation in this offering by our existing shareholders and/or their affiliated entities may reduce the public float for our ordinary shares.

To the extent our existing shareholders who are our affiliates or their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our ordinary shares after this offering, which is the number of ordinary shares that are not held by our officers, directors and affiliated shareholders. A reduction in the public float could reduce the number of ordinary shares that can be traded at any given time, which could adversely impact the liquidity of our ordinary shares and depress the price at which you may be able to sell ordinary shares purchased in this offering.

## We have never paid cash dividends, do not anticipate paying any cash dividends and our ability to pay dividends, or repurchase or redeem our ordinary shares, is limited by law.

We have never declared or paid cash dividends on our ordinary shares and do not anticipate paying any dividends on our ordinary shares in the foreseeable future. Any determination to pay dividends in the future will be at the sole discretion of our board of directors after considering our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions and other factors our board of directors deems relevant, and subject to compliance with applicable laws, including the Irish Companies Act 2014 (as amended), referred to herein as the Irish Companies Act, which requires Irish companies to have distributable reserves available for distribution equal to or greater than the amount of the proposed dividend. Distributable reserves are the accumulated realized profits of the company that have not previously been utilized in a distribution or capitalization less accumulated realized losses that have not previously been written off in a reduction or reorganization of capital. Unless the company creates sufficient distributable reserves from its business activities, the creation of such distributable reserves would involve a reduction of the company's share premium account or other

undenominated capital account, which would require the approval of (i) 75% of our shareholders present and voting at a shareholder meeting, and (ii) the Irish High Court. In the event that we do not undertake a reduction of capital to create distributable reserves, no distributions by way of dividends, share repurchases or otherwise will be permitted under Irish law until such time as the company has created sufficient distributable reserves from its business activities. The determination as to whether or not the company has sufficient distributable reserves to fund a dividend must be made by reference to "relevant accounts" of the company. The "relevant accounts" are either the last set of unconsolidated annual audited financial statements or unaudited financial statements prepared in accordance with the Irish Companies Act, which give a "true and fair view" of the company's unconsolidated financial position in accordance with accepted accounting practice in Ireland.

We intend to retain earnings, if any, for use in our business and do not anticipate paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, on our ordinary shares will be your sole source of gains for the foreseeable future, and you will suffer a loss on your investment if you are unable to sell your ordinary shares at or above the initial public offering price. Any recommendation by our board of directors to pay dividends will depend on many factors, including our financial condition (including losses carried forward), results of operations, legal requirements and other factors. We are unlikely to pay dividends or other distributions in the foreseeable future. If the price of our ordinary shares declines before we pay dividends, you will incur a loss on your investment, without the likelihood that this loss will be offset in part or at all by potential future cash dividends. Investors seeking cash dividends should not purchase our ordinary shares in this offering.

#### Dividends paid may be subject to Irish dividend withholding tax.

In certain circumstances, as an Irish tax resident company, we will be required to deduct Irish dividend withholding tax (currently at the rate of 25%) from dividends paid to our shareholders. Shareholders that are resident in the United States, EU countries (other than Ireland) or other countries with which Ireland has signed a tax treaty (whether the treaty has been ratified or not) generally should not be subject to Irish dividend withholding tax so long as the shareholder has provided its broker, for onward transmission to our qualifying intermediary or other designated agent (in the case of shares held beneficially), or us or our transfer agent (in the case of shares held directly), with all the necessary documentation by the appropriate due date prior to payment of the dividend.

## We have broad discretion in the use of the net proceeds from the offering and may not use them effectively.

Our board of directors will have broad discretion in the application of the net proceeds from the offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares. The failure by our board of directors to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our ordinary shares to decline and delay the development of our GH001 and GH002 product candidates or any future product candidates. Pending their use, we may invest the net proceeds from the offering in a manner that does not produce income or that losses value.

#### If securities or industry analysts do not publish research or publish inaccurate research or unfavorable research about our business, the price of our ordinary shares and trading volume could decline.

The trading market of our ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have control over these analysts. We do not currently have research coverage, and there can be no assurance that analysts will cover us, or provide favorable coverage. If no or few securities or industry analysts cover our company, the trading price of our ordinary shares would be negatively impacted. If one or more of the analysts who covers us downgrades our ordinary shares or publishes incorrect or unfavorable research about our business, the



price of our ordinary shares would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our ordinary shares, demand for our ordinary shares could decrease, which could cause the price of our ordinary shares or trading volume to decline.

## Future sales of our securities by existing shareholders could depress the market price of our ordinary shares.

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of ordinary shares in the public market after the 180-day contractual lock-up and other legal restrictions on resale discussed elsewhere in this prospectus lapse, the trading price of our ordinary shares could decline significantly and could decline below the public offering price. Upon completion of this offering, and assuming no exercise of the underwriters' option to purchase additional ordinary shares, we will have outstanding 48,854,183 ordinary shares. Substantially all of our ordinary shares outstanding prior to this offering are subject to the 180-day contractual lock-up referred to above. Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated may permit us, our directors and executive officers and shareholders to sell ordinary shares prior to the expiration of the lock-up agreements. See "Underwriting."

After the lock-up agreements pertaining to the offering expire, the ordinary shares subject to such lock-up agreements will be eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, in the case of our affiliates.

Following the offering, we intend to file one or more registration statements with the SEC covering ordinary shares available for future issuance under our equity incentive plans. Upon effectiveness of such registration statements, any ordinary shares subsequently issued under such plans will be eligible for sale in the public market, except to the extent that they are restricted by the lock-up agreements referred to above and subject to compliance with Rule 144 of the Securities Act, or Rule 144, in the case of our affiliates. We will also enter into the Registration Rights Agreement pursuant to which we will grant demand, short form and piggyback registration rights to our existing shareholders. Sales of a large number of the ordinary shares issued under these plans in the public market could have an adverse effect on the market price of our ordinary shares. These sales might also make it more difficult for us to issue or sell equity or equity-related securities in the future at a time and a price that we deem appropriate. See the section of this prospectus titled "Shares Eligible for Future Sale" for a more detailed description of sales that may occur in the future. If these additional ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline substantially.

## If you purchase our ordinary shares in the offering, you will experience substantial and immediate dilution.

If you purchase our ordinary shares in this offering, you will experience substantial and immediate dilution of \$10.17 per ordinary share in the net tangible book value after giving effect to the offering at an assumed public offering price of \$15.00 per ordinary share, the midpoint of the estimated price range set forth on the cover page of this prospectus, because the price that you pay will be substantially greater than the net tangible book value per ordinary share that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the public offering price when they purchased their ordinary shares. You will experience additional dilution if we issue additional ordinary shares below the public offering price. For a further description of the dilution that you will experience immediately after the offering, see the section of this prospectus titled "Dilution."

# Shareholders could be diluted in the future if we increase our issued share capital because of the disapplication of statutory preemption rights. In addition, shareholders in certain jurisdictions, including the United States, may not be able to exercise their preemption rights even if those rights have not been disapplied.

As a matter of Irish law, holders of our ordinary shares will have a preemption right with respect to any issuance of our ordinary shares for cash consideration or the granting of rights to subscribe for our ordinary shares for cash consideration, unless such preemption right is disapplied, in whole or in part,

either in the Constitution or by resolution of our shareholders at a general meeting of shareholders or otherwise. However, we have opted out of these preemption rights in the Constitution as permitted under Irish company law (for a period of five years). Thus, our board of directors will be permitted to issue up to all of our authorized but unissued share capital on a non-preemptive basis for cash consideration at any stage during the period of five years after the date of adoption of the Constitution. In addition, even if the disapplication of preemption rights contained in the Constitution expires (and is not renewed by shareholders at a general meeting) or is terminated by our shareholders in a general meeting, due to laws and regulations in certain jurisdictions outside Ireland, shareholders in such jurisdictions may not be able to exercise their preemption rights unless we take action to register or otherwise qualify the rights offering under the laws of that jurisdiction. For example, in the United States, U.S. holders of our ordinary shares may not be able to exercise preemption rights unless a registration statement under the Securities Act is declared effective with respect to our ordinary shares issuable upon exercise of such rights or an exemption from the U.S. registration requirements is available. If shareholders in such jurisdictions are unable to exercise their preemption rights, their ownership interest would be diluted. Any future issuance of shares or debt instruments convertible into shares where preemption rights are not available or are excluded would result in the dilution of existing shareholders and reduce the earnings per share, which could have a material adverse effect on the price of shares.

## Following the completion of the offering, we may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical and biopharmaceutical companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm the trading price of our ordinary shares.

## A future transfer of ordinary shares, other than one effected by means of the transfer of book entry interests in DTC, may be subject to Irish stamp duty.

Transfers of ordinary shares effected by means of the transfer of book entry interests in the Depository Trust Company, or DTC, should not be subject to Irish stamp duty where ordinary shares are traded through DTC, either directly or through brokers that hold such shares on behalf of customers through DTC. However, if you hold your ordinary shares as of record rather than beneficially through DTC, any transfer of ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty to arise could adversely affect the price of our ordinary shares. For more information, see "Tax Considerations—Material Irish Tax Consequences—Stamp Duty."

Our Constitution to be effective in connection with this offering will provide that the courts of Ireland will be the exclusive forum for the resolution of all shareholder complaints other than complaints asserting a cause of action arising under the Securities Act and the Exchange Act, and that the U.S. federal district courts will be the exclusive forum for the resolution of any shareholder complaint asserting a cause of action arising under the Securities Act and the Exchange Act.

Our Constitution to be effective in connection with this offering will provide that the courts of Ireland will be the exclusive forum for resolving all shareholder complaints other than shareholder complaints asserting a cause of action arising under the Securities Act and the Exchange Act, and that the U.S. federal district courts will be the exclusive forum for resolving any shareholder complaint asserting a cause of action arising under the Securities Act and the Exchange Act, including applicable claims arising out of this offering. This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. The enforceability of similar exclusive forum provisions (including exclusive federal forum provisions for actions, suits or proceedings asserting a cause of action arising under the Securities' organizational documents has been challenged in legal

proceedings, and there is uncertainty as to whether courts would enforce the exclusive forum provisions in our Constitution. Additionally, our shareholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find either choice of forum provision contained in our Constitution to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our results of operations and financial condition.

#### Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated and have our registered office in, and are currently existing under the laws of, Ireland. In addition, certain members of our board of directors and senior management are nonresidents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States upon such persons or to enforce judgments obtained in U.S. courts against them or us possible for investors to effect service of process within the United States upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

The United States and Ireland do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in Ireland. In addition, uncertainty exists as to whether Irish courts would entertain original actions brought in Ireland against us or our directors or senior management predicated upon the securities laws of the United States or any state in the United States. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by Irish courts as a cause of action in itself and sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that certain requirements are met. Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws, including whether the award of monetary damages under such laws would constitute a penalty is an issue subject to determination by the court making such decision. If an Irish court gives judgment for the sum payable under a U.S. judgment, the Irish judgment will be enforceable by methods generally available for this purpose. These methods generally permit the Irish court discretion to prescribe the manner of enforcement.

As a result, U.S. investors may not be able to enforce against us or our senior management, board of directors or certain experts named herein who are residents of Ireland or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

## There can be no assurance that we will not be a passive foreign investment company for any taxable year, which could subject U.S. investors in our ordinary shares to significant adverse U.S. federal income tax consequences.

Under the Internal Revenue Code of 1986, as amended, or the Code, we will be a passive foreign investment company, or PFIC, for any taxable year in which, after the application of certain look-through rules with respect to our subsidiaries, either (1) 75% or more of our gross income consists of "passive income;" or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, "passive income." Passive income generally includes dividends, interest, certain non-active rents and royalties, and capital gains. Based on our current operations, income, assets and certain estimates and projections, including as to the relative values of our assets, including goodwill, which is based on the expected price of our ordinary shares, we do not expect to be a PFIC for our 2021 taxable year. In addition, whether we will be a PFIC in 2021 or any future year is uncertain because, among other things, (1) we will hold a substantial amount of cash following this offering, which is generally categorized as a passive asset; and (2) our PFIC status for any taxable year will depend on the composition of our income and assets and the value of our assets from time to time (which may be

determined, in part, by reference to the market price of our ordinary shares, which could be volatile). Accordingly, there can be no assurance that we will not be a PFIC for any taxable year.

If we are a PFIC for any taxable year during which a U.S. investor holds ordinary shares, we generally would continue to be treated as a PFIC with respect to that U.S. investor for all succeeding years during which the U.S. investor holds ordinary shares, even if we ceased to meet the threshold requirements for PFIC status. Such a U.S. investor may be subject to adverse U.S. federal income tax consequences, including (1) the treatment of all or a portion of any gain on disposition as ordinary income; (2) the application of a deferred interest charge on such gain and the receipt of certain dividends; and (3) compliance with certain reporting requirements. A "mark-to-market" election may be available that will alter the consequences of PFIC status if our ordinary shares are regularly traded on a qualified exchange. For further discussion, see "Tax Considerations—Material U.S. Federal Income Tax Consequences for U.S. Holders."

## We are an "emerging growth company" and are availing ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year (i) in which we have total annual gross revenue of \$1.07 billion; (ii) following the fifth anniversary of the date of the completion of the offering; or (iii) in which we are deemed to be a "large accelerated filer," which requires the market value of our ordinary shares that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three-year period. We cannot predict if investors will find our ordinary shares less attractive because we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

# As a foreign private issuer, we are permitted to adopt certain home country requirements in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with corporate governance listing standards.

As a foreign private issuer, we are permitted to follow certain home country corporate governance requirements as opposed to those requirements that would otherwise be required by Nasdaq for domestic U.S. issuers. Following our home country governance practices allows us to follow Irish corporate law and the Irish Companies Act with regard to certain corporate governance matters as opposed to the requirements that would otherwise apply to U.S. companies listed on Nasdaq may provide less protection to our shareholders than what is accorded to investors under Nasdaq rules applicable to domestic U.S. issuers.

As a foreign private issuer, we are exempt from the rules and regulations under the Exchange Act related to the furnishing and content of proxy statements. Our officers, directors and principal shareholders are also exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file reports and financial statements with the SEC as frequently or as promptly as U.S. domestic companies whose

securities are registered under the Exchange Act and we are exempt from filing quarterly reports with the SEC under the Exchange Act. Moreover, we are not required to comply with Regulation FD, which restricts the selective disclosure of material information, although we have voluntarily adopted a corporate disclosure policy substantially similar to Regulation FD. These exemptions and leniencies will reduce the frequency and scope of information and protections to which you may otherwise have been eligible in relation to a U.S. domestic issuer.

Additionally, when our ordinary shares are listed on Nasdaq, we intend to continue to follow Irish corporate governance requirements in lieu of the corporate governance requirements of Nasdaq in respect of the following:

- the majority independent director requirement under Nasdaq listing rules;
- the requirement under Nasdaq listing rules that a compensation committee composed solely of independent directors governed by a compensation committee charter oversee executive compensation;
- the requirement under Nasdaq listing rules that director nominees be selected or recommended for selection by either a majority of the independent directors or a nominations committee composed solely of independent directors;
- the requirement under Nasdaq listing rules that a quorum must consist of at least 33<sup>1</sup>/<sub>3</sub> percent of the outstanding shares of a listed company's common voting stock; and
- the requirement under Nasdaq listing rules that the independent directors have regularly scheduled meetings with only the independent directors present.

Furthermore, Nasdaq's corporate governance rules require listed U.S. companies to, among other things, seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares, which we are not required to follow as a foreign private issuer. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

## We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2021.

In the future, we would lose our foreign private issuer status if we were to fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of our executive officers or members of our board of directors are residents or citizens of the United States, we could lose our foreign private issuer status.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

## As a newly established public company, we will incur significant additional costs, and our management will be required to devote substantial time and attention to our public reporting obligations.

As a publicly traded company, we will incur significant additional legal, accounting and other expenses compared to historical levels. In addition, new and changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations promulgated and to be promulgated thereunder, as well as under the Sarbanes-Oxley Act, the JOBS Act and the rules and regulations of the SEC and Nasdaq, have created uncertainty for public companies and increased our costs and time that our board of directors and management must devote to complying with these rules and regulations. We expect these rules and regulations to increase our legal and financial compliance costs substantially and lead to diversion of management time and attention from revenue-generating activities.

### Irish law differs from the laws in effect in the United States and may afford less protection to holders of our securities.

You may have difficulties enforcing, in actions brought in courts in jurisdictions located outside the United States, judgments obtained in the U.S. courts under the U.S. securities laws. In particular, if you sought to bring proceedings in Ireland based on U.S. securities laws, the Irish court might consider:

- that it did not have jurisdiction;
- that it was not the appropriate forum for such proceedings;
- that, applying Irish conflict of law rules, U.S. law (including U.S. securities laws) did not apply to the relationship between you and us or our directors and officers; or
- that the U.S. securities laws were of a penal nature and violated Irish public policy and should not be enforced by the Irish court.

It may not be possible to enforce court judgments obtained in the United States against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liabilities provisions of the U.S. federal or state securities laws. We have been advised that the United States currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

A judgment obtained against us will be enforced by the courts of Ireland only if the following general requirements are met:

- U.S. courts must have had jurisdiction in relation to the particular defendant according to Irish
  conflict of law rules (the submission to jurisdiction by the defendant would satisfy this rule); and
- the judgment must be final and conclusive and the decree must be final and unalterable in the court which pronounces it.

A judgment can be final and conclusive even if it is subject to appeal or even if an appeal is pending. But where the effect of lodging an appeal under the applicable law is to stay execution of the judgment, it is possible that in the meantime the judgment may not be actionable in Ireland. It remains to be determined whether final judgment given in default of appearance is final and conclusive. Irish courts may also refuse to enforce a judgment of the U.S. courts which meets the above requirements for one of the following reasons:

- the judgment is not for a definite sum of money;
- the judgment was obtained by fraud;

- the enforcement of the judgment in Ireland would be contrary to natural or constitutional justice;
- the judgment is contrary to Irish public policy or involves certain U.S. laws which will not be enforced in Ireland; or
- jurisdiction cannot be obtained by the Irish courts over the judgment debtors in the enforcement proceedings by personal service in Ireland or outside Ireland under Order 11 of the Irish Superior Courts Rules.

As an Irish company, we are governed by the Irish Companies Act, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a jurisdiction of the United States.

You should also be aware that Irish law does not allow for any form of legal proceedings directly equivalent to the class action available in the United States. For further information with respect to your rights as a shareholder, see "Description of Share Capital and Constitution."

### As an Irish public limited company, certain capital structure decisions require shareholder approval, which may limit our flexibility to manage our capital structure.

Under Irish law, our authorized share capital can be increased by an ordinary resolution of our shareholders and the directors may issue new ordinary shares up to a maximum amount equal to the authorized but unissued share capital, without shareholder approval, once authorized to do so by our Constitution or by an ordinary resolution of our shareholders. Additionally, subject to specified exceptions, Irish law grants statutory preemption rights to existing shareholders where shares are being issued for cash consideration but allows shareholders to disapply such statutory preemption rights either in our Constitution or by way of special resolution. Such disapplication can either be generally applicable or be in respect of a particular allotment of shares. Accordingly, our Constitution adopted on closing of this offering will contain, as permitted by Irish company law, provisions authorizing the board to issue new shares, and to disapply statutory preemption rights must both be renewed by the shareholders at least every five years, and we cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our securities.

#### Provisions of our Constitution could delay or prevent a third party's effort to acquire us.

Our Constitution could delay, defer or prevent a third party from acquiring us, even where such a transaction would be beneficial to the holders of ordinary shares, or could otherwise adversely affect the price of ordinary shares. For example, certain provisions of our Constitution:

- impose advance notice requirements for shareholder proposals and director nominations to be considered at annual shareholder meetings; and
- require the approval of 75% of the voting power of our shares entitled to vote at a general meeting of shareholders to amend or repeal any provisions of our Constitution.

We believe these provisions, if implemented in compliance with applicable law, may provide some protection to holders of ordinary shares from coercive or otherwise unfair takeover tactics. These provisions are not intended to make us immune from takeovers. They will, however, apply even if some holders of ordinary shares consider an offer to be beneficial and could delay or prevent an acquisition that our board of directors determines is in the best interest of the holders of ordinary shares. Certain of these provisions may also prevent or discourage attempts to remove and replace incumbent directors.

In addition, mandatory provisions of Irish law could prevent or delay an acquisition of the Company by a third party. For example, Irish law does not permit shareholders of an Irish public limited company to take action by written consent with less than unanimous consent. In addition, an effort to acquire us may be subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in ordinary shares in certain circumstances.

## Irish law differs from the laws in effect in the United States with respect to defending unwanted takeover proposals and may give our board of directors less ability to control negotiations with hostile offerors.

Following the authorization for trading of our ordinary shares on Nasdaq, we became subject to the Irish Takeover Panel Act, 1997, Irish Takeover Rules 2013, or the Irish Takeover Rules. Under the Irish Takeover Rules, our board of directors is not permitted to take any action that might frustrate an offer for our ordinary shares once our board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of shares, options, restricted share units or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our board of directors has reason to believe an offer is or may be imminent. These provisions may give our board of directors less ability to control negotiations with hostile offerors than would be the case for a corporation incorporated in a jurisdiction of the United States.

## The operation of the Irish Takeover Rules may affect the ability of certain parties to acquire our ordinary shares.

Under the Irish Takeover Rules, if an acquisition of ordinary shares were to increase the aggregate holding of the acquirer and its concert parties to ordinary shares that represent 30% or more of the voting rights of the company, the acquirer and, in certain circumstances, its concert parties would be required (except with the consent of the Irish Takeover Panel) to make an offer for the outstanding ordinary shares at a price not less than the highest price paid for the ordinary shares by the acquirer or its concert parties during the previous 12 months. This requirement would also be triggered by an acquisition of ordinary shares by a person holding (together with its concert parties) ordinary shares that represent between 30% and 50% of the voting rights in the company if the effect of such acquisition were to increase that person's percentage of the voting rights by 0.05% within a 12-month period. Following the authorization for trading of our ordinary shares on Nasdaq, under the Irish Takeover Rules, certain separate concert parties are presumed to be acting in concert. Our board of directors and their relevant family members, related trusts and "controlled companies" are presumed to be acting in concert with any corporate shareholder who holds 20% or more of our shares. The application of these presumptions may result in restrictions upon the ability of any of the concert parties and/or members of our board of directors to acquire more of our securities, including under the terms of any executive incentive arrangements. Following the listing of our ordinary shares on Nasdaq, we may consult with the Irish Takeover Panel with respect to the application of this presumption and the restrictions on the ability to acquire further securities, although we are unable to provide any assurance as to whether the Irish Takeover Panel will overrule this presumption. For a description of certain takeover provisions applicable to us, see the section titled "Description of Share Capital and Constitution-Irish Takeover Rules and Substantial Acquisition Rules." Accordingly, the application of the Irish Takeover Rules may restrict the ability of certain of our shareholders and directors to acquire our ordinary shares.

#### **Risks Related to Our Controls Over Financial Reporting**

If we fail to establish and maintain proper and effective internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming

effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with this offering, we intend to begin the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as an Irish public company listed in the United States.

Implementing any appropriate changes to our internal controls may distract our officers and employees from day-to-day business operations, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm the price of our ordinary shares.

We have identified material weaknesses in our internal control over financial reporting in connection with the audit of our financial statements for the years ended December 31, 2019 and 2020, and we may identify additional material weaknesses. If our remediation of these material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, our ability to accurately or timely report our financial condition or results of operations may be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles, or GAAP. As a result of becoming a public company, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of the registration statement of which this prospectus is a part. This assessment will need to include disclosures of any material weaknesses identified by our management in our internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We are in the very early stages of the costly and challenging process of planning the activities necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act.

In connection with the preparation of our financial statements for the years ended December 31, 2019 and 2020, we identified material weaknesses in our internal control over financial reporting. Specifically, we determined that we lack a sufficient number of trained professionals with an appropriate level of accounting knowledge, training and experience to: (a) design and maintain formal accounting policies, procedures and controls over the fair presentation of our financial statements; and (b) design and maintain controls over the preparation and review of account reconciliations, journal entries and financial statements, including maintaining appropriate segregation of duties.

These control deficiencies did not result in a material misstatement to the financial statements. However, each of these control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

Prior to the completion of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. We are progressing with the activities necessary to implement the appropriate accounting policies, processes and controls required to comply with Section 404 of the Sarbanes-Oxley Act and are in the process of identifying the relevant individuals with

the requisite expertise to assist in implementation activities designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses, including hiring additional finance and accounting personnel and initiating design and implementation of our financial control environment. We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting nor that they will prevent or avoid potential future material weaknesses. We cannot assure you that all of our existing material weaknesses have been identified, or that we will not in the future identify additional material weaknesses.

If we are unsuccessful in building an appropriate accounting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures, or comply with existing or new reporting requirements. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences that could materially harm our business. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our share price. In addition, we may be required to incur additional costs in improving our internal control system and the hiring of additional personnel.

#### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains statements that are, or may deemed to be, forward-looking statements. All statements other than statements of historical fact included in this prospectus, including statements regarding our future results of operations and financial position, business strategy, product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations are forward-looking statements. Many of the forward-looking statements contained in this prospectus can be identified by the use of forward-looking words such as "may," "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "will," "potential" and "ongoing," among others.

Forward-looking statements appear in a number of places in this prospectus and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section entitled "Risk Factors" in this prospectus. These risks and uncertainties include, among others, factors relating to:

- the timing, progress and results of developing and conducting clinical trials for our GH001 and GH002 product candidates and the medical devices required to deliver these product candidates for our initial and potential additional indications;
- our efforts to expand into other jurisdictions such as the United States and in the European Union;
- our expectations related to the technical development and expansion of our external manufacturing capabilities for our GH001 and GH002 product candidates as well as the medical devices required to deliver these product candidates;
- our reliance on the success of our GH001 and GH002 product candidates;
- the timing, scope or likelihood of regulatory filings and approvals by the FDA, EMA or other comparable foreign regulatory authorities, for our GH001 and GH002 product candidates and our initial and potential additional indications;
- our expectations regarding the size of the eligible patient populations for our GH001 and GH002 product candidates, if approved for commercial use;
- our ability to identify third-party clinical sites to conduct trials and our ability to identify and train
  appropriately qualified therapists to administer our investigational therapy;
- the effect of the COVID-19 pandemic on aspects of our business or operations, including delays in the regulatory approval process, contracting with clinical sites and engaging in clinical trials;
- our ability to implement our business model and our strategic plans for our business and GH001 and GH002 product candidates;
- our ability to identify, develop or acquire and obtain approval by the FDA, EMA or other comparable foreign regulatory authorities of medical devices required to deliver our GH001 and GH002 product candidates;
- our commercialization and marketing capabilities and strategy;
- the effects of undesirable clinical trial outcomes and potential adverse public perception regarding the use of 5-MeO-DMT and psychedelics generally on the regulatory approval process and future development of our product;
- the pricing, coverage and reimbursement of our GH001 and GH002 product candidates, if approved;
- the scalability and commercial viability of our manufacturing methods and processes;

- the rate and degree of market acceptance and clinical utility of our GH001 and GH002 product candidates;
- our reliance on third-party suppliers for our nonclinical study and clinical trial drug substance and product candidate supplies, as well as key raw materials used in our manufacturing processes;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our expectations regarding potential benefits of our GH001 and GH002 product candidates and our approach generally;
- our expectations around regulatory development paths and with respect to Controlled Substances Act designation;
- the scope of protection we and any current or future licensors or collaboration partners are able to establish and maintain for intellectual property rights covering our GH001 and GH002 product candidates;
- our ability to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to protect our intellectual property rights, including enforcing and defending intellectual property-related claims;
- regulatory developments in the United States, under the laws and regulations of the European Union and other jurisdictions;
- developments and projections relating to our competitors and our industry;
- our ability to remediate our material weaknesses in our internal control over financial reporting;
- our expectations related to the use of proceeds from this offering and the amount of time that our existing cash, together with the net proceeds from this offering, will be sufficient to fund our operations and capital expenditures;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- whether we are classified as a Passive Foreign Investment Company for current and future periods;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act and as a foreign private issuer;
- the future trading price of the ordinary shares and impact of securities analysts' reports on these prices; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained

herein, whether as a result of any new information, future events, changed circumstances or otherwise. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act, which does not extend to initial public offerings. You should read this prospectus and the documents that we have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

#### **USE OF PROCEEDS**

We estimate that the net proceeds to us in this offering will be \$112.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. If the underwriters exercise their option to purchase additional ordinary shares in full, we estimate that the net proceeds to us from this offering will be \$129.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$15.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us from this offering by \$7.8 million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. A 1,000,000 share increase or decrease in the number of ordinary shares offered by us would increase or decrease the net proceeds to us from this offering by approximately \$14.0 million, assuming that the initial public offering price per share remains the same, and after deducting underwriting discounts and commissions and estimated offering underwriting discounts and commissions and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We expect to use the net proceeds from this offering, together with our existing cash, as follows:

- approximately \$110 million to fund clinical trials, and other activities to support the development
  of our product candidate GH001 through completion of all ongoing trials, the planned Phase 2a
  trials in at least two new indications and the planned multi-center, randomized, controlled Phase
  2b trial in TRD;
- approximately \$10 million to fund clinical trials with our product candidate GH002 and one additional potential product candidate through completion of Phase 2a trials;
- approximately \$65 million to fund the technical development of our active pharmaceutical ingredients, product candidates, and the medical devices used for the administration of our product candidates, as well as the expansion of our external manufacturing capabilities, and to fund the nonclinical development activities related to our product candidates; and
- the remainder to fund general and administrative expenses, working capital and other general corporate purposes, including business development activities.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the cost necessary to develop product candidates and commercialize approved products can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our therapeutic candidate and any unforeseen cash needs. Our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering and our existing cash, including the net proceeds from the Series B Financing, we estimate that such funds will be sufficient to fund our operations and capital expenditure requirements into 2024, although there can be no assurance in that regard. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Our management will have broad discretion over the use of the net proceeds from this offering. The amounts and timing of our expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing, cost and success of preclinical studies and any ongoing clinical trials or clinical trials we may commence in the future, the timing of regulatory submissions, our ability to obtain additional financing, the amount of cash obtained through our existing collaborations and future collaborations, if any, and any unforeseen cash needs.

Pending our use of proceeds from this offering, we plan to invest these net proceeds in a variety of capital preservation instruments, including short-term, interest bearing obligations and investment-grade instruments.

#### **DIVIDEND POLICY**

We have never declared or paid cash dividends on our share capital. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Under Irish law, among other things, we may only pay dividends if we have sufficient distributable reserves (on a non-consolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized, less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital. In addition, no distribution or dividend may be made if the net assets of GH Research PLC are not, or if making such distribution or dividend will cause the net assets of GH Research PLC to not be, equal to or in excess of the aggregate of GH Research PLC's called up share capital plus undistributable reserves.

As we are an Irish company, Irish dividend withholding tax, or DWT, currently at a rate of 25%, will arise in respect of dividends or other distributions to our shareholders unless an exemption applies. There are exemptions that may be available to U.S. Holders (as defined in "Material U.S. Federal Income Tax Considerations for U.S. Holders"); such shareholders should consult their respective tax advisors. Where DWT arises, we are responsible for deducting DWT at source and accounting for the relevant amount to the Revenue Commissioners of Ireland. See "Tax Considerations—Material Irish Tax Consequences—Withholding Tax on Dividends" and "Description of Share Capital and Constitution—Dividends."

#### CORPORATE REORGANIZATION AND SHARE CONSOLIDATION

GH Research PLC was incorporated on March 29, 2021 with an authorized share capital of €25,000, which is the minimum required share capital for an Irish public limited company, divided into 25,000 A ordinary shares of nominal value €1.00 each. The sole subscriber to the incorporation constitution of GH Research PLC was Florian Schönharting who subscribed for 25,000 A ordinary shares of €1.00 each.

#### **Increase of Authorized Share Capital**

On May 27, 2021, GH Research PLC altered its share capital such that its authorized share capital was increased to €25,000 and \$1,000,000,000 divided into:

- 25,000 A ordinary shares, nominal value €1.00 each;
- 5,923,079 Series A preferred shares, nominal value \$0.01 each;
- 25,379,047 Series B preferred shares, nominal value \$0.01 each; and
- 99,968,697,874 ordinary shares, nominal value \$0.01 each.

#### Share Exchange

Pursuant to the terms of a share for share exchange agreement dated May 27, 2021 as part of our Corporate Reorganization, all shareholders of GH Research Ireland Limited exchanged each of the shares held by them in GH Research Ireland Limited for shares of GH Research PLC of the same share classes with the same shareholders rights as the shares held by them in GH Research Ireland Limited became a wholly owned subsidiary of GH Research PLC.

We refer to the reorganization, pursuant to which GH Research PLC acquired all of the interests in GH Research Ireland Limited in exchange for the issuance of the same classes of newly issued shares of GH Research PLC to the shareholders of GH Research Ireland Limited, as our "Corporate Reorganization."

#### **Redemption of A Ordinary Shares**

Upon the completion of the offering, GH Research PLC will redeem 25,000 A ordinary shares of €1.00 each at par registered in the name of Florian Schönharting out of the proceeds of the new issue of ordinary shares issued as part of the offering and, following the redemption, in accordance with the Constitution, will cancel the 25,000 A ordinary shares of €1.00 each.

#### **Conversion and Share Consolidation**

Pursuant to a shareholder resolution of GH Research PLC, we expect to effect (a) the conversion of (i) 5,923,079 Series A preferred shares of nominal value \$0.01 each into 5,923,079 ordinary shares of nominal value \$0.01 each and (ii) 25,379,047 Series B preferred shares of nominal value \$0.01 each into 25,379,047 ordinary shares of nominal value \$0.01 each and (b) the 2.50-for-one share consolidation of the existing ordinary shares into ordinary shares of nominal value \$0.025 each, subject to the SEC declaring this registration statement effective such that the authorized share capital of the Company shall be \$1,000,000,000 divided into 40,000,000 ordinary shares of nominal value \$0.025 each immediately following the SEC declaring this registration statement effective. We refer to the foregoing as our "Share Consolidation."

The investors in this offering will only acquire, and this prospectus only describes the offering of, the ordinary shares of GH Research PLC.



## CAPITALIZATION

The following table sets forth our total cash and capitalization as of March 31, 2021:

- on an actual basis, not reflecting the Corporate Reorganization and the Share Consolidation to be effected immediately and conditional upon the SEC declaring this registration statement effective;
- on a pro forma basis to give effect to (i) the consummation of the Series B Financing and our receipt of net proceeds therefrom, (ii) our Corporate Reorganization and (iii) the Share Consolidation into an aggregate of 40,520,850 ordinary shares, to be effected immediately and conditional upon the SEC declaring this registration statement effective, and
- on a pro forma as adjusted basis giving effect to the pro forma adjustments set forth above and to give further effect to our issuance and sale of 8,333,333 ordinary shares in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, assuming the underwriters do not exercise their over-allotment option to purchase additional ordinary shares.

You should read this table in conjunction with our financial statements and related notes included in this prospectus as well as "Use of Proceeds," "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of March 31, 2021			
	Actual	Pro Forma	Pro Forma As Adjusted <sup>(1)</sup>	
	(in USD th	nousands except f	or share data)	
Cash	\$ 4,576	\$123,404	\$236,154	
Shareholders' equity:				
Ordinary shares, par value €0.01, 70,000,000 shares issued and outstanding, actual; par value \$0.025, 40,520,850 shares issued and outstanding, pro forma; par value \$0.025, 48,854,183 shares issued and outstanding, pro forma as adjusted	801	1,013	1,221	
Series A preferred shares, par value €0.01, 5,923,079 shares issued and outstanding, actual; no shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	70	_	_	
Share premium	5,430	124,116	236,658	
Foreign currency translation reserve	(2)	(2)	(2)	
Accumulated deficit	(1,984)	(1,984)	(1,984)	
Total equity	4,315	123,143	235,893	
Total capitalization	\$ 4,315	\$123,143	\$235,893	

(1) The pro forma as adjusted information set forth above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash, total equity and total capitalization by \$7.8 million, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Each 1,000,000 increase or decrease in the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash total equity and total capitalization by \$14.0 million, assuming the

assumed initial public offering price of \$15.00 per share, the midpoint of the price range set forth on the cover page of this prospectus remains the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The number of ordinary shares outstanding in the table above does not include:

- 1,202,734 ordinary shares that will be made available for future issuance under our Share Option Plan, which will become effective in connection with this offering; and
- 50,487 ordinary shares issuable upon the exercise of options to purchase our ordinary shares granted on June 4, 2021, with an exercise price of \$12.32 per share.

### DILUTION

If you invest in our ordinary shares in this offering, your interest will be immediately diluted to the extent of the difference between the initial public offering price per share in this offering and the pro forma as adjusted net tangible book value per share after this offering. Dilution results from the fact that the initial public offering price per share is substantially in excess of the net tangible book value per share.

Our historical net tangible book value as of March 31, 2021 was \$4.3 million, or \$0.057 per share (or \$0.14 per share, after giving effect to the Share Consolidation). Net tangible book value per share is determined by dividing our tangible net worth (defined as total assets, less intangible assets, less total liabilities) by the number of our ordinary and preferred shares outstanding.

As of March 31, 2021, our pro forma net tangible book value would have been \$123.1 million, or \$3.04 per share. Pro forma net tangible book value represents the amount of our total tangible assets, less our total liabilities, after giving effect to (i) consummation of the Series B Financing and our receipt of net proceeds therefrom, (ii) our Corporate Reorganization and (iii) the Share Consolidation to be effected immediately and conditional upon the SEC declaring this registration statement effective. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2021, after giving effect to the pro forma adjustments described above.

After giving effect to (i) the Series B Financing; (ii) the Corporate Reorganization; (iii) the Share Consolidation; and (iv) the sale of 8,333,333 ordinary shares in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at March 31, 2021 would have been \$4.83 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$1.79 per share to existing shareholders and immediate dilution of \$10.17 per share to new investors.

The following table illustrates this dilution to new investors purchasing ordinary shares in this offering:

Assumed initial public offering price per share		\$15.00
Historical net tangible book value per share as of March 31, 2021 following the Share Consolidation	\$0.14	
Increase per share attributable to the pro forma adjustments described above	\$2.90	
Pro forma net tangible book value per share as of March 31, 2021	\$3.04	
Increase attributable to new investors purchasing shares in this offering	\$1.79	
Pro forma as adjusted net tangible book value per share after giving effect to this offering		\$ 4.83
Dilution per share to investors participating in this offering		<u>\$10.17</u>

Each \$1.00 increase or decrease in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease our pro forma as adjusted net tangible book value after this offering by \$0.16 per share, and would increase or decrease dilution to new investors by \$0.84 per share, assuming that the number of ordinary shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us. Each increase of 1,000,000 in the number of ordinary shares we are offering would increase our pro forma as adjusted net tangible book value after this offering by \$0.18 per share, and would decrease dilution to new investors by \$0.18 per share, assuming the assumed initial public offering price per share remains the same and after deducting underwriting discounts and commissions and commissions and the estimated offering price per share remains the same and after deducting underwriting discounts and commissions and the assumed initial public offering price per share remains the same and after deducting underwriting discounts and commissions and the estimated offering price per share remains the same and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us. Each decrease of 1,000,000 in the number of ordinary shares we are offering would decrease our pro forma as adjusted net tangible book value after this offering by \$0.19 per share, and would increase dilution to new investors by \$0.19 per share, assuming an initial public offering

price per share remains the same and after deducting underwriting discounts and commissions and the estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option to purchase additional ordinary shares in full, the pro forma as adjusted net tangible book value per share after the offering would be \$5.05, the increase in net tangible book value per share to existing shareholders would be \$2.01 and the immediate dilution in net tangible book value per share to new investors in this offering would be \$9.95.

The following table summarizes, on the pro forma as adjusted basis described above as of March 31, 2021, the differences between the existing shareholders and the new investors in this offering with respect to the number of ordinary shares purchased from us, the total consideration paid to us and the average price per share, based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Total Sha	Total Consi	Total Consideration		
	Number	Number Percent		Percent	Per Share
	(in USD tho	usands exc	ept for share a	and per sha	re data)
Existing shareholders before this offering	40,520,850	83%	\$131,501	51%	\$ 3.25
Investors participating in this offering	8,333,333	<u>17</u> %	\$125,000	<u>49</u> %	\$15.00
Total	48,854,183	<u>100</u> %	\$256,501	<u>100</u> %	<u>\$ 5.25</u>

If the underwriters exercise their option to purchase additional ordinary shares in full, the percentage of ordinary shares held by existing shareholders will decrease to 80.9% of the total number of ordinary shares outstanding after the offering, and the number of shares held by new investors will be increased to 9,583,333, or 19.1% of the total number of ordinary shares outstanding after this offering.

The above discussion and tables are based on 40,520,850 ordinary shares issued and outstanding as of March 31, 2021 after giving effect to the Series B Financing and the Share Consolidation prior to the closing of this offering.

The above discussion and tables excludes (i) 1,202,734 ordinary shares that will be made available for future issuance under our Share Option Plan, which will become effective in connection with this offering and (ii) 50,487 ordinary shares issuable upon the exercise of options to purchase our ordinary shares granted on June 4, 2021, with an exercise price of \$12.32 per share. To the extent that options are issued under our Share Option Plan, or we issue additional ordinary shares in the future, there will be further dilution to investors participating in this offering.

## SELECTED FINANCIAL DATA

The selected historical financial data for the years ended December 31, 2020 and 2019 and as of December 31, 2020 and 2019 are derived from our audited financial statements included elsewhere in this prospectus and, other than pro forma amounts, do not reflect the Corporate Reorganization and the Share Consolidation to be effected immediately and conditional upon the SEC declaring this registration statement effective. Our historical results are not necessarily indicative of the results that may be expected in the future and the results for the three months ended March 31, 2021 are not necessarily indicative of the results to be expected for the full year ending December 31, 2021 or any other interim period. We derived the summary historical financial data for the three months ended March 31, 2021 and 2020 and as of March 31, 2021 from the unaudited condensed interim financial statements included elsewhere in this prospectus, which have been prepared on the same basis as the audited financial statements and, other than pro forma amounts, do not reflect the Corporate Reorganization and the Share Consolidation to be effected immediately and conditional upon the SEC declaring this registration statements and, other than pro forma amounts, do not reflect the Corporate Reorganization and the Share Consolidation to be effected immediately and conditional upon the SEC declaring this registration statement effective. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the information under the sections titled "Capitalization" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Our audited financial statements are prepared in accordance with IFRS and presented in U.S. dollars.

Our functional currency is the euro. For financial reporting purposes, our financial statements, which are prepared using the functional currency, have been translated into U.S. dollars. Our assets and liabilities are translated at the exchange rates at the balance sheet date, our revenue and expenses are translated at average exchange rates and shareholders' equity/(deficit) is translated based on historical exchange rates. Translation adjustments are not included in determining net loss for the period but are included in foreign exchange translation adjustment to other comprehensive loss, a component of total equity.

		Three Months Ended March 31				Year I Decen	Ended Iber 3	
		2021		2020		2020		2019
		(in USD	thou	sands, excep	t share	and per sha	are dat	ta)
Income Statement Data:								
Operating Expenses:								
Research and development	\$	(692)	\$	(11)	\$	(338)	\$	(296)
General and administrative		(448)		(8)		(108)		(14)
Loss from operations		(1,140)		(19)		(446)		(310)
Foreign currency translation differences		(9)						_
Loss for the period	\$	(1,149)	\$	(19)	\$	(446)	\$	(310)
Basic and diluted loss per share		(0.015)		(0.000)		(0.006)		(0.004)
Weighted average number of shares outstanding - basic and diluted loss	75,	923,079	70	0,000,000	70,	898,420	70	,000,000
Pro forma basic and diluted loss per share <sup>(1)</sup>		(0.038)		(0.001)		(0.016)		(0.011)
Pro forma weighted average ordinary shares outstanding - basic and diluted <sup>(1)</sup>	30,	369,232	28	3,000,000	28,	359,368	28	,000,000

(1) Pro forma basic and diluted loss per share and pro forma weighted average ordinary shares outstanding - basic and diluted gives effect to (i) our Corporate Reorganization and (ii) the Share Consolidation as if such transactions had occurred on January 1, 2019.

		As of March 31	March 31 As of Dece	
		2021	2020	2019
			(in USD the	ousands)
Balance Sheet Data:				
Cash		\$4,576	\$5,895	\$498
Total assets		5,556	5,912	504
Share capital		871	871	801
Total equity		\$4,315	\$5,666	\$400
	109			

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected Financial Data" and our financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and our expectations with respect to liquidity and capital resources, includes forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, those risks and uncertainties described in "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in this prospectus. Our actual results could differ materially from the results described in or implied by these forward-looking statements.

On March 29, 2021, GH Research PLC was incorporated under the laws of Ireland to become the ultimate holding company for GH Research Ireland Limited pursuant to our corporate reorganization. See "Corporate Reorganization and Share Consolidation." Prior to this offering, GH Research PLC has only engaged in activities incidental to its formation, the corporate reorganization and this offering. Accordingly, a discussion and analysis of the results of operations and financial condition of GH Research PLC for the period of its operations prior to the corporate reorganization would not be meaningful and are not presented. Following the corporate reorganization, the historical financial statements of GH Research Ireland Limited included in this Registration Statement will become part of the historical consolidated financial statements of GH Research PLC.

## Overview

We are a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. Our initial focus is on developing our novel and proprietary 5-Methoxy-N,N-Dimethyltryptamine, or 5-MeO-DMT, therapies for the treatment of patients with Treatment-Resistant Depression, or TRD. Our portfolio currently includes GH001, our proprietary inhalable 5-MeO-DMT product candidate which is delivered via a vaporization device produced by a third party, and GH002, our proprietary injectable 5-MeO-DMT product candidate. We have completed a Phase 1 healthy volunteer clinical trial, in which administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in an individualized dosing regimen with intra-subject dose escalation within a single day. GH001 is currently being investigated in the Phase 2 part of an ongoing Phase 1/2 clinical trial in patients with TRD. Based on observed clinical activity, we believe that administration of a single dose of GH001 has the potential to induce ultra-rapid remissions as measured by the Montgomery-Åsberg Depression Rating Scale, or MADRS, in certain patients, driven by the ultrarapid onset of psychoactive effects (commonly within seconds) and an intense and short-lived (commonly five to 30 minutes) initial psychoactive experience. The goal of the ongoing Phase 2 part of the trial is to assess whether an individualized dosing regimen with intra-subject dose escalation within a single day can further increase the MADRS remission rate as compared to a single GH001 dose.

We have incurred recurring operating losses since inception, including net losses of \$1,149 thousand, \$310 thousand and \$446 thousand for the three months ended March 31, 2021 and the years ended December 31, 2019 and 2020, respectively. As of March 31, 2021, we had an accumulated deficit of \$2 million. We expect to incur significant expenses and operating losses for the foreseeable future as we expand our research and development activities. In addition, our losses from operations may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

 continue to develop and conduct clinical trials, including in expanded geographies such as the United States, for GH001, our inhalable 5-MeO-DMT product candidate, and GH002, our injectable 5-MeO-DMT product candidate, for our initial indications and additional potential indications;

- continue both the technical development and expansion of our external manufacturing capabilities for our current product candidates GH001 and GH002 and of the medical devices required to deliver these product candidates;
- initiate and continue research and development, including nonclinical, clinical, and discovery efforts for any future product candidates;
- seek to identify additional product candidates;
- seek regulatory approvals for our product candidates GH001 and GH002, including the medical devices required to deliver these product candidates, or any other product candidates that successfully complete clinical development;
- add operational, financial and management information systems and personnel, including personnel to support our product candidate and device development and help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, quality control, scientific, commercial, sales, marketing and administrative personnel;
- continue to prepare, file, prosecute, maintain, protect and enforce our intellectual property rights and claims;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval;
- comply with ongoing regulatory requirements for products approved for commercial sale, if ever;
- acquire or in-license other product candidates, medical devices to deliver our product candidates, and other technologies; and
- incur increased costs as a result of operating as a public company.

In addition, as we progress toward marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our product candidates or other research and development initiatives, which could have a material adverse effect on our business, results of operations, and financial condition. We will need to generate significant revenue to achieve profitability, and we may never do so.

We are subject to a number of risks comparable to those of other similar companies, including dependence on key individuals; the need to develop product candidates with the required safety and efficacy profile and which support regulatory approval and are commercially viable; competition from other companies, many of which are larger and better capitalized; and the need to obtain adequate additional financing to fund the development of our product candidates.

As of March 31, 2021, we had cash of \$4.6 million. We believe that our existing cash, together with the net proceeds of \$118.8 million from the Series B Financing that closed in April 2021 and the expected

net proceeds from this offering, will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources—Funding Requirements" below.

# **COVID-19 Business Update**

With the global spread of the ongoing COVID-19 pandemic in 2021, we have followed guidance issued by national and local governments to address and mitigate the impact of the COVID-19 pandemic on our employees and our business, including our nonclinical studies and clinical trials. We are focused on the health and safety of our employees, and have, among other things, implemented a work-from-home policy and eliminated nonessential business travel. While we are experiencing limited financial impacts at this time, the extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains highly uncertain. The overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic as well as any economic slowdown as a result of the COVID-19 pandemic, could materially and adversely affect our business, financial condition and results of operations. We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy.

In addition, our planned clinical trials have been and may continue to be affected by the COVID-19 pandemic, including (i) delays or difficulties in enrolling and retaining patients in our planned clinical trials, including patients that may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services; (ii) delays or difficulties in clinical site initiation, including difficulties in recruiting and retaining clinical site investigators and clinical site staff as well as closures of trial sites; (iii) diversion or prioritization of healthcare resources away from the conduct of clinical trials and towards the COVID-19 pandemic, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, and because, who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations; (iv) interruption of our future clinical supply chain or key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal, state/provincial or municipal governments, employers and others; and (v) limitations in outsourced third-party resources that would otherwise be focused on the conduct of our planned clinical trials, including because of sickness of third-party personnel or their families, or the desire of third-party personnel to avoid contact with large groups of people.

# **Financial Operations Overview**

## Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in regulatory approval or collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements that we may enter into with third parties. Because of the numerous risks and uncertainties associated with product development, regulatory approval and market acceptance, we are unable to predict the amount or timing of product revenue.

## **Operating Expenses**

# Research and Development Expenses

Research and development expenses primarily represent costs incurred by us for the following:

- development costs, including expenses incurred under agreements with third parties, such as consultants, investigational sites and CROs, that conduct our nonclinical studies and clinical trials and other scientific development services;
- costs to develop our manufacturing technology and infrastructure, including costs incurred with third-party CMOs to acquire, develop and manufacture drug substance, drug product, and delivery device materials for nonclinical studies and clinical trials;

- costs incurred to maintain compliance with regulatory requirements; and
- other expenses, including costs of outside consultants, insurance and other operating costs.

We expense research and development costs as incurred. We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors and our clinical investigative sites. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as other current assets or other current liabilities. To date, substantially all of our research and development costs have been incurred pursuant to the development of GH001. Therefore, we have not historically tracked expenses by product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and related product manufacturing expenses. As a result, we expect that our research and development expenses will continue to increase over the next several years as we: (i) advance the clinical development of GH001 for TRD; (ii) advance GH001 into clinical development in additional psychiatric and neurological disorders beyond TRD; (iii) advance GH002 and any potential future product candidate into clinical development; and (iv) build our third-party or in-house process development, analytical, manufacturing and related capabilities, increase personnel costs and prepare for regulatory filings related to our potential or future product candidates. We also expect to incur additional IP-related expenses as we file further patent applications and prosecute our intellectual property to protect innovations arising from our research and development activities.

The successful development and commercialization of GH001, GH002 and any potential future product candidate is highly uncertain. This is due to the numerous risks and uncertainties associated with development and commercialization, including the following:

- successful enrollment in and completion of clinical trials;
- successful completion of nonclinical studies;
- sufficiency of our financial and other resources to complete the necessary technical development work, nonclinical studies and clinical trials;
- receiving regulatory approvals or clearance for conducting our planned clinical trials or future clinical trials;
- receiving positive data from our clinical trials that support an acceptable risk-benefit profile of GH001, GH002 and any future product candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing and scaling up, through third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any product candidates are approved;
- entry into collaborations to further the development of GH001, GH002 and any future product candidates, including any required medical devices;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for GH001, GH002 and any future product candidates;
- successfully launching commercial sales of GH001, GH002 and any future product candidates, if approved;
- acceptance of our current and future product candidates' benefits and uses, if approved, by patients, the medical community and third-party payors; and



 maintaining a continued acceptable safety profile of GH001, GH002 and our future product candidates following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates in nonclinical and clinical development could mean a significant change in the costs and timing associated with their development. For example, if we are required by the FDA, or other comparable foreign regulatory authorities, to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for our product candidates or for the medical devices required to deliver our product candidates, or if there are any delays in completing our clinical trials or the development of any of our product candidates or of the medical devices required to deliver.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of initiation of clinical trials and enrollment of patients in clinical trials. Research and development expenses are expected to increase as we advance the clinical development of our inhalable 5-MeO-DMT product candidate GH001, and further advance the research and development of our injectable 5-MeO-DMT product candidate GH002 and any future product candidates. The successful development of our product candidates is highly uncertain.

# General and Administrative Expenses

General and administrative expenses consist primarily of:

- professional fees, including consulting, accounting, legal, tax and audit services;
- personnel expenses, including salaries and related expenses; and
- other expenses, including expenses for rent and maintenance of facilities, insurance and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, investor and public relations costs and costs associated with other administrative and professional services.

# Foreign currency translation differences

Foreign currency translation differences consist of foreign exchange impacts arising from foreign currency transactions.

### Taxation

We are subject to corporate taxation in Ireland. Due to the nature of our business, we have generated losses since inception and have therefore not paid Irish corporation tax.

We have unused net operating losses of \$389 thousand, \$835 thousand and \$2 million as of December 31, 2019 and 2020 and March 31, 2021, respectively. In order to utilize these unused tax losses, we would need to be regarded as carrying on a trade for Irish corporate tax purposes. Once regarded as carrying on a trade and subject to other conditions being met, the unused tax losses can be carried forward indefinitely against future trading income. On this basis, we have decided not to recognize any deferred tax assets at December 31, 2020 or 2019. There is no certainty that we will generate sufficient taxable profits within the required timeframe to be able to utilize these tax loss carry-forwards in full.



## **Results of Operations**

# Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our results of operations for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Month March	Change	
	2021	2020	
Operating Expenses:			
Research and development	\$ (692)	\$(11)	\$ (681)
General and administrative	(448)	(8)	(440)
Loss from operations	(1,140)	(19)	(1,121)
Foreign currency translation differences	(9)	—	(9)
Loss for the period	<u>\$(1,149</u> )	<u>\$(19</u> )	<u>\$(1,130</u> )

# Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Montl March	Change	
	2021	2020	
External costs	\$(587)	\$(11)	\$(576)
Employee expenses	(104)	—	(104)
Depreciation property, plant and equipment	<u>(1</u> )		(1)
Research and development	\$(692)	<u>\$(11</u> )	<u>\$(681</u> )

Research and development expenses increased by \$681 thousand from \$11 thousand for the three months ended March 31, 2020, to \$692 thousand for the three months ended March 31, 2021. The increase was primarily due to increased external costs relating to our technical developments and clinical trials and employee expenses relating to the hiring of personnel in our research and development team to support the requirements of increased clinical activities.

## General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2021 and 2020 (in thousands):

	Three Montl March		Change
	2021	2020	
General and administrative	\$(448)	\$(8)	\$(440)

General and administrative expenses increased by \$440 thousand from \$8 thousand for the three months ended March 31, 2020, to \$448 thousand for the three months ended March 31, 2021. The increase was primarily due to costs incurred in preparation for our initial public offering, including increased costs associated with compliance with exchange listing and SEC requirements as a public company, and the hiring of personnel in our general and administrative functions to support our growth initiatives.

### Foreign currency translation differences

Foreign currency translation differences increased by \$9 thousand from \$nil for the three months ended March 31, 2020, to a loss of \$9 thousand for the three months ended March 31, 2021, due to an increase in foreign currency transactions.

## Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019 (in thousands):

		Year Ended December 31		
	2020	2020 2019		
Operating Expenses:				
Research and development	\$(338)	\$(296)	\$ (42)	
General and administrative	(108)	(14)	(94)	
Loss from operations	(446)	(310)	(136)	
Loss for the year	<u>\$(446)</u>	<u>\$(310)</u>	<u>\$(136</u> )	

### Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2020 and 2019 (in thousands):

		Ended 1ber 31	Change
	2020	2019	
External costs	<u>\$(338</u> )	<u>\$(296</u> )	<u>\$(42</u> )
Research and development	<u>\$(338</u> )	<u>\$(296</u> )	<u>\$(42</u> )

Research and development expenses increased by \$42 thousand from \$296 thousand for the year ended December 31, 2019, to \$338 thousand for the year ended December 31, 2020. The increase was primarily due to increased costs relating to our technical developments and clinical trials. We did not incur any research and development related employee expenses or depreciation charges in the years ended December 31, 2020 or 2019.

We expect these costs to increase materially in the near future, consistent with our plan to advance our GH001 and GH002 product candidates through clinical development. Because substantially all of our research and development costs to date have been incurred pursuant to the development of GH001, we have not historically tracked expenses by product candidate.

# General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2020 and 2019 (in thousands):

	Year E Decem		Change
	2020	2019	
General and administrative	\$(108)	\$(14)	\$(94)

General and administrative expenses increased by \$94 thousand from \$14 thousand for the year ended December 31, 2019, to \$108 thousand for the year ended December 31, 2020. The increase was primarily due to costs incurred in preparation for our initial public offering, including increased costs associated with compliance with exchange listing and SEC requirements as a public company, and to support our growth initiatives.

### Liquidity and Capital Resources

## Sources of Liquidity

We have incurred operating losses since inception, and we have not generated any revenue from any product sales or any other sources. We have not yet commercialized any of our product candidates, which are in various phases of technical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We have funded our operations to date primarily with proceeds from the sale of ordinary shares and preferred stock:

- In 2019, we received net cash proceeds of \$797 thousand from the issuance of ordinary shares.
- In 2020, we received net cash proceeds of \$5.5 million from the issuance of Series A preferred shares.
- In 2021, we received net cash proceeds of \$118.8 million from the issuance of Series B preferred shares.
- As of December 31, 2019 and 2020 and March 31, 2021, we had cash of \$498 thousand, \$5.9 million and \$4.6 million, respectively.

We plan to continue to fund our operating and capital funding needs through sales of additional equity or other forms of financing. We may also consider pursuing strategic partnerships for clinical development and commercialization of our product candidates. The sale of additional equity would result in additional dilution to our shareholders.

# Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2021 and 2020, as well as for the years ended December 31, 2020 and 2019 (in thousands):

	Three Months Ended March 31 Chang		Change	Year E Decem	Change	
	2021	2020		2020	2019	
Cash flows used in operating activities	\$(1,087)	\$(102)	\$ (985)	\$ (330)	\$(289)	\$ (41)
Cash flows used in investing activities	(21)	—	(21)	—	—	—
Cash flows from financing activities				5,500	797	4,703
Net (decrease)/increase in cash	\$(1,108)	<u>\$(102</u> )	\$(1,006)	\$5,170	\$ 508	\$4,662

# Cash Flows Used in Operating Activities

Cash flows used in operating activities increased to \$1,087 thousand for the three months ended March 31, 2021 from \$102 thousand for the three months ended March 31, 2020, an increase of \$985 thousand. The increase was primarily due to a \$1,130 thousand increase in loss from operations, partially offset by an increase in changes to working capital of \$144 thousand.

Cash flows used in operating activities increased to \$330 thousand for the year ended December 31, 2020 from \$289 thousand for the year ended December 31, 2019, an increase of \$41 thousand. The increase was primarily due to a \$136 thousand increase in loss from operations, partially offset by an increase in changes to working capital of \$95 thousand.

### Cash Flows Used in Investing Activities

Cash flows used in investing activities increased to \$21 thousand for the three months ended March 31, 2021 from \$nil for the three months ended March 31, 2020, an increase of \$21 thousand. The increase was due to purchase of property, plant and equipment.

During the years ended December 31, 2020 and December 31, 2019, there were no cash flows used in investing activities.



## Cash Flows from Financing Activities

During the three months ended March 31, 2020 and March 31, 2019, there were no cash flows from financing activities.

Cash flows from financing activities increased to \$5.5 million for the year ended December 31, 2020 from \$797 thousand for the year ended December 31, 2019, an increase of \$4.7 million. The increase was due proceeds from the issuance of Series A preferred shares.

## **Funding Requirements**

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance the technical development work, nonclinical studies and clinical trials of our product candidates and the medical devices required to deliver such product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Furthermore, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials, including in expanded geographies such as the United States, for our product candidates GH001 and GH002 for our initial indication and additional potential indications;
- continue both the technical development and expansion of external manufacturing capabilities for our current product candidates GH001 and GH002 and of the medical devices required to deliver these product candidates;
- initiate and continue research and development, including nonclinical, clinical, and discovery efforts for any future product candidates;
- seek to identify additional product candidates;
- seek regulatory approvals for our product candidates GH001 and GH002, including the medical devices required to deliver these product candidates, or any other product candidates that successfully complete clinical development;
- add operational, financial and management information systems and personnel, including personnel to support our product candidate and device development and help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, quality control, scientific, commercial, sales, marketing and administrative personnel;
- continue to prepare, file, prosecute, maintain, protect and enforce our intellectual property rights and claims;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval;
- comply with ongoing regulatory requirements for products approved for commercial sale, if ever;
- acquire or in-license other product candidates, medical devices to deliver our product candidates, and other technologies; and
- incur increased costs as a result of operating as a public company.

As of March 31, 2021, we had cash of \$4.6 million. Based on our current operating plan, we believe that our existing cash, combined with the net proceeds of \$118.8 million from the Series B Financing that closed in April 2021 and the expected net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements into 2024. However, we have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with product development, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our GH001 and GH002 product candidates, additional 5-MeO-DMT delivery approaches and the medical devices required to deliver these therapies for our initial and potential additional indications, as well as other product candidates we may develop;
- the timing and uncertainty of, and the costs involved in, obtaining marketing approvals for our GH001 and GH002 product candidates including the medical devices required to deliver these therapies for our initial and potential additional indications, and other product candidates we may develop and pursue;
- the number of future product candidates that we may pursue and their development requirements;
- the number of jurisdictions in which we plan to seek regulatory approvals;
- if approved, the costs of commercialization activities for GH001 and GH002 for any approved indications, or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution, and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of GH001 and GH002 and the respective medical devices for any approved indications or any other product candidates;
- the extent to which we may in-license or acquire rights to other products, product candidates, medical devices or technologies;
- our headcount growth and associated costs as we expand our research and development, increase our office space, and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property-related claims;
- the effect of competing product and market developments; and
- the ongoing costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, convertible debt financings, strategic collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may result in fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through collaborations or marketing, distribution, licensing and royalty arrangements with third parties, we may have to relinquish valuable rights to our intellectual property or technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us or issue and sell our shares, which may result in dilution to our shareholders. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

For more information as to the risks associated with our future funding needs, see "Risk Factors."

# **Contractual Obligations and Commitments**

As of December 31, 2019 and 2020, we had no material unavoidable contractual obligations or commitments.

# **Off-Balance Sheet Arrangements**

During the periods presented, we did not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

## Critical Accounting Policies and Significant Judgments and Estimates

# Deferred tax balances and the valuation of tax operating losses

During the period from incorporation to March 31, 2021, we have incurred tax losses, which are a potential benefit in the event that we report a taxable profit in the future. In preparing our financial statements, we have assessed that the likelihood of a taxable profit is currently not sufficiently certain for these potential benefits to be recognized as a deferred tax asset. This assessment is based on the status of the research into our principal investigational product and the significant challenges that remain before operating profits can be assured.

# Internal Control Over Financial Reporting

In connection with the preparation of our financial statements for the years ended December 31, 2019 and 2020, we identified material weaknesses in our internal control over financial reporting. Specifically, we determined that we lack a sufficient number of trained professionals with an appropriate level of accounting knowledge, training and experience to: (a) design and maintain formal accounting policies, procedures and controls over the fair presentation of our financial statements; and (b) design and maintain controls over the preparation and review of account reconciliations, journal entries and financial statements, including maintaining appropriate segregation of duties.

These control deficiencies did not result in a material misstatement to the financial statements. However, each of these control deficiencies could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

Prior to the completion of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. We are progressing with the activities necessary to implement the appropriate accounting policies, processes and controls required to comply with Section 404 of the Sarbanes-Oxley Act and are in the process of identifying the relevant individuals with the requisite expertise to assist in implementation activities designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses, including hiring additional finance and accounting personnel and initiating design and implementation of our financial control environment. We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to these material weaknesses in our internal control over financial reporting nor that they will prevent or avoid potential future material weaknesses. We cannot assure you that all of our existing material weaknesses have been identified, or that we will not in the future identify additional material weaknesses. See "Risk Risks Related to the Offering and Ownership of Our Ordinary Shares—We have identified Factorsmaterial weaknesses in our internal control over financial reporting in connection with the audit of our financial statements for the years ended December 31, 2019 and 2020, and we may identify additional material weaknesses. If our remediation of these material weaknesses is not effective, or if we experience additional material weaknesses or otherwise fail to maintain an effective system of internal controls in the future, our ability to accurately or timely report our financial condition or results of operations may be adversely affected."

## **Emerging Growth Company Status**

On April 5, 2012, the JOBS Act was enacted. As an emerging growth company, or EGC, under the JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002. Additionally, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This transition period is only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the International Accounting Standards Board. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

We will remain classified as an EGC until the earlier of (1) the last day of the fiscal year (i) in which we have total annual gross revenue of \$1.07 billion; (ii) following the fifth anniversary of the date of the completion of the offering; or (iii) in which we are deemed to be a "large accelerated filer," which requires the market value of our ordinary shares that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three-year period.

## **Recently Issued Accounting Pronouncements**

As disclosed in Note 2 to our financial statements appearing elsewhere in this prospectus, there are no standards issued but not yet adopted which will have an impact on our financial statements.

### **Quantitative and Qualitative Disclosures About Market Risks**

The statements about market risk below relate to our historical financial information included in this prospectus.

### Foreign exchange risk

We operate internationally and are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to pounds sterling.

Transaction exposure arises because the amount of local currency paid or received in transactions denominated in foreign currencies may vary due to changes in exchange rates. Foreign exchange risk arises from:

- forecast expenses denominated in a currency other than the entity's functional currency; and
- recognized assets and liabilities denominated in a currency other than the entity's functional currency.

Management believes that foreign exchange risk is minimal, as we currently maintain our cash balance in euro and our expenses are mainly incurred in euro. We currently have no revenue generating activities.

# Credit risk

We are not currently exposed to credit risk except on our cash balances. Our cash balance is maintained with well established, highly rated financial institutions. As of March 31, 2021, the cash balance is held at one bank that has S&P's credit rating of BBB+. We do not invest in equity instruments or derivatives.

# Liquidity risk

Liquidity risk is the risk that we may not be able to generate sufficient cash resources to settle our obligations in full as they fall due or can do so only on terms that are materially disadvantageous. Prudent liquidity risk management implies maintaining sufficient cash to cover working capital requirements.

Cash is monitored by management. Funding and liquidity risks are reviewed regularly by our board of directors and management. We fund our capital requirements through capital raising.

### BUSINESS

# Overview

We are a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. Our initial focus is on developing our novel and proprietary 5-Methoxy-N,N-Dimethyltryptamine, or 5-MeO-DMT, therapies for the treatment of patients with Treatment-Resistant Depression, or TRD. Our portfolio currently includes GH001, our proprietary inhalable 5-MeO-DMT product candidate which is delivered via a vaporization device produced by a third party, and GH002, our proprietary injectable 5-MeO-DMT product candidate. We have completed a Phase 1 healthy volunteer clinical trial, in which administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in an individualized dosing regimen with intra-subject dose escalation within a single day. GH001 is currently being investigated in the Phase 2 part of an ongoing Phase 1/2 clinical trial in patients with TRD. Based on observed clinical activity, we believe that administration of a single dose of GH001 has the potential to induce ultra-rapid remissions as measured by the Montgomery–Åsberg Depression Rating Scale, or MADRS, in certain patients. The goal of the ongoing Phase 2 part of the trial is to assess whether an individualized dosing regimen with intra-subject dose escalation within a single day can further increase the MADRS remission rate as compared to a single GH001 dose.

Patients with MDD who have not adequately responded to therapy clearly have harder-to-treat depression, generally referred to as TRD. There is no consensus definition for TRD, but in the context of clinical trials, failure of at least one pharmacotherapy, one pharmacotherapy and one psychotherapy, or two pharmacotherapies has been used, the latter group having been referred to by regulatory authorities as patients with TRD. The Sequenced Treatment Alternatives to Relieve Depression, or STAR\*D study, a collaborative study funded by the U.S. National Institute of Mental Health, demonstrated that approximately 37% of patients with MDD did not achieve a response despite two treatment steps. Based on this result we estimate that there are approximately nine million TRD patients in the United States and Europe who would be candidates for treatment. TRD has a greater economic and societal cost than non-TRD MDD. For instance, direct medical costs are approximately two- to threefold higher for TRD patients compared to non-TRD MDD patients.

Despite the significant unmet medical need in TRD and the substantial patient population, there are only two pharmacotherapies specifically approved for TRD in the United States: esketamine, as well as a combination of olanzapine and fluoxetine, an antipsychotic and antidepressant, respectively, both of which have shown mixed efficacy in clinical trials and are associated with potential side effects. Outside of pharmacotherapies, psychotherapies are also employed in the treatment of TRD, but involve a lengthy time commitment and are subject to large variability in availability, administration and effectiveness. Multiple forms of somatic intervention, such as rTMS, ECT, VNS and DBS, are another common treatment approach for TRD, although these treatments are often deemed invasive and/or onerous, and there are limited data supporting long-term therapeutic benefit. Despite the range of treatments available for TRD, there is a large unmet medical need for new therapies to bring more patients into rapid and durable remissions and to reduce social and economic burden.

5-MeO-DMT is a serotonergic psychedelic, a class of psychoactive drugs that act primarily through an agonist action on serotonin, or 5-HT, receptors and cause an altered state of consciousness. *In vivo* and *in vitro* research from academic studies suggest that 5-MeO-DMT is active at both the 5-HT1A and 5-HT2A receptors, which are expressed in neurons in different areas of the central nervous system. 5-MeO-DMT appears to have a higher affinity for the 5-HT1A receptor subtype and a more selective pattern of distribution across various neurotransmitter receptor types compared to other tryptamines, such as psilocin and N,N-Dimethyltryptamine, or DMT, both of which have stronger affinity for the 5-HT2A receptor subtype and a less selective receptor binding profile.

Our goal is to develop novel and proprietary 5-MeO-DMT therapies for patients with TRD that are highly effective, rapidly acting, well tolerated and conveniently administered. We believe that various distinguishing features of our 5-MeO-DMT product candidates, including our lead product candidate GH001, will allow us to achieve those goals.

First, we believe that GH001 has a high propensity to induce intense psychoactive effects, or Peak Experiences, or PEs, which we believe may be correlated with ultra-rapid induction of durable remissions in patients with TRD. Second, we believe that there is no clinically relevant tolerance development to 5-MeO-DMT when the drug is re-administered within hours and, therefore, no diminished psychoactive effects. Together with the ultra-rapid onset and short duration of psychoactive effects, this aspect allows re-administration of GH001 in an individualized dosing regimen where GH001 can be administered several times within one day. We are currently investigating whether this individualized dosing regimen has the ability to increase the rate of occurrence of PEs in patients with TRD compared to administration of a single dose and whether this results in an increased rate of ultra-rapid remissions, while at the same time avoiding unnecessarily high doses. Third, we believe that the ultra-rapid onset and short duration of the psychoactive effects may confer a significant convenience and feasibility advantage compared to other serotonergic psychoactive agents studied for the treatment of mental disorders, in which the initial psychoactive effects have a slower onset and can last for several hours. We further believe that those features and the type of psychoactive effects induced by GH001 allow for GH001 dosing without the need for lengthy and complex patient preparation prior to the treatment, with only limited required support from a healthcare provider during the experience and without the need for frequent psychological integration work after the experience. GH002 and potential additional product candidates will follow a similar treatment paradigm.

We have completed a Phase 1 clinical trial with seven days of follow-up of GH001, our inhalable 5-MeO-DMT product candidate, in 22 healthy volunteers. Administration via inhalation was observed to be well tolerated at the investigated single dose levels and in the individualized dosing regimen.

We are currently conducting a Phase 1/2 clinical trial with seven days of follow-up of GH001 in 16 patients with TRD. In the completed single-dose Phase 1 part of this trial with two dose levels (12 mg, 18 mg), administration of single doses of GH001 via inhalation was again observed to be well tolerated. We also evaluated clinical activity, as characterized by MADRS remission and MADRS clinical response. Two patients in the 12 mg group and one patient in the 18 mg group of Part A achieved a MADRS remission on day seven after dosing, as well as a MADRS clinical response, and one further patient in the 18 mg group achieved a MADRS clinical response on day seven after dosing.

The ongoing open-label, single-arm Phase 2 part of this trial aims to assess whether applying our individualized dosing regimen with intra-patient dose escalation of GH001 can further increase the MADRS remission rate compared to a single GH001 dose in patients with TRD.

We intend to request a pre-Investigational New Drug application, or pre-IND, meeting with the FDA and a Scientific Advice meeting with the European Medicines Agency, or EMA, and pending the outcome of these meetings, we plan to initiate a multi-center, randomized, controlled Phase 2b trial in TRD. Subject to completing clinical development, we plan to seek regulatory approval of GH001 in both the United States and Europe.

GH002 is our next 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. We believe GH002 has the potential to be an attractive therapeutic option, e.g., in patients with underlying airway or pulmonary disease or in situations where it is difficult to assure that the GH001 inhalation is performed adequately, such as in acute psychiatric emergency care situations where a patient may be unable to properly use an inhalation device. GH002 is currently in preclinical development and we anticipate developing GH002 in indications within our focus area of psychiatric and neurological disorders.

# **Our Pipeline**

We are developing our 5-MeO-DMT product candidates, GH001 and GH002, in our focus area of psychiatric and neurological disorders. Our lead program, GH001, is currently in the Phase 2 part of an ongoing Phase 1/2 clinical trial in patients with TRD. In light of our completed Phase 1 clinical trial of GH001 in healthy volunteers, we plan to request clearance from European regulatory authorities to begin two additional Phase 2 clinical trials in patients with psychiatric or neurological disorders.

## **Our Strategy**

Our mission is to develop novel proprietary 5-MeO-DMT therapies to induce ultra-rapid and durable remissions in patients with psychiatric and neurological disorders. In order to achieve this mission, key elements of our strategy include:

Advancing GH001, our inhalable 5-MeO-DMT product candidate, for the treatment of TRD through clinical development, regulatory approval and commercialization, if approved

In TRD, there is a large unmet need for new therapies to bring more patients into rapid and durable remissions. We estimate that approximately nine million people in the United States and Europe have TRD. We have completed a Phase 1 healthy volunteer clinical trial, in which administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in the individualized dosing regimen with intra-subject dose escalation within a single day. GH001 is currently being investigated in the Phase 2 part of an ongoing open-label, single-arm Phase 1/2 clinical trial in patients with TRD. We expect to complete our ongoing Phase 1/2 clinical trial in the second half of 2021. In the completed Phase 1 part of this ongoing trial, no serious adverse events, or SAEs, were observed and all adverse drug reactions, or ADRs, were mild and resolved spontaneously. Based on observed clinical activity in this part of the trial, we also believe that administration of a single dose of GH001 has the potential to induce ultra-rapid MADRS remissions in certain patients. The goal of the ongoing Phase 2 part of the trial is to assess whether an individualized dosing regimen with intra-subject dose escalation within a single day can further increase the MADRS remission rate as compared to a single GH001 dose. We plan to request a pre-IND meeting with the FDA and a Scientific Advice meeting with the EMA and, pending the outcome of these meetings, we plan to initiate a multi-center, randomized, controlled Phase 2b trial in TRD.

 Advancing GH001, into clinical development in additional psychiatric and neurological disorders beyond TRD

Given GH001's mechanism of action, we believe that GH001 may confer beneficial effects as an earlier line of treatment in MDD, including potential to serve as a front-line treatment, as well as in other psychiatric and neurological disorders with unmet medical need. We plan to initiate proof-of-concept Phase 2a trials in two such disorders in the second half of 2021.

Advancing GH002, our injectable 5-MeO-DMT product candidate, into clinical development

We believe our injectable 5-MeO-DMT product candidate, GH002, has the potential to be an attractive therapeutic option, e.g., in patients with underlying airway or pulmonary disease or in situations where it is difficult to assure that the GH001 inhalation is performed adequately, such as in acute psychiatric emergency care situations where a patient may be unable to properly use an inhalation device. GH002 is currently in preclinical development and we anticipate advancing GH002 into clinical development in indications within our focus area of psychiatric and neurological disorders.

Investigating additional delivery systems and additional routes of administration for 5-MeO-DMT

We plan to investigate additional delivery systems and additional routes of administration for 5-MeO-DMT which we believe could expand the patient population that could benefit from our product candidates.

Expanding our intellectual property portfolio around 5-MeO-DMT

We have filed several patent applications covering novel aerosol compositions of matter of 5-MeO-DMT, novel manufacturing methods for the purification of 5-MeO-DMT, high purity 5-



MeO-DMT and novel uses of 5-MeO-DMT in various disorders. We are committed to exploring additional opportunities with 5-MeO-DMT through ongoing research and development, including for use of 5-MeO-DMT in new indications where 5-MeO-DMT has the potential to provide a therapeutic benefit and for additional drug delivery approaches that provide alternatives to the patient.

Maximizing the value of our product portfolio by building internal commercialization infrastructure and entering selective partnerships

We retain global development and commercialization rights for our product candidates and are developing a commercialization plan where we anticipate working with payors to enable reimbursement and with health systems to enable broad patient access. Subject to regulatory approval of our product candidates, we plan to develop and use our own sales and marketing capabilities to target public and private healthcare providers and clinic networks. We may also enter into commercialization collaborations with third parties who have complementary commercial capabilities.

# **Our Market Opportunity**

We are developing our 5-MeO-DMT product candidates for the treatment of a range of psychiatric and neurological disorders, with an initial focus on TRD, where there is a large unmet medical need. Our goal is to develop new therapies that are rapidly acting, highly effective, well tolerated and conveniently administered.

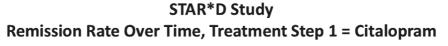
## MDD and TRD Overview

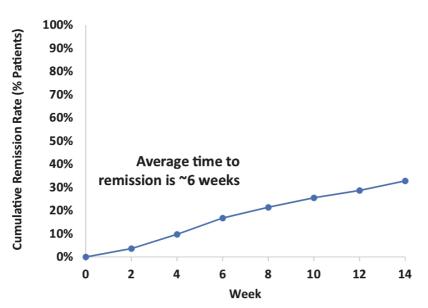
MDD is a serious mental health condition characterized by recurring episodes where feelings of sadness, loss of interest and other heightened negative emotions occur most of the day, nearly every day. MDD is associated with substantial morbidity, diminished quality of life and reduced life expectancy. The World Health Organization, or WHO, estimated that, as of 2015, more than 320 million people suffered from MDD worldwide and concluded that MDD is the single largest contributor to global disability, accounting for 7.5% of all years lived with disability.

Many experts believe the global burden of MDD will further increase significantly in the wake of the coronavirus disease 2019, or COVID-19, pandemic. Depression symptom prevalence among adults in the United States has been reported to be threefold higher during the COVID-19 pandemic than before.

Unfortunately, the efficacy of the existing anti-depressive treatments is limited by a slow onset of response, and a significant proportion of patients do not adequately respond even after multiple lines of therapy. The STAR\*D study, a collaborative study funded by the U.S. National Institute of Mental Health, was designed to assess effectiveness of four different treatment steps, which included both pharmacological and psychotherapeutic approaches, in a generalizable population of patients with depression. An American Journal of Psychiatry report on the STAR\*D study by John Rush and co-authors summarized the acute and longer-term outcomes for all four successive treatment steps. The study reported both rates of remission, defined as a score of equal or less than 5 on the 16-item, clinician-rated Quick Inventory of Depressive Symptomatology, or QIDS-C16, and rates of response, defined as at least a 50% reduction in QIDS-C16 from treatment step entry. This STAR\*D study found that remission rates were approximately 37%, 31%, 14% and 13% for the first, second, third and fourth treatment steps, respectively, and that the average time to remission in those who did remit across all treatment steps extended to about five to seven weeks. Approximately 33% of patients in the STAR\*D study did not achieve a remission despite undergoing four treatment steps.

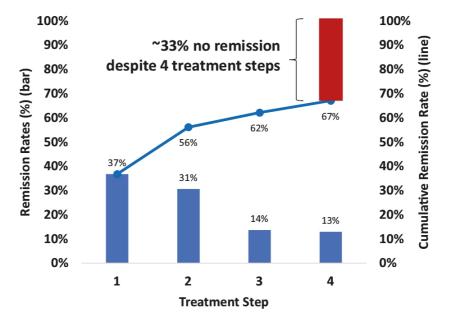






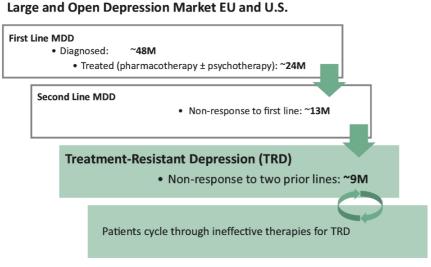
Based on: Trivedi et al., Evaluation of Outcomes With Citalopram for Depression Using Measurement-Based Care in STAR\*D: Implications for Clinical Practice, Am J Psychiatry 2006

# STAR\*D Study Remission Rates Treatment Steps 1 to 4



Based on: Rush et al., Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR\*D Report, Am J Psychiatry 2006

Patients with MDD who have not adequately responded to adequate therapy clearly have harder-totreat depression, generally referred to as TRD. There is no consensus definition for TRD, but in the context of clinical trials, failure of at least one pharmacotherapy, one pharmacotherapy and one psychotherapy, or two pharmacotherapies have been used, the latter having been referred to by regulatory authorities as patients with TRD. The STAR\*D study demonstrated that approximately 37% of patients with MDD did not achieve a response despite two treatment steps. Based on this result and based on an estimated number of approximately 48 million MDD patients in the United States and Europe according to the National Institute of Mental Health and an article published in European Neuropsychopharmacology, of which, according to the National Institute of Mental Health, about 50% receive treatment with pharmacotherapy or pharmacotherapy and psychotherapy, we estimate that there are approximately nine million TRD patients in the United States and Europe who would be candidates for treatment.



Despite this substantial patient population, only two pharmacotherapies have been approved specifically for the treatment of TRD in the United States: esketamine and a combination of olanzapine and fluoxetine, an antipsychotic and antidepressant, respectively.

## Economic and Societal Burden

Global mental illness-associated costs, including direct costs associated with diagnosis, treatment and care and indirect costs associated with lost productivity and income, were estimated at \$2.5 trillion for the year 2010, with the cost projected to surge to \$6 trillion by 2030, whereby about two-thirds of the total cost comes from indirect costs, according to a report by the World Economic Forum and the Harvard School of Public Health, According to an article published in the Journal of Clinical Psychiatry, for the United States, the economic burden of MDD alone is estimated to be over \$200 billion per year as of 2010, and roughly 47% of this amount is attributable to direct costs, and between 2005 and 2010, the total economic burden of MDD increased by approximately 22%.

TRD has a greater economic and societal cost than non-TRD MDD. TRD patients are often unable to perform daily tasks, are less productive at work and have higher rates of unemployment. They are also more likely to receive disability or welfare benefits and are reported to have a higher rate of co-occurring conditions, including diabetes, anemia and hypertension. According to an article published in the Journal of the Oklahoma State Medical Association, the TRD patient population has an approximate sevenfold

estimates based on: https://www.nimh.nih.gov/health/statistics/major-depression.shtml; Wittchen et al., The size and burden of mental disorders and other disorders of the brain in Europe 2010, Neuropsychopharmacology (2011); Rush et al., Acute and Longer-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR\*D Report, Am J Psychiatry 2006

increase in suicide rates compared to non-TRD MDD patients. Research conducted in 2018 and published in the Journal of Affective Disorders suggests that the proportion of patients suffering with TRD attempting suicide at least once during their lifetime could be as high as 30%.

According to a report published in the Journal of Affective Disorders, direct medical costs are approximately two- to threefold higher for TRD patients compared to non-TRD MDD patients. TRD patients have higher prescriptions costs, require more doctor visits and experience increased rates of hospitalization. They also have, on average, twice the number of inpatient visits compared with non-TRD MDD patients and their hospital stays are approximately 36% longer on average, according to an article published in the Journal of Clinical Psychiatry.

# **Existing Therapies for Depression**

Because depression has a diverse set of biological, social, psychological, environmental, genetic and stressrelated determinants, many of which co-occur, treatment options are wide-ranging and often combined. Current pharmacological and non-pharmacological treatments are efficacious only for a subset of MDD patients, and many patients do not respond or experience relapses. Clinicians lack high-quality evidence of whether certain therapies are suitable for certain patients and often rely on a lengthy trial-and-error approach, course-correcting as patients experience relapses or difficult side effects.

Therapy	Route	Frequency and duration	Reimbursement <sup>1</sup>	Approximate annual cost per patient <sup>2</sup>
Pharmacotherapies				
Antidepressants: SSRI/SNRI*	Oral	1/day, chronic	Broad	Generic: \$150 – 250 Brand: \$1,500 – 3,500
Atypical antipsychotics	Oral	1/day, chronic	Broad	Generic: \$300 <sup>3</sup> Brand: \$5,000 <sup>3</sup>
Esketamine	Intranasal	Up to 56 sessions/year, under supervision of a healthcare professional	Limited	\$33,000 - 49,000
Ketamine	Intravenous	Up to 6 injections, then every 4 – 6 weeks	No	\$5,500 - 8,000
Psychotherapy				
CBT (cognitive behavioral therapy)	Face-to-face or online	10 – 20 sessions, 3 – 4 months	Broad	Averaging \$1,000
Somatic Therapies				
rTMS (repetitive transcranial magnetic stimulation)	Magnetic brain stimulation without anaesthesia	5 sessions/week, 4 – 5 weeks,	Limited	\$6,000 - 12,000
ECT (electroconvulsive therapy)	Electric brain stimulation under anaesthesia	3 sessions/week, 4+ weeks	Limited	\$5,000 - 15,000
VNS (vagus nerve stimulation)	Electric pulses sent to the brain	Duration varies from patient to patient – stimulator must first be implanted and given at a starting low dose every 5 minutes from day to night	Limited	\$40,000 – 45,000 for surgical implementation (excluding costs of post-operative device adjustments)
DBS (deep brain stimulation)	Electrical impulses to the brain through implanted electrodes	3 – 6 hour operations; follow-up visits	Limited	\$64,000 for surgical implementation (excluding costs for DBS-related follow-up procedures and battery replacements)

\* SSRI = selective serotonin reuptake inhibitor, SNRI = serotonin-norepinephrine reuptake inhibitor

1 Government reimbursement or private insurance coverage; 2 Assumes one treatment course over the year, direct treatment cost only (not total healthcare costs); 3 Quetiapine extended-release 150mg/day

### Pharmacotherapies

There are five main categories of antidepressants available. These are:

- 1. selective serotonin reuptake inhibitors, or SSRIs;
- 2. serotonin-norepinephrine reuptake inhibitors, or SNRIs;
- 3. atypical antidepressants;
- 4. monoamine oxidase inhibitors, or MAOIs; and
- 5. tricyclic antidepressants, or TCAs.

Antidepressants are frequently used in first- and second-line treatment of depression and can also be used after this point. As observed in the STAR\*D study, only about 37% of patients achieve a remission with their initial antidepressant treatment. Failure rates of subsequent treatment regimens increase dramatically. For example, according to the STAR\*D study, once patients have failed two lines of prior therapies, only about 14% of patients achieve a remission with their third antidepressant treatment, and less than 5% stay in remission for one year.

The current main categories of antidepressants have significant additional limitations, including delayed onset of action, poor therapy adherence rates and various side effects. The onset of action for the most commonly used antidepressants is typically between two and three weeks, but the average time to remission in those who remit extends to about five to seven weeks, according to the STAR\*D study. Adherence levels are low, with less than 50% of individuals in primary and psychiatric care not adhering to their prescribed antidepressant medication after three months.

There is limited evidence to effectively guide clinical decisions following non-response or partial response to first-line antidepressant medications. Recommended treatment approaches include optimizing the current antidepressant dose or switching to another antidepressant. Partial response or lack of response thereafter is recommended to be addressed by combining antidepressants from different pharmacological classes or augmenting with an alternative medication, primarily with atypical antipsychotics but also mood stabilizers, anticonvulsants, thyroid hormones and stimulants.

Antipsychotics, such as olanzapine, quetiapine and aripiprazole, are typically used as adjunctive therapies when there is a lack of notable efficacy with an antidepressant. Despite there being an approved combination of olanzapine and fluoxetine for TRD that is administered once daily, research shows that combining antidepressants and antipsychotics can have serious side effects, such as weight gain, other metabolic complications, sedation, extrapyramidal side effects, which are drug-induced movement disorders, and QTc prolongation, which means the ventricles of the heart take longer than usual to recharge between beats.

Ketamine is an N-methyl-D-aspartate, or NMDA, receptor antagonist that has been used for several decades for sedation, anesthesia and chronic pain and is being used as an off-label treatment for TRD. The S-enantiomer of ketamine, esketamine, is administered via a nasal spray and was approved by the FDA in 2019 for the treatment of TRD. Due to the fact that ketamine and esketamine treatments typically require frequent administration — for example, for esketamine, administration is initially twice weekly, followed by once weekly administration — in a controlled environment under medical supervision, administration is costly for payors and burdensome for patients, which has resulted in further stunted clinical adoption and patient access.

## **Psychotherapies**

Psychotherapy is a form of talk therapy, which is often the preferred first-line treatment in patients with mild MDD. Psychotherapy is also used in combination with a primary pharmacotherapy, or as a substitute for primary pharmacotherapy, in patients with more severe MDD or in later-line treatments,

including in patients with TRD. Two frequently used psychotherapies for depression are cognitive behavioral therapy, or CBT, and interpersonal therapy, or IPT. CBT focuses on changing negative thought and behavior patterns. IPT also assesses negative thoughts and behaviors, but only as they apply to interpersonal relationships and social functioning. Psychotherapeutic approaches can be effective for certain individuals but require a significant time commitment from patients and are subject to variability in their availability, delivery and effectiveness.

### **Somatic Therapies**

Severe TRD patients who have undergone several courses of therapy are often treated with resource-intensive somatic therapies like electroconvulsive therapy, or ECT; repetitive transcranial magnetic stimulation, or rTMS; vagal nerve stimulation, or VNS; or deep brain stimulation, or DBS. These therapies are generally administered in inpatient settings. These treatments are typically reserved for patients who have not adequately responded to other treatments and are characterized as high-cost treatment options with limited reimbursement.

### Summary

MDD is a serious mental health condition with substantial morbidity, diminished quality of life, reduced life expectancy and significant economic and societal burden. All of these issues are further accentuated in patients with TRD. Despite the availability of two pharmacotherapies approved specifically for the treatment of TRD in the United States, we believe currently available options do not adequately meet the needs of patients suffering from TRD and there is a significant need for a new therapeutic approach to bring more patients into rapid, durable remission.

We believe that the development of a safe, effective and convenient therapy for TRD is one of the biggest unmet needs and challenges in healthcare and that our 5-MeO-DMT product candidates, GH001 and GH002, have the potential to address this unmet need.

# Our Solution - GH001 and GH002

We are developing two 5-MeO-DMT product candidates, GH001 and GH002. Our lead product candidate, GH001, is formulated for 5-MeO-DMT administration via a proprietary inhalation approach. We are currently investigating administration of GH001 as a single-dose induction regimen and in an individualized dosing regimen where up to three escalating doses of GH001 are given on the same day. With GH001, we have completed a Phase 1 healthy volunteer clinical trial, in which administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in the individualized dosing regimen. GH001 is currently being investigated in the Phase 2 part of an ongoing open-label, single-arm Phase 1/2 clinical trial in patients with TRD. In the completed Phase 1 part of this ongoing trial, no SAEs were observed and all adverse drug reactions, or ADRs, were mild and resolved spontaneously. Based on clinical activity that we observed, we also believe that administration of a single dose of GH001 has the potential to induce ultra-rapid MADRS remissions in certain patients. The goal of the ongoing Phase 2 part of the trial is to assess whether an individualized dosing regimen with intrasubject dose escalation within a single day can further increase the MADRS remission rate as compared to a single GH001 dose. We expect to complete our ongoing Phase 1/2 clinical trial in the second half of 2021. We plan to request a pre-IND meeting with the FDA and a Scientific Advice meeting with the EMA, and pending the outcome of these meetings, we plan to initiate a multi-center, randomized, controlled Phase 2b trial in TRD. Our next product candidate, GH002, is being formulated for 5-MeO-DMT administration via a proprietary injectable formulation and is currently in preclinical development.

# History of 5-MeO-DMT Usage

# Broader Emergence of Psychoactive Drugs

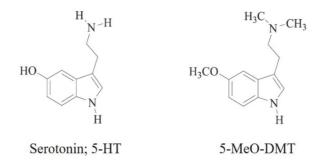
5-MeO-DMT is a serotonergic psychedelic, a class of psychoactive drugs that act primarily through an agonist action on serotonin receptors and cause an altered state of consciousness. Serotonergic psychedelics also include other tryptamines such as psilocybin and N,N-Dimethyltryptamine, or DMT; ergolines such as lysergic acid diethylamide, or LSD; and phenethylamines such as mescaline.

In the 1960s, clinical research in psychedelics was widespread, prior to the overall group of psychedelics being classified as Schedule I drugs in the early 1970s. Combining findings from these earlier studies with more recent data, accumulating evidence suggests that certain serotonergic psychedelics may have beneficial effects on a variety of psychiatric and neurological disorders. More recent insight in the psychopharmacology of certain serotonergic psychedelics, as well as initial evidence of their therapeutic benefit, has driven a resurgence of interest in the evaluation of serotonergic psychedelics for therapeutic use to treat a range of psychiatric and neurological disorders.

The promise of therapeutic approaches using psychoactive agents for the treatment of psychiatric and neurological disorders is highlighted by recent regulatory developments and increased research efforts. For instance, the FDA has granted Breakthrough Therapy Designation twice to psilocybin for the treatment of TRD and also to 3,4-methylenedioxy-methamphetamine, or MDMA,-assisted psychotherapy for the treatment of post-traumatic stress disorder. Further, major research institutions in the United States and Europe have recently established large centers dedicated to therapeutic research on psychoactive agents, including the Johns Hopkins Center for Psychedelic & Consciousness Research, the Mount Sinai Center for Psychedelic Psychotherapy and Trauma Research and the Imperial College London Centre for Psychedelic Research.

# 5-MeO-DMT Overview

The molecule 5-MeO-DMT is a naturally occurring structural analogue of serotonin (5hydroxytryptamine, or 5-HT), as depicted below, belonging to the class of psychoactive tryptamines.



5-MeO-DMT was first identified in the bark of *Dictyoloma incanescens*, but it is also contained in other plants, and it has been identified as a psychoactive ingredient in the venom of *Bufo alvarius* toads. These natural materials, as well as non-pharmaceutical grade 5-MeO-DMT, have a history of naturalistic use, where their potential to induce altered states of consciousness has been applied in spiritual or self-exploratory contexts.

# Mechanism of Action of Our Product Candidates

## Molecular Effects of 5-MeO-DMT

*In vivo* and *in vitro* research from academic studies suggest that 5-MeO-DMT acts primarily as a serotonin agonist, active at both the 5-HT1A and 5-HT2A receptors, which are expressed in neurons in different areas of the central nervous system. 5-MeO-DMT appears to have a higher affinity for the 5-HT1A receptor subtype and a more selective pattern of distribution across various neurotransmitter receptor types compared to other tryptamines, such as psilocin and DMT, both of which have stronger affinity for the 5-HT2A receptor subtype and a less selective receptor binding profile.

Further academic research suggests that 5-MeO-DMT may also act as regulator of inflammation and immune homeostasis through the sigma-1 receptor and that it may affect structural neuroplasticity, meaning that it may induce proliferation, survivability and accelerate maturation of specific neurons in the brain. Such mechanisms have the potential to address some of the hypothesized root causes of

depression, including reduced neural connectivity and a proinflammatory state. However, it is not known whether these mechanisms have any clinical relevance in the context of single day administration of 5-MeO-DMT as tested in the current development program.

## Relevance of the Intensity of the Psychoactive Effects

We believe that the intensity of the acute psychoactive effects after administration of 5-MeO-DMT may correlate with short- and long-term clinical improvement across various psychiatric and neurological disorders. Such a correlation has been shown for other serotonergic psychedelics in various academic studies. We have defined an intense psychoactive effect as a PE. We assess the occurrence of PEs using a proprietary visual analogue scale, or PE scale, which averages answers scored by the patient from 0 to 100 for three parameters of the experience: intensity, feelings of loss of control and profoundness. A PE is determined to have been achieved if the patient's average score across these three parameters is at least 75 on this scale. We use the occurrence or non-occurrence of a PE for dose selection of our product candidates in our individualized dosing regimen.

## Resetting Functional Connectivity

We believe that the mechanism of action of our product candidates, as well as the correlation between the intensity of the psychoactive effects and therapeutic outcomes, can be explained by recent observations regarding human brain functional connectivity, or FC, via so-called resting-state networks, or RSNs. These RSNs have been shown in academic studies to be responsible for various aspects of complex cognitive function, and it has been found that patients with mental disorders can have disturbed RSN connectivity. It has further been found that the administration of serotonergic psychedelics can lead to decreased connectivity within those RSNs. In addition, depending on the intensity of the short-term psychoactive effects, an increased reorganization of RSN activity can be observed following the experience, and we believe this reorganization could also correlate with treatment response.

We believe that administration of our product candidates has the potential to result in:

- acute decreased functional connectivity within the relevant RSNs;
- subsequent reintegration and resumption of normal functional connectivity, or a "re-set", of the relevant RSNs; and
- resolution of depressive thought patterns and improvement in other symptoms of mental disorders.

We believe that the occurrence of PEs as assessed by our proprietary PE scale is predictive of the "re-set" and may be indicative of therapeutic activity.

Our lead product candidate, GH001, is designed to produce an ultra-rapid onset of psychoactive effects (commonly within seconds) and an intense and short-lived (commonly five to 30 minutes) initial psychoactive experience. Although the initial psychoactive effects are short-lived, we believe the ensuing "re-set" of normal functional connectivity has the potential to create durable therapeutic benefits. Our approach of quantifying PEs allows for a simple assessment of psychoactive effects, and our PE-guided individualized dosing regimen aims to optimize the therapeutic outcome. GH002 and potential additional products candidates will follow a similar treatment paradigm.

# **Our 5-MeO-DMT Product Candidates**

### Inhalable 5-MeO-DMT Product Candidate – GH001

### Summary

Our lead 5-MeO-DMT product candidate, GH001, is formulated for administration via a proprietary inhalation approach. For GH001, we use synthetically developed, pharmaceutical grade 5-MeO-DMT, manufactured in accordance with current Good Manufacturing Practices, or cGMP, standards. We are currently investigating administration of GH001 as a single-dose induction regimen and in an individualized dosing regimen, where up to three escalating doses of GH001 are administered via inhalation on a single day. We have completed a Phase 1 healthy volunteer clinical trial for GH001, in

which administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in the individualized dosing regimen. GH001 is currently being investigated in the Phase 2 part of an ongoing open-label, single-arm Phase 1/2 trial in patients with TRD. In the completed Phase 1 part of this ongoing trial, no SAEs were observed and all ADRs were mild and resolved spontaneously. Based on clinical activity that we observed, we also believe that administration of a single dose of GH001 has the potential to induce ultra-rapid MADRS remissions in certain patients. The goal of the ongoing Phase 2 part of the trial is to assess whether an individualized dosing regimen with intra-subject dose escalation within a single day can further increase the MADRS remission rate as compared to a single GH001 dose. Subject to the outcome of regulatory interactions, we plan to initiate a multi-center, randomized, controlled Phase 2b trial. Clinical trials with GH001 in additional psychiatric and neurological disorders are also being planned.

## Advantages of GH001

We are developing GH001 as a treatment for patients with TRD. We believe that GH001, if approved, may provide significant benefits for the treatment of patients with TRD. We aim to achieve the following goals:

- Ultra-Rapid Induction of Remissions
- Maximized Rate of Remissions
- Convenience

We believe that the following features of GH001 will allow us to achieve those goals:

- High Propensity to Induce Peak Experiences: We believe that GH001 has a high propensity to induce PEs. This is important because we believe that the occurrence of PEs may be correlated with ultra-rapid induction of durable remissions in patients with TRD, and thereby we believe may potentially act as a marker for therapeutic effects.
- Individualized Dosing Regimen: We believe that there is no clinically relevant tolerance development to 5-MeO-DMT when the drug is re-administered within hours, or in other words, no diminished psychoactive effects. Together with the ultra-rapid onset and short duration of psychoactive effects, this aspect allows re-administration of GH001 in an individualized dosing regimen where GH001 can be administered several times within one day. We are currently investigating whether this individualized dosing regimen can increase the rate of occurrence of PEs in patients with TRD compared with administration of a single dose and whether this results in an increased rate of ultra-rapid remissions, while at the same time avoiding unnecessarily high doses. We believe that treatment optimization within the same day is important, not only because of the direct patient benefit, but also because patients with insufficient response can be identified early, without the need for lengthy trial-and-error approaches, during which time the patient is often exposed to potential side effects of ineffective treatments.
- Treatment Regimen: We believe that the ultra-rapid onset and short duration of psychoactive effects may confer a significant convenience and feasibility advantage compared to other serotonergic psychoactive agents studied for the treatment of mental disorders, where the initial psychoactive effects have a slower onset and can last for several hours. We further believe that those features and the type of psychoactive effects induced by GH001 allow for dosing without the need for lengthy and complex patient preparation prior to treatment, with only limited required support from a healthcare provider during the experience and without the need for frequent psychological integration work after the experience. This reduces training requirements for healthcare providers and creates a convenient and efficient potential therapeutic paradigm overall.

Based on these features, we believe that GH001 has the potential to provide an attractive alternative to currently available therapies and other therapies in development for the treatment of TRD.



### **Clinical Experience**

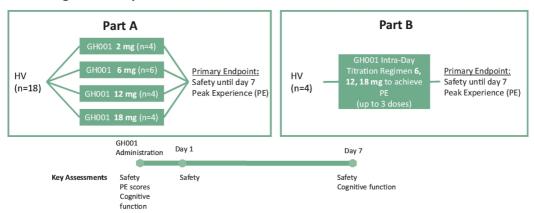
# Phase 1: Healthy Volunteer Trial (NCT04640831)

We have completed a Phase 1 clinical trial of GH001, our inhalable 5-MeO-DMT product candidate, in healthy volunteers.

# Trial Design

The trial was designed in two parts, as depicted below: Part A was an open-label, single-arm, singledose trial with four dose levels (2 mg, 6 mg, 12 mg, 18 mg) of GH001 being investigated and Part B was an open-label, single-arm, intra-subject dose escalation trial, where an individualized dosing regimen was administered on a single day with up to three increasing doses of GH001 (6 mg as the first dose, 12 mg as the second dose and 18 mg as the third dose). The second and third doses were only administered in the event that the subject did not achieve a PE at the lower dose, as assessed by our proprietary PE scale.

The primary endpoint of this trial was to assess the safety of GH001 and its dose-related psychoactive effects in healthy volunteers. Participants were monitored on the dosing day, with additional follow-up visits on day one and on day seven after dosing. A study safety group, or SSG, which included external experts, was established to evaluate the safety and psychoactive effect data from all participants at each visit.



# **Design of Healthy Volunteer Trial**

#### **Baseline Characteristics**

18 participants (2 mg (n=4), 6 mg (n=6), 12 mg (n=4), 18 mg (n=4)) were recruited into Part A, and four participants were recruited in Part B. Median age in Part A was 27 years and into Part B was 30 years.

## Results

All participants completed all planned visits. No SAEs were reported. 12 of 18 subjects (66.67%) in Part A and 3 of 4 subjects (75%) in Part B experienced at least one ADR. All ADRs were mild, except an ADR of "heart rate increased" at the 12 mg dose level in Part A and an ADR of "fatigue" in one subject in Part B (after having received the 6 mg and 12 mg dose), which were moderate in intensity. All ADRs resolved spontaneously. In Part A, the ADRs reported were: nausea (4 participants), headache (3 participants), anxiety (2 participants), clumsiness, feeling hot, vision blurred, heart rate increased, hyperacusis, mental fatigue, flashback, hallucination, abnormal dreams, insomnia, fatigue, euphoric mood and confusional state (each in 1 participant). In Part B, the ADRs reported were: nausea (2 participants), fatigue, head discomfort and headache (each in 1 participant). No clinically significant signals were observed in the safety laboratory analyses, and no clinically relevant changes were observed in the

psychiatric safety assessments or any of the measures of cognitive function. With the exception of a temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001, no noteworthy changes in vital parameters occurred. The SSG observed no unexpected, no severe and no lasting adverse effects for all single doses from 2 mg to 18 mg in Part A and the dose escalation from 6 mg to 12 mg, and then up to 18 mg in Part B.

With regard to the intensity of the psychoactive effects as measured by the PE scale in Part A, a dose-related trend for the mean PE total score and for the fraction of patients who achieved a PE was observed for the 2 mg dose (PE total score 9.0, zero of four participants with a PE), 6 mg dose (PE total score 43.8, one of six participants with a PE) and 12 mg dose (PE total score 65.5, two of four participants with a PE). This dose-related trend did not continue for the 18 mg dose (PE total score 59.2, one of four participants with a PE).

In Part B, it was observed that the intensity of the psychoactive effects increased with the increasing dosage amounts in all participants. Further, all participants were able to achieve a PE at their maximum individual dose level, which was the initial dose of 6 mg for one participant, the second dose of 12 mg for two participants and the final dose of 18 mg for one participant. At this maximum individual dose level, the mean PE total score was higher (PE total score 89.3) than in all dose groups of Part A.

## Phase 1/2: Ongoing Clinical Trial of GH001 in Patients with TRD (NCT04698603)

We are conducting a Phase 1/2 clinical trial of GH001 in patients with TRD, who in their current depressive episode have failed at least two adequate courses of pharmacological therapy or one adequate course of pharmacological therapy and at least one adequate course of evidence-based psychotherapy, as assessed by the Antidepressant Treatment History Form – Short Form, or ATHF-SF.

### Trial Design

The trial is designed in two parts: a completed Part A (n=8), which is an open-label, single-arm, single-dose Phase 1 trial with two dose levels (12 mg, 18 mg) of GH001 being investigated and an ongoing Part B (n=8), which is an open-label, single-arm Phase 2 trial applying our individualized dosing regimen with intra-patient dose escalation with GH001. In Part B, patients will receive at least one and up to three doses of GH001 in a single day; the three dose steps applied are 6 mg, 12 mg and 18 mg. The administration of a higher dose level will be guided by an evaluation of whether the patient achieves a PE at the previously administered dose. Patients of 18 to 64 years of age (inclusive) will be enrolled in the trial.

The primary endpoint of the Phase 1 Part A is to assess the safety and tolerability of single dosing of GH001 in patients with TRD. The primary endpoint of the Phase 2 Part B is to assess the effects on the severity of depression, as assessed by the proportion of patients in remission on day seven after dosing, defined as a MADRS total score of less than or equal to 10. The MADRS is a widely accepted scale for depression that ranges from zero to 60 that has been used as a primary endpoint in pivotal trials of other depression treatments. Participants are monitored on the dosing day, with additional follow-up visits on day one and day seven after dosing. An SSG, which included external experts, was established to evaluate the safety and efficacy data from all patients after completion of each dose level of Part A and after the completion of Part B.

## Status

We completed patient dosing of GH001 in the Phase 1 Part A of the trial; the Phase 2 Part B is ongoing.

### Baseline Characteristics for Patients in Part A

Eight patients were recruited into Part A. The median age was 29 years. The median baseline severity of depression by MADRS was 33. Four patients received 12 mg and four patients received 18 mg of GH001.

### Interim Results for Part A

All patients completed all planned visits. No SAEs were reported. 3 of 4 patients (75%) in the 12 mg group and 3 of 4 patients (75%) in the 18 mg group experienced at least one ADR. All ADRs were mild and resolved spontaneously. The ADRs reported were: headache (3 patients), feeling abnormal, flashback (each in 2 patients), dizziness and muscle spasms (each in 1 patient). Based on the available data from Part A, the SSG concluded that in Part A no unexpected or severe adverse effects and no clinically significant changes were observed in any of the safety laboratory analyses, vital signs, psychiatric safety assessments or measures of cognitive function.

As a secondary objective in Part A, we also evaluated clinical activity, including MADRS remission, defined as a MADRS total score of less than or equal to 10, and MADRS clinical response, defined as a reduction of 50% or more from baseline in the MADRS total score. Two patients in the 12 mg group and one patient in the 18 mg group of Part A had a MADRS remission on day seven after dosing, as well as a MADRS clinical response, and one further patient in the 18 mg group had a MADRS clinical response on day seven after dosing. The other four patients also exhibited improvement on the basis of the MADRS scale on day seven compared to baseline, but did not achieve a MADRS remission or MADRS clinical response. The mean MADRS reduction at day seven was 65% in the 12 mg group and 41% in the 18 mg group. The mean PE total score was 58.2 in the 12 mg group and 59.1 in the 18 mg group. Two of four patients achieved a PE in the 12 mg group, both of which achieved a MADRS remission.

# Ongoing Part B

The ongoing Phase 2 Part B of this clinical trial will include the potential for up to three doses of GH001 on the same administration day, in the event a PE was not met with the initial or second dose. The goal of this individualized dosing regimen is to increase the rate of occurrence of PEs and the clinical remission rate compared to a single GH001 dose in patients with TRD.

### **Planned Regulatory Interactions**

To date, our clinical trials have been conducted in the Netherlands. We intend to request a pre-IND meeting with the FDA and a Scientific Advice meeting with the EMA to discuss the adequacy of the following:

- the data from our completed clinical trial in healthy volunteers and ongoing clinical trial in patients with TRD;
- the design of our planned Phase 2b trial of GH001 in TRD;
- the current status and plans for our nonclinical studies;
- the current status and plans for the pharmaceutical manufacturing of our active pharmaceutical ingredient, or API, and GH001 drug product;
- the current status and plans for the device required to administer GH001; and
- any additional topics as requested by the regulatory agencies.

# **Planned Clinical Trials**

We plan to conduct the following trials with GH001:

- A multi-center, randomized, controlled Phase 2b trial evaluating safety and efficacy in TRD patients, including a long-term, open-label follow-up study;
- Phase 2a trials evaluating safety and efficacy in two or more additional psychiatric or neurological disorders; and
- A clinical pharmacology trial in healthy volunteers, designed to further elucidate the pharmacokinetic profile of GH001.

The outcomes of these trials will help inform our future clinical development plans and shape the most efficient path to market for GH001. Subject to completing clinical development, we plan to seek regulatory approval of GH001 in both the United States and Europe.



### Indication Expansion Opportunities for GH001

Given GH001's proposed mechanisms of resetting functional connectivity and serotonergic agonism, we believe that it represents a compelling therapeutic option for multiple psychiatric and neurological disorders other than TRD. Through collaborations with academic institutions and CROs we intend to explore the benefits of GH001 in additional psychiatric or neurological indications. We plan to initiate proof-of-concept Phase 2a trials in two or more psychiatric or neurological disorders.

# Injectable 5-MeO-DMT Product Candidate GH002

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. We believe GH002 has the potential to be an attractive therapeutic option, e.g., in patients with underlying airway or pulmonary disease or in situations where it is difficult to assure that the GH001 inhalation is performed adequately, such as in acute psychiatric emergency care situations where a patient may be unable to use an inhalation device. GH002 is currently in preclinical development and we anticipate developing GH002 in indications within our focus area of psychiatric and neurological disorders.

Planned clinical trials with GH002 include:

- A Phase 1 trial in healthy volunteers to characterize the appropriate dose range when administered as an injectable;
- A Phase 2a trial in a psychiatric or neurological disorder following completion of the Phase 1 healthy volunteer trial.

# **Nonclinical Experience**

5-MeO-DMT *in vitro* and *in vivo* toxicology data from published academic literature allowed initiation of our clinical trials. We have initiated a nonclinical study program with additional *in vitro* and *in vivo* toxicology studies as well as safety pharmacology studies, including studies evaluating genotoxicity and cardiotoxicity with our high-purity API. The results of these studies are intended to support the initiation of our Phase 2b clinical trial of GH001 in patients with TRD and may also form the basis of our clinical programs with additional product candidates, including GH002, our injectable 5-MeO-DMT product candidate.

# Delivery Systems and Routes of Administration for 5-MeO-DMT

We are working to optimize current delivery systems and to investigate additional delivery systems and additional routes of administration for 5-MeO-DMT, which we believe could expand the patient population that could benefit from our product candidates.

Currently, GH001 has been vaporized using an inhalation device purchased from a third party, which is a CE-marked medical device in the European Union and licensed as a medical device in Canada and Australia. In parallel, we are exploring plans to develop our own proprietary inhalation device or license an alternative device. We expect that GH001, along with the accompanying inhalation device, will be regulated by the FDA as a drug-device combination product.

## Manufacturing and Supply

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on contract development and manufacturing organizations, or CDMOs, to further develop and synthesize the API that is contained in our GH001 and GH002 product candidates and to further develop and manufacture our product candidates. The manufacturing processes are contracted so that the relevant API and product candidate manufacturing steps are compliant with cGMP. We expect to continue to rely upon third parties for the development and production of all clinical supply API and drug product that we may use. We also use contract manufacturers to fill, label, package, store and distribute our product candidates. We currently rely on a single supplier for our API and a single supplier for our GH001 product candidate, and because we maintain only a limited supply of API and GH001 product candidate

we may not be able to avoid a material disruption in the event of any need to replace one or more of our suppliers. We currently acquire from a third party the vaporization device used to create the inhaled aerosol from our GH001 product candidate. We do not have a commercial supply agreement with this third party, nor have we established license or development agreements with any alternative provider of a suitable vaporization device. It is, however, our intention, for GH001 and for any future delivery platforms that include the use of a device, to either in-license technology for such device or work with a CDMO to develop such device and establish manufacturing capabilities for such device.

## Commercialization

If either of our GH001 and GH002 product candidates are approved, we plan to use our own sales and marketing capabilities, targeting public and private healthcare providers and clinic networks in the United States and major European markets. However, depending on the situation, we may enter into commercialization collaborations, partnering or licensing agreements with third parties who have complementary commercial capabilities.

# Competition

Our industry is characterized by many newly emerging and innovative technologies, intense competition and a strong emphasis on proprietary product rights. While we believe that our GH001 and GH002 product candidates represent a fundamental shift in the treatment paradigm relative to other TRD treatments on the market and under development, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, non-profit organizations, governmental agencies and medical research organizations. Any product candidates that we successfully develop and commercialize, including our GH001 and GH002 product candidates, will compete with the standard of care and new therapies, both pharmacological and somatic, which may become available in the future.

Based on the current understanding of regulatory agencies, TRD encompasses patients who have not been helped by two or more MDD pharmacotherapies. Currently, only two pharmacotherapies are approved for TRD in the United States: Spravato (esketamine), marketed by Janssen, which is an NMDA receptor antagonist; and olanzapine and fluoxetine hydrochloride capsules, which are available generically. Because of this, antidepressants indicated for use in MDD are frequently prescribed, combined or augmented with a second agent to treat TRD patients. Several biopharmaceutical companies have therapies, including other psychedelic-based compounds, in preclinical and clinical development being evaluated or planned to be evaluated in mental illness, including in TRD patients, including Axsome Therapeutics, Beckley Psytech, COMPASS Pathways, Cybin, Entheon, Mindmed, Perception Neuroscience, Praxis Precision Medicines, Relmada Therapeutics, Sage Therapeutics, Small Pharma and Viridia Life Sciences. Of the programs with other psychedelic-based compounds, the most advanced is COMPASS Pathways' investigational therapy COMP360 given in conjunction with psychological support, which is currently in a Phase 2b trial in TRD, expected to report data by the end of 2021.

Many of the pharmaceutical, biopharmaceutical and biotechnology companies with whom we may compete have established markets for their therapies and have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market superior products or therapies. In addition, many of these potential competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new therapeutic substances and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA or EMA approval for alternative or superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. A growing number of companies are increasing their efforts in discovery of new psychedelic compounds.

# **Intellectual Property**

Our commercial success is to some extent tied to obtaining, maintaining and enforcing intellectual property rights protection in patents, trade secrets and other proprietary rights in the European Union,

United States, United Kingdom and other jurisdictions. We plan to continue to strategically protect our innovations with a parallel IP strategy, combining patent protection with regulatory and market exclusivity. We also may rely on trade secrets and know-how relating to our proprietary technologies, on continuing innovation and on future in-licensing opportunities to develop, strengthen and maintain the strength of our competitive position.

## Patent Strategy

We have filed four patent applications covering novel aerosol compositions of matter of 5-MeO-DMT, novel manufacturing methods for the purification of 5-MeO-DMT, high purity 5-MeO-DMT and novel uses of 5-MeO-DMT in various disorders. We are committed to exploring additional opportunities with 5-MeO-DMT through continuous research and development and will continue to seek patent protection for all our innovations.

# Patent Applications

Our patent applications, WO2020169850 and WO2020169851, which collectively cover novel uses of 5-MeO-DMT in various disorders, including the use of 5-MeO-DMT for treatment of TRD when administered by inhalation, or by nasal, buccal, sublingual, intravenous, intramuscular or subcutaneous administration, were filed on February 24, 2020, with a priority date of February 22, 2019. An additional patent application, WO2020254584, which covers novel manufacturing methods for the purification of 5-MeO-DMT and high purity 5-MeO-DMT, was filed on June 19, 2020, with a priority date of June 19, 2019. A further patent application was filed on February 24, 2021, with a priority date of February 24, 2020. This application, which has not yet been published, has been assigned the international application number PCT/EP2021/054502 and covers novel aerosol compositions of matter of 5-MeO-DMT, including the aerosol that is generated for the administration of GH001.

Each of our patent applications are international Patent Cooperation Treaty, or PCT, applications. PCT applications are not eligible to become an issued patent until, among other things, we file one or more national state patent applications within, depending on the country, 30 to 32 months of the PCT application's priority date in the countries in which we seek patent protection. We have not yet filed any national stage applications. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such patent applications. While we intend to timely file national stage patent applications relating to our PCT patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

# **Government Regulation**

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, record keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

# **FDA Approval Process**

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The FDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, record keeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products and medical devices. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as a clinical hold, FDA refusal to approve a pending new drug application, or NDA, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product in the United States, including a drug-device combination product, typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, or product CMC, information about the device component of a drug-device combination product and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Clinical trials involve the administration of the IND to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practices, or GCPs, which are standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may be combined or overlap. Phase 1 involves the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial may be sufficient in rare instances, including (i) where the study is a large multi-center trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (ii) when in conjunction with other confirmatory evidence.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or lifethreatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. In the case of a drug-device combination product, the NDA must also include design, testing, manufacturing and quality information to support the device constituent, including information to support its use and compatibility with the drug constituent. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA is also subject to an annual program fee. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for standard review drug products that are new molecular entities, or NMEs, are reviewed within 10 months of the date that the FDA files the NDA; most applications for priority review drugs that are NMEs are reviewed within six months of the date that the FDA files the NDA; most applications for priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will generally inspect the facility or the facilities at which the drug and in the case of a drug-device combination product, the device constituent, is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the NDA contains data that demonstrate that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

## **Combination Products**

A combination product is a product comprising (i) two or more regulated components, i.e., drugdevice, biologic-device, drug/biologic or drug-device/biologic, that are physically, chemically or otherwise combined or mixed and produced as a single entity; (ii) two or more separate products packaged together in a single package or as a unit and comprising drug and device products, device and biological products or biological and drug products; (iii) a drug, device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, for example, to reflect a change in intended use, dosage form, strength, route of administration or significant change in dose; or (iv) any investigational drug, device or biological product packaged separately that, according to its proposed labeling, is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

The FDA is divided into various branches, or Centers, by product type. Different Centers typically review drug, biologic or device applications. In order to review an application for a combination product, the FDA must decide which Center should be responsible for the review. FDA regulations require that the FDA determine the combination product's primary mode of action, which is the single mode of a combination product that provides the most important therapeutic action of the combination product. The Center that regulates that portion of the product becomes the lead evaluator. When evaluating an application, a lead Center may consult other Centers but still retain complete reviewing authority, or it may collaborate with another Center, by which the Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, an applicant submits a single marketing application to the Center selected to be the lead evaluator, although separate applications for each constituent part may be submitted to the applicable Centers. One reason to submit multiple evaluations is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each may be evaluated by a different lead Center.

In a drug-device combination product, where the device component is a pre-filled drug delivery device, the primary mode of action is typically a drug mode of action with the Center for Drug Evaluation and Research, or CDER, as the lead Center. CDER would review the NDA in consultation with the Center for Devices and Radiological Health on device-specific issues. For co-packaged or single entity combination products, such as pre-filled drug delivery devices, there are two ways to comply with cGMP requirements. Manufacturers can either (i) demonstrate compliance with all cGMP regulations applicable to each of the constituent parts in the combination product or (ii) in the case of drug-device combination products, demonstrate compliance with either the drug cGMP regulations or the device quality system requirements, or device QSR, and also demonstrate compliance with additional provisions from the other of these two sets of cGMP requirements, as specified in the combination products regulations.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning or untitled letters, fines, injunctions, civil or criminal penalties, recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production, refusal or denial of submissions for new products or withdrawal of clearance, authorization or approval.

# **Expedited Development and Review Programs for Drugs**

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or

conditions. These programs include Fast Track Designation, Breakthrough Therapy Designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs.

A drug is eligible for Fast Track Designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track Designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review of a marketing application. Rolling review means that the Agency may review portions of the marketing application before the sponsor submits the complete application, though the review clock does not begin until all portions of the application have been submitted.

In addition, a drug may be eligible for Breakthrough Therapy Designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy Designation provides all the features of Fast Track Designation in addition to intensive guidance on an efficient drug development program and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy Designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review designation, once an NDA is submitted, if the drug that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. If the FDA grants priority review, the FDA's goal date to take action on the marketing application is six months compared to 10 months for a standard review.

A product is eligible for Accelerated Approval if it can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Accelerated Approval is contingent on a sponsor's agreement to conduct additional postapproval studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence, and, in most cases, the FDA may require that the trial be designed, initiated and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. In addition, the FDA generally requires, as a condition for Accelerated Approval, that all advertising and promotional materials intended for dissemination or publication be submitted to the FDA for review.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track Designation, Breakthrough Therapy Designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

## **Orphan Drugs**

Under the Orphan Drug Act, the FDA may grant orphan drug designation to products intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States or more than 200,000 individuals in the United States but for which there

is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first NDA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which it has such designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care, or in instances of drug supply issues. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition or the same drug for a different disease or condition. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the NDA application fee.

# **Disclosure of Clinical Trial Information**

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on ClinicalTrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

# **Pediatric Information**

Under the Pediatric Research Equity Act, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers or deferrals for submission of data.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

# **Post-Approval Requirements**

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug

manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered.

The FDA strictly regulates marketing, labeling, advertising and promotion of drugs that are placed on the market. Advertising and promotion of drugs must be in compliance with the FDCA and its implementing regulations and only for the approved indications and in a manner consistent with the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

## **The Hatch-Waxman Amendments**

#### Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

To the extent that a Section 505(b)(2) applicant is relying on the FDA's prior findings of safety or effectiveness for an already approved product, the applicant is required to certify to the FDA concerning

any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

# Exclusivity

Upon NDA approval of a new chemical entity, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA cannot receive any ANDA seeking approval of a generic version of that drug. An ANDA may be submitted one year before new chemical entity exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. Certain changes to a drug, such as the addition of a new indication to the package insert, can be the subject of a three-year period of exclusivity if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. The FDA cannot approve an ANDA for a generic drug that includes the change during the exclusivity period.

The FDCA alternatively provides three years of marketing exclusivity for an NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

# Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval), up to a maximum of five years. The extension period can be shortened if, among other things, the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension granted, the post-approval patent extension is reduced by one year. To obtain interim patent extension, the director of the United States Patent and Trademark Office, or USPTO, must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

# **Controlled Substances**

The federal Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act, or CSA, and its implementing regulations, establish a "closed system" of manufacturer and distribution of controlled substances. The CSA and regulations promulgated by the U.S. Drug Enforcement Administration, or DEA, impose registration, security, record keeping and reporting, storage and other requirements on individuals and other entities that handle controlled substances. The DEA is the federal agency responsible for regulating controlled substances and requires those individuals or entities that manufacture, import, export, distribute, research or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

The DEA categorizes controlled substances into one of five schedules—Schedule I, II, III, IV or V depending on the relative potential for dependence and abuse. Schedule I substances by definition have the highest potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products that have some abuse potential but do have a currently accepted medical use and are approved for marketing are classified in Schedule II, III, IV or V. Among controlled substances that can be marketed, Schedule II substances are considered to have the highest potential for abuse and physical or psychological dependence, and Schedule V substances the lowest relative potential for abuse and dependence.

5-MeO-DMT is currently classified as a Schedule I drug and, if approved for marketing in the United States, will need to be rescheduled by the DEA before it can be commercially marketed, distributed and sold. Rescheduling is dependent on FDA approval and an FDA recommendation to the DEA as to the appropriate schedule. The DEA must conduct notice and comment rulemaking to reschedule a substance. Such action is subject to public comment and potential requests for administrative hearing on any such action. In addition, each state or jurisdiction must also take appropriate administrative or legislative action to reschedule based on federal action.

Manufacturers, importers, exporters and distributors must register annually with the DEA to handle controlled substances. Pharmacies and physicians must register every three years. The DEA registration is specific to each facility (i.e., physical location) and the activity(ies) and controlled substance schedule(s) handled at each location.

The DEA inspects all manufacturing, importing and distribution facilities to review security, record keeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers, importers and distributors of Schedule I and Schedule II substances. Required security measures include restricted access and physical control of controlled substances through storage in approved vaults, safes and cages and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and inventory and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances and other designated substances. All DEA registrants (including manufacturers, importers and distributors) must comply with security, record keeping and reporting requirements such as reporting any controlled substance thefts or significant losses and following appropriate procedures to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic and submit import or export declarations for Schedule III, IV and V non-narcotics. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary, to ensure that the United States complies with its obligations under international drug control treaties.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. Each manufacturer must apply for an individual manufacturing or procurement quota which represents the amount each facility can manufacture in a given year. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas a few times per year and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments for individual companies.

Different states within the United States also maintain separate controlled substance laws and regulations, including licensing, record keeping, security, distribution and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state.

Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

The United States and the majority of countries are signatories to the UN international drug control treaties which dictate certain scheduling, licensing, restrictions and other requirements involving controlled substances. Because 5-MeO-DMT is classified as a Schedule I controlled substance under the UN Convention on Psychotropic Substances, 1971 most countries maintain laws and regulations comparable to those in the United Stated related to 5-MeO-DMT and other controlled substances.

# Regulation and Procedures Governing Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the European Union generally follows similar pathways as in the United States, although the approval of a medicinal product in the United States is no guarantee of approval of the same product in the European Union, either at all or within the same timescale as approval may be granted in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization for a marketing authorization application, or MAA, and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union or its member states (as well as Iceland, Norway and Liechtenstein). If we fail to comply with applicable requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

# Clinical Trial Approval

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a EU member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted in a number of member states. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion in relation to the clinical trial. The clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new legislation, which will be directly applicable in all EU member states (meaning that no national implementing legislation in each EU member state is required), aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single-entry point and strictly defined deadlines for the assessment of clinical trial

applications. It is expected that the new Clinical Trials Regulation (EU) No. 536/2014 will come into effect following confirmation of full functionality of the Clinical Trials Information System, the centralized EU portal and database for clinical trials foreseen by the new Clinical Trials Regulation, through an independent audit. The currently anticipated date is January 31, 2022.

## Marketing Authorization

To obtain a marketing authorization for a product under the EU regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in EU member states (decentralized procedure, national procedure or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all EU member states (as well as Iceland, Norway and Liechtenstein). Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of TRD. For those products for which the use of the centralized procedure is not mandatory, applicants may elect to use the centralized procedure where either the product contains a new active substance indicated for the treatment of other diseases or where the applicant can show that the product constitutes a significant therapeutic, scientific or technical innovation or for which a centralized process is in the interest of patients at an EU level.

Under the centralized procedure, the Committee for Medicinal Products for Human use, or the CHMP, which is the EMA's committee that is responsible for human medicines, established at the EMA is responsible for conducting the assessment of whether a medicine meets the required quality, safety and efficacy requirements and whether the product has a positive risk/benefit/risk profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days from the receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

# PRIME Scheme

The EMA offers a scheme that is intended to reinforce early dialogue with, and regulatory support from, the EMA in order to stimulate innovation, optimize development and enable accelerated assessment of PRIority MEdicines, or PRIME. It is intended to build upon the scientific advice scheme and accelerated assessment procedure offered by the EMA. The scheme is voluntary and eligibility criteria must be met for a medicine to qualify for PRIME.

The PRIME scheme is open to medicines under development and for which the applicant intends to apply for an initial marketing authorization application through the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the European Union or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods or therapy or improving existing ones. Applicants will typically be at the exploratory clinical trial phase of development and will have preliminary clinical evidence in patients to demonstrate the promising activity of the medicine and its potential to address to a significant extent an unmet medical need. In exceptional cases, applicants from the academic sector or SMEs (small and medium sized enterprises) may submit an eligibility request at an earlier stage of development if

compelling nonclinical data in a relevant model provide early evidence of promising activity, and first in man studies indicate adequate exposure for the desired pharmacotherapeutic effects and tolerability.

If a medicine is selected for the PRIME scheme, the EMA:

- appoints a rapporteur from the CHMP or from the Committee for Advanced Therapies, or CAT, to
  provide continuous support and to build up knowledge of the medicine in advance of the filing of
  a marketing authorization application;
- issues guidance on the applicant's overall development plan and regulatory strategy;
- organizes a kick-off meeting with the rapporteur and experts from relevant EMA committees and working groups;
- provides a dedicated EMA contact person; and
- provides scientific advice at key development milestones, involving additional stakeholders, such as health technology assessment bodies and patients, as needed.

Medicines that are selected for the PRIME scheme are also expected to benefit from the EMA's accelerated assessment procedure at the time of application for marketing authorization. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

# Pediatric Development

In the European Union, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, (i.e., because the relevant disease or condition occurs only in adults). The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP unless a waiver applies or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are elevated and submitted.

#### Regulatory Data Protection in the European Union

In the European Union, new chemical entities approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon grant of a marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No. 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. During the additional two-year period of market exclusivity, a generic marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity period. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

# Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a re-evaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing member state. To that end, the marketing authorization holder must provide the EMA or the

competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the EU market (in the case of the centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid.

## Controlled Drugs Classification

In Ireland, 5-MeO-DMT is considered a Schedule 1 drug under the Misuse of Drugs Regulations 2017, as amended. Schedule 1 of the Misuse of Drugs Regulations 2017 lists those drugs to which the most restrictive controls apply: they are considered to have no legitimate or medicinal use and can only be imported, exported, produced, supplied and such like under a license issued by the Irish Health Products Regulatory Authority (HPRA), on behalf of the Department of Health. The position in the member states of the European Union is not harmonized. Member states have implemented the relevant UN Conventions (the Single Convention of Narcotic Drugs 1961 and the Convention on Psychotropic Substances 1971) into their national legislation, which has led to differences in how controlled substances are regulated in different countries of the European Union. It is therefore important to determine at a national level whether a substance is controlled and to comply with the applicable legal requirements. If we are successful in obtaining a marketing authorization in key EU member states, it is likely that rescheduling of 5-MeO-DMT will also be required to enable prescribing. There can be no guarantee that such rescheduling would be successful.

In the United Kingdom, where part of our manufacturing process takes place, 5-MeO-DMT is considered a Class A drug under the Misuse of Drugs Act 1971, as amended, and as a Schedule 1 drug under the Misuse of Drugs Regulations 2001, as amended. Class A drugs are considered to be the most potentially harmful and have the highest level of control exerted over them under the Misuse of Drugs Act 1971. Similarly, Schedule 1 of the Misuse of Drugs Regulations 2001 lists those drugs to which the most restrictive controls apply: they are considered to have no legitimate or medicinal use and can only be imported, exported, produced and supplied under a license issued by the UK government's Home Office. If and when it is granted a marketing authorization by the MHRA in respect of the United Kingdom, 5-MeO-DMT would still remain a Schedule 1 drug until rescheduled by the UK government's Home Office. Unless and until 5-MeO-DMT is rescheduled under the Misuse of Drugs Regulations 2001, and unless a statutory exemption was to be passed for GH001 or GH002 following the grant of a UK marketing authorization and before rescheduling, any prescribing doctors in the United Kingdom would require a Home Office license to prescribe GH001 or GH002, and, similarly, any patients to whom GH001 or GH002 was prescribed would require a Home Office license to possess GH001 or GH002. There can be no guarantee that such Home Office licenses would be granted or that rescheduling would be successful.

#### Regulatory Requirements After Marketing Authorization

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product.

These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

In addition, all new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk minimization measures or post-

authorization obligations may include additional safety monitoring, more frequent submission of PSURs or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

Furthermore, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products, are strictly regulated in the European Union under Directive 2001/83/EC, as amended. The advertising of prescription-only medicines to the general public is not permitted in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU Directive 2001/83/EC, as amended, the details and enforcement are governed by regulations in each EU member state (as well as Iceland, Norway and Liechtenstein) and differ from one country to another.

## **Coverage, Pricing and Reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any 5-MeO-DMT therapy for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement for our products from third-party payors, such as government healthcare programs, such as Medicare and Medicaid, managed care providers, private health insurers, health maintenance organizations and other organizations. These third-party payors decide which medications they will pay for and will establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as novel therapies. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS. CMS decides whether and to what extent our products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to successfully commercialize our product candidates, whether as a single agent or combination therapy, will depend in part on the extent to which coverage and adequate reimbursement for our products and related treatments will be available from third-party payors. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development.

No uniform policy for coverage and reimbursement for products exist among third-party payors in the United States. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor's determination to provide coverage for a medical product or service does not ensure that other

payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

A decision by a third-party payor not to cover or not to separately reimburse for our medical products or therapies using our products could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. If there is coverage for our product candidates, or therapies using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future. Further, if we or our collaborators develop therapies for use with our product candidates, we, or our collaborators, will be required to obtain coverage and reimbursement for these therapies separate and apart from the coverage and reimbursement we seek for our product candidates, once approved.

Further, third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to secure coverage and reimbursement for any product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of such product, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may, nonetheless, not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product, after approval, as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Lastly, in some foreign countries, the proposed pricing for a drug and its reimbursement status must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, in the European Union, pricing and reimbursement schemes are determined by each member state. Some EU member states provide that products may be marketed only after a reimbursement price has been agreed. Some EU member states may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so-called health technology assessments) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Approaches between EU member states are diverging. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The United Kingdom, on the other hand, operates a system for innovator medicines of direct or indirect controls on the profitability of the company placing the medicinal product on the market. The price of medicines is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Other EU member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the level of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in

light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results-based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Notwithstanding any of the above, as a Schedule I substance under the CSA, 5-MeO-DMT is currently deemed to have no accepted medical use and therapies that use 5-MeO-DMT are currently precluded from reimbursement in the United States.

# **Other Healthcare Laws and Compliance Requirements**

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable federal and state fraud and abuse laws, as well as other healthcare laws and regulations. These laws may impact, among other things, our business or financial arrangements and relationships through which we research, as well as market, sell and distribute the product candidates for which we obtain approval. In addition, we may be subject to health information privacy regulation by both the federal government and the United States in which we conduct our business. In the United States, the laws that may affect our ability to operate include, among others:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been interpreted broadly to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers and formulary managers on the other. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA, or federal civil money penalties statute. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;
- The federal civil and criminal false claims laws, such as the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third-party payors, that are false, fictitious or fraudulent; from knowingly making, using or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit property to the federal government; or from knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they

are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transferring of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of items or services reimbursable by a federal or state healthcare program;
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (i.e., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its respective implementing regulations, which imposes, among other things, certain requirements on covered entities, including certain covered healthcare providers, health plans and healthcare clearinghouses and their respective business associates relating to the privacy, security and transmission of individually identifiable health information as well as their covered subcontractors. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions;
- The federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, or the ACA, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives;
- Federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

Analogous state and foreign equivalents of each of the healthcare laws and regulations described above, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require pharmaceutical companies to comply with the pharmaceutical industry voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government, such as the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals; state laws that require the reporting of information related to drug pricing; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws that require the licensure and/or registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information that may be more stringent than those in the United States (such as the European Union, which adopted the GDPR), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The full scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued to increase their scrutiny on interactions between healthcare companies and healthcare providers, which has led to a number of significant investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including our arrangements with physicians and other healthcare providers and entities, such as our Centers of Excellence or therapists, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), imprisonment and additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our Centers of Excellence and therapists, are found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions.

Ensuring that our current and future business arrangements with third parties, and our business generally, comply with applicable healthcare laws and regulations, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

# Other Healthcare Laws and Compliance Requirements outside the United States

Outside of the United States, individual countries impose a variety of anti-corruption laws, most notable of which is the UK Bribery Act 2010 because of its apparent extra-territorial effect. Within the European Union, most member states our operations will be subject to anti-corruption laws. There is a heightened risk both from application of the FCPA and from national laws in many European and other countries because many of their healthcare professionals are categorized government officials. These laws will impose a variety of strictures on our business which are time consuming and expensive, including limiting engagements with healthcare professionals, the requirement to obtain prior authorizations for promotional activities from employers and/ or government or industry bodies, and the

requirement to supply transparency information regarding the interactions. Failure to comply with these laws is potentially very costly and can lead to reputational damage, fines, penalties and imprisonment as well as investigations and additional oversight of our business activities.

# Our Data Collection is Governed by Stringent Regulations Governing the Use, Processing and Cross-border Transfer of Personal Information.

In the event we decide to conduct future clinical trials in Europe, the United States or other jurisdictions, we may be subject to additional privacy and data protection requirements and restrictions. The collection, use, storage, disclosure, transfer or other processing of personal data regarding individuals in the European Economic Area, including personal health data, is subject to EU and national level data protection and privacy laws including, most notably, the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on entities that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging thirdparty processors that will have access to personal data. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Economic Area, including the United States and the United Kingdom. Entities that fail to comply with the requirements of the GDPR may be subject to very significant penalties, including potential fines of up to the greater of €20 million or 4% of annual global revenue. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. The United Kingdom has legislation equivalent to GDPR, and a decision is awaited from the European Union whether that legislation is adequate to allow free transfers of personal data from the European Union to the United Kingdom. Compliance with the GDPR will be a rigorous, costly and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European personal data processing activities.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health and personal information privacy laws, and federal and state consumer protection laws, govern the collection, use, processing, storage, transmission, disclosure, destruction and protection of health-related and other personal information. For example, the California Consumer Privacy Act of 2018, or CCPA, became effective on January 1, 2020 and creates new individual privacy rights for California consumers and places increased privacy and security obligations on entities handling certain personal data of California consumers. The CCPA requires companies subject to the legislation to provide new disclosure to consumers about such companies' data collection, use and sharing practices and provide such consumers new ways to opt-out of certain sales or transfers of personal information. The CCPA provides for civil penalties as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. In addition, California voters recently approved the California Privacy Rights Act of 2020, or CPRA, which goes into effect on January 1, 2023. It is expected that the CPRA would, among other things, give California residents the ability to limit the use of their personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action and establish a new California Privacy Protection Agency to implement and enforce the CCPA and CPRA. Other states and the U.S. federal government are considering comprehensive privacy laws, and on March 2, 2021, the Virginia Consumer Data Protection Act, or CDPA, was signed into law and will go into effect on January 1, 2023. Moreover, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach.

The regulatory framework for data privacy and security issues in the United States and abroad is rapidly evolving and likely to remain uncertain for the foreseeable future. Compliance with applicable U.S.

and foreign privacy and data protection laws and regulations is a rigorous and time-intensive process and could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose certain data, or in some cases, impact our ability to operate in certain jurisdictions.

# **Healthcare Reform**

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. For example, the Affordable Care Act substantially changed the way health care is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. The Affordable Care Act contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the HHS Secretary as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The Affordable Care Act made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Additionally, for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, President Trump signed several executive orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress considered legislation to repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have passed. In 2017, the Tax Cuts and Jobs Act, or the Tax Act, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare Part D drug plans. In April 2020, the U.S. Supreme Court reversed a federal circuit decision that previously upheld Congress' denial of \$12 billion in "risk corridor" funding. In December 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, in December 2019, the U.S Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing this case, although it is unclear when a decision will be made or how the U.S. Supreme Court will rule. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special

enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the U.S. Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business. We will continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business. Complying with any new legislation, resulting in a material adverse effect on our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 unless additional congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020, through December 31, 2021. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. The Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. Additionally, the FDA released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. It is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic, which may impact our business. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of health care and

containing or lowering the cost of health care. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

# Legal Proceedings

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our results of operations, cash flows and financial position. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We were not a party to any material litigation as of March 31, 2021. We were not a party to any material contingency reserves established for any liabilities as of December 31, 2020 and March 31, 2021.

## Facilities

We lease a facility of 106 square meters of office space, located at 28 Baggot Street lower, Dublin 2, Ireland. We believe our facilities are adequate for our current needs, including our short-term needs, and that suitable additional or substitute space would be available in Dublin, if needed.

# Employees

As of May 31, 2021, we had eight employees. Of our workforce, five full-time equivalent employees are directly engaged in research and development with the rest providing administrative, business and operations support.

None of our employees are represented by labor unions or covered by collective bargaining agreements. We have not experienced any employee litigation or claims and consider our employee relations to be good. We regularly discuss with our whole team to obtain feedback and ideas for improvement.

## MANAGEMENT

## **Executive Officers and Board of Directors**

The following table presents information about our executive officers and directors, after giving effect to the Corporate Reorganization and immediately following the pricing of this offering and prior to the listing of our ordinary shares on Nasdaq. The term of each of our directors is one year and, accordingly, will expire at our annual general meeting of shareholders to be held in 2022.

Name	Position(s)	Age	
Executive Officers:			
Theis Terwey	Chief Executive Officer	45	
Magnus Halle	Managing Director, Ireland	24	
Julie Ryan	Group Finance Director	35	
Non-Executive Directors:			
Florian Schönharting	Chairman of the Board of Directors	52	
Spike Loy	Director	41	
Michael Forer	Director	56	

# **Executive Officers**

**Theis Terwey, PD, Dr. Med.**, will serve as our Chief Executive Officer. Dr. Terwey is one of our cofounders and was a Director from our founding in 2018 to 2020. Currently, Dr. Terwey also serves as a Senior Consultant for Forward Pharma A/S, a position he has held since 2015. Previously, Dr. Terwey was Partner at NB Capital ApS, a position he held from 2015 to 2020, and he served in a variety of roles at NB Capital Research GmbH, where he was Managing Director from 2012 to 2015, and Medical Advisor from 2009 to 2012. Dr. Terwey holds a Dr. Med. from Charité — University Medicine Berlin, where he also is a private lecturer (Privatdozent), and completed his specialist degree for Internal Medicine.

**Magnus Halle**, has served as our Managing Director, Ireland since November 2020, is one of our cofounders, and served as a consultant to us from our founding in 2018 to 2020. Previously, Mr. Halle served as Analyst at NB Capital ApS, a position he held from 2018 to 2021. Additionally, from 2019, he served as the Money Laundering Reporting Officer at NB Capital ApS. Prior to that, from 2016 to 2018, he was the Personal Assistant to Florian Schönharting at NB Capital ApS. Mr. Halle holds a BSc in economics and business administration from Copenhagen Business School.

**Julie Ryan, ACA**, has served as our Group Finance Director since January 2021. Previously, Ms. Ryan has served in a number of senior finance roles including Ardagh Group plc, where she was Group Reporting Manager from 2018 to 2020, Sherry FitzGerald, where she was Commercial Business Partner in 2018, ICON plc, where she was Assistant Manager, Commercial/Finance Business Partnering from 2015 to 2018 and Brambles Ltd, where she was Finance Manager from 2013 to 2015. Ms. Ryan qualified as a chartered accountant with PricewaterhouseCoopers and holds a B.Comm (Acc) from University College Dublin and a MAcc from University College Dublin's Michael Smurfit Graduate Business School.

## **Non-Executive Directors**

**Florian Schönharting**, has served as the Chairman of our board of directors since 2018. Mr. Schönharting is one of our co-founders. Mr. Schönharting is also co-founder of Forward Pharma A/S, has served on its board of directors since 2005 and Chairman of the board of directors since 2011. He has also founded or co-founded several other biopharmaceutical companies, including Genmab A/S, Veloxis A/S (f/k/a Life Cycle Pharma A/S), Zealand Pharma A/S and Acadia Pharmaceuticals Inc. Mr. Schönharting has more than 25 years of investment executive experience in public and private equity funds involved in the biopharmaceutical industry. We believe that Mr. Schönharting is qualified to serve on our board of directors because of his experience, attributes and skills, including his extensive pharmaceutical and executive experience.

**Spike Loy, JD,** has served as a member of our board of directors since November 2020. Mr. Loy is currently Managing Director of BVF Partners LP, where he has served in various capacities since 2009. Mr. Loy holds a B.A. in human biology from Stanford University and a J.D. from Harvard Law School. We believe that Mr. Loy is qualified to serve on our board of directors because of his experience, attributes and skills, including his extensive executive experience.

**Michael Forer, LL.B.,** has served as a member of our board of directors since December 2020. Mr. Forer is currently Vice Chairman of the board of directors and Executive Vice President of ADC Therapeutics SA, a position he has held since June 2015. Mr. Forer has also been General Counsel of ADC Therapeutics SA since October 2020. From 2016 to 2020, Mr. Forer was Chief Financial Officer of ADC Therapeutics SA, and from 2011 to 2015, Mr. Forer was the Chief Executive Officer of ADC Therapeutics SA. From 2009 to 2013, Mr. Forer was a board member and Executive Director of Spirogen. Prior to that, Mr. Forer was the Managing Director for the investment activities of Auven Therapeutics Holdings L.P. from 2008 to 2015, the co-founder and Managing Director of Rosetta Capital Limited, and an Investment Manager at Rothschild Asset Management from 1998 to 2001. Mr. Forer holds a B.A. in economics from the University of Western Ontario and an LL.B. from the University of British Columbia. We believe that Mr. Forer is qualified to serve on our board of directors because of his experience, attributes and skills, including his extensive pharmaceutical experience.

## **Board Composition and Election of Directors After This Offering**

Our board of directors is composed of three members. The current members of our board of directors will serve until our first annual general meeting of shareholders as a public company in 2022.

We are a foreign private issuer under the rules of the SEC. As a result, in accordance with Nasdaq listing requirements, we will rely on home country governance requirements and certain exemptions thereunder rather than on the stock exchange corporate governance requirements. There are no family relationships among any of our directors or executive officers. For an overview of our corporate governance principles, see "Description of Share Capital and Constitution."

We are subject to the Irish Corporate Governance Annex. There is no mandatory obligation for us to rotate or retire directors under home country legislation.

# **Foreign Private Issuer Status**

Nasdaq listing rules include certain accommodations in the corporate governance requirements that allow foreign private issuers, such as us, to follow "home country" corporate governance practices in lieu of the otherwise applicable corporate governance standards of Nasdaq. The application of such exceptions requires that we disclose each non-compliance with listing rules that we do not follow and describe the Irish corporate governance requirements we do follow in lieu of the relevant Nasdaq corporate governance standard. When our ordinary shares are listed on Nasdaq, we intend to continue to follow Irish corporate governance practices in lieu of the corporate governance requirements of Nasdaq in respect of the following:

- the majority independent director requirement under Nasdaq listing rules;
- the requirement under Nasdaq listing rules that a compensation committee composed solely of independent directors governed by a compensation committee charter oversee executive compensation;
- the requirement under Nasdaq listing rules that director nominees be selected or recommended for selection by either a majority of the independent directors or a nominations committee composed solely of independent directors;
- the requirement under Nasdaq listing rules that a quorum must consist of at least 33<sup>1</sup>/<sub>3</sub> percent of the outstanding shares of a listed company's common voting stock; and
- the requirement under Nasdaq listing rules that the independent directors have regularly scheduled meetings with only the independent directors present.

Irish law does not impose a mandatory requirement that the board consist of a majority of independent directors or that such independent directors meet regularly without other members present. Nor does Irish law impose specific requirements on the establishment of a compensation committee or nominating committee or nominating process.

Because we are a foreign private issuer, our directors and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and Nasdaq listing rules.

Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq. For an overview of our corporate governance principles, see "Description of Share Capital and Constitution."

# Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements.

## **Committees of the Board of Directors**

Our board of directors will establish a separate audit committee, nominating and corporate governance committee and compensation committee at or prior to the closing of this offering.

# Audit Committee

The audit committee, which is expected to consist of Michael Forer (chair), Florian Schönharting and Spike Loy, will assist our board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee will be directly responsible for the compensation, retention and oversight of the work of our independent registered public accounting firm that our shareholders elect as our external auditors. The audit committee will consist exclusively of members of our board of directors who are financially literate, and Michael Forer is considered an "audit committee financial expert" as defined by the SEC. Our board of directors has determined that Michael Forer satisfies the "independence" requirements set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended.

Under Nasdaq Listing Rule 5615(b)(1), a company listing in connection with its initial public offering is permitted to phase in its compliance with the independent committee requirements and the committee composition requirements. Accordingly, a company listing in connection with its initial public offering is permitted to phase in its compliance with the committee composition requirements set forth in Nasdaq Listing Rule 5605(d)(2) and (e)(1)(B) as follows: (1) one member must satisfy the requirement at the time of listing; (2) a majority of members must satisfy the requirement within 90 days of listing; and (3) all members must satisfy the requirement within one year of listing. We intend to rely on the phase-in schedules set forth in the aforementioned Nasdaq Listing Rule with respect to the composition of our audit committee.

The audit committee will be governed by a charter that complies with Nasdaq rules that apply to us. The audit committee will have the responsibility for, among other things:

- recommending the appointment of the independent auditor to shareholders for approval at the general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full board of directors on at least an annual basis;
- reviewing and discussing with management and our independent registered public accounting firm our financial statements and our financial reporting process; and
- reviewing, approving or ratifying any related party transactions.

# Nominating and Corporate Governance Committee

The nominating and corporate governance committee, which is expected to consist of Florian Schönharting (chair), Michael Forer and Spike Loy, will assist our board of directors in identifying individuals qualified to become members of the board of directors and recommend to the board of directors the director nominees for the next annual general meeting of shareholders or to fill an existing or newly created vacancy on the board of directors.

The nominating and corporate governance committee will have the responsibility for, among other things:

- drawing up selection criteria and appointment procedures for directors;
- assessing the functioning of individual members of our board of directors and executive officers and reporting the results of such assessment to our board of directors;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by shareholders;
- reviewing the composition of our board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- recommending to our board of directors the persons to be nominated for election as directors and to each of our board of directors' committees;
- developing and recommending to our board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

## Compensation Committee

The compensation committee, which is expected to consist of Michael Forer (chair), Florian Schönharting and Spike Loy, will assist our board of directors in setting the remuneration of the board of directors, executive officers of the company and such other members of senior management as the committee is designated by the board of directors to set remuneration for.

The compensation committee will have the responsibility for, among other things:

- identifying, reviewing and proposing policies relevant to the compensation and benefits of our directors and executive officers;
- evaluating the performance of senior management in light of such policies and reporting to the board; and



 overseeing and administering our employee share option scheme or equity incentive plans in operation from time to time.

#### **Code of Business Conduct and Ethics**

In connection with this offering, we will adopt a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees, executive officers and directors. At or prior to the closing of this offering, the Code of Conduct will be available on our website at www.ghres.com. The audit committee of our board of directors will be responsible for overseeing the Code of Conduct and will be required to approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

## **Compensation of Executive Officers and Directors**

For the year ended December 31, 2020, the aggregate compensation paid to the members of our board of directors and our executive officers for services in all capacities, including retirement and similar benefits, was \$5 thousand.

#### **Equity Incentive Plans**

#### Share Option Plan

In connection with this offering, we intend to adopt a share option plan (the "Share Option Plan"), under which grants of options will be made to eligible participants. The purpose of the Share Option Plan is to attract, retain and motivate employees and directors to provide for competitive compensation opportunities, to encourage long term service, to recognize individual contributions and reward achievement of performance goals, and to promote the creation of long term value for our shareholders.

*Plan Administration*: The Share Option Plan is administered by our compensation committee, subject to the compensation committee's discretion to delegate such authority to other members of our board or our officers or managers.

*Eligible Participants*: Under the Share Option Plan, any director (including our directors and directors of any other member of our group who are not active employees of the Company or any other company that is a member of our group) or employee of a member of the group or key consultant (the "Eligible Person") is eligible to be nominated by our compensation committee to receive options. The compensation committee will retain absolute discretion in determining whether or not the Eligible Person shall be nominated to participate in the Share Option Plan. No person will be entitled as of right to participate in the Share Option Plan.

Awards: The number of ordinary shares in respect of which options may be granted under the Share Option Plan will not, when added to the number of ordinary shares which have been or remain to be issued or purchased pursuant to options granted during the immediately preceding 10 year period, exceed 1,202,734 ordinary shares, until otherwise resolved in general meetings. Under the Share Option Plan, equity will be awarded in the form of options. Options will have an exercise price determined by the compensation committee but will not (unless otherwise determined) be less than the market value of an ordinary share on the day preceding the date of grant. The term of each option will be determined by the compensation committee, but will not be longer than eight years from the date of grant.

*Limitation as to Participation*: Under the Share Option Plan, no option will be capable of being granted for more than 10 years from the date of adoption of the Share Option Plan.

*Participation*: The conditions for participation in the Share Option Plan, including the time or times at which options may be exercised, will be determined by the compensation committee and set forth in the applicable option plan documentation. Unless otherwise outlined, the options will be personal to the participant and will lapse if a participant purports to assign, transfer, sell, mortgage, pledge or encumber the option.

*Termination of Service and Change in Control:* In the event of a participant's termination of employment or service, (1) any part of an option that has not vested as of the date of cessation will lapse immediately, and (2) any part of an option that has vested as at the date of cessation will lapse in full 30 days after the date of cessation to the extent not exercised by such date.

If a participant dies, the compensation committee may determine that either the whole or a specified percentage of any option held by such participant at the date of their death will be capable of vesting, or being exercised by or otherwise transferred to their legal personal representative.

In the event of a participant's termination of employment where such participant is considered a good leaver, the compensation committee may in its absolute discretion determine the extent to which the option may be vested or exercised.

In the event of a change of control that involves a merger, a sale of all or substantially all of the Company's assets, or a takeover or other reorganization, the compensation committee will be entitled to, in its discretion, (1) accelerate the vesting of the whole or a specified portion of the options, (2) agree that outstanding options will be assumed or substituted by the surviving company or its parent for options which are equivalent to the options originally granted under the plan but which relate to shares in the surviving company or its parent, (3) arrange for the continuation of outstanding options, (4) make payment of a cash settlement to the participants equal (per share) to the amount to be paid for one share under the agreement of merger or takeover, or (5) vary the outstanding options on such terms as the committee may decide.

Termination and Amendment: Unless terminated earlier by resolution, the Share Option Plan will continue for a term of 10 years. Our compensation committee may at any time by resolution amend or revoke any provision of the Share Option Plan subject to shareholder approval if required by applicable law or stock exchange rules. However, no such action may materially adversely affect the rights of the participant of any options unless agreed to by the participant.

## **Employment Agreements**

We have entered into employment agreements with certain of our executive officers. Each of these agreements provides for an initial salary, and generally requires advance notice of termination, typically three months. Some of our executive officers have agreed to covenants not to compete against us or solicit our employees or customers during employment and for a period of up to 12 months following termination.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into since January 1, 2018 with any members of our board of directors, our executive officers and the holders of more than 5% of our ordinary shares, other than compensation arrangements which are described under "Management."

The share and per share numbers set forth below under this "Certain Relationships and Related Party Transactions" section do not give effect to the Share Consolidation, to be effected immediately and conditional upon the SEC declaring this registration statement effective.

#### Sales of Securities

## Share Issuances

In October 2018, we issued 20,000,000 ordinary shares, par value €0.01 per share, in connection with the incorporation of GH Research Ireland Limited, at an issue price of €0.01 per share for a total consideration of €200 thousand.

The following table summarizes the ordinary shares purchased by members of our board of directors, executive officers or their affiliates and holders of more than 5% of our outstanding share capital. The terms of these purchases were the same for all purchasers of our ordinary shares.

Stockholder	Ordinary Shares	Aggregate Purchase Price Paid
Florian Schönharting	12,740,000	€127,400.00
Theis Terwey	5,460,000	€ 54,600.00
Magnus Halle	100,000	€ 1,000.00

In December 2018, we issued an additional 50,000,000 ordinary shares, par value  $\notin 0.01$  per share, at an issue price of  $\notin 0.01$  per share for a total consideration of  $\notin 500$  thousand.

The following table summarizes the ordinary shares purchased by members of our board of directors, executive officers or their affiliates and holders of more than 5% of our outstanding share capital. The terms of these purchases were the same for all purchasers of our ordinary shares.

Stockholder	Ordinary Shares	Aggregate Purchase Price Paid
Entities affiliated with BVF <sup>(1)</sup>	12,250,000	€122,500.00
Florian Schönharting	24,046,750	€240,467.50
Theis Terwey	10,305,750	€103,057.50
Magnus Halle	188,750	€ 1,887.50

(1) Consists of Biotechnology Value Trading Fund OS, L.P., Biotechnology Value Fund II, L.P. and Biotechnology Value Fund, L.P. Spike Loy, a member of our board of directors, is a managing director at BVF.

## Series A Preferred Financing

In November 2020 and December 2020, we completed the initial closings of our Series A financing by issuing an aggregate of 5,923,079 Series A preferred shares at an issue price of \$0.93 per share for an aggregate purchase price of \$5.5 million to certain investors, pursuant to the share purchase agreements entered into with these investors.

The following table summarizes the Series A preferred shares purchased by members of our board of directors, executive officers or their affiliates and holders of more than 5% of our outstanding share capital in the initial closings of our Series A financing. The terms of these purchases were the same for all purchasers of our Series A preferred shares.

Stockholder	Series A Preferred Shares	Aggregate Purchase Price Paid
Entities affiliated with BVF <sup>(1)</sup>	4,307,695	\$4,000,002.50
Florian Schönharting	686,000	\$ 637,000.00
Theis Terwey	294,000	\$ 273,000.00
Magnus Halle	5,384	\$ 4,999.43
Michael Forer	107,692	\$ 100,000.08

(1) Consists of Biotechnology Value Trading Fund OS, L.P., Biotechnology Value Fund II, L.P. and Biotechnology Value Fund, L.P. Spike Loy, a member of our board of directors, is a managing director at BVF.

# Series B Preferred Financing

In April 2021, we entered into an investment and subscription agreement pursuant to which we issued and sold an aggregate of 25,379,047 Series B preferred shares at an issue price of \$4.93 per share for an aggregate purchase price of \$125.2 million to certain investors.

The following table summarizes the Series B preferred shares purchased by members of our board of directors, executive officers or their affiliates and holders of more than 5% of our outstanding share capital in the initial closings of our Series B Financing. The terms of these purchases were the same for all purchasers of our Series B preferred shares.

Stockholder	Series B Preferred Shares	Aggregate Purchase Price Paid
Entities affiliated with BVF	5,067,701	\$25,000,002.87
Florian Schönharting	202,699	\$ 999,955.52

#### **Capital Increase Agreements**

Our wholly owned subsidiary, GH Research Ireland Limited, entered into a capital increase agreement with certain investors on December 2018 in relation to the issuance of 50,000,000 ordinary shares described above.

GH Research Ireland Limited subsequently entered into another capital increase agreement with certain investors on November 2020, as well as a deed of adherence in December 2020, each in connection with the issuance of Series A preferred shares described above. The agreement contained provisions in relation to tag-along rights, drag rights and preemptive rights and also outlined that the investors shall have certain registration rights in case of a public offering on a recognized stock exchange. The agreement was superseded by the shareholders' agreement described below.

## **Share Option Contract**

On June 4, 2021, we granted the option to purchase 126,218 ordinary shares of GH Research PLC to Julie Ryan, Group Finance Director at an exercise price of \$4.93 per share. Following the Share Consolidation, the entitlement will adjust to an option to purchase 50,487 ordinary shares of \$0.025 at an exercise price of \$12.32 per share. The fair market value of such shares will be the midpoint of the price range set forth on the cover page of this prospectus.

## Shareholders' Agreement

In connection with the consummation of the Series B Financing in April 2021, we entered into a shareholders' agreement with our shareholders. Among other things, the shareholders' agreement provides our shareholders with certain registration rights, information rights and rights of first refusal. In

addition, the shareholders' agreement contains provisions that allow each of RA Capital and RTW Investments, LP, to appoint one nonvoting observer to our board of directors. As of the date hereof, Zach Scheiner and Connor Williams have been appointed by RA Capital and RTW Investments, LP, respectively, under the terms of this agreement. In accordance with its terms, the shareholders' agreement will automatically terminate in connection with this offering and such nonvoting observers will step down from their roles.

# **Registration Rights Agreement**

In connection with the Series B Financing, we have agreed with our existing shareholders that we will enter into a Registration Rights Agreement in connection with this offering, pursuant to which our existing shareholders will be granted registration rights.

At any time beginning 180 days following the closing of this offering, subject to several exceptions, including underwriter cutbacks and our right to defer a demand registration under certain circumstances, our existing shareholders may require that we register for public resale under the Securities Act all ordinary shares constituting registrable securities that they request be registered so long as the securities requested to be registered in each registration statement represent an aggregate price to the public that is reasonably expected to equal at least \$50 million. If we become eligible to register the sale of our securities on Form F-3 under the Securities Act, which will not be until at least twelve months after the date of this prospectus, our existing shareholders have the right to require us to register the sale of the registrable securities held by them on Form F-3, subject to offering size and other restrictions.

If we propose to register any of our securities under the Securities Act for our own account or the account of any other holder (excluding any registration related to employee benefit plan, a Rule 145 transaction, a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the registrable securities or a registration in which the only ordinary shares being registered are ordinary shares issuable upon conversion of debt securities that are also being registered), our existing shareholders are entitled to notice of such registration and to request that we include registrable securities for resale on such registration statement, and we are required, subject to certain exceptions, to include such registrable securities in such registration statement.

In connection with the transfer of their registrable securities, the parties to the Registration Rights Agreement may assign certain of their respective rights under the Registration Rights Agreement under certain circumstances. In connection with the registrations described above, we will indemnify any selling shareholders and we will bear all fees, costs and expenses (except underwriting discounts and spreads).

# **GH Research OÜ Asset Purchase**

In 2018, we agreed to purchase all of the assets of GH Research OÜ, a private company owned by Florian Schönharting and Theis Terwey, which consisted of certain raw materials and technology as well as data collected from internet databases, for an aggregate consideration of €67 thousand, which was recognized in the fiscal year ended December 31, 2018.

On January 11, 2019, we finalized and executed an asset purchase agreement with GH Research OÜ to memorialize the above-referenced arrangement. GH Research OÜ was dissolved in August 2019.

# Indemnification Agreements

Our Constitution requires us to indemnify our directors and executive officers, employees and other officials serving at the specific direction of the company to the fullest extent permitted by Irish law.

#### **Related Person Transaction Policy**

Prior to the consummation of this offering, we intend to enter into a new related person transaction policy. Pursuant to such related person transaction policy, any related person transaction must be approved or ratified by our board of directors or a designated committee thereof. In determining whether

to approve or ratify a transaction with a related person, our board of directors or the designated committee will consider all relevant facts and circumstances, including without limitation the commercial reasonableness of the terms, the benefit and perceived benefit, or lack thereof, to us, opportunity costs of alternate transactions, the materiality and character of the related person's direct or indirect interest and the actual or apparent conflict of interest of the related person. Our board of directors or the designated committee will not approve or ratify a related person transaction unless it has determined that, upon consideration of all relevant information, such transaction is in, or not inconsistent with, our best interests and the best interests of our shareholders.

## PRINCIPAL SHAREHOLDERS

The following table sets forth certain information known to us regarding beneficial ownership of our ordinary shares immediately prior to the completion of this offering, for:

- each person or group of affiliated persons known by us to be the beneficial owner of 5% or more of our ordinary shares;
- each of our named executive officers;
- each of our directors: and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Except as otherwise indicated, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all ordinary shares shown as beneficially owned by them.

The percentage of beneficial ownership prior to this offering in the table below is based on 40,520,850 ordinary shares deemed to be outstanding immediately prior to the completion of this offering. See "-Corporate Reorganization and Share Consolidation." The percentage of shares beneficially owned after completion of this offering is based on 48,854,183 ordinary shares outstanding after this offering, including 8.333.333 ordinary shares issued in connection with this offering, and assumes no exercise of the underwriters' option to purchase additional shares. Options to purchase shares that are exercisable within 60 days are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage.

As of the date of this prospectus, to our knowledge, 24 U.S. record holders held approximately 41.1% of our issued and outstanding ordinary shares after giving effect to the Series B Financing and the exchange of all of our preferred shares for ordinary shares, which will occur in connection with the Corporate Reorganization and Share Consolidation.

Ireland.	ch PLC, 28 Ba	ggot Street Lo	ower, Dublin 2,	D02 NX43,
	Shares Beneficially Owned Before This Offering		Shares Benefic After This	
Name of Beneficial Owner	Number	Percent	Number	Percent

Except as otherwise indicated in the table below, addresses of the directors, executive officers and
named beneficial owners are in care of GH Research PLC, 28 Baggot Street Lower, Dublin 2, D02 NX43,
Ireland.

Name of Beneficial Owner	Number	Percent	Number	Percent
5% or Greater Shareholders				
Entities affiliated with BVF <sup>(1)</sup>	8,650,158	21.3%	8,650,158	17.7%
Executive Officers and Directors				
Theis Terwey	6,423,900	15.9%	6,423,900	13.1%
Magnus Halle	*	*%	*	*%
Julie Ryan <sup>(2)</sup>	*	*%	*	*%
Florian Schönharting	15,070,179	37.2%	15,070,179	30.8%
Spike Loy <sup>(3)</sup>	*	*%	*	*%
Michael Forer <sup>(4)</sup>	*	*%	*	*%
All executive officers and directors as a group (6 persons)	21,654,810	53.4%	21,654,810	44.3%

Represents beneficial ownership of less than 1%.



- Consists of 4,507,690 ordinary shares held by Biotechnology Value Fund, L.P., ("BVF") including (1) 3,531,790 ordinary shares held by Biotechnology Value Fund II, L.P. ("BVF2"), and 610,678 ordinary shares held by Biotechnology Value Trading Fund OS L.P. ("Trading Fund OS"), BVF ("BVF GP"), as the general partner of BVF, may be deemed to beneficially own the 4,507,690 shares beneficially owned by BVF. BVF II GP L.L.C. ("BVF2 GP"), as the general partner of BVF2, may be deemed to beneficially own the 3,531,790 shares beneficially owned by BVF2. BVF Partners OS Ltd. ("Partners OS"), as the general partner of Trading Fund OS, may be deemed to beneficially own the 610,678 shares beneficially owned by Trading Fund OS. BVF GP Holdings L.L.C., ("BVF GPH"), as the sole member of each of BVF GP and BVF2 GP, may be deemed to beneficially own the 8,039,480 shares beneficially owned in the aggregate by BVF and BVF2. BVF Partners L.P. ("Partners"), as the general partner of BVF and BVF2, the sole member of Partners OS, and the investment manager of Trading Fund OS, may be deemed to beneficially own the 8,650,158 shares beneficially owned in the aggregate by BVF, BVF2 and Trading Fund OS. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the 8,650,158 shares beneficially owned by Partners. Mark Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the 8,650,158 shares beneficially owned by BVF Inc. The address of the above persons and entities is 44 Montgomery Street, 40th Floor, San Francisco, CA 94104.
- (2) Excludes options to purchase a total of 50,487 ordinary shares that are not exercisable by Ms. Ryan within 60 days of the date of this prospectus.
- (3) Mr. Loy, a Managing Director of BVF Partners LP, disclaims beneficial ownership with respect to the 8,650,158 ordinary shares held of record by entities affiliated with BVF except to the extent of his pecuniary interest therein. See footnote (1).
- (4) Does not include 212,850 ordinary shares held by Dune Capital Inc., a company which is wholly owned by a trust whose beneficiaries include Mr. Forer and his family. Mr. Forer does not exercise investment or voting control over the trust, and therefore such shares do not appear in the table above.

#### DESCRIPTION OF SHARE CAPITAL AND CONSTITUTION

The following description of our share capital summarizes the material terms and provisions of the ordinary shares that we may offer under this prospectus, as well as a description of certain provisions of our Constitution. The following description does not purport to be complete and is subject to, and qualified in its entirety by, the Constitution, which is an exhibit to the registration statement of which this prospectus forms a part, and by applicable law.

# General

We were incorporated pursuant to the laws of Ireland as GH Research PLC on March 29, 2021 to become the holding company for GH Research Ireland Limited. GH Research Limited, the operating company and subsidiary of GH Research PLC, was incorporated on October 16, 2018. GH Research Limited was re-registered as GH Research Ireland Limited on March 29, 2021. Pursuant to the terms of the Corporate Reorganization, all shareholders of GH Research Ireland Limited have exchanged each of the shares held by them for shares in GH Research PLC of the same share classes with the same shareholder rights and, as a result, GH Research Ireland Limited has become a wholly owned subsidiary of GH Research PLC. See the section above titled "Corporate Reorganization and Share Consolidation" for more information.

We are registered with the Companies Registration Office in Ireland under company registration number 691405 and our registered office is at 28 Baggot Street Lower, Dublin 2, Dublin, D02 NX43, Ireland.

As part of our Share Consolidation, certain resolutions were passed by our shareholders prior to the completion of this offering, including the adoption of our Constitution. See "Key Provisions of our Post-IPO Constitution" below.

## Authorized and Issued Share Capital

As of March 31, 2021, the issued and outstanding share capital of GH Research Ireland Limited was 70,000,000 ordinary shares and 5,923,079 Series A preferred shares. The nominal value of each of our ordinary and Series A preferred shares is €0.01 per share and each issued share is fully paid.

Immediately following the Corporate Reorganization, the issued share capital of GH Research PLC (aside from the subscriber shares) mirrored the issued and outstanding share capital of GH Research Ireland Limited, except that the nominal value of each share is \$0.01. Following the conversion of each of the different classes of shares in GH Research PLC, the Share Consolidation and this offering, the authorized share capital of GH Research PLC immediately upon the SEC declaring this registration statement effective will be 40,000,000,000 ordinary shares of nominal value \$0.025 each.

# **Ordinary Shares**

Our ordinary shares will have a nominal value of \$0.025 per share. Further details of the rights attaching to the ordinary shares are set out in the comparison table below and in the Constitution. In accordance with the Constitution, the following summarizes the rights of our ordinary shares:

- The holders of ordinary shares are entitled to one vote for each ordinary share held of record on all matters submitted to a vote of the shareholders;
- The holders of our ordinary shares shall be entitled to receive notice of, attend, speak and vote at our general meetings and receive a copy of every report, accounts, circular or other documents sent out by us to our shareholders; and
- The holders of our ordinary shares are entitled to receive such dividends as are recommended by our directors and declared by our shareholders or in the case of an interim dividend, declared by our directors.

# Listing

We have applied to list our ordinary shares on Nasdaq under the symbol "GHRS."

Initial settlement of our ordinary shares will take place on the closing date of this offering through DTC in accordance with its customary settlement procedures for equity securities. Each person owning ordinary shares held through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the ordinary shares. Persons wishing to obtain certificates for their ordinary shares must make arrangements with DTC.

# **Transfer Agent and Registrar**

The transfer agent and registrar for shares of our ordinary shares will be Computershare Trust Company, N.A. Its address is 150 Royall Street, Canton, Massachusetts 02021.

# Key Provisions of our Post-IPO Constitution

The Constitution is expected to be approved by our shareholders and be adopted prior to the completion of the offering. A summary of certain key provisions of the Constitution is set out below. The summary below is not a complete copy of the terms of the Constitution. For further information, please refer to the full version of the Constitution filed as an exhibit to the registration statement of which this prospectus forms a part.

The Constitution contains, among other things, provisions to the following effect:

# Share Capital

The share capital will consist of ordinary shares, nominal value \$0.025 per share. Immediately after completion of this offering, our authorized share capital will be \$1,000,000,000 divided into 40,000,000 ordinary shares, nominal value \$0.025 per share.

We may issue shares subject to the maximum authorized share capital contained in our Constitution. The authorized share capital may be increased or reduced by a simple majority of the votes of the shareholders cast at a general meeting (which is referred to under Irish law as an ordinary resolution). The shares comprising our authorized share capital may be divided into shares of such nominal value as such resolution shall prescribe. As a matter of Irish company law, the directors of a company may issue new ordinary shares without shareholder approval once authorized to do so by the Constitution or by an ordinary resolution adopted by the shareholders at a general meeting. The authorization may be granted for a maximum period of five years, so it must be renewed by the shareholders by an ordinary resolution on or before the expiry of this term (if we wish to issue shares). The Constitution authorizes our board of directors to allot new ordinary shares without shareholder approval for a period of five years from the date of adoption of the Constitution.

The rights and restrictions to which the ordinary shares will be subject will be prescribed in the Constitution.

The holders of our ordinary shares are entitled to one vote for each ordinary share upon all matters presented to our shareholders. Subject to any preferences granted to other classes of our securities that may be outstanding in the future (including any preferred shares that may be created), there are no voting right restrictions or preferences with respect to our shareholders.

Irish law does not recognize fractional shares held of record. Accordingly, the Constitution will not provide for the issuance of fractional shares of ours, and our register of members, or the register of members, will not reflect any fractional shares.

Whenever an alteration or reorganization of the share capital of ours would result in any of our shareholders becoming entitled to fractions of a share, our board of directors may, on behalf of those shareholders that would become entitled to fractions of a share, arrange for the sale of the shares representing fractions and the distribution of the net proceeds of sale in due proportion among the shareholders who would have been entitled to the fractions.

# Voting

The presence, in person or by proxy, of one or more persons holding or representing by proxy at least a majority in nominal value of the class or, at any adjourned meeting of such holders, one holder holding or representing by proxy at least a majority in nominal value of the issued shares of the class constitutes a quorum for the conduct of business.

At any of our meetings, all resolutions put to our shareholders will be decided on a poll.

Irish company law requires certain matters to be approved by not less than 75% of the votes cast at a general meeting of our shareholders (which is referred to under Irish law as a special resolution). Examples of matters requiring special resolutions include:

- amending the Constitution;
- approving a change of name of GH Research PLC;
- authorizing the entering into of a guarantee or provision of security in connection with a loan, quasi-loan or credit transaction to a director or connected person;
- opting out of preemption rights on the issuance of new shares for cash;
- our re-registration from a public limited company to a private company;
- variation of class rights attaching to classes of shares (where the Constitution does not provide otherwise);
- purchase of our shares off-market;
- reduction of issued share capital;
- sanctioning a compromise/scheme of arrangement;
- resolving that we be wound up by the Irish courts;
- resolving in favor of a shareholders' voluntary winding up;
- re-designation of shares into different share classes; and
- setting the reissue price of treasury shares.

# Variation of Rights

Where our shares are divided into different classes, the rights attaching to a class of shares may only be varied or abrogated if (a) the holders of 75% in nominal value of the issued shares of that class consent in writing to the variation, or (b) a special resolution, passed at a separate general meeting of the holders of that class, sanctions the variation. The quorum at any such separate general meeting, other than an adjourned meeting, shall be one or more persons holding or representing by proxy at least 25% of the votes that may be cast by shareholders at the relevant time. The rights conferred upon the holders of any class of shares issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by a purchase or redemption by us of our own shares or by the creation or issue of further shares ranking pari passu therewith or subordinate thereto.

# Dividends

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves, broadly, means the accumulated realized profits of a company, less accumulated realized losses of the company on a standalone basis. In addition, no dividend or distribution may be made unless the net assets of a company are not less than the aggregate of the company's called up share capital plus undistributable reserves and the distribution does not reduce the company's net assets below such aggregate. Undistributable reserves include a company's undenominated capital (effectively its share premium and capital redemption reserve) and the amount by which the company's accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed the company's

accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital. The determination as to whether or not the company has sufficient distributable reserves to fund a dividend must be made by reference to "relevant accounts" of the company. The "relevant accounts" are either the last set of unconsolidated annual audited financial statements or unaudited financial statements prepared in accordance with the Irish Companies Act, which give a "true and fair view" of the company's unconsolidated financial position in accordance with accepted accounting practice in Ireland. These "relevant accounts" must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

The Constitution authorizes the Board to declare such interim dividends as appear justified from the profits of the company without the approval of the shareholders. The dividends can be declared and paid in the form of cash or noncash assets, subject to applicable law. We may pay dividends in any currency. The Board may deduct from any dividend or other moneys payable to any shareholder all sums of money, if any, due from the shareholder to the company in respect of our ordinary shares.

We may, by ordinary resolution, declare final dividends to be paid to our shareholders. However, no dividend shall exceed the amount recommended by the board of directors. The board of directors may also pay to the shareholders such dividends as interim or final dividends as appear to the directors to be justified by our profits.

We have never declared or paid any cash dividend, and do not anticipate declaring or paying any cash dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. See "Risk Factors—Risks Related to the Offering and Ownership of Our Ordinary Shares." Because there is no present intention to pay dividends on our ordinary shares for the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

Under Irish law, among other things, we may only pay dividends if we have sufficient distributable reserves (on a nonconsolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

For information about the Irish tax considerations relating to dividend payments, see "Material Irish Tax Consequences."

# Liquidation

Our duration will be unlimited. We may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding up, a special resolution of the shareholders is required. We may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure in case we fail to file certain returns.

The rights of the shareholders to a return of our assets on dissolution or winding up, following the settlement of all claims of creditors, are prescribed in the Constitution and may be further prescribed in the terms of any preferred shares we issue from time to time. In particular, if we have issued any preferred shares, holders of such preferred shares may have the right to priority in our dissolution or winding up. The Constitution provides that, subject to the priorities of any creditors, the assets will be distributed to the shareholders in proportion to the paid up nominal value of the shares held by such shareholder. The Constitution provides that the shareholders are entitled to participate pro rata in a winding up, but their right to do so is subject to the rights of any holders of the shares issued upon special terms and conditions to participate under the terms of any series or class of such shares.

# **Preemption Rights**

Under Irish law, certain statutory preemption rights apply automatically in favor of shareholders where shares are to be issued for cash. However, we have opted out of these preemption rights in the Constitution as permitted under Irish company law for a period of five years from the date of adoption of

the Constitution. Generally, this opt-out is to be renewed at least every five years approved by a special resolution of our shareholders. If the opt-out is not renewed, as a general rule, shares issued for cash must be offered to our existing shareholders on a pro rata basis to their existing shareholding before any of our shares may be issued to any new shareholders. Statutory preemption rights do not apply (i) where shares are issued wholly or partly for noncash consideration (such as in a stock-for-stock acquisition), (ii) to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution) or (iii) where shares are issued pursuant to an employee option or similar equity plan.

# **Alteration of Share Capital**

Under our Constitution, we may, by ordinary resolution, divide any or all of our share capital into shares of a smaller nominal value than our existing shares (often referred to as a share split) or consolidate any or all of our share capital into shares of larger nominal value than our existing shares (often referred to as a reverse share split).

We may, by ordinary resolution, reduce the authorized but unissued share capital. We may, by special resolution and subject to confirmation by the Irish High Court, reduce the issued share capital and any undenominated share capital.

# **Board of Directors**

# Appointment of Directors

The Constitution provides for a minimum of two directors and a maximum of nine directors. Our shareholders may from time to time increase or reduce the maximum number, or increase the minimum number, of directors by ordinary resolution. Our Board of Directors determines the number of directors within the range of two to nine.

# **Proceedings of Directors**

Subject to the provisions of our Constitution, our board of directors may regulate their proceedings as they deem appropriate. A director may, and the secretary at the request of a director shall, call a meeting of the directors. The quorum for a meeting of our board of directors shall be fixed from time to time by decision of the board of directors, but it must never be fewer than two directors (or duly appointed alternate directors). Questions and matters requiring resolution arising at a meeting shall be decided by a majority of votes of the participating directors, with each director having one vote. In the case of an equality of votes, the chairperson will have a second or casting vote (unless the chairperson is not entitled to vote on the resolution in question).

# **Conflicts of Interest**

Our directors have certain statutory and fiduciary duties as a matter of Irish law. All of the directors have equal and overall responsibility for management of our company (although directors who also serve as employees may have additional responsibilities and duties arising under their employment agreements (if applicable), and it is likely that more will be expected of them in compliance with their duties than non-executive directors). The Irish Companies Act provides specifically for certain fiduciary duties of the directors of Irish companies, including duties:

- to act in good faith and in the best interests of the company;
- to act honestly and responsibly in relation to the company's affairs;
- to act in accordance with the company's constitution and to exercise powers only for lawful purposes;
- not to misuse the company's property, information and/or opportunity;
- not to fetter their independent judgment;
- to avoid conflicts of interest;

- to exercise care, skill and diligence; and
- to have regard for the interests of the company's shareholders.

Other statutory duties of directors include ensuring the maintenance of proper books of account, having annual accounts prepared, having an annual audit performed, maintaining certain registers, making certain filings and disclosing personal interests. Directors of public limited companies such as ourselves will have a specific duty to ensure that the company secretary is a person with the requisite knowledge and experience to discharge the role. Directors may rely on information, opinions, reports or statements, including financial statements and other financial data, prepared or presented by (1) other directors, officers or employees of the company whom the director reasonably believes to be reliable and competent in the matters prepared or presented, (2) legal counsel, public accountants or other persons as to matters the director reasonably believes to be within their professional or expert competence or (3) a committee of the board of which the director reasonably believed to merit confidence.

# Directors' and Officer's Indemnity

To the fullest extent permitted by Irish law, the Constitution contains indemnification for the benefit of, amongst others, our directors, company secretary and executive officers. However, as to our directors and company secretary, this indemnity is limited by the Irish Companies Act, which prescribes that an advance commitment to indemnify only permits a company to pay the costs or discharge the liability of a director or company secretary where judgment is given in favor of the director or company secretary in any civil or criminal action in respect of such costs or liability, or where an Irish court grants relief because the director or company secretary acted honestly and reasonably and ought fairly to be excused. Any provision whereby an Irish company seeks to commit in advance to indemnify its directors or company secretary. This restriction does not apply to our executive officers who are not directors, or other persons who would not be considered "officers" within the meaning of the Irish Companies Act.

We are permitted under the Constitution and the Irish Companies Act to take out directors' and officers' liability insurance, as well as other types of insurance, for our directors, officers, employees and agents. In order to attract and retain qualified directors and officers, we expect to purchase and maintain customary directors' and officers' liability insurance and other types of comparable insurance.

# **General Meetings**

We will be required to hold an annual general meeting within 18 months of incorporation and at intervals of no more than 15 months thereafter, provided that an annual general meeting is held in each calendar year following the first annual general meeting and no more than nine months after our fiscal year-end.

Notice of an annual general meeting must be given to all of our shareholders and to our auditors. The Constitution provides for a minimum notice period for an annual general meeting of 21 days, which is the minimum permitted under Irish law.

Generally speaking, the only matters which must, as a matter of Irish company law, be transacted at an annual general meeting are the presentation of the annual statutory financial statements, balance sheet and reports of the directors and auditors, the appointment of new auditors and the fixing of the auditor's remuneration (or delegation of same). If no resolution is made in respect of the reappointment of an existing auditor at an annual general meeting, the existing auditor will be deemed to have continued in office.

As provided under Irish law, extraordinary general meetings may be convened (i) by our board of directors, (ii) by request of our shareholders holding not less than 10% of our paid up share capital carrying voting rights for so long as our shares are not admitted to trading on a regulated market in any

member state of the European Union, (iii) by request of our statutory auditor in connection with its resignation or (iv) in exceptional cases, by court order.

Notice of an extraordinary general meeting must be given to all our shareholders and to our auditors. Under Irish law and the Constitution, the minimum notice period of 21 days' prior written notice applies, except that in the case of an extraordinary general meeting, if the company offers facilities to members to vote by electronic means and shareholders have passed a special resolution at the immediately preceding general meeting approving such shortened notice period, an extraordinary general meeting can be called with 14 days' prior written notice (provided that no special resolutions are proposed to be put to a vote at that meeting). The notice periods prescribed for the convening of general meetings are on the basis of "clear" days, meaning the deemed date of receipt of the notice and the date of the meeting itself are not counted towards the minimum number of days' notice required.

In the case of an extraordinary general meeting convened by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of any such valid requisition notice, the board of directors has 21 days to convene a meeting of our shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If the board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of our receipt of the requisition notice.

If the board of directors becomes aware that our net assets are not greater than half of the amount of our called up share capital, the directors must convene an extraordinary general meeting of shareholders not later than 28 days from the date that they learn of this fact to consider how to address the situation.

# **Borrowing Powers**

Subject to the Constitution and the Irish Companies Act, our board of directors may exercise all of our powers to:

- (i) borrow money;
- (ii) indemnify and guarantee;
- (iii) mortgage or charge;
- (iv) create and issue debentures and other securities; and
- (v) give security either outright or as collateral security for any of our debt, liability or obligation or any of a third party.

# **Uncertificated Shares**

Shares in an Irish public limited company such as ours can, in principle, be issued and held either in a so-called certificated (*i.e.*, hard copy share certificates are issued to shareholders) or a so-called uncertificated (*i.e.*, dematerialized) form. All shareholders' names must be entered into the register of members maintained by an Irish public limited company in order to acquire legal title to the shares.

To make shares in an Irish public limited company deliverable for trading on an exchange, the shares are required to be issued in uncertificated form.

# Amendment of Constitution

Irish company law requires a special resolution of our shareholders (approval by not less than 75% of the votes cast at a general meeting of our shareholders) to approve any amendments to the Constitution.

# Other Relevant Irish Laws and Regulations

# Anti-Takeover Provisions of Irish Law

# **Business Combinations with Interested Shareholders**

# Irish Takeover Rules and Substantial Acquisition Rules

A transaction in which a third party seeks to acquire 30% or more of our voting rights and any other acquisitions of our securities will be governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules made thereunder, the Irish Takeover Panel Act, 1997, Takeover Rules, 2013, or the Irish Takeover Rules, and will be regulated by the Irish Takeover Panel. The general principles of the Irish Takeover Rules, or the General Principles, and certain important aspects of the Irish Takeover Rules are described below.

# **General Principles**

The Irish Takeover Rules are built on the following General Principles which will apply to any transaction regulated by the Irish Takeover Panel:

- (i) in the event of an offer, all holders of securities of the target company must be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- (ii) the holders of securities in the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer; where it advises the holders of securities, the Board of Directors of the target company must give its views on the effects of the implementation of the offer on employment, employment conditions and the locations of the target company's place of business;
- (iii) a target company's Board of Directors must act in the interests of that company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- (iv) false markets must not be created in the securities of the target company, the bidder or any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;
- (v) a bidder can only announce an offer after ensuring that he or she can fulfill in full the consideration offered, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- (vi) a target company may not be hindered in the conduct of its affairs longer than is reasonable by an offer for its securities; and
- (vii) a "substantial acquisition" of securities, whether such acquisition is to be effected by one transaction or a series of transactions, shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure.

# Mandatory Bid

Under certain circumstances, a person who acquires shares, or other voting securities, of a company may be required under the Irish Takeover Rules to make a mandatory cash offer for the remaining outstanding voting securities in that company at a price not less than the highest price paid for the securities by the acquiror, or any parties acting in concert with the acquiror, during the previous 12 months. This mandatory bid requirement is triggered if an acquisition of securities would increase the aggregate holding of an acquiror, including the holdings of any parties acting in concert with the acquiror, to securities representing 30% or more of the voting rights in a company, unless the Irish Takeover Panel

otherwise consents. An acquisition of securities by a person holding, together with its concert parties, securities representing between 30% and 50% of the voting rights in a company would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person, together with its concert parties, would increase by 0.05% within a 12-month period. Any person, excluding any parties acting in concert with the holder, holding securities representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements in purchasing additional securities.

# Voluntary Bid; Requirements to Make a Cash Offer and Minimum Price Requirement

If a person makes a voluntary offer to acquire our outstanding ordinary shares, the offer price must not be less than the highest price paid for our ordinary shares by the bidder or its concert parties during the three-month period prior to the commencement of the offer period. The Irish Takeover Panel has the power to extend the "look back" period to 12 months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired our ordinary shares (1) during the 12-month period prior to the commencement of the offer period that represent more than 10% of our total ordinary shares or (2) at any time after the commencement of the offer period, the offer must be in cash or accompanied by a full cash alternative and the price per share must not be less than the highest price paid by the bidder or its concert parties during, in the case of clause (1), the 12-month period prior to the commencement of the offer period. The Irish Takeover Panel may apply this Rule to a bidder who, together with its concert parties, has acquired less than 10% of our total ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence from the date of the first announcement of the offer or proposed offer.

# Substantial Acquisition Rules

The Irish Takeover Rules also contain rules governing substantial acquisitions of shares and other voting securities which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of the voting rights of the company. Except in certain circumstances, an acquisition or series of acquisitions of shares or rights over shares representing 10% or more of the voting rights of the company is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of the voting rights of the company and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

# **Frustrating Action**

Under the Irish Takeover Rules, our Board of Directors is not permitted to take any action that might frustrate an offer for our shares once our Board of Directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (1) the issue of shares, options, restricted share units or convertible securities, (2) material acquisitions or disposals, (3) entering into contracts other than in the ordinary course of business or (4) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which our Board of Directors has reason to believe an offer is or may be imminent. Exceptions to this prohibition are available where:

- (a) the action is approved by our shareholders at a general meeting; or
- (b) the Irish Takeover Panel has given its consent, where:
  - (i) it is satisfied the action would not constitute frustrating action;



- (ii) our shareholders holding more than 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;
- (iii) the action is taken in accordance with a contract entered into prior to the announcement of the offer, or any earlier time at which our Board of Directors considered the offer to be imminent; or
- (iv) the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

# Shareholders' Rights Plan

Irish law does not expressly authorize or prohibit companies from issuing share purchase rights or adopting a shareholder rights plan as an anti-takeover measure. However, there is no directly relevant case law on the validity of such plans under Irish law. In addition, such a plan would be subject to the Irish Takeover Rules and the General Principles underlying the Irish Takeover Rules. The Constitution allows our Board of Directors to adopt a shareholder rights plan upon such terms and conditions as our Board of Directors deems expedient and in the best interests of us, subject to applicable law.

Subject to the Irish Takeover Rules, our Board of Directors also has power to issue any of our authorized and unissued shares on such terms and conditions as it may determine and any such action should be taken in our best interests. It is possible, however, that the terms and conditions of any issue of preference shares could discourage a takeover or other transaction that holders of some or a majority of the ordinary shares believe to be in their best interests or in which holders might receive a premium for their shares over the then-market price of the shares.

# Disclosure of Interests in Shares

Under the Irish Companies Act, our shareholders must notify us if, as a result of a transaction, the shareholder will become interested in 3% or more of our voting shares, or if as a result of a transaction a shareholder who was interested in 3% or more of our voting shares ceases to be so interested. Where a shareholder is interested in 3% or more of our voting shares, the shareholder must notify us of any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the voting shares in which the shareholder is interested as a proportion of the entire nominal value of our issued share capital (or any such class of share capital in issue). Where the percentage level of the shareholder's interest does not amount to a whole percentage, this figure may be rounded down to the next whole number. We must be notified within five business days of the transaction or alteration of the shareholder's interests that gave rise to the notification requirement. If a shareholder fails to comply with these notification requirements, the shareholder's rights in respect of any of our shares it holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

In addition to these disclosure requirements, we, under the Irish Companies Act, may, by notice in writing, require a person whom we know or have reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in our relevant share capital to (i) indicate whether or not it is the case and (ii) where such person holds or has during that time held an interest in our shares, provide additional information, including the person's own past or present interests in our shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, we may apply to the Irish court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Irish Companies Act, as follows:

- (i) any transfer of those shares or, in the case of unissued shares, any transfer of the right to be issued with shares and any issue of shares, shall be void;
- (ii) no voting rights shall be exercisable in respect of those shares;



- (iii) no further shares shall be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and
- (iv) no payment shall be made of any sums due from us on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event we are in an offer period pursuant to the Irish Takeover Rules, accelerated disclosure provisions apply for persons holding an interest in our securities of 1% or more.

# COMPARISON OF IRISH LAW AND DELAWARE LAW

As a public limited company incorporated under the laws of Ireland, the rights of our shareholders are governed by applicable Irish law, including the Irish Companies Act, and not by the law of any U.S. state. As a result, our directors and shareholders are subject to different responsibilities, rights and privileges than are applicable to directors and shareholders of U.S. corporations. The applicable provisions of the Irish Companies Act differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the Irish Companies Act applicable provisions in respect of Delaware relating to shareholders' rights and protections. The applicable provisions in respect of the Company under the Constitution is also set out where relevant. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and Irish law. You are also urged to carefully read the relevant provisions of the Delaware General Corporation Law and the Irish Companies Act for a more complete understanding of the differences between Delaware and Irish law.

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Number of Directors	The Irish Companies Act provides for a minimum of two directors. The Constitution provides for a minimum of two directors and a maximum of nine. Our shareholders may from time to time increase or reduce the maximum number, or increase the minimum number, of directors by ordinary resolution. Our Board of Directors determines the number of directors within the range of two to nine.	A typical certificate of incorporation and bylaws would provide that the number of directors on the board of directors will be fixed from time to time by a vote of the majority of the authorized directors. Under Delaware law, a board of directors can be divided into classes and cumulative voting in the election of directors is only permitted if expressly authorized in a corporation's certificate of incorporation.
Removal of Directors	Under the Irish Companies Act, the shareholders may, by ordinary resolution, remove a director from office before the expiration of his or her term, at a meeting held with no less than 28 days' notice and at which the director is entitled to be heard. Because of this provision of the Irish Companies Act, a director may be so removed before the expiration of his or her period of office. The power of removal is without prejudice to any claim for damages for breach of contract (e.g., employment contract) that the director may have against the Company in respect of his or her removal. The Constitution also provides that the office of a director will also be vacated if the director is restricted or disqualified to act as a director under the Irish Companies Act; resigns his or her office by notice in writing to us or in writing offers to resign and the directors resolve to accept such offer; or is requested to resign in writing by not less than 75% of the other directors.	A typical certificate of incorporation and bylaws provide that, subject to the rights of holders of any preferred shares, directors may be removed at any time by the affirmative vote of the holders of at least a majority, or in some instances a supermajority, of the voting power of all of the then outstanding shares entitled to vote generally in the election of directors, voting together as a single class. A certificate of incorporation could also provide that such a right is only exercisable when a director is being removed for cause (removal of a director only for cause is the default rule in the case of a classified board).
Vacancies on the Board of Directors	Any vacancy on our Board of Directors, including a vacancy resulting from an increase in the number of directors or from the death,	A typical certificate of incorporation and bylaws provide that, subject to the rights of the holders of any preferred shares, any vacancy, whether

resignation, retirement, disqualification or removal of a director, shall be deemed a casual vacancy. Any casual vacancy shall only be filled by the decision of a majority of our Board of Directors then in office, provided that a quorum is present and provided that the appointment does not cause the number of directors to exceed any number fixed by or in accordance with the Constitution as the maximum number of directors.

Any director elected to fill a vacancy resulting from an increase in the number of directors of such class shall hold office for the remaining term of that class. Any director elected to fill a vacancy not resulting from an increase in the number of directors shall have the same remaining term as that of his predecessor. A director retiring at a meeting shall retain office until the close or adjournment of the meeting.

Annual General Meeting We are required to hold annual general meetings at intervals of no more than 15 months after the previous annual general meeting, provided that an annual general meeting is held in each calendar year following our first annual general meeting, no more than nine months after our fiscal year-end.

The only matters which must, as a matter of Irish company law, be transacted at an annual general meeting are the consideration of the Irish statutory financial statements, the report of the directors, the report of the auditors on those statements and that report and a review by the members of our affairs. If no resolution is made in respect of the reappointment of an auditor at an annual general meeting, the previous auditor will be deemed to have continued in office.

General Meeting Our extraordinary general meetings may be convened by (i) our Board of Directors, (ii) on requisition of shareholders holding not less than 10% of our paid up share capital carrying voting rights or (iii) on requisition of our auditors. Extraordinary general meetings are generally held for the purposes of approving shareholder resolutions as may be required from time to time.

If our directors become aware that our net assets are half or less of the amount of our called up share capital, our directors must

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arising through death, resignation, retirement, disqualification, removal, an increase in the number of directors or any other reason, may be filled by a majority vote of the remaining directors, even if such directors remaining in office constitute less than a quorum, or by the sole remaining director. Any newly elected director usually holds office for the remainder of the full term expiring at the annual meeting of shareholders at which the term of the class of directors to which the newly elected director has been elected expires.

Typical bylaws provide that annual meetings of shareholders are to be held on a date and at a time fixed by the board of directors.

Under Delaware law, a special meeting of shareholders may be called by the board of directors or by any other person authorized to do so in the certificate of incorporation or the bylaws.

convene an extraordinary general meeting of our shareholders not later than 28 days from the date that they learn of this fact. This meeting must be convened for the purposes of considering whether any, and if so what, measures should be taken to address the situation.

Notice of General Meetings

Quorum

Notice of a general meeting must be given to all our shareholders and to our auditors. The Constitution provides that the maximum notice period is 60 days. The minimum notice periods are 21 days' notice in writing for an annual general meeting or an extraordinary general meeting to approve a special resolution and 14 days' notice in writing for any other extraordinary general meeting. General meetings may be called by shorter notice, but only with the consent of our auditors and all of our shareholders entitled to attend and vote thereat. Because of the 21-day and 14-day requirements described in this paragraph, the Constitution includes provisions reflecting these requirements of Irish law.

In the case of an extraordinary general meeting convened by our shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of this requisition notice, our Board of Directors has 21 days to convene a meeting of our shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If our Board of Directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one-half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the receipt of the requisition notice.

The presence, in person or by proxy, of one or more persons holding or representing by proxy at least 25% of the votes that may be cast at the relevant time or, at any adjourned meeting of such holders, one holder holding or representing by proxy at least a majority in nominal value of the issued shares of the class constitutes a quorum for the conduct of business. No business may take place at a general meeting if a quorum is not present in person or by proxy. Our Board of Directors has no authority to waive quorum Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour and purpose or purposes of the meeting.

Under Delaware law, a corporation's certificate of incorporation or bylaws can specify the number of shares which constitute the quorum required to conduct business at a meeting, provided that in no event shall a quorum consist of less than one-third of the shares entitled to vote at a meeting.

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requirements stipulated in the Constitution. Abstentions and broker non-votes will be counted as present for purposes of determining whether there is a quorum in respect of the proposals.

Under Irish law, a shareholder may designate another person to attend, speak and vote at a general meeting of the company on their behalf by proxy, which proxy need not be a shareholder.

> Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy.

Voting rights may be exercised by shareholders registered in the share register as of the record date for the meeting or by a duly appointed proxy of such a registered shareholder, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, this company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in accordance with the Constitution. The Constitution permits the appointment of proxies by our shareholders to be notified to us electronically, when permitted by our directors.

Under the Constitution, we may issue shares Issue of New Shares subject to the maximum authorized share capital contained in the Constitution. The authorized share capital may be increased or reduced by a resolution approved by a simple majority of the votes cast at a general meeting of our shareholders, referred to under Irish law as an "ordinary resolution." As a matter of Irish law, the directors of a company may issue new ordinary shares without shareholder approval once authorized to do so by its constitution or by an ordinary resolution adopted by our shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it may be renewed by shareholders by an ordinary resolution. Accordingly, the Constitution authorizes our Board of Directors to issue new ordinary shares without shareholder approval for a period of five years from the date of the adoption of the Constitution.

Preemptive Under Irish law, unless otherwise authorized, Rights when an Irish public limited company issues Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Under Delaware law, if the company's certificate of incorporation so provides, the directors have the power to authorize the issuance of additional stock. The directors may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the company or any combination thereof.

Under Delaware law, stockholders have no preemptive rights to subscribe to additional

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shares for cash to new shareholders, it is required first to offer those shares on the same or more favorable terms to existing shareholders of the company on a pro rata basis, commonly referred to as the statutory preemption right. However, we have opted out of these preemption rights in the Constitution as permitted under Irish law. Because Irish law permits this opt-out to last for a maximum of five years, the Constitution provides that this opt-out will lapse five years after the adoption of the Constitution. Such opt-out may be renewed by a special resolution of the shareholders. A special resolution requires not less than 75% of the votes cast at a general meeting of our shareholders. If the opt-out is not renewed, shares issued for cash must be offered to our preexisting shareholders pro rata before the shares can be issued to any new shareholders. The statutory preemption rights do not apply where shares are issued for noncash consideration and do not apply to the issue of non-equity shares (that is, shares that have the right to participate only up to a specified amount in any income or capital distribution).

Authority to Allot Under the Constitution, we may issue shares subject to the maximum authorized share capital contained in the Constitution. The authorized share capital may be increased or reduced by a resolution approved by a simple majority of the votes cast at a general meeting of our shareholders, referred to under Irish law as an "ordinary resolution." Our authorized share capital may be divided into shares of such nominal value as the resolution shall prescribe. As a matter of Irish law, the directors of a company may issue new ordinary shares without shareholder approval once authorized to do so by its constitution or by an ordinary resolution adopted by our shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it may be renewed by shareholders by an ordinary resolution. Accordingly, the Constitution authorizes our Board of Directors to issue new ordinary shares without shareholder approval for a period of five years from the date of the adoption of the Constitution.

Acquisition of Own Shares Under Irish law, a company may issue redeemable shares and redeem them out of distributable reserves or the proceeds of a new

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issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.

Under Delaware law, if the corporation's charter or certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. The board may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.

Under Delaware law, any corporation may purchase or redeem its own shares, except that generally it may not purchase or redeem these

issue of shares for that purpose. All redeemable shares must also be fully paid. Redeemable shares may, upon redemption, be cancelled or held in treasury. The Constitution provides that shareholder approval will not be required to deem any shares redeemable. We may also be given an additional general authority by our shareholders to purchase our own shares onmarket, which would take effect on the same terms and be subject to the same conditions as applicable to purchases by our subsidiaries as described below.

Repurchased and redeemed shares may be cancelled or held as treasury shares. The nominal value of treasury shares that we hold at any time must not exceed 10% of the nominal value of our issued share capital. We may not exercise any voting rights in respect of any shares held as treasury shares. We may either cancel or, subject to certain conditions, reissue Treasury shares.

Under Irish law, an Irish or non-Irish subsidiary may purchase our shares either on-market or off-market. For a subsidiary of ours to make onmarket purchases of our shares, the shareholders must provide general authorization for such purchase by way of ordinary resolution. However, as long as this general authority has been granted, no specific shareholder authority for a particular on-market purchase by a subsidiary of our shares is required. For an offmarket purchase by a subsidiary of ours, the proposed purchase contract must be authorized by special resolution of our shareholders before the contract is entered into. This authority must specify the date on which the authority is to expire, which shall not be more than 18 months from the date the special resolution was passed. The person whose shares of ours are to be bought cannot vote in favor of the special resolution and, for at least 21 days prior to the special resolution being passed, the purchase contract must be on display or must be available for inspection by our shareholders at our registered office.

Different Classes of Shares Without prejudice to any rights attached to any existing shares, We may issue shares with such rights or restrictions as we determine by an ordinary resolution approved by our shareholders. As a matter of Irish company law,

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shares if the capital of the corporation is impaired at the time or would become impaired as a result of the redemption. A corporation may, however, purchase or redeem out of capital shares that are entitled upon any distribution of its assets to a preference over another class or series of its shares if the shares are to be retired and the capital reduced.

A company's Delaware's certificate of incorporation may authorize the board of directors:

 to provide for the issuance of one or more series of preferred stock;

the directors of a company may issue new ordinary shares without shareholder approval once authorized to do so by the constitution or by an ordinary resolution adopted by the shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it must be renewed by the shareholders by an ordinary resolution (if we wish to issue shares). The Constitution authorizes our board of directors to issue new ordinary shares without shareholder approval for a period of five years from the date of adoption of such constitution, which is expected to be effective as of the completion of the business combination. We may also issue shares which are, or are liable to be, redeemed at the option of us or the holder.

Whenever our share capital is divided into different classes of shares, the special rights attached to any class may be varied or abrogated either with the written consent of the holders of 75% in nominal value of the issued shares of the class (excluding shares held as treasury shares) or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of the class (but not otherwise), and may be so varied or abrogated either while we are a going concern or during or in contemplation of a winding up.

The rights conferred upon the holders of any class of shares issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by our purchase or redemption of our own shares or by the creation or issue of further shares ranking pari passu therewith or subordinate thereto.

Dividends Under Irish law, dividends and distributions may only be made from distributable reserves which are, generally, a company's accumulated realized profits less its accumulated realized losses. In addition, no distribution or dividend may be made if our net assets are not, or if making such distribution or dividend will cause our net assets to not be, equal to, or in excess of, the aggregate of our called up share capital plus undistributable reserves.

> Undistributable reserves include the company's undenominated capital and the amount by which a company's accumulated unrealized

- (2) to establish from time to time the number of shares to be included in such series; and
- (3) to fix the designations, preferences and relative, participating, optional or other special rights, and qualifications, limitations or restrictions of each such series.

Under Delaware law, subject to any restriction in the corporation's certificate of incorporation, the Board may declare and pay dividends out of:

- surplus of the corporation, which is defined as net assets less statutory capital; or
- (2) if no surplus exists, out of the net profits of the corporation for the year in which the dividend is declared and/or the preceding year;

provided, however, that if the capital of the corporation has been diminished to an amount less than the aggregate amount of capital

#### IRELAND

profits exceeds its accumulated unrealized losses. The determination as to whether or not we have sufficient distributable reserves to fund a dividend must be made by reference to our most recent unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Irish Companies Act. The relevant financial statements must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

The Constitution authorizes our board of directors to declare an interim dividend without shareholder approval to the extent they appear justified by profits. Our board of directors may also recommend a dividend to be approved and declared by the shareholders at a general meeting, provided that no dividend issued may exceed the amount recommended by the directors.

General Provisions Governing a Liquidation; Liquidation Distributions Our duration will be unlimited. We may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding up, a special resolution of our shareholders is required. We may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where we have failed to file certain returns.

The rights of the shareholders to a return of our assets on dissolution or winding up, following the settlement of all claims of creditors, are prescribed in the Constitution.

Amendment of Constitution Irish company la of our sharehold 75% of the vote

Irish company law requires a special resolution of our shareholders (approval by not less than 75% of the votes cast at a general meeting of our shareholders) to approve any amendments to the Constitution.

#### DELAWARE

represented by the issued and outstanding stock of all classes having preference upon the distribution of assets, the Board may not declare and pay dividends out of the corporation's net profits until the deficiency in the capital has been repaired.

Upon the dissolution of a Delaware corporation, after satisfaction of the claims of creditors, the assets of that corporation would be distributed to stockholders in accordance with their respective interests, including any rights a holder of shares of preference shares may have to preferred distributions upon dissolution or liquidation of the corporation.

# Amendment of Certification of Incorporation and Bylaws

Under Delaware law, amendments to a corporation's certificate of incorporation require the approval of stockholders holding a majority of the outstanding shares entitled to vote on the amendment.

If a class vote on the amendment is required by the Delaware General Corporation Law, a majority of the outstanding stock of the class is required, unless a greater proportion is specified in the certificate of incorporation or by other provisions of the Delaware General

Corporation Law. Under the Delaware General Corporation Law, the board of directors may amend bylaws if so authorized in the certificate of incorporation. The stockholders of a Delaware corporation also have the power to amend bylaws.

Acquisition of Treasury Share and Reduction of Share Capital We may reduce our authorized but unissued share capital in any manner permitted by the Irish Companies Act. We also may, by special resolution (approved by not less than 75% of the votes cast at a general meeting of our shareholders) and subject to confirmation by the Irish High Court, reduce our issued share capital in any way permitted by the Irish Companies Act.

For purposes of Irish law, repurchases of our shares may be effected by a redemption if the repurchased shares are redeemable shares or are deemed to be redeemable shares by the Constitution.

The Constitution provides that, unless the board of directors determines otherwise, each of our shares shall be deemed to be a redeemable share on, and from the time of, the existence or creation of an agreement, transaction or trade between us and any person pursuant to which we acquire or will acquire our shares, or an interest in our shares, from the relevant person. Redeemable shares of ours shall have the same characteristics as any other of our shares save that they shall be redeemable in accordance with the arrangement.

Rights of Inspection Under Irish law, our shareholders have the right to: (i) receive a copy of the Constitution; (ii) inspect and obtain copies of the minutes of our general meetings and resolutions; (iii) inspect and receive a copy of our register of members, register of directors and secretaries, register of directors' interests, register of directors' service contracts and memoranda and other statutory registers that we maintain; (iv) receive copies of balance sheets and directors' and auditors' reports that have previously been sent to our shareholders prior to an annual general meeting; and (v) receive balance sheets of any of our subsidiaries that have previously been sent to our shareholders prior to an annual general meeting for the preceding 10 years.

Under Delaware law, a corporation, by an affirmative vote of a majority of the board of directors, may reduce its capital by reducing or eliminating the capital represented by shares of capital stock which have been retired, by applying to an already authorized purchase redemption, conversion or exchange of outstanding shares of its capital stock some or all of the capital represented by shares being purchased, redeemed, converted or exchanged or any capital that has not been allocated to any particular class of capital stock or by transferring to surplus capital some or all of the capital not represented by any particular class of its capital stock or the capital associated with certain issued shares of its par value capital stock. No reduction of capital may be made unless the assets of the corporation remaining after the reduction are sufficient to pay any debts for which payment has not otherwise been provided.

Delaware law allows any stockholder in person or by attorney or other agent, upon written demand under oath stating the purpose thereof, during the usual hours for business to inspect for any proper purpose, and to make copies and extracts from:

- the corporation's stock ledger, a list of its stockholders, and its other books and records; and
- (2) a subsidiary's books and records, to the extent that:
  - (a) the corporation has actual possession and control of such records of such subsidiary; or
  - (b) the corporation could obtain such records through the exercise of control over such subsidiary, provided that as of the date of the

making of the demand:

- the stockholder inspection of such books and records of the subsidiary would not constitute a breach of an agreement between the corporation or the subsidiary and a person or persons not affiliated with the corporation: and
- (ii) the subsidiary would not have the right under the law applicable to it to deny the corporation access to such books and records upon demand by the corporation.

Delaware law permits a corporation's certificate of incorporation to include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:

- any breach of his or her duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- (3) intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or
- (4) any transaction from which he or she derives an improper personal benefit.

Liability of Directors and Officers To the fullest extent permitted by Irish law, the Constitution contains indemnification for the benefit of, among others, our directors, company secretary and executive officers. However, as to our directors and company secretary, this indemnity is limited by the Irish Companies Act, which prescribes that an advance commitment to indemnify only permits a company to pay the costs or discharge the liability of a director or company secretary where judgment is given in favor of the director or company secretary in any civil or criminal action in respect of such costs or liability, or where an Irish court grants relief because the director or company secretary acted honestly and reasonably and ought fairly to be excused. Any provision whereby an Irish company seeks to commit in advance to indemnify its directors or company secretary over and above the limitations imposed by the Irish Companies Act will be void, whether contained in its Constitution or any contract between the company and the director or company secretary. This restriction does not apply to our executive officers who are not directors, our company secretary or other persons who would be considered "officers" within the meaning of the Irish Companies Act.

We are permitted under the Constitution and the Irish Companies Act to take out directors' and officers' liability insurance, as well as other types of insurance, for our directors, officers, employees and agents. In order to attract and retain qualified directors and officers, we expect to purchase and maintain customary directors' and officers' liability insurance and other types of comparable insurance.

TABLE OF CONTENTS						
IRELAND						
Voting Rights	Under the Constitution, each holder of our ordinary shares is entitled to one vote for each ordinary share that he or she holds as of the record date for the meeting. We may not exercise any voting rights in respect of any shares held as treasury shares. Any shares held by our subsidiaries will count as treasury shares for this purpose, and such subsidiaries cannot therefore exercise any voting rights in respect of those shares.	Each stockho share of capit unless the ce otherwise. If issued, the stock will be o incorporation with respect t				
Shareholder Vote on Certain Transactions	<ul> <li>Pursuant to Irish law, shareholder approval in connection with a transaction involving the Company would be required under the following circumstances: <ul> <li>in connection with a scheme of arrangement, both a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve such a scheme would be required;</li> <li>in connection with an acquisition of the Company by way of a merger with an EU company under the EU Cross-Border Mergers Directive 2005/56/EC, (as replaced by Directive (EU) 2017/1132 of June 14, 2017), approval by a special resolution of the shareholders would be required; and</li> </ul> </li> <li>in connection with a merger with an Irish company under the Irish Companies Act, approval by a special resolution of shareholders would be required.</li> </ul>	Generally, un certificate of i of a larger po merger, cons of all or subst or dissolution • the app • the app • the app • the cer more o majority stock o the ma				
Standard of Conduct for Directors	The directors of the Company have certain statutory and fiduciary duties as a matter of Irish law. All of the directors have equal and overall responsibility for the management of the Company (although directors who also serve as employees may have additional responsibilities and duties arising under their employment agreements (if applicable), and it is likely that more will be expected of them in compliance with their duties than non-executive directors). The Irish Companies Act provides specifically for certain fiduciary duties of the directors of Irish companies, including duties: • to act in good faith and in the best interests of the company:	Delaware law provisions se of a director. directors is ge the State of E a duty to act v informed bas believe to be stockholders. Directors of a fiduciary dutie corporation a care generall good faith. w				

interests of the company; to act honestly and responsibly in relation to the company's affairs;

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older is entitled to one vote for each ital stock held by the stockholder, ertificate of incorporation provides

voting rights of holders of preferred determined by the certificate of n or the certificate of designation to such preferred stock.

nder Delaware law, unless the incorporation provides for the vote ortion of the stock, completion of a solidation, sale, lease or exchange stantially all of a corporation's assets n requires:

- proval of the board of directors; and
- proval by the vote of the holders of prity of the outstanding stock or, if rtificate of incorporation provides for or less than one vote per share, a ty of the votes of the outstanding of the corporation entitled to vote on atter.

w does not contain specific etting forth the standard of conduct The scope of the fiduciary duties of enerally determined by the courts of Delaware. In general, directors have without self-interest, on a wellsis and in a manner they reasonably in the best interests of the

a Delaware corporation owe ies of care and loyalty to the and to its shareholders. The duty of Ily requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information

- to act in accordance with the company's constitution and to exercise powers only for lawful purposes;
- not to misuse the company's property, information and/or opportunity;
- not to fetter their independent judgment;
- to avoid conflicts of interest;
- to exercise care, skill and diligence; and
   to have regard for the interests of the
- to have regard for the interests of the company's shareholders.

Other statutory duties of directors include ensuring the maintenance of proper books of account, having annual accounts prepared, having an annual audit performed, maintaining certain registers, making certain filings and disclosing personal interests. Directors of public limited companies such as GH will have a specific duty to ensure that the company secretary is a person with the requisite knowledge and experience to discharge the role. Directors may rely on information, opinions, reports or statements, including financial statements and other financial data, prepared or presented by (1) other directors, officers or employees of the company whom the director reasonably believes to be reliable and competent in the matters prepared or presented, (2) legal counsel, public accountants or other persons as to matters the director reasonably believes to be within their professional or expert competence or (3) a committee of the board of which the director does not serve as to matters within its designated authority, which committee the director reasonably believed to merit confidence.

Shareholder Suits In Ireland, the decision to institute proceedings is generally taken by a company's board of directors, who will usually be empowered to manage the company's business. In certain limited circumstances, a shareholder may be entitled to bring a derivative action on behalf of the company.

The central question at issue in deciding whether a minority shareholder may be permitted to bring a derivative action is whether, unless the action is brought, a wrong committed against the company would otherwise go unredressed.

The principal case law in Ireland indicates that to bring a derivative action a person must first

reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.

In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or breakup of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Under Delaware law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself or herself and other similarly situated stockholders where the requirements for maintaining a class action under the Delaware General Corporation Law have been met. A person may institute and maintain such a suit only if such person was a stockholder at the time of the transaction which is the subject of the suit or his or her shares thereafter devolved upon him or her by operation of law. Additionally, under Delaware case law, the plaintiff generally must be a stockholder not only at the time of the

establish a prima facie case (i) that the company is entitled to the relief claimed and (ii) that the action falls within one of the five exceptions derived from case law, as follows:

- where an ultra vires or illegal act is perpetrated;
- (2) where more than a bare majority is required to ratify the "wrong" complained of:
- (3) where the shareholders' personal rights are infringed;
- (4) where a fraud has been perpetrated upon a minority by those in control; or
- (5) where the justice of the case requires a minority to be permitted to institute proceedings.

Shareholders may also bring proceedings against the company where the affairs of the company are being conducted, or the powers of the directors are being exercised, in a manner oppressive to the shareholders or in disregard of their interests. Oppression connotes conduct that is burdensome, harsh or wrong.

Conduct must relate to the internal management of the company. This is an Irish statutory remedy and the court can grant any order it sees fit, usually providing for the purchase or transfer of the shares of any shareholder.

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transaction which is the subject of the suit, but also through the duration of the derivative suit. The Delaware General Corporation Law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff, unless such demand would be futile.

# SHARES ELIGIBLE FOR FUTURE SALE

Prior to the completion of this offering, there has been no public market for our ordinary shares. Based on the number of ordinary shares outstanding as of March 31, 2021, upon completion of the Share Consolidation and this offering, and assuming no exercise of the underwriters' option to purchase additional ordinary shares, 48,854,183 of our ordinary shares will be outstanding, assuming the issuance of 8,333,333 ordinary shares offered by us in this offering. Future sales of ordinary shares in the public market after this offering, and the availability of ordinary shares for future sale, could adversely affect the prevailing market price of our ordinary shares from time to time. Some of the ordinary shares are subject to contractual and legal restrictions on resale as described below. There may be sales of substantial amounts of our ordinary shares in the public market after such restrictions lapse, which could adversely affect the prevailing market prices of our ordinary shares.

We expect that 8,333,333 ordinary shares, or 9,583,333 ordinary shares if the underwriters exercise in full their option to purchase additional ordinary shares, sold in this offering will be freely transferable without restriction, except for any shares purchased by one or more of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. We expect that substantially all of the remaining 40,520,850 ordinary shares outstanding after this offering will be subject to the contractual 180-day lockup period described below. This may adversely affect the prevailing market price of our ordinary shares and our ability to raise equity capital in the future.

# Rule 144

In general, persons who have beneficially owned restricted ordinary shares for at least six months, and any of our affiliates who own either restricted or unrestricted securities, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

# Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of a prior owner other than one of our affiliates;
- we have been subject to the Exchange Act, periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of restricted securities without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

#### Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

1% of the number of ordinary shares then outstanding, which will equal approximately 488,541 shares immediately after the completion of this offering based on the number of ordinary shares outstanding as of March 31, 2021; or



the average weekly trading volume of our ordinary shares on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

# **Rule 701**

In general, under Rule 701 of the Securities Act, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory share or option plan or other written agreement before the effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described below, beginning 90 days after the date of this prospectus, may be sold by persons other than "affiliates," as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by "affiliates" under Rule 144 without compliance with its one-year minimum holding period requirement.

# **Regulation S**

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act, provided that no directed selling efforts (as that term is defined in Regulation S) are made in the United States, and subject to certain other conditions. In general, this means that our ordinary shares may be sold in some manner outside the United States without requiring registration in the United States.

# Lock-Up Agreements

All of our directors, executive officers and substantially all of our shareholders have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of our ordinary shares, ordinary shares or such other securities for a period of 180 days after the date of this prospectus, without the prior written consent of Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated, who may waive the provisions of these agreements, in full or in part, at any time in their sole discretion. See "Underwriting."

# **Registration Rights Agreement**

Certain of our shareholders will have the right, subject to the lock-up agreements described above, to require us to register our ordinary shares for resale in some circumstances. See "Certain Relationships and Related Party Transactions—Registration Rights Agreement."

# TAX CONSIDERATIONS

The following summary contains a description of material Irish and U.S. federal tax consequences of the acquisition, ownership and disposition of our ordinary shares. This summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decision to acquire ordinary shares in this offering.

# Material U.S. Federal Income Tax Considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to U.S. Holders, as defined below, of owning and disposing our ordinary shares. It does not describe all tax consequences that may be relevant to a particular person's decision to acquire ordinary shares.

This discussion applies only to a U.S. Holder that holds ordinary shares as capital assets for U.S. federal income tax purposes (generally, property held for investment). In addition, it does not describe any tax consequences other than U.S. federal income tax consequences, including state and local tax consequences and estate tax consequences, and does not describe all of the U.S. federal income tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential application of the provisions of the Code known as the Medicare contribution tax, special tax accounting rules under Section 451(b) of the Code, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares as part of a straddle, wash sale, conversion transaction or other integrated transaction or persons entering into a constructive sale with respect to the ordinary shares;
- persons who acquired ordinary shares pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities or arrangements classified as partnerships or S corporations for U.S. federal income tax purposes (and investors therein);
- tax-exempt entities, including an "individual retirement account" or "Roth IRA" or governmental entities;
- real estate investment trusts or regulated investment companies;
- former U.S. citizens or long-term residents of the United States;
- persons that own or are deemed to own 10% or more of the voting power or value of our shares; or
- persons holding ordinary shares in connection with a trade or business conducted outside of the United States or in connection with a permanent establishment or other fixed place of business outside of the United States.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares and partners in such partnerships should consult their tax advisers as to the particular U.S. federal income tax consequences of owning and disposing of the ordinary shares in their circumstances.

This discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between Ireland and the United States (the "Treaty"), all as of the date hereof, any of which is subject to change or differing interpretations, possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares, who is eligible for the benefits of the Treaty and who is:

- a citizen or individual resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws
  of the United States, any state therein or the District of Columbia; or
- an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ordinary shares in their particular circumstances.

Except where otherwise indicated, this discussion assumes that we are not, and will not become, PFIC, as described below.

#### **Taxation of Distributions**

As discussed above under "Dividend Policy," we do not currently expect to make distributions on our ordinary shares. In the event that we do make distributions of cash or other property, distributions paid on ordinary shares, other than certain *pro rata* distributions of ordinary shares, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not maintain calculations of our earnings and profits under U.S. Holders as dividends. Subject to the discussion under "—Passive Foreign Investment Company Rules" below, for so long as our ordinary shares are listed on Nasdaq or we are eligible for benefits under the Treaty, dividends paid to certain non-corporate U.S. Holders will be eligible for taxation as "qualified dividend income" and therefore, subject to applicable holding period requirements, will be taxable at rates not in excess of the long-term capital gain rate applicable to such U.S. Holder.

The amount of a dividend will include any amounts withheld by us in respect of Irish income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in Euros will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder's particular circumstances, Irish income taxes withheld from dividends on ordinary shares (at a rate not exceeding the rate provided by the Treaty) will be creditable against the U.S. Holder's U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any Irish income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

# Sale or Other Disposition of Ordinary shares

Gain or loss realized by a U.S. Holder on the sale or other disposition of ordinary shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder's holding period for such ordinary shares was more than one year as of the date of the sale or other disposition. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares disposed

of and the amount realized on the disposition, in each case as determined in U.S. dollars. Long-term capital gain recognized by a non-corporate U.S. Holder is subject to U.S. federal income tax at rates lower than the rates applicable to ordinary income and short-term capital gains, while short-term capital gains are subject to U.S. federal income tax at the rates applicable to ordinary income. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to various limitations.

#### Passive Foreign Investment Company Rules

Under the Code, we will be a PFIC for any taxable year in which, after the application of certain "lookthrough" rules with respect to our subsidiaries, either (i) 75% or more of our gross income consists of "passive income," or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, "passive income." For purposes of the above calculations, we will be treated as if we hold our proportionate share of the assets of, and receive directly our proportionate share of the income of, any other corporation in which we directly or indirectly own at least 25%, by value, of the shares of such corporation. Passive income generally includes dividends, interest, rents, certain non-active royalties, and capital gains. Based on our current operations, income, assets and certain estimates and projections, including as to the relative values of our assets, including goodwill, which is based on the expected price of our ordinary shares, we do not expect to be a PFIC for our 2021 taxable year. In addition, whether we will be a PFIC in 2021 or any future year is uncertain because, among other things, (i) we will hold a substantial amount of cash following this offering, which is generally categorized as a passive asset; (ii) our PFIC status for any taxable year will depend on the composition of our income and assets and the value of our assets from time to time (which may be determined, in part, by reference to the market price of our ordinary shares, which could be volatile), and (iii) the categorization of our goodwill as active or passive will depend on the character of our business assets and the law applicable to making this determination is subject to varying interpretation. Accordingly, there can be no assurance that we will not be a PFIC for any taxable year. If we are a PFIC for any year during which a U.S. Holder holds ordinary shares, we would generally continue to be treated as a PFIC with respect to such holder for all succeeding years during which such holder holds ordinary shares, even if we ceased to meet the threshold requirements for PFIC status.

If we were a PFIC for any taxable year and any of our subsidiaries or other companies in which we owned or were treated as owning equity interests were also a PFIC (any such entity, a "Lower-tier PFIC"), a U.S. Holder would be deemed to own a proportionate amount (by value) of the shares of each Lower-tier PFIC and would be subject to U.S. federal income tax according to the rules described in the subsequent paragraph on (i) certain distributions by a Lower-tier PFIC; and (ii) dispositions of shares of Lower-tier PFICs, in each case as if such holder held such shares directly, even though such holder will not have received the proceeds of those distributions or dispositions.

If we were a PFIC for any taxable year during which a U.S. Holder held any of our ordinary shares, such holder would generally be subject to adverse tax consequences. Generally, gain recognized upon a disposition (including, under certain circumstances, a pledge) of ordinary shares would be allocated ratably over a U.S. Holder's holding period for the ordinary shares. The amounts allocated to the taxable year of disposition and to years before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for that taxable year for individuals or corporations, as appropriate, and an interest charge would be imposed on the tax on such amount. Further, to the extent that any distributions received on a U.S. Holder's ordinary shares during a taxable year exceeded 125% of the average of the annual distributions on those shares during the preceding three years or such holder's holding period, whichever was shorter, those distributions would be subject to taxation in the same manner as gain, described immediately above.

Alternatively, if we were a PFIC and if the ordinary shares were "regularly traded" on a "qualified exchange," a U.S. Holder may avoid the general PFIC tax consequences discussed above if such U.S. Holder makes a mark-to-market election with respect to the ordinary shares at the close of the first taxable year in which such holder holds our ordinary shares. The ordinary shares would be treated as "regularly traded" for the year of this offering if more than a de minimis quantity of the ordinary shares

were traded on a qualified exchange on at least 1/6 of the days remaining in the quarter in which this offering occurs, and on at least 15 days during each remaining calendar quarter (the "15-Day Test"), and for years other than this year based on the 15-Day Test. Nasdaq, on which the ordinary shares are expected to be listed, is a qualified exchange for this purpose. Once made, the election cannot be revoked without the consent of the IRS unless the shares cease to be marketable.

If a U.S. Holder makes the mark-to-market election with respect to the first taxable year that we are a PFIC, such holder will generally recognize as ordinary income any excess of the fair market value of such holder's ordinary shares at the end of each taxable year in which we are a PFIC over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of such taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The U.S. Holder's tax basis in their ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). Any gain or loss recognized on the sale or other disposition of ordinary shares in a year when we are not a PFIC will generally be taxed in a manner described above under "-Sale or Other Dispositions of Ordinary Shares." Subject to the discussion in the immediately succeeding paragraph, any distributions will generally be taxed in a manner described above under "-Taxation of Distributions." This election will not apply to any of our non-U.S. subsidiaries. Accordingly, a U.S. Holder may continue to be subject to tax under the PFIC excess distribution regime with respect to any Lower-tier PFICs notwithstanding a mark-to-market election for the ordinary shares.

In addition, if we were a PFIC for any taxable year in which we paid a dividend or for the prior taxable year, the preferential dividend rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If a company that is a PFIC provides certain information to U.S. Holders, a U.S. Holder can then avoid certain adverse tax consequences described above by making a "qualified electing fund" election to be taxed currently on its proportionate share of the PFIC's ordinary income and net capital gains. However, because we do not intend to prepare or provide the information necessary for a U.S. Holder to make a qualified electing fund election, such election is not expected to be available to U.S. Holders.

U.S. Holders should consult their tax advisers regarding whether we are a PFIC and the potential application of the PFIC rules.

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC or in which we hold a direct or indirect equity interest in a Lower-tier PFIC, the U.S. Holder generally must file an annual report on IRS Form 8621 with respect to each such PFIC containing such information as the U.S. Treasury may require, generally with the U.S. Holder's U.S. federal income tax return for the relevant year. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with respect to the items required to be included in such report until three years after the U.S. Holder files the annual report and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period.

# PROSPECTIVE U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISERS REGARDING THE CONSEQUENCES OF OUR POTENTIAL PFIC STATUS ON AN INVESTMENT IN ORDINARY SHARES.

# Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the U.S. Holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

# Information with Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for ordinary shares held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisers regarding the effect, if any, of this legislation on their ownership and disposition of the ordinary shares.

#### Material Irish Tax Consequences

The following is a summary of the material Irish tax consequences for certain beneficial holders of ordinary shares. The summary is based upon Irish tax laws and the practice of the Revenue Commissioners of Ireland in effect on the date of this prospectus and correspondence with the Revenue Commissioners of Ireland. Changes in law and/or administrative practice may result in alteration of the tax considerations described below, possibly with retrospective effect.

The summary does not constitute tax advice and is intended only as a general guide. The summary is not exhaustive and holders of ordinary shares should consult their own tax advisors about the Irish tax consequences (and the tax consequences under the laws of other relevant jurisdictions) of this offering, including the acquisition, ownership and disposal of ordinary shares. The summary applies only to shareholders who will own ordinary shares as capital assets and does not apply to other categories of shareholders, such as dealers in securities, trustees, insurance companies, collective investment schemes and shareholders who have, or who are deemed to have, acquired ordinary shares by virtue of an Irish office or employment (performed or carried on in Ireland).

# Tax on Chargeable Gains

The current rate of tax on chargeable gains (where applicable) in Ireland is 33%.

A disposal of our ordinary shares by a shareholder who is not resident or ordinarily resident for tax purposes in Ireland will not give rise to Irish tax on any chargeable gain realized on such disposal unless such ordinary shares are used in or for the purposes of a trade carried on by such shareholder in Ireland through a branch or agency, are used or held or acquired for use by or for the purposes of such a branch or agency, or the shares derive the greater part of their value from Irish land.

A holder of our ordinary shares who is an individual and who is temporarily non-resident in Ireland may, under Irish anti-avoidance legislation, be liable to Irish tax on any chargeable gain realized on a disposal of our ordinary shares during the period in which such individual is non-resident.

# Stamp Duty

A transfer of shares of GH Research PLC from a seller who holds shares beneficially (i.e., through DTC) to a buyer who holds the acquired shares through DTC will not be subject to Irish stamp duty (unless the transfer involves a change in the nominee that is the record holder of the transferred shares).

A transfer of shares of GH Research PLC by a seller who holds shares directly to any buyer, or by a seller who holds the shares beneficially to a buyer who holds the acquired shares directly, may be subject

to Irish stamp duty (currently at the rate of 1% of the price paid or the market value of the shares acquired, if higher). Stamp duty is a liability of the buyer or transferee. A shareholder who holds shares of GH Research PLC directly may transfer those shares into his or her own broker account (or vice versa) without giving rise to Irish stamp duty provided there is no change in the ultimate beneficial ownership of the shares as a result of the transfer and the transfer is not in contemplation of a sale of the shares. In order to benefit from this exemption from stamp duty, the seller must confirm to GH Research PLC's transfer agent that there is no change in the ultimate beneficial ownership of the shares as a result of the transfer is not in contemplation of a sale of the shares as a result of the transfer agent that there is no change in the ultimate beneficial ownership of the shares as a result of the transfer is not in contemplation of a sale of the shares as a result of the transfer agent that there is no change in the ultimate beneficial ownership of the shares as a result of the transfer is not in contemplation of a sale of the shares as a result of the transfer and the transfer is not in contemplation of a sale of the shares.

Because of the potential Irish stamp duty on transfers of shares of GH Research PLC, any person who wishes to acquire shares of GH Research PLC should consider acquiring such shares through DTC.

# Withholding Tax on Dividends

We do not expect to pay dividends for the foreseeable future. To the extent that we do make dividend payments (or other returns to shareholders that are treated as "distributions" for Irish tax purposes), it should be noted that such distributions made by us will, in the absence of one of many exemptions, be subject to Irish dividend withholding tax, which is referred to in this prospectus as DWT, currently at a rate of 25%.

For DWT purposes, a distribution includes any distribution that may be made by us to our shareholders, including cash dividends, non-cash dividends and additional stock taken in lieu of a cash dividend. Where an exemption does not apply in respect of a distribution made to a particular shareholder, we are responsible for withholding DWT prior to making such distribution.

# **General Exemptions**

The following is a general overview of the scenarios where it will be possible for us to make payments of dividends without deduction of DWT.

Irish domestic law provides that a non-Irish resident shareholder is not subject to DWT on dividends received from us if such shareholder is beneficially entitled to the dividend and is either:

- a person (not being a company) resident for tax purposes in a Relevant Territory (including the United States) and is neither resident nor ordinarily resident in Ireland (the current list of Relevant Territories for DWT purposes are: Albania, Armenia, Australia, Austria, Bahrain, Belarus, Belgium, Bosnia & Herzegovina, Botswana, Bulgaria, Canada, Chile, China, Croatia, Cyprus, Czech Republic, Denmark, Egypt, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Hong Kong, Hungary, Iceland, India, Israel, Italy, Japan, Kazakhstan, Korea, Kuwait, Latvia, Lithuania, Luxembourg, Macedonia, Malaysia, Malta, Mexico, Moldova, Montenegro, Morocco, Netherlands, New Zealand, Norway, Pakistan, Panama, Poland, Portugal, Qatar, Romania, Russia, Saudi Arabia, Serbia, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Thailand, The Republic Of Turkey, Ukraine, United Arab Emirates, United Kingdom, United States, Uzbekistan, Vietnam and Zambia);
- a company which is not resident for tax purposes in Ireland but is resident for tax purposes in a Relevant Territory, provided such company is not under the control, whether directly or indirectly, of a person or persons who is or are resident in Ireland;
- a company, which is not resident for tax purposes in Ireland, that is controlled, directly or indirectly, by persons resident in a Relevant Territory and who is or are (as the case may be) not controlled by, directly or indirectly, persons who are not resident in a Relevant Territory;
- a company, which is not resident for tax purposes in Ireland, whose principal class of shares (or those of its 75% direct or indirect parent) is substantially and regularly traded on a stock exchange in Ireland, on a recognized stock exchange in a Relevant Territory or on such other stock exchange approved by the Irish Minister for Finance; or

a company, which is not resident for tax purposes in Ireland, that is wholly owned, directly or indirectly, by two or more companies where the principal class of shares of each of such companies is substantially and regularly traded on a stock exchange in Ireland, on a recognized stock exchange in a Relevant Territory or on such other stock exchange approved by the Irish Minister for Finance,

and provided, in all cases noted above, we have received from the shareholder, where required, the relevant DWT Form(s) prior to the payment of the dividend and such DWT Form(s) remain valid

For non-Irish resident shareholders that cannot avail themselves of one of Ireland's domestic law exemptions from DWT, it may be possible for such shareholders to rely on the provisions of a double tax treaty to which Ireland is party to reduce the rate of DWT.

Our shareholders that do not fall within any of the categories specifically referred to above may nonetheless fall within other exemptions from DWT (subject if required to certain administrative obligations being satisfied). If any shareholders are exempt from DWT, but receive dividends subject to DWT, such shareholders may apply for refunds of such DWT from the Revenue Commissioners of Ireland.

# Income Tax on Dividends Paid on our Ordinary Shares

Irish income tax may arise for certain persons in respect of dividends received from Irish resident companies. A shareholder that is not resident or, in the case of individuals, ordinarily resident in Ireland and that is entitled to an exemption from DWT generally has no liability to Irish income tax or the universal social charge on a dividend received from us. An exception to this position may apply where such shareholder holds our ordinary shares through a branch or agency in Ireland through which a trade is carried on.

A shareholder that is not resident or ordinarily resident in Ireland and that is not entitled to an exemption from DWT generally has no additional Irish income tax liability or a liability to the universal social charge. The DWT deducted by us discharges the liability to income tax. An exception to this position may apply where the shareholder holds our ordinary shares through a branch or agency in Ireland through which a trade is carried on.

# **Capital Acquisitions Tax**

Irish capital acquisitions tax, or CAT, comprises principally gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland for Irish CAT purposes as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 33% above certain tax-free thresholds. The appropriate tax free threshold is dependent upon (i) the relationship between the donor and the donee, and (ii) the aggregation of the values of previous taxable gifts and taxable inheritances received by the donee from persons within the same group threshold. Gifts and inheritances passing between spouses of the same marriage or civil partners of the same civil partnership are exempt from CAT. Children have a tax free threshold of €335 thousand in respect of taxable gifts or inheritances received from their parents. Our shareholders should consult their own tax advisors as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

There is also a "small gift exemption" from CAT whereby the first €3 thousand of the taxable value of all taxable gifts taken by a donee from any one donor, in each calendar year, is exempt from CAT and is also excluded from any future aggregation. This exemption does not apply to an inheritance.

THE IRISH TAX CONSIDERATIONS SUMMARIZED ABOVE ARE FOR GENERAL INFORMATION ONLY. HOLDERS OF OUR ORDINARY SHARES SHOULD CONSULT WITH THEIR TAX ADVISORS REGARDING THE TAX CONSEQUENCES IN IRELAND, INCLUDING RELATING TO THE ACQUISITION, OWNERSHIP AND DISPOSAL OF OUR ORDINARY SHARES.

# UNDERWRITING

We and Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated, as the representatives of the several underwriters for the offering named below, have entered into an underwriting agreement with respect to the ordinary shares being offered. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of ordinary shares set forth opposite its name below. Cowen and Company and Stifel, Nicolaus & Company, Incorporated are the representatives of the underwriters.

Underwriters	
Cowen and Company, LLC	
Stifel, Nicolaus & Company, Incorporated	
Canaccord Genuity LLC	
JMP Securities LLC	
Total	8,333,333

The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters have agreed, severally and not jointly, to purchase all of the ordinary shares sold under the underwriting agreement if any of these ordinary shares are purchased, other than those ordinary shares covered by the option to purchase additional ordinary shares described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the ordinary shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Option to Purchase Additional Ordinary Shares. We have granted to the underwriters an option to purchase up to additional ordinary shares at the public offering price, less the underwriting discounts and commissions. This option is exercisable for a period of 30 days from the date of this prospectus. To the extent that the underwriters exercise this option, the underwriters will purchase additional ordinary shares from us in approximately the same proportion as shown in the table above.

*Discounts and Commissions.* The following table shows the public offering price, underwriting discounts and commissions and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ordinary shares.

We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$3.5 million and are payable by us. We also have agreed to reimburse the underwriters for up to \$40,000 for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

			Total		
		Per Share	Without Option	With Option	
Public offering price					
Underwriting discount					
Proceeds, before expenses, to us					
	208				

The underwriters propose to offer the ordinary shares to the public at the public offering price set forth on the cover of this prospectus. The underwriters may offer the ordinary shares to securities dealers at the public offering price less a concession not in excess of \$ per share. If all of the ordinary shares are not sold at the public offering price, the underwriters may change the offering price and other selling terms. Sales of ordinary shares made outside of the United States may be made by affiliates of certain of the underwriters. Certain of the underwriters may sell ordinary shares through one or more of their affiliates as selling agents.

*Discretionary Accounts*. The underwriters do not intend to confirm sales of the ordinary shares to any accounts over which they have discretionary authority.

*Market Information.* Prior to this offering, there has been no public market for the ordinary shares. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In addition to prevailing market conditions, the factors to be considered in these negotiations will include:

- the history of, and prospects for, our company and the industry in which we compete;
- our past and present financial information;
- an assessment of our management; its past and present operations, and the prospects for, and timing of, our future revenue;
- the present state of our development; and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the ordinary shares may not develop. It is also possible that after the offering the ordinary shares will not trade in the public market at or above the initial public offering price.

We have applied to list our ordinary shares on Nasdaq under the symbol "GHRS."

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase ordinary shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the ordinary shares while the offering is in progress.
- Over-allotment transactions involve sales by the underwriters of ordinary shares in excess of the number of ordinary shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of ordinary shares over-allotted by the underwriters is not greater than the number of ordinary shares that they may purchase pursuant to the option to purchase additional ordinary shares. In a naked short position, the number of ordinary shares that the underwriters have the option to purchase. The underwriters may close out any short position by exercising their option to purchase additional ordinary shares and/or purchasing ordinary shares in the open market.
- Syndicate covering transactions involve purchases of ordinary shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of ordinary shares to close out the short position, the underwriters will consider, among other things, the price of ordinary shares available for purchase in the open market as compared with the price at which they may purchase ordinary shares through exercise of the option to purchase additional ordinary shares. If the underwriters sell more ordinary shares than could be covered by exercise of the option to purchase additional ordinary shares and, therefore, have a naked short position, the position can be closed out only by buying ordinary shares in the

open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the ordinary shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the ordinary shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our ordinary shares or preventing or retarding a decline in the market price of our ordinary shares. As a result, the price of our ordinary shares in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our ordinary shares. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

*Passive Market Making.* In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our ordinary shares on Nasdaq in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of ordinary shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, such bid must then be lowered when specified purchase limits are exceeded.

Lock-Up Agreements. Pursuant to certain "lock-up" agreements, we and our executive officers, directors and substantially all of our other shareholders have agreed, subject to certain exceptions, not to and will not cause or direct any of our affiliates to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into, or announce the intention to enter into, any swap, hedge or similar agreement or arrangement (including, without limitation, the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) that transfers, is designed to transfer or reasonably could be expected to transfer (whether by the stockholder or someone other than the stockholder) that transfers, in whole or in part, directly or indirectly the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act relating to, any ordinary shares or securities convertible into or exchangeable or exercisable for any ordinary shares without the prior written consent of Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated for a period of 180 days after the date of the pricing of the offering. Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated may waive the provisions of these agreements, in full or in part, at any time in their sole discretion.

This lock-up provision applies to ordinary shares and to securities convertible into or exchangeable or exercisable for ordinary shares. It also applies to ordinary shares owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The restrictions described herein do not apply to our directors, officers and securityholders with respect to:

- transactions relating to ordinary shares or any security convertible into ordinary shares acquired in the offering (other than any issuer-directed ordinary shares purchased in the offering by our officers or directors) or in open market transactions after the completion of the offering;
- transfers or distributions as a bona fide gift or for bona fide estate planning purposes or to a charitable organization or educational institution;

- (iii) transfers or distributions to any immediate family member of such person, affiliate or any trust or trustee or beneficiary thereof for the direct or indirect benefit of such person or the immediate family of such person (for this purpose, "immediate family" means any relationship by blood, marriage, domestic partnership or adoption, not more remote than first cousin);
- transfers or distributions to any corporation, partnership, limited liability company or other entity or affiliate of such person or the immediate family of such person;
- (v) transfers or distributions (a) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of such person upon the death of such person; (b) by operation of law pursuant to a domestic order or negotiated divorce settlement;
- (vi) transfers or distributions to another corporation, member, partnership, limited liability company, trust or other entity that is a direct or indirect affiliate (as defined under Rule 12b-2 of the Exchange Act), or to an investment fund or other entity that controls or manages, or is under common control with, such person, or distributions to partners, members, shareholders, beneficiaries or other equity holders of such person;
- (vii) transfers or distributions to us (a) in connection with the repurchase of such securities with respect to the termination of such person's employment with us or (b) pursuant to contractual arrangements described in this prospectus;
- (viii) transfers or distributions (including through a "cashless" exercise or on a "net exercise basis") to us in connection with the conversion of any convertible security into, or the exercise of any option or warrant for, ordinary shares (including to satisfy withholding obligations or the payment of taxes in connection therewith); provided that (a) any such ordinary shares received by such person shall be subject to the lock-up agreement and (b) no filing under Section 16(a) of the Exchange Act (or its foreign equivalent) reporting a reduction in beneficial ownership of ordinary shares shall be required or shall be voluntarily made during the restricted period;
- transfers or distributions prior to the date of the public filing of the registration statement of which this prospectus forms a part and pursuant to our shareholders' agreement;
- transfers or distributions to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (x) above, provided that any ordinary shares shall be subject to the terms of the lock-up agreement;
- (xi) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act (or its foreign equivalent) for the transfer of ordinary shares, provided that (a) such plan does not provide for the transfer of ordinary shares during the restricted period and (b) to the extent a public announcement or filing under the Exchange Act (or its foreign equivalent), if any, is required of or voluntarily made by or on behalf of such person or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of ordinary shares may be made under such plan during the restricted period;
- (xii) transfers or dispositions pursuant to a bona fide tender offer for our capital shares, merger, consolidation or other similar transaction made to all holders of our securities involving a change of control of us (including without limitation, the entering into of any lock-up, voting or similar agreement pursuant to which such person may agree to transfer, sell, tender or otherwise dispose of ordinary shares or any security convertible into ordinary shares in connection with such transaction) that has been approved by our board of directors; provided that, in the event that such change of control transaction is not consummated, this paragraph shall not be applicable and such person's shares and other securities shall remain subject to the lock-up agreement (for this purpose, "change of control" means the transfer whether by

tender offer, merger, consolidation or other similar transaction), in one transactions or a series of related transactions, to a person or group of affiliated persons (other than the underwriters pursuant to this offering), of our voting securities if, after such transfer, such person or group of affiliated persons would hold greater than 50% of our outstanding voting securities); or

(xiii) the conversion, exercise or exchange of our preferred shares, options to purchase ordinary shares, warrants or any security convertible into ordinary shares pursuant to any reorganization, conversion or share split, as such terms are described in this prospectus; provided that any such securities shall remain subject to the lockup agreement,

provided that, (1) with respect to paragraphs (ii)-(iv) and (vi) above, the representatives receive a signed lock-up agreement for the balance of the restricted period from each done, trustee, distribute or transferee, as the case may be, and (2) with respect to paragraphs (ii)-(vi) above, no public announcement or filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of ordinary shares, shall be required or voluntarily made during the restricted period (other than, in the case of a transfer or other disposition pursuant to paragraphs (v) and (vii), any Form 4 or 5 required to be filed under the Exchange Act (or its foreign equivalent) if such person is subject to Section 16 reporting with respect to our shares under the Exchange Act (or its foreign equivalent) shall indicate by footnote the nature of the transfer or disposition.

Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated, in their sole discretion, may release our ordinary shares and other securities subject to the lock-up agreements described above in whole or in part at any time. When determining whether or not to release our ordinary shares and other securities from lock-up agreements, Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated will consider, among other factors, the holder's reasons for requesting the release, the number of ordinary shares for which the release is being requested and market conditions at the time of the request. In the event of such a release or waiver for one of our directors or officers, Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated shall provide us with notice of the impending release or waiver at least three business days before the effective date of such release or waiver and we will announce the impending release or waiver.

*Other Relationships.* The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses. Cowen and Company, LLC, an underwriter of this offering, acted as a placement agent in connection with the private placement of our Series B Preferred Shares and received cash compensation in connection therewith. An affiliate of Cowen and Company, LLC is holder of an aggregate of 202,709 shares of our Series B preferred stock, which will automatically convert into an aggregate of 81,083 shares of our common stock in connection with this offering. Such shares were acquired during the sale of our Series B Preferred Shares in April 2021.

# **Selling Restrictions**

*Canada*. The ordinary shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the ordinary shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a

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misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to Section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

*Switzerland.* The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

*European Economic Area.* In relation to each member state of the European Economic Area, each a member state, no ordinary shares have been offered or will be offered pursuant to the offering to the public in that member state prior to the publication of a prospectus in relation to the ordinary shares which has been approved by the competent authority in that member state or, where appropriate, approved in another member state and notified to the competent authority in that member state, all in accordance with the Prospectus Regulation, except that ordinary shares may be made to the public in that member state at any time:

- (A) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- (B) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the underwriters; or
- (C) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ordinary shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to ordinary shares in any member state means the communication in any form and by any means of sufficient information on the terms of the offer and any ordinary shares to be offered so as to enable an investor to decide to purchase or subscribe for any ordinary shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

*United Kingdom.* No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

- (A) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- (B) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (C) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in

is:

relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Hong Kong. The ordinary shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the ordinary shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to ordinary shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

*Singapore.* Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has not offered or sold any ordinary shares or caused the ordinary shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any ordinary shares or cause the ordinary shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any ordinary shares or cause the ordinary shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ordinary shares, whether directly or indirectly, to any person in Singapore other than:

- (A) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;
- (B) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or
- (C) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the ordinary shares are purchased under Section 275 of the SFA by a relevant person which

- (A) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (B) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (however described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the ordinary shares pursuant to an offer made under Section 275 of the SFA except:



- to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (ii) where no consideration is or will be given for the transfer;
- (iii) where the transfer is by operation of law;
- (iv) as specified in Section 276(7) of the SFA; or
- (v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Singapore SFA Product Classification – In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of ordinary shares, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the ordinary shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

*Israel.* In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase ordinary shares under the Israeli Securities Law, 5728 - 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728 - 1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 - 1968, subject to certain conditions, collectively, the Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. We have not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 - 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our ordinary shares to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in the First Addendum to the Israeli Securities Law, 5728 - 1968. In particular, we may request, as a condition to be offered ordinary shares, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 - 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 - 1968 and the regulations promulgated thereunder in connection with the offer to be issued ordinary shares; (iv) that the ordinary shares that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 - 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 - 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the ordinary shares, other than the underwriters, is authorized to make any further offer of ordinary shares on our behalf or on behalf of the underwriters.

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*Electronic Offer, Sale and Distribution of Ordinary Shares.* A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically and Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated may agree to allocate a number of ordinary shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

#### **EXPENSES OF THIS OFFERING**

Set forth below is an itemization of the total expenses, excluding the underwriting discounts and commissions, which are expected to be incurred in connection with this offering. With the exception of the registration fee payable to the SEC, the Nasdaq listing fee and the filing fee payable to FINRA, all amounts are estimates.

Expense		Amount
SEC registration fee	\$	16,729
Nasdaq listing fee		210,000
FINRA filing fee		23,500
Printing expenses		100,000
Legal fees and expenses	2	,400,000
Accounting fees and expenses		300,000
Transfer agent and registrar fees and expenses		155,000
Miscellaneous fees and expenses		294,771
Total	\$3	3,500,000

## LEGAL MATTERS

We are being represented by Davis Polk & Wardwell LLP with respect to certain legal matters as to U.S. federal securities and New York State law. The underwriters are being represented by Cooley LLP with respect to certain legal matters as to U.S. federal securities and New York State law, and Arthur Cox LLP with respect to certain legal matters as to Irish law. The validity of the ordinary shares offered in this offering and legal matters as to Irish law will be passed upon for us by Dentons Ireland LLP.

#### **EXPERTS**

The financial statements as of December 31, 2020 and 2019 and for each of the two years in the period ended December 31, 2020 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers SA, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. PricewaterhouseCoopers SA is a member of EXPERTsuisse—Swiss Expert Association for Audit, Tax and Fiduciary.

The registered business address of PricewaterhouseCoopers SA is Avenue C.-F. Ramuz 45, Lausanne CH-1001, Switzerland.

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# SERVICE OF PROCESS AND ENFORCEMENT OF LIABILITIES

GH Research PLC is organized under the laws of Ireland and substantial portions of its assets will be located outside of the United States. In addition, certain members of the GH Research PLC board of directors, and certain members and officers of GH Research PLC, as well as certain experts named herein, reside outside the United States. As a result, it may be difficult for investors to effect service of process within the United States upon GH Research PLC or such other persons residing outside the United States upon GH Research PLC or such other persons residing outside the United States, or to enforce outside the United States judgments obtained against such persons in U.S. courts in any action, including actions predicated upon the civil liability provisions of the U.S. federal securities laws. In addition, it may be difficult for investors to enforce, in original actions brought in courts in jurisdictions located outside the United States, rights predicated upon the U.S. federal securities laws.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an internet site at www.sec.gov that contains reports, proxy and information statements and other information we have filed electronically with the SEC. As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We maintain a corporate website at www.ghres.com. The reference to our website is an inactive textual reference only and information contained in or connected to our website is not incorporated into this prospectus or the registration statement of which it forms a part.

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# **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of GH Research Ireland Limited

#### **Opinion on the Financial Statements**

We have audited the accompanying statement of financial position of GH Research Ireland Limited (the "Company") as of December 31, 2020 and 2019, and the related statement of comprehensive income, the statement of changes in equity, and the statement of cash flows for the years then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

# **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers SA

Lausanne, Switzerland April 20, 2021

We have served as the Company's auditor since 2020.

## **GH RESEARCH IRELAND LIMITED**

# Statement of comprehensive income

	Year	Year ended December 31,		
	Note	2020 \$'000	2019 \$'000	
Operating expenses				
Research and development		(338)	(296)	
General and administration		(108)	(14)	
Loss from operations		(446)	(310)	
Loss for the year		(446)	(310)	
Other comprehensive income/(expense)				
Items that may be reclassified to profit or loss				
Currency translation adjustment		212	(12)	
Total comprehensive loss for the year		(234)	(322)	
Attributable to owners:				
Loss for the year		(446)	(310)	
Comprehensive loss for the year		(234)	(322)	
Loss per share				
Basic and diluted loss per share (in USD)	12	(0.006)	(0.004)	
The economic increases to the financial statements are an in	to aval nort of these fine			

The accompanying notes to the financial statements are an integral part of these financial statements.

# **GH RESEARCH IRELAND LIMITED**

Statement of financial position

		At December 31,		
	Note	2020 \$'000	2019 \$'000	
ASSETS				
Current assets				
Cash		5,895	498	
Other current assets		17	6	
Total current assets		5,912	504	
Total assets		5,912	504	
LIABILITIES AND EQUITY				
Current liabilities				
Trade payables		1	93	
Other current liabilities	8	245	11	
Total current liabilities		246	104	
Total liabilities		246	104	
Equity attributable to owners				
Share capital	9	871	801	
Share premium		5,430	—	
Foreign currency translation reserve		200	(12)	
Accumulated deficit		(835)	<u>(389</u> )	
Total equity		5,666	400	
Total liabilities and equity		5,912	504	

The accompanying notes to the financial statements are an integral part of these financial statements.

# **GH RESEARCH IRELAND LIMITED**

# Statement of changes in equity

		Attributable to owners			
	Share capital \$'000 Note 9	Share premium \$'000	Foreign currency translation reserve \$'000	Accumulated deficit \$'000	Total \$'000
At January 1, 2019	801	_	_	(79)	722
Loss for the year	—	—	—	(310)	(310)
Translation adjustment		—	<u>(12</u> )		(12)
Total comprehensive loss for the year			<u>(12</u> )	<u>(310)</u>	(322)
At December 31, 2019	801		<u>(12</u> )	<u>(389</u> )	400
At January 1, 2020	801	_	(12)	(389)	400
Loss for the year	—	—	—	(446)	(446)
Translation adjustment			212		212
Total comprehensive loss for the year	_	_	212	(446)	(234)
Issue of share capital	70	5,430	_		5,500
Total transactions with owners	70	5,430	_		5,500
At December 31, 2020	871	5,430	200	<u>(835</u> )	5,666

The accompanying notes to the financial statements are an integral part of these financial statements.

# **GH RESEARCH IRELAND LIMITED**

Statement of cash flows

	Year ended December 31,		ber 31,
	Note	2020 \$'000	2019 \$'000
Cash flows from operating activities			
Loss for the year		(446)	(310)
Movement in working capital		116	21
Cash flows used in operating activities		(330)	(289)
Cash flows from financing activities			
Proceeds from capital contributions	9	5,500	797
Net increase in cash		5,170	508
Cash at the beginning of the year		498	_
Impact of foreign exchange on cash		227	(10)
Cash at the end of the year		5,895	498

The accompanying notes to the financial statements are an integral part of these financial statements.

#### 1. Corporate information

GH Research Ireland Limited (the "Company" or "GH Research"), formerly known as GH Research Limited, was incorporated on October 16, 2018 under the laws of Ireland with an authorized share capital of €1,000,000 divided into 100,000,000 shares of €0.01 each. The registered office of the Company is located at 28 Baggot Street Lower, Dublin 2, Ireland. The Company neither controls nor exercises significant influence over any other entities.

We are a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. Our initial focus is on developing our novel and proprietary 5-MeO-DMT therapies for the treatment of patients with Treatment Resistant Depression, or TRD. Our portfolio currently includes GH001, our proprietary inhalable 5-MeO-DMT product candidate, and GH002, our proprietary injectable 5-MeO-DMT product candidate.

These financial statements were presented to the board of directors and approved by them on April 9th, 2021.

# 2. Basis of preparation, significant judgments, and accounting policies

The basis of preparation, significant judgments and principal accounting policies applied in the preparation of these financial statements are set out below. These elements have been consistently applied to all the years presented. Only those accounting policies relevant to the transactions, balances and activities during the periods presented are disclosed. In particular, policies related to revenue recognition, consolidation and employee benefits (other than salary) are, at the balance sheet date, not applicable to the Company's activities.

## **Basis of preparation**

#### Compliance with International Financial Reporting Standards

These financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). The functional currency of the Company is the euro. The financial statements are presented in U.S. dollar rounded to the nearest thousand which is the Company's presentation currency.

#### Historical cost convention

The financial statements have been prepared under the historical cost convention.

#### Standards adopted by the Company

The Company has adopted all the financial reporting standards enacted at the balance sheet date. There are no standards issued but not yet adopted by the Company, which will have an impact on the financial statements.

#### Going concern basis

GH Research is a clinical-stage biopharmaceutical company developing innovative therapeutics. The Company is exposed to all risks inherent in establishing and developing its business, including the substantial uncertainty that current projects will succeed. Research and development expenses have been incurred from the start of the Company's activities, generating negative cash flows from operating activities since formation.

Since its incorporation, the Company has funded its growth through capital increases. The Company has never taken bank loans nor otherwise incurred debt on its balance sheet. As a result, the Company is not exposed to liquidity risk through requests for early repayment of loans.



In 2019, the Company received net cash proceeds of \$797 thousand from the issuance of ordinary shares.

In 2020, the Company received net cash proceeds of \$5.5 million from the issuance of Series A preferred shares.

In April 2021, the Company issued Series B preferred shares. Gross proceeds from the issuance of the shares are \$125.2 million (refer to note 13).

The board of directors believes that the Company has sufficient financial resources available to cover its planned cash outflows for the next twelve months from the date of issuance of these financial statements. Thus, the Company has concluded that there is no substantial doubt about its ability to continue as a going concern and has prepared the financial statements under the going concern assumption.

# Significant estimates and judgments

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. The estimate, assumption and judgment that has a risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year is addressed relative to the carrying value of tax operating losses and is described below.

# Deferred tax balances and the valuation of tax operating losses

During the period from incorporation to December 31, 2020, the Company has incurred tax losses, which are a potential benefit in the event that the Company reports a taxable profit in the future. In preparing these financial statements, the Company has assessed that the likelihood of a taxable profit is currently not sufficiently certain for these potential benefits to be recognized as a deferred tax asset. This assessment is based on the status of the research into the Company's principal investigational product and the significant challenges that remain before operating profits can be assured (refer to note 7 "Deferred income taxes").

# Accounting policies

#### Foreign currency translation

## Functional and presentation currency

Items included in the financial statement of the Company are measured using the currency of the primary economic environment in which the entity operates ("the functional currency") which is the euro. These financial statements are presented in U.S. dollars ("USD" or "Dollars"), which is the Company's presentation currency.

## Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

Share capital issuances are translated into U.S. dollars at the exchange rate prevailing when the contractual commitment is made. Foreign currency differences can arise on translation where the cash inflows are received in a different period to the contractual commitment.

#### Cash

Cash represents cash held on bank current accounts and is carried at amortized cost.

#### Trade payables and other current liabilities

Trade payables and other current liabilities are recognized initially at fair value and subsequently measured at amortized cost.

## Fair value estimation

At December 31, 2020, the carrying amount is considered to be identical to the fair value for the following financial assets and liabilities:

- Cash
- Other current assets
- Trade payables and other current liabilities

In 2020, there were no significant changes in the business or economic circumstances that affect the fair value of the Company's financial assets and financial liabilities.

#### Share capital and share premium

#### Share capital

The Company has issued two different classes of shares, all of which are classified as equity (see note 9 "Share capital").

# Share premium

Amounts of contribution in excess of par value are accounted for as share premium. Share premium also arises from additional capital contributions from shareholders. Incremental costs directly attributable to equity transactions such as the issue of new capital shares are shown in equity as a deduction, net of tax, from the proceeds within share premium. Transaction costs that relate to equity and non-equity transactions are allocated to those transactions using a basis of allocation that is rational and consistent with similar transactions.

## Leases and right-of-use assets

The Company recognizes a right-of-use asset and a corresponding lease liability for all arrangements in which it is a lessee, except for leases with a term of 12 months or less (short-term leases) and lowvalue leases. For these short-term and low-value leases, the Company recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease. Currently all of the Company's lease arrangements comply with the criteria for exception.

#### **Research and development costs**

Research and development costs consist of expenses incurred in performing research and development activities, including external costs of outside vendors engaged to manufacture clinical trial materials and conduct clinical development activities.

Research expenditure is recognized as an expense in the year in which it is incurred. Internal development expenditure is capitalized only if it meets the recognition criteria of IAS 38 "Intangible Assets". Where regulatory and other uncertainties are such that the criteria are not met, which is almost invariably the case prior to approval of the drug by the relevant regulatory authority, the expenditure is recognized in the income statement. Where, however, recognition criteria are met, internal development expenditure is capitalized and amortized on a straight-line basis over its useful economic life.

## General and administrative expenses

General and administrative expenses relate to the administration of the Company including salaries and related expenses, legal and accounting fees.

#### Current and deferred income tax

The tax expense for the period comprises current and deferred tax. Tax is recognized in the income statement, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case the related tax is recognized in other comprehensive income or directly in equity, respectively.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date where the Company generates taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Taxes on income are accrued in the same periods as the revenues and expenses to which they relate. Current income tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities.

Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences or the unused tax losses can be utilized. Deferred income tax assets from tax credit carry-forwards are recognized to the extent that the national tax authority confirms the eligibility of such a claim and that the realization of the related tax benefit through future taxable profits is probable.

#### Segment reporting

The Company is managed and operated as one business. A single management team that reports to the Chairman of the board of directors comprehensively manages the entire business. Accordingly, the Company views its business and manages its operations as one operational and reportable segment.

## Loss per share

Basic loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares in issue during the year.

## 3. Financial risk management

## **Financial risk factors**

The board of directors currently reviews the Company cash forecast and liquidity requirements. It considers that other financial risks are currently inconsequential to the Company's activities and outlook. More sophisticated tools for financial risk management will be implemented once such risks are deemed consequential.

#### Foreign exchange risk

The Company operates internationally and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to pounds sterling. Transaction exposure arises because the amount of local currency paid or received in transactions denominated in foreign currencies may vary due to changes in exchange rates. Foreign exchange risk arises from:

- forecast expenses denominated in a currency other than the entity's functional currency; and
- recognized assets and liabilities denominated in a currency other than the entity's functional currency.

Management believes that foreign exchange risk is minimal, as the Company currently maintains its cash balance in euro and its expenses are mainly incurred in euro. The Company currently has no revenue generating activities.



#### Credit risk

The Company is not currently exposed to significant credit risk except on its cash balances. The Company's cash balance is maintained with well established, highly rated financial institutions. As of December 31, 2020, the cash balance is held at one bank that has S&P's credit rating of BBB+. The Company does not invest in equity instruments or derivatives.

## Liquidity risk

Liquidity risk is the risk that the Company may not be able to generate sufficient cash resources to settle its obligations in full as they fall due or can do so only on terms that are materially disadvantageous. Prudent liquidity risk management implies maintaining sufficient cash to cover working capital requirements. Cash is monitored by the Company's management.

Funding and liquidity risks are reviewed regularly by the board of directors and management. The Company funds its capital requirements through capital raising.

## **Capital management**

The Company considers equity as equivalent to the IFRS equity on the balance sheet (including share capital, share premium and all other equity reserves attributable to the owners of the Company). The Company has no interest-bearing debt.

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern and to provide returns to its shareholders through advancing our investigational pharmaceutical product candidates towards regulatory approval.

## 4. Employee expenses

	Year ended	December 31,
	2020	2019
	\$'000	\$'000
Salary and related expenses	5	<u>0</u>

# 5. Leases

During 2020, the Company incurred lease expenses for short-term leases as follows:

	Year ended I	Year ended December 31,	
	2020	2019	
	\$'000	\$'000	
Lease expenses for short-term leases	5	0	

# 6. Income tax

The Company's expected tax charge/(credit) for each year is based on the applicable tax rate in Ireland and reconciles to the actual tax charge/(credit) as follows:

	Year ended	Year ended December 31,		
	2020	2019		
	\$'000	\$'000		
Loss before tax	446	310		
Tax credit calculated at the domestic tax rate 12.5%	(56)	(39)		
Tax effects of:				
Tax losses for which no deferred tax asset was recognized	56	39		
Tax charge/(credit)	0	0		

#### GH RESEARCH IRELAND LIMITED NOTES TO THE FINANCIAL STATEMENTS (continued) 7. Deferred income taxes

At December 31, 2020, the Company had unused net operating losses of \$835 thousand (2019: \$389 thousand). In order to utilize unused tax losses, the Company would need to be regarded as carrying on a trade for Irish corporate tax purposes. Once regarded as carrying on a trade and subject to other conditions being met, the unused tax losses can be carried forward indefinitely against future trading income. On this basis, the Company has decided not to recognize any deferred tax assets at December 31, 2020 or 2019.

# 8. Other current liabilities

Other current liabilities represent amounts accrued for the provision of manufacturing, research and consulting services.

#### 9. Share capital

Issued shares:	Ordinary shares (par value €0.01)	Series A Preferred shares (par value €0.01)	Total shares	Total (\$'000)
At January 1, 2019	70,000,000	_	70,000,000	801
Issuance of share capital				_
At December 31, 2019	70,000,000	_	70,000,000	801
Issuance of share capital		5,923,079	5,923,079	70
At December 31, 2020	70,000,000	5,923,079	75,923,079	<u>871</u>

In 2018, the Company issued 70,000,000 ordinary shares for which a receivable was recognized and the related cash flow occurred in 2019.

On November 2, 2020, the Company increased its share capital through the issuance of 5,384,617 Series A preferred shares at a par value of €0.01 resulting in proceeds of \$5 million. On December 22, 2020, a further increase of share capital was completed through the issuance of 538,462 Series A preferred shares resulting in proceeds of \$500 thousand. The Series A preferred shares benefit from a non-participating liquidation preference to a value of 1x multiple of invested capital. The holders of Series A preferred shares are entitled to receive dividends in proportion to the nominal value of their shareholding if dividends are paid to the holder of ordinary shares. Each Series A preferred share has one vote.

### Dividend

At the next ordinary Annual General Meeting, the board of directors will not propose any dividend in respect of fiscal year 2020 (2019: nil).

#### 10. Contingent liabilities and commitments

The Company has no contingent liabilities or material unavoidable commitments at the balance sheet date.

# 11. Related party disclosures

Parties are considered to be related if one party has the ability, directly or indirectly, to control the other party or exercise significant influence over the other party in making financial and operating decisions.

The following individuals and entities have been considered to be related parties as a result of the equity holding in the company:

Florian Schönharting

Theis Terwey

BVF Partners and affiliated companies

In addition, the following parties are also considered to be related parties:

All other members of the board of directors

GH Research OÜ (now liquidated)

Other than the issuance of share capital, there have been no transactions with related parties in 2020 or 2019.

# Key Management Compensation

Key management are those persons who have the authority and responsibility for planning, directing and controlling the activities of the Company. Key management is comprised of executive officers and the board of directors who served during the reporting period.

	Year ended	Year ended December 31,	
	2020	2019	
	\$'000	\$'000	
Salary and related expenses	<u>5</u>	<u>0</u>	

# 12. Loss per share

The Company's shares comprise two classes of shares, ordinary and Series A preferred. The net loss is allocated to each class pro rata to its weighted average number of shares in issue during the period. The basic loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares in issue during the period as follows:

	Ordinary shares	Series A Preferred shares
Year ended December 31, 2020		
Net loss attributable to shareholders (in \$'000)	(440)	(6)
Weighted average number of shares in issue	70,000,000	898,420
Basic and diluted loss per share (in USD)	(0.006)	(0.006)
Year ended December 31, 2019		
Net loss attributable to shareholders (in \$'000)	(310)	
Weighted average number of shares in issue	70,000,000	_
Basic and diluted loss per share (in USD)	(0.004)	_

# 13. Events after the reporting date

On March 29, 2021, GH Research Limited was re-registered as GH Research Ireland Limited.

On April 8, 2021, the Company issued 25,379,047 Series B preferred shares at a par value of €0.01. Gross proceeds from the issuance of the shares are \$125.2 million. The Series B preferred shares benefit from a non-participating liquidation preference to a value of 1x multiple of invested capital, the same as the Series A non-participating liquidation preference. The holders of Series B preferred shares are entitled to receive dividends in proportion to the nominal value of their shareholding if dividends are paid to the holders of ordinary shares and Series A preferred shares. Each Series B preferred share has one vote.

# **GH RESEARCH IRELAND LIMITED**

Condensed interim statement of comprehensive income

		Three n end Marc	ed
	Note	2021 \$'000	2020 \$'000
Operating expenses			
Research and development		(692)	(11)
General and administration		(448)	(8)
Loss from operations		<u>(1,140</u> )	(19)
Foreign currency translation differences		(9)	
Loss for the period		<u>(1,149</u> )	(19)
Other comprehensive income/(expense)			
Items that may be reclassified to profit or loss Currency translation adjustment		(202)	(6)
Total comprehensive loss for the period		<u>(1,351</u> )	(25)
Attributable to owners:			
Loss for the period		(1,149)	(19)
Comprehensive loss for the period		(202)	(6)
Loss per share			
Basic and diluted loss per share (in USD)	7	(0.015)	(0.000)
The accompanying notes are an integral part of these unaudited condensed inter	im finaı	ncial state	ements.

# **GH RESEARCH IRELAND LIMITED**

Condensed interim statement of financial position

		At March 31,	At December 31,
	Note	2021 \$'000	2020 \$'000
ASSETS			
Current assets			
Cash		4,576	5,895
Other current assets	3	961	17
Total current assets		5,537	5,912
Non-current assets			
Property, plant and equipment		19	
Total non-current assets		19	
Total assets		5,556	5,912
LIABILITIES AND EQUITY			
Current liabilities			
Trade payables		75	1
Other current liabilities		1,166	245
Total current liabilities		1,241	246
Total liabilities		1,241	246
Equity attributable to owners			
Share capital	4	871	871
Share premium		5,430	5,430
Foreign currency translation reserve		(2)	200
Accumulated deficit		<u>(1,984</u> )	(835)
Total equity		4,315	5,666
Total liabilities and equity		5,556	5,912

The accompanying notes are an integral part of these unaudited condensed interim financial statements.

# GH RESEARCH IRELAND LIMITED

# Condensed interim statement of changes in equity

	Attributable to owners				
	Share capital \$'000 Note 4	Share premium \$'000	Foreign currency translation reserve \$'000	Accumulated deficit \$'000	Total \$'000
At January 1, 2021	871	5,430	200	(835)	5,666
Loss for the period	—	_	_	(1,149)	(1,149)
Translation adjustment			<u>(202</u> )		(202)
Total comprehensive loss for the period			<u>(202</u> )	<u>(1,149</u> )	<u>(1,351</u> )
At March 31, 2021	871	5,430	<u>(2</u> )	<u>(1,984</u> )	4,315
At January 1, 2020	801	_	(12)	(389)	400
Loss for the period	—	—	—	(19)	(19)
Translation adjustment	_		(6)		<u>(6</u> )
Total comprehensive loss for the period	_		(6)	(19)	(25)
At March 31, 2020	801		(18)	(408)	375

The accompanying notes are an integral part of these unaudited condensed interim financial statements.

# **GH RESEARCH IRELAND LIMITED**

# Condensed interim statement of cash flows

	Three months ended March 31,	
	2021 \$'000	2020 \$'000
Cash flows from operating activities		
Loss for the period	(1,149)	(19)
Depreciation	1	—
Movement in working capital	61	(83)
Cash flows used in operating activities	(1,087)	(102)
Cash flows used in investing activities		
Purchase of property, plant and equipment	(21)	
Net decrease in cash	(1,108)	(102)
Cash at the beginning of the period	5,895	498
Impact of foreign exchange on cash	(211)	(8)
Cash at the end of the period	4,576	388

The accompanying notes are an integral part of these unaudited condensed interim financial statements.

## GH RESEARCH IRELAND LIMITED NOTES TO THE CONDENSED INTERIM FINANCIAL STATEMENTS

# 1. Corporate information

GH Research Ireland Limited (the "Company" or "GH Research") was originally incorporated on October 16, 2018 as GH Research Limited under the laws of Ireland with an authorized share capital of €1,000,000 divided into 100,000,000 shares of €0.01 each. GH Research Limited was re-registered as GH Research Ireland on March 29, 2021. The registered office of the Company is located at 28 Baggot Street Lower, Dublin 2, Ireland. The Company neither controls nor exercises significant influence over any other entities.

We are a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. Our initial focus is on developing our novel and proprietary 5-MeO-DMT therapies for the treatment of patients with Treatment Resistant Depression, or TRD. Our portfolio currently includes GH001, our proprietary inhalable 5-MeO-DMT product candidate, and GH002 our proprietary injectable 5-MeO-DMT product candidate.

These unaudited condensed interim financial statements were presented to the board of directors and approved by them on June 4, 2021.

#### 2. Basis of preparation, significant judgments, and accounting policies

#### **Basis of preparation**

#### Compliance with International Financial Reporting Standards

The unaudited condensed interim financial statements for the three months ended March 31, 2021 have been prepared in accordance with IAS 34 "Interim Financial Reporting". The unaudited condensed interim financial statements do not include all of the information required for full annual financial statements and should be read in conjunction with the financial statements for the year ended December 31, 2020 which were prepared in accordance with International Financial Reporting Standards ("IFRS"). The functional currency of the Company is the euro. The unaudited condensed interim financial statements are presented in U.S. dollar rounded to the nearest thousand which is the Company's presentation currency.

#### New and amended IFRS standards

There are no new IFRS standards, amendments to standards or interpretations that are mandatory for the financial year beginning on January 1, 2021, that are relevant to the Company and that have had any impact in the interim period. New standards, amendments to standards and interpretations that are not yet effective, which have been deemed by the Company as currently not relevant, are not listed here.

#### Going concern basis

GH Research is a clinical-stage biopharmaceutical company developing innovative therapeutics. The Company is exposed to all risks inherent in establishing and developing its business, including the substantial uncertainty that current projects will succeed. Research and development expenses have been incurred from the start of the Company's activities, generating negative cash flows from operating activities since formation.

Since its incorporation, the Company has funded its growth through capital increases. The Company has never taken bank loans nor otherwise incurred debt on its balance sheet. As a result, the Company is not exposed to liquidity risk through requests for early repayment of loans.

As of March 31, 2021, the Company's cash amounted to \$4.6 million (December 31, 2020: \$5.9 million).

# GH RESEARCH IRELAND LIMITED NOTES TO THE CONDENSED INTERIM FINANCIAL STATEMENTS (continued)

In April 2021, the Company issued Series B preferred shares. Gross proceeds from the issuance of the shares are \$125.2 million (refer to note 8).

The board of directors believes that the Company has sufficient financial resources available to cover its planned cash outflows for at least the next twelve months from the date of issuance of these unaudited condensed interim financial statements. Thus, the Company has concluded that there is no substantial doubt about its ability to continue as a going concern and has prepared these unaudited condensed interim financial statements under the going concern assumption.

# Use of estimates and judgments

The preparation of the unaudited condensed interim financial statements requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

In preparing these unaudited condensed interim financial statements, the significant judgements made by management in applying the Company's accounting policies and the key sources of estimation uncertainty included those that applied to the financial statements for the year ended December 31, 2020.

#### **Deferred Transaction Costs**

The Company capitalizes deferred transaction costs within other current assets. The deferred transaction costs will be offset against proceeds upon the consummation of the Series B Financing or an offering. Should the planned IPO be abandoned, the deferred IPO costs will be expensed immediately. The Company recorded \$0.8 million of deferred transaction costs as of March 31, 2021.

## Accounting policies

The accounting policies, presentation and methods of computation followed in the unaudited condensed interim financial statements are consistent with those applied in the Company's most recent annual financial statements and have been applied consistently to all periods presented in the unaudited condensed interim financial statements.

#### Property, plant and equipment

Property, plant and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

	Estimated Useful Life
IT equipment	3 years
Medical equipment	2 years

#### **Transaction costs**

Incremental transaction costs are capitalized as incurred and will be shown in equity as a deduction, net of tax, from the proceeds received from future financing rounds or an initial public offering. If the equity instruments are not subsequently issued, the transaction costs would be expensed.

# 3. Other current assets

Other current assets represent deferred transaction costs, VAT receivable and prepayments.

#### **GH RESEARCH IRELAND LIMITED**

NOTES TO THE CONDENSED INTERIM FINANCIAL STATEMENTS (continued)

4. Share capital

Issued and fully paid shares:	Ordinary shares (par value €0.01)	Series A Preferred shares (par value €0.01)	Total shares	Total (\$'000)
At December 31, 2020	70,000,000	5,923,079	75,923,079	871
Issuance of share capital				
At March 31, 2021	70,000,000	5,923,079	75,923,079	871

There were no share transactions in the three months ended March 31, 2021.

#### 5. Contingent liabilities and commitments

The Company has no contingent liabilities or material unavoidable commitments at the balance sheet date.

#### 6. Related party disclosures

Parties are considered to be related if one party has the ability, directly or indirectly, to control the other party or exercise significant influence over the other party in making financial and operating decisions.

The following individuals and entities have been considered to be related parties as a result of the equity holding in the company:

Florian Schönharting

Theis Terwey

BVF Partners and affiliated companies

In addition, the following parties are also considered to be related parties:

All other members of the Board of Directors

**GH Research PLC** 

There have been no transactions in the three months ended March 31, 2021 with related parties that had a material effect on the financial position or performance of the Company.

# 7. Loss per share

The Company's shares comprise two classes of shares, ordinary and Series A preferred. The net loss is allocated to each class pro rata to its weighted average number of shares in issue during the period. The basic loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares in issue during the period as follows:

	Ordinary shares	Series A Preferred shares
Three months ended March 31, 2021		
Net loss attributable to shareholders (in \$'000)	(1,059)	(90)
Weighted average number of shares in issue	70,000,000	5,923,079
Basic and diluted loss per share (in USD)	(0.015)	(0.015)
Three months ended March 31, 2020		
Net loss attributable to shareholders (in \$'000)	(19)	_
Weighted average number of shares in issue	70,000,000	_
Basic and diluted loss per share (in USD)	(0.000)	_

#### **GH RESEARCH IRELAND LIMITED**

# NOTES TO THE CONDENSED INTERIM FINANCIAL STATEMENTS (continued)

#### 8. Events after the reporting date

On April 8, 2021, the Company issued 25,379,047 Series B preferred shares at a par value of €0.01. Gross proceeds from the issuance of the shares are \$125.2 million. The Series B preferred shares benefit from a non-participating liquidation preference to a value of 1x multiple of invested capital, the same as the Series A non-participating liquidation preference. The holders of Series B preferred shares are entitled to receive dividends in proportion to the nominal value of their shareholding if dividends are paid to the holders of ordinary shares and Series A preferred shares. Each Series B preferred share has one vote.

On May 27, 2021, all shareholders of GH Research Ireland Limited exchanged each of the shares held by them in GH Research Ireland Limited for shares of GH Research PLC of the same share classes with the same shareholders rights as the shares held by them in GH Research Ireland Limited, and as a result, GH Research Ireland Limited became a wholly owned subsidiary of GH Research PLC.

On June 4, 2021, GH Research PLC granted the option to purchase 126,218 ordinary shares of GH Research PLC to Julie Ryan, Group Finance Director.

8,333,333 Ordinary Shares

# **GH Research PLC**

PRELIMINARY PROSPECTUS

, 2021

Cowen

Canaccord Genuity

Stifel

**JMP Securities** 

Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

#### PART II INFORMATION NOT REQUIRED IN PROSPECTUS

## Item 6. Indemnification of Directors and Officers.

To the fullest extent permitted by Irish law, our Constitution (which is substantially in the form attached as Exhibit 3.2 to this registration statement) will confer an indemnity on our directors and officers. However, this indemnity is limited by the Irish Companies Act, which prescribes that an advance commitment to indemnify only permits a company to pay the costs or discharge the liability of a director or corporate secretary where judgment is given in favor of the director or corporate secretary in any civil or criminal action in respect of such costs or liability, or where an Irish court grants relief because the director or corporate secretary acted honestly and reasonably and ought fairly to be excused. Any provision whereby an Irish company seeks to commit in advance to indemnify its directors or corporate secretary over and above the limitations imposed by the Irish Companies Act will be void under Irish law, whether contained in its Constitution or any contract between the company and the director or corporate secretary. This restriction does not apply to our executives who are not directors or other persons who would not be considered "officers" within the meaning of that term under the Irish Companies Act.

Our Constitution will also contain indemnification and expense advancement provisions for persons who are not directors or our corporate secretary.

We plan to purchase directors' and officers' liability insurance, as well as other types of insurance, for our directors, officers, employees and agents, which is permitted under our Constitution and the Irish Companies Act.

We and certain of our subsidiaries intend to enter into agreements to indemnify our directors to the maximum extent allowed under applicable law.

# Item 7. Recent Sales of Unregistered Securities.

During the past three years, we have issued and sold the securities described below without registering the securities under the Securities Act. The share and per share numbers set forth below do not give effect to the Share Consolidation, to be effected immediately and conditional upon the SEC declaring this registration statement effective.

Name or Class of Purchasers	Date of Sale or Issuance	Title of Securities	Number of Securities	Consideration (in millions of \$)
Various private equity investment funds, institutional investors, directors and officers	April 8, 2021	Series B preferred shares	25,379,047	125.2
Entities affiliated with BVF, directors, officers and private investors	November 2, 2020 December 22, 2020	Series A preferred shares	5,923,079	5.5
Entities affiliated with BVF, directors, officers and private investors	October 16, 2018 December 20, 2018	Ordinary Shares	70,000,000	0.8

In addition, on June 4, 2021, we granted the option to purchase 126,218 ordinary shares of GH Research PLC to Julie Ryan, Group Finance Director at an exercise price of \$4.93 per share.

The offers, sales and issuances of the securities described above were exempt from registration either (i) under Section 4(a)(2) of the Securities Act and the rules and regulations promulgated thereunder in that the transactions were between an issuer and sophisticated investors or members of its senior executive management and did not involve any public offering within the meaning of Section 4(a)(2), (ii) under Regulation S promulgated under the Securities Act in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States, (iii) under Rule 144A under the Securities Act in that the shares were offered and sold by the initial purchasers to qualified institutional buyers or (iv) under Rule 701 promulgated under the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation.

#### Item 8. Exhibits and Financial Statement Schedules

#### Exhibits

The exhibits to the registration statement are listed in the exhibit index attached hereto and are incorporated by reference herein.

#### **Financial Statement Schedules**

None. All schedules have been omitted because the information required to be set forth therein is not applicable or has been included in the financial statements and related notes.

# Item 9. Undertakings

- (a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- (c) The undersigned registrant hereby undertakes that:
  - (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
  - (2) For the purpose of determining any liability under the Securities Act of 1933, each posteffective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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# EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT
<u>1.1</u>	Form of Underwriting Agreement.
<u>3.1</u>	Constitution of GH Research PLC, as currently in effect.
<u>3.2</u>	Form of Constitution of GH Research PLC (to be adopted immediately prior to the completion of this offering).
<u>5.1</u>	Opinion of Dentons Ireland LLP.
<u>10.1</u>	Form of Registration Rights Agreement between the registrant and the shareholders listed therein.
<u>10.2</u>	GH Research PLC Share Option Plan.
<u>21.1*</u>	Subsidiaries of GH Research PLC.
<u>23.1</u>	Consent of independent registered public accounting firm.
<u>23.2</u>	Consent of Dentons Ireland LLP (included in Exhibit 5.1).
<u>24.1*</u>	Power of Attorney (included on signature page to this registration statement).

\* Previously filed.

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## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Dublin, Ireland, on the 21<sup>st</sup> day of June, 2021.

# GH RESEARCH PLC

By: /s/ Theis Terwey

Name: Theis Terwey

Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Theis Terwey Theis Terwey	Chief Executive Officer (Principal Executive Officer)	June 21, 2021
/s/ Julie Ryan Julie Ryan	Group Finance Director (Principal Financial Officer and Principal Accounting Officer)	June 21, 2021
* Magnus Halle	Managing Director, Ireland	June 21, 2021
* Florian Schönharting	Director	June 21, 2021
*	Director	June 21, 2021
Spike Loy *	Director	June 21, 2021
Michael Forer	Authorized representative in the United	June 21, 2021
Colleen A. De Vries *By: /s/ Julie Ryan	States	
Julie Ryan Attorney-in-Fact	_	

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Exhibit 1.1

# **GH Research PLC**

# [•] Ordinary Shares

# (Nominal Value \$[•] Each)

# **UNDERWRITING AGREEMENT**

[Date], 2021

COWEN AND COMPANY, LLC STIFEL, NICOLAUS & COMPANY, INCORPORATED

As Representatives of the several Underwriters

c/o Cowen and Company, LLC 599 Lexington Avenue New York, New York 10022

c/o Stifel, Nicolaus & Company, Incorporated 787 7<sup>th</sup> Avenue, 11<sup>th</sup> Floor New York, New York 10019

Dear Sirs and Madams:

1. *INTRODUCTORY.* GH Research PLC, a public limited company incorporated under the laws of Ireland (the "*Company*"), proposes to issue, pursuant to the terms of this Agreement (the "*Agreement*"), to the several underwriters named in <u>Schedule A</u> hereto (the "*Underwriters*," or, each, an "*Underwriter*"), an aggregate of [•] ordinary shares, nominal value \$0.025 each, of the Company (each, an "*Ordinary Share*"). The [•] Ordinary Shares to be issued by the Company are hereinafter referred to as the "*Firm Shares*." The Company also proposes to issue to the Underwriters, upon the terms and conditions set forth in Section 3 hereof, up to an additional [•] Ordinary Shares (the "*Optional Shares*"). The Firm Shares and, if and to the extent such option is exercised, the Optional Shares are referred to herein as the "*Shares*." Cowen and Company, LLC ("*Cowen*") and Stifel, Nicolaus & Company, Incorporated ("*Stifel*") are acting as representatives of the several Underwriters and in such capacity are hereinafter referred to as the "*Representatives*."

As described more fully in the Registration Statement, General Disclosure Package and Prospectus, in connection with and prior to the completion of the offering contemplated by this Agreement, (i) all shareholders of GH Research Ireland Limited, a private limited company incorporated under the laws of Ireland with registered number 635933, exchanged each of the shares held by them in GH Research Ireland Limited for the same amount of shares in the same class in GH Research PLC, a public limited company incorporated under the laws of Ireland with registered number 691405, (ii) GH Research PLC, a public limited company incorporated under the laws of Ireland with registered number 691405, (ii) GH Research Ireland Limited became a wholly owned subsidiary of GH Research PLC (iii) all of the Series A Preferred shares, nominal value \$0.01 each, in the Company will be converted into [•] Ordinary Shares, nominal value \$0.025 each (collectively, the "*Corporate Reorganization*").

2. *REPRESENTATIONS AND WARRANTIES OF THE COMPANY.* The Company represents and warrants to the several Underwriters, as of the date hereof and as of each Closing Date (as defined below), and agrees with the several Underwriters, that:

Registration Statement. A registration statement of the Company on Form F-1 (File No. 333-256796) (a) (including all amendments thereto, the "Initial Registration Statement") in respect of the Shares has been filed with the Securities and Exchange Commission (the "*Commission*"). The Initial Registration Statement and any post-effective amendment thereto, each in the form heretofore delivered to you, and, excluding exhibits thereto, to you for each of the other Underwriters, have been declared effective by the Commission in such form and meet the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the rules and regulations of the Commission thereunder (the "Rules and Regulations"). Other than (i) the Initial Registration Statement, (ii) a registration statement, if any, increasing the size of the offering filed pursuant to Rule 462(b) under the Securities Act and the Rules and Regulations (a "Rule 462(b) Registration Statement"), (iii) any Preliminary Prospectus (as defined below), (iv) the Prospectus (as defined below) contemplated by this Agreement to be filed pursuant to Rule 424(b) of the Rules and Regulations in accordance with Section 4(a) hereof and (v) any Issuer Free Writing Prospectus (as defined below), no other document with respect to the offer or sale of the Shares has heretofore been filed with the Commission. No stop order suspending the effectiveness of the Initial Registration Statement, any post-effective amendment thereto or the Rule 462(b) Registration Statement, if any, has been issued and no proceeding for that purpose or pursuant to Section 8A of the Securities Act has been initiated or, to the Company's knowledge, threatened by the Commission (any preliminary prospectus included in the Initial Registration Statement or filed with the Commission pursuant to Rule 424 of the Rules and Regulations is hereinafter called a "Preliminary Prospectus"). The Initial Registration Statement including all exhibits thereto and including the information contained in the Prospectus filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations and deemed by virtue of Rule 430A under the Securities Act to be part of the Initial Registration Statement at the time it became effective is hereinafter collectively called the "*Registration Statement*." If the Company has filed a Rule 462(b) Registration Statement, then any reference herein to the term "Registration Statement" shall be deemed to include such Rule 462 Registration Statement. The final prospectus, in the form filed pursuant to and within the time limits described in Rule 424(b) under the Rules and Regulations, is hereinafter called the "*Prospectus*."

(b) <u>General Disclosure Package</u>. As of the Applicable Time (as defined below) and as of the Closing Date or the Option Closing Date (as defined below), as the case may be, neither (i) the General Use Free Writing Prospectus(es) (as defined below) issued at or prior to the Applicable Time, the Pricing Prospectus (as defined below) and the information included on <u>Schedule C</u> hereto, all considered together (collectively, the "*General Disclosure Package*"), (ii) any individual Limited Use Free Writing Prospectus (as defined below), (iii) the bona fide electronic roadshow (as defined in Rule 433(h)(5) of the Rules and Regulations); nor (iv) any individual Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included or will include any untrue statement of a material fact or omitted or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided, however*, that the Company makes no representations or warranties as to information contained in or omitted from the Pricing Prospectus or any Issuer Free Writing Prospectus (as defined below), in reliance upon, and in conformity with, written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information (as defined in Section 18). As used in this paragraph (b) and elsewhere in this Agreement:

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"*Applicable Time*" means [•] [A/P].M., New York time, on the date of this Agreement or such other time as agreed to by the Company and the Representatives.

*"Pricing Prospectus"* means the Preliminary Prospectus relating to the Shares that is included in the Registration Statement immediately prior to the Applicable Time.

"*Issuer Free Writing Prospectus*" means any "issuer free writing prospectus," as defined in Rule 433 of the Rules and Regulations relating to the Shares in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) of the Rules and Regulations.

"General Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is identified on <u>Schedule B</u> to this Agreement.

"*Limited Use Free Writing Prospectuses*" means any Issuer Free Writing Prospectus that is not a General Use Free Writing Prospectus.

*"Written Testing-the-Waters Communication"* means any Testing-the-Waters Communication (as defined below) that is a written communication within the meaning of Rule 405 of the Rules and Regulations.

(c) <u>No Stop Orders; No Material Misstatements</u>. No order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus relating to the proposed offering of the Shares has been issued by the Commission, and no proceeding for that purpose or pursuant to Section 8A of the Securities Act has been instituted or threatened by the Commission, and each Preliminary Prospectus, at the time of filing thereof, conformed in all material respects to the requirements of the Securities Act and the Rules and Regulations, and did not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided, however*, that the Company makes no representations or warranties as to information contained in or omitted from any Preliminary Prospectus, in reliance upon, and in conformity with, written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information.

(d) <u>Registration Statement and Prospectus Contents</u>. At the respective times the Registration Statement and any amendments thereto became or become effective as to the Underwriters and at each Closing Date, the Registration Statement and any amendments thereto conformed and will conform in all material respects to the requirements of the Securities Act and the Rules and Regulations and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading; and the Prospectus and at each Closing Date, conformed and will conform in all material respects to the requirements of the Securities Act and the Rules and Regulations and did not and will conform in all material respects to the requirements of the Securities Act and the Rules and Regulations and did not and will conform in all material respects to the requirements of the Securities Act and the Rules and Regulations and did not and will not contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading; *provided, however*, that the foregoing representations and warranties in this paragraph (d) shall not apply to information contained in or omitted from the Registration Statement, or the Prospectus, or any amendment or supplement thereto, in reliance upon, and in conformity with, written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information.

(e) <u>Issuer Free Writing Prospectus</u>. Each Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Shares or until any earlier date that the Company notified or notifies the Representatives as described in Section 4(f), did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Pricing Prospectus or the Prospectus, or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, *provided*, *however*, that the foregoing representations and warranties in this paragraph (e) shall not apply to information contained in or omitted from the Registration Statement, or the Prospectus, or any amendment or supplement thereto, in reliance upon, and in conformity with, written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information.

(f) <u>Foreign Private Issuer</u>. The Company is a "foreign private issuer" within the meaning of Rule 405 under the Securities Act.

(g) <u>Distribution of Offering Materials</u>. The Company has not, directly or indirectly, distributed and will not distribute any offering material in connection with the offering and sale of the Shares other than any Preliminary Prospectus, the Prospectus and other materials, if any, permitted under the Securities Act and consistent with Section 4(c) below. The Company will file with the Commission all Issuer Free Writing Prospectuses (other than a "road show" as described in Rule 433(d)(8) of the Rules and Regulations) in the time and manner required under Rules 163(b)(2) and 433(d) of the Rules and Regulations. From and after twelve (12) months prior to the date of this Agreement, the Company has not taken any action which would constitute an offer of the Shares to the public in any Member State of the European Economic Area and the United Kingdom (each, a "*Relevant State*") for which a prospectus would need to be approved and published, in accordance with the Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the Shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129, as amended.

(h) <u>Emerging Growth Company</u>. From the time of the initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communications) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "*Emerging Growth Company*"). "*Testing-the-Waters Communication*" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) or 163B of the Securities Act.

(i) <u>Not an Ineligible Issuer</u>. At the time of filing the Initial Registration Statement, any Rule 462(b) Registration Statement and any post-effective amendments thereto, and at the date hereof, the Company was not, and the Company currently is not, an "ineligible issuer," as defined in Rule 405 of the Rules and Regulations.

(j) <u>Testing the Waters Communications</u>. The Company (a) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (b) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications.

(k) Incorporation and Good Standing. The Company and each of its subsidiaries (as defined in Section 15) have been duly incorporated and are validly existing as corporations or other legal entities in good standing (or such equivalent concept to the extent it exists in Ireland) under the laws of Ireland. The Company and each of its subsidiaries are duly qualified to do business and are in good standing as foreign corporations or other legal entities in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification and have the corporate power and authority necessary to own or hold their respective properties and to conduct the businesses in which they are engaged, except where the failure to so qualify or have such power or authority would not (i) have, singularly or in the aggregate, a material adverse effect on the business, properties, management, financial position, shareholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole, or (ii) impair in any material respect the ability of the Company to perform its obligations under this Agreement or to consummate any transactions contemplated by this Agreement, the General Disclosure Package or the Prospectus (any such effect as described in clauses (i) or (ii), a "Material Adverse Effect"). The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21 to the Registration Statement

Company.

(l)

<u>Underwriting Agreement</u>. This Agreement has been duly authorized, executed and delivered by the

(m) <u>The Shares</u>. The Shares to be issued and sold by the Company to the Underwriters hereunder have been duly and validly authorized and, when issued and delivered against payment therefor as provided herein, will be duly and validly issued, fully paid and non-assessable and will conform in all material respects to the descriptions thereof in the Registration Statement, the General Disclosure Package and the Prospectus; and the issuance of the Shares is not subject to any preemptive or similar rights.

(n) <u>Corporate Reorganization</u>. The agreements entered into to give effect to the Corporate Reorganization (the "*Reorganization Agreements*") constitute valid and legally binding obligations of each of the Company and its subsidiaries (as applicable), enforceable in accordance with their respective terms, and each of the Company and its subsidiaries (as applicable) has the full right, power and authority to execute and deliver the Reorganization Agreements and to perform their obligations thereunder, and the transactions contemplated thereby have been carried out in accordance with all applicable laws.

Capitalization. The authorized, issued and outstanding share capital of the Company is, and upon (0)completion of the Corporate Reorganization will be, as set forth in the Registration Statement, the Pricing Prospectus and the Prospectus under the caption "Capitalization" as of the respective dates set forth therein. The Company has an authorized capitalization as set forth under the heading "Capitalization" in the Pricing Prospectus, and all of the issued share capital of the Company have been duly and validly authorized and issued, are fully paid and non-assessable have been issued in compliance with the Company's memorandum and articles of association and applicable company and federal and state securities laws, and conform to the description thereof contained in the General Disclosure Package and the Prospectus. All of the Company's options, warrants and other rights to purchase or exchange any securities for shares of the Company's share capital have been duly authorized and validly issued and were issued in compliance with applicable company and securities laws. None of the outstanding Ordinary Shares were issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. As of the date set forth in the General Disclosure Package, there were no authorized or outstanding share capital, options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those described above or accurately described in the General Disclosure Package. Since such date, the Company has not issued any securities other than Ordinary Shares issued pursuant to the exercise of warrants or upon the exercise of stock options or other awards outstanding under the Company's stock option plans, options or other securities granted or issued pursuant to the Company's existing equity compensation plans or other plans, and the issuance of Ordinary Shares pursuant to employee stock purchase plans. The description of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, as described in the General Disclosure Package and the Prospectus, accurately and fairly present the information required to be shown with respect to such plans, arrangements, options and rights. All the outstanding share capital (if any) of each subsidiary of the Company have been duly authorized and validly issued, are fully paid and nonassessable and, except to the extent set forth in the General Disclosure Package or the Prospectus, are owned by the Company directly or indirectly through one or more wholly-owned subsidiaries, free and clear of any claim, lien, encumbrance, security interest, restriction upon voting or transfer or any other claim of any third party.

No Conflicts. The execution, delivery and performance of this Agreement by the Company, and of each (p) of the Reorganization Agreements by the Company and its subsidiaries (as applicable), the issue and sale of the Shares by the Company, and the consummation of the transactions contemplated hereby will not (with or without notice or lapse of time or both) (i) conflict with or result in a breach or violation of any of the terms or provisions of, constitute a default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, encumbrance, security interest, claim or charge upon any property or assets of the Company or any subsidiary pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, (ii) result in any violation of the provisions of the articles of association (or analogous governing instruments, as applicable) of the Company or any of its subsidiaries or (iii) result in the violation of any federal, state, local or foreign law, statute, rule, regulation, judgment, order or decree of any court or governmental or regulatory agency or body, domestic or foreign, having jurisdiction over the Company or any of its subsidiaries or any of their properties or assets except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation or default that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. A "Debt Repayment Triagering Event" means any event or condition that gives, or with the giving of notice or lapse of time would give the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(q) <u>No Consents Required</u>. Except for the registration of the Shares under the Securities Act and applicable state securities laws and such consents, approvals, authorizations, orders and registrations or qualifications as may be required by the Financial Industry Regulatory Authority (*"FINRA"*), The Nasdaq Global Market (the *"Exchange"*), or in connection with the purchase and distribution of the Shares by the Underwriters, the listing of the Shares on the Exchange, no consent, approval, authorization or order of, or filing, qualification or registration (each, an *"Authorization"*) with, any court, governmental or regulatory agency or body, foreign or domestic, which has not been made, obtained or taken and is not in full force and effect, is required for the execution, delivery and performance of this Agreement by the Company, the issuance and sale of the Shares, or the consummation of the transactions contemplated hereby; and no event has occurred that allows or results in, or after notice or lapse of time or both would allow or result in, revocation, suspension, termination or invalidation of any such Authorization or any other impairment of the rights of the holder or maker of any such Authorization. All corporate approvals (including those of stockholders) necessary for the Company to consummate the transactions contemplated by this Agreement have been obtained and are in effect.

(r) <u>Independent Auditors</u>. PricewaterhouseCoopers Ltd, who have certified certain financial statements of the Company and its subsidiaries included in the Registration Statement, the General Disclosure Package and the Prospectus, and have audited the Company's internal control over financial reporting and management's assessment thereof, is an independent registered public accounting firm with respect to the Company and its subsidiaries within the meaning of Article 2-01 of Regulation S-X and the Public Company Accounting Oversight Board (United States) (the "*PCAOB*") and applicable laws of Ireland.

Financial Statements. The financial statements, together with the related notes, included in the General (s) Disclosure Package, the Prospectus and in the Registration Statement present fairly in all material respects the financial position and the results of operations and changes in financial position of the Company and its subsidiaries at the respective dates or for the respective periods therein specified. Such statements and related notes have been prepared in accordance with the International Financial Reporting Standards ("IFRS") applied on a consistent basis throughout the periods involved except as may be set forth in the related notes included in the General Disclosure Package. The financial statements, together with the related notes, included in the General Disclosure Package and the Prospectus comply in all material respects with Regulation S-X. No other financial statements or supporting schedules or exhibits are required by Regulation S-X to be described or included in the Registration Statement, the General Disclosure Package or the Prospectus. There is no pro forma financial information which is required to be included in the Registration Statement, the General Disclosure Package or the Prospectus in accordance with Regulation S-X which has not been included or incorporated as so required. The summary and selected financial data included in the General Disclosure Package, the Prospectus and the Registration Statement present fairly in all material respects the information shown therein as at the respective dates and for the respective periods specified and are derived from the consolidated financial statements set forth in the Registration Statement, the Pricing Prospectus and the Prospectus and other financial information. All information contained in the Registration Statement, the General Disclosure Package and the Prospectus regarding "non-IFRS financial measures" (as defined in Regulation G) complies with Regulation G and Item 10 of Regulations S-K, to the extent applicable.

(t) <u>No Material Adverse Change</u>. Neither the Company nor any of its subsidiaries has sustained, since the date of the latest audited financial statements included in the General Disclosure Package, (i) any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or action, order or decree of any court or governmental or regulatory authority, otherwise than as set forth or contemplated in the General Disclosure Package, (ii) any change in the capital stock (other than changes as a result of the Corporate Reorganization and/or the issuance of Ordinary Shares upon exercise of stock options and warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Registration statement, the General Disclosure Package and the Prospectus) or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse changes, or any development that would reasonably be expected to result in a prospective material adverse change, in or affecting the business, properties, assets, general affairs, management, financial position, prospects, shareholders' equity or results of operations of the Company and its subsidiaries taken as a whole, otherwise than as set forth or contemplated in the General Disclosure Package.

(u) <u>Legal Proceedings</u>. Except as set forth in the General Disclosure Package, there is no legal or governmental proceeding pending to which the Company or any of its subsidiaries is a party or of which any property or assets of the Company or any of its subsidiaries is the subject that is required to be described in the Registration Statement, the General Disclosure Package or the Prospectus and is not described therein, or which, singularly or in the aggregate, if determined adversely to the Company or any of its subsidiaries, could reasonably be expected to have a Material Adverse Effect; and no such proceedings are threatened or, to the Company's knowledge, contemplated by governmental or regulatory authorities or threatened by others.

(v) Healthcare Regulatory Proceedings. Except as set forth in the General Disclosure Package, there is no legal or governmental proceeding to which the Company or any of its subsidiaries is a party or of which any property or assets of the Company or any of its subsidiaries is the subject, including any proceeding before the United States Food and Drug Administration of the U.S. Department of Health and Human Services ("FDA"), the Drug Enforcement Administration ("DEA"), the European Medicines Agency ("EMA"), the Medicines and Healthcare Products Regulatory Agency ("MHRA") or comparable federal, state, local or foreign governmental bodies (it being understood that the interaction between the Company and its subsidiaries, and the FDA, the DEA, the EMA, the MHRA and such comparable governmental bodies relating to the clinical development and product approval process shall not be deemed proceedings for purposes of this representation), which is required to be described in the Registration Statement, the General Disclosure Package or the Prospectus and is not described therein, or which, singularly or in the aggregate, if determined adversely to the Company or any of its subsidiaries, could reasonably be expected to have a Material Adverse Effect; and no such proceedings are threatened in writing or, to the Company's knowledge, contemplated by governmental or regulatory authorities. The Company is in compliance with all applicable federal, state, local and foreign laws, regulations, orders and decrees governing its business as prescribed by the FDA, the DEA, the EMA, the MHRA or any other federal, state or foreign agencies or bodies engaged in the regulation of pharmaceuticals or biohazardous substances or materials, except where noncompliance would not, singly or in the aggregate, have a Material Adverse Effect. All preclinical and clinical studies conducted by or on behalf of the Company to support approval for commercialization of the Company's products have been conducted by the Company, or to the Company's knowledge by third parties, in compliance with all applicable federal, state or foreign laws, rules, orders and regulations, except for such failure or failures to be in compliance as could not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect. Neither the Company nor any of its subsidiaries is a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company, any of its subsidiaries nor, any of their respective employees, officers, directors, or, to the Company's knowledge, their respective agents has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

(w) <u>No Violation or Default</u>. Neither the Company nor any of its subsidiaries is (i) in violation of its articles of association (or analogous governing instrument, as applicable), (ii) in default in any respect, and no event has occurred which, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement, lease or other agreement or instrument to which it is a party or by which it is bound or to which any of its property or assets is subject or (iii) in violation in any respect of any law, ordinance, governmental rule, regulation or court order, decree or judgment to which it or its property or assets may be subject (including, without limitation, those administered by the FDA, the DEA, the EMA, the MHRA or by any foreign, federal, state or local governmental or regulatory authority performing functions similar to those performed by the FDA, the DEA, the EMA, the MHRA) except, in the case of clauses (ii) through (iii) above, for any such violation or default that would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect.

Licenses or Permits. The Company and each of its subsidiaries possess all licenses, certificates, (x) authorizations and permits issued by, and have made all declarations and filings with, the appropriate local, state, federal or foreign governmental or regulatory agencies or bodies (including, without limitation, those administered by the FDA, the DEA, the EMA, the MHRA and any other state, federal, national and foreign agencies or bodies performing similar functions to the FDA, the DEA, the EMA and MHRA or engaged in the regulation of pharmaceuticals or biohazardous materials) that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the General Disclosure Package and the Prospectus (collectively, the "Governmental Permits") except where any failures to possess or make the same would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company and its subsidiaries are in compliance with all such Governmental Permits, except where the failure so to comply would not, singularly or in the aggregate, reasonably be expected to result in a Material Adverse Effect; all such Governmental Permits are valid and in full force and effect, except where the validity or failure to be in full force and effect would not, singularly or in the aggregate, have a Material Adverse Effect. Neither the Company nor any subsidiary has received notification of any revocation, modification, suspension, termination or invalidation (or proceedings related thereto) of any such Governmental Permit, which, singularly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to result in a Material Adverse Effect. The Company has no reason to believe that any such Governmental Permit will not be renewed, except where the failure to renew would not, singularly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The Company and each of its subsidiaries have filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any applicable laws or Governmental Permits, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all material respects (or were corrected or supplemented by a subsequent submission).

Regulatory Matters. The studies, tests and preclinical studies or clinical trials conducted by or on behalf (v) of the Company that are described in the General Disclosure Package and the Prospectus (the "Company Studies and Trials") were and, if still pending, are being, conducted in all material respects with all applicable federal, state and foreign laws, rules, orders and regulations, as well as in accordance with experimental protocols that were submitted to the relevant regulatory authority; the descriptions of the results of the Company Studies and Trials contained in the Registration Statement, General Disclosure Package and Prospectus are accurate in all material respects; the Company has no knowledge of any other studies or trials not described in the General Disclosure Package and the Prospectus, the results of which are inconsistent with or call in question the results described or referred to in the General Disclosure Package and the Prospectus; and the Company has not received any written notices or correspondence with the FDA, the DEA, the EMA, the MHRA or any foreign, state or local governmental body exercising comparable authority requiring the termination, suspension or material modification of any Company Studies or Trials that termination, suspension or material modification would reasonably be expected to have a Material Adverse Effect and, to the Company's knowledge, there are no reasonable grounds for the same. The Company has obtained (or caused to be obtained) informed consent by or on behalf of each human subject who participated in the Company Studies and Trials. In using or disclosing patient information received by the Company in connection with the Company Studies or Trials, the Company has complied in all material respects with all federal, state, local or foreign applicable laws and regulatory rules or requirements, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 and the rules and regulations thereunder ("HIPAA"). Neither the Company, nor its subsidiaries or any of their respective directors, officers, employees or, to the Company's knowledge, agents is or has been debarred, suspended or excluded, or has been convicted of any crime or, to the knowledge of the Company or its subsidiaries, engaged in any conduct that would result in a debarment, suspension or exclusion from any U.S. federal or state government health care program or human clinical research. To the Company's knowledge, none of the Company Studies and Trials involved any investigator, as such term is defined in Title 21, Section 50.3 of the U.S. Code of Federal Regulations, who has been disqualified as a clinical investigator or has been found by the FDA to have engaged in scientific misconduct. To the Company's knowledge, the manufacturing facilities and operations of its suppliers are operated in compliance in all material respects with all applicable statutes, rules and regulations of the FDA, the DEA, the EMA, the MHRA or comparable regulatory agencies outside of the United States to which the Company is subject.

Regulatory Compliance. Neither the Company nor any of its subsidiaries has received any unresolved (z) FDA Form 483, notice of adverse filing, warning letter, untitled letter or other correspondence or notice from the FDA, or any other court or arbitrator or federal, state, local, or foreign governmental or regulatory authority, alleging or asserting noncompliance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) (the "FDCA"). The Company and its subsidiaries and their respective directors, officers, employees and agents is and have been in material compliance with applicable health care laws, including without limitation, the FDCA, the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)), the civil False Claims Act (31 U.S.C. §3729 et seq.), the criminal False Claims Law (42 U.S.C. §1320a-7b(a), 18 U.S.C. §§286 and 287, the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (42 U.S.C. § 17921 et seq.), the exclusions law (42 U.S.C. §1320a-7), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), and the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, including without limitation, the Physician Payments Sunshine Act (42 U.S.C. §1320a-7h), and the regulations promulgated pursuant to such laws, and comparable state laws, and all other local, state, federal, national, supranational, and foreign laws, manual provisions, policies and administrative guidance relating to the regulation of the Company (collectively, "Health Care Laws"). The Company has not, either voluntarily or involuntarily, initiated, conducted or issued or caused to be initiated. conducted or issued, any recall of any clinical trial materials. Further, the Company and its subsidiaries have not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation of the Company or any of its subsidiaries is in violation of any Health Care Laws nor, to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened, except as would not, singularly or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(aa) <u>Criminal Laws</u>. Neither the Company nor any of its subsidiaries has engaged in, or will engage in, (i) any direct or indirect dealings or transactions in violation of applicable criminal laws, including, without limitation, the Controlled Substances Act of 1970, the Racketeering Influenced and Corrupt Practices Act of 1977, the Fraud Act of 2006, the Theft Act of 1968, the Travel Act of 1961 or any anti-money laundering statute, or (ii) any "aiding and abetting" in any violation of applicable criminal laws. No action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to applicable criminal laws is pending or threatened.

(bb) <u>Investment Company Act</u>. Neither the Company nor any of its subsidiaries is or, after giving effect to the offering of the Shares and the application of the proceeds thereof as described in the General Disclosure Package and the Prospectus, will be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder.

(cc) <u>Related Party Transactions</u>. There are no business relationships or related person transactions involving the Company or any of its subsidiaries or any other person required to be described in the General Disclosure Package and the Prospectus that have not been described as required.

(dd) <u>No Stabilization</u>. Neither the Company nor, to the Company's knowledge, any of its officers, directors or affiliates has taken or will take, directly or indirectly, any action designed or intended to stabilize or manipulate the price of any security of the Company, or which caused or resulted in, or which might in the future reasonably be expected to cause or result in, stabilization or manipulation of the price of any security of the Company.

Intellectual Property. Except as would not reasonably be expected to have, singly or in the aggregate, a (ee) Material Adverse Effect, the Company and each of its subsidiaries own or possess the valid right to use all (i) patents, patent applications, trademark registrations, trademark applications, service mark applications, service mark registrations, Internet domain name registrations, copyright registrations, trade secret rights ("Intellectual Property Rights") and (ii) inventions, software, works of authorships, trademarks, service marks, trade names, databases, formulae, know how and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or procedures) (collectively, "Intellectual Property Assets") necessary to conduct their respective businesses as currently conducted, and as proposed to be conducted and described in the General Disclosure Package and the Prospectus. To the Company's knowledge, the Company and each of its subsidiaries' respective businesses as now conducted and as proposed to be conducted as described in the Registration Statement. General Disclosure Package and the Prospectus do not and will not give rise to any infringement of, any misappropriation of, or other violation of, any valid and enforceable Intellectual Property Rights of any other party, except as would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect. Except as would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect, (x) to the Company's knowledge, there is no infringement by third parties of any Intellectual Property Assets described in the Registration Statement, the General Disclosure Package and the Prospectus as being owned by or licensed to the Company, (y) all licenses for the use of the Intellectual Property Rights material to its business described in the Registration Statement, the General Disclosure Package and the Prospectus are valid, binding upon and enforceable by or against the Company or one or more of its subsidiaries and by or against the other parties thereto in accordance to their terms and (z) the Company and each of its subsidiaries has complied with, and has not received any written asserted or threatened claim of breach of, any license agreement for the use of Intellectual Property Rights to which it is party, and the Company has no knowledge of any breach or anticipated breach by any other party to any such license agreement. Except as described in the General Disclosure Package or as would not reasonably be excepted to have, singly or in the aggregate, a Material Adverse Effect, there is no pending, or threatened in writing action, suit, proceeding, or claim against the Company or one or more of its subsidiaries (A) alleging the infringement by the Company or one or more of its subsidiaries of any Intellectual Property Rights of any third party; or (B) challenging the validity, enforceability, or scope of any Intellectual Property Rights owned by the Company, including any interferences, oppositions, reexaminations, or government proceedings, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding, or claim. Except as would not reasonably be expected to have, singly or in the aggregate, a Material Adverse Effect, (1) the Company and each of its subsidiaries have taken all reasonable steps to protect, maintain and safeguard their Intellectual Property Rights, including the execution of appropriate nondisclosure and confidentiality agreements, (2) the Company and each of its subsidiaries has taken all reasonable actions to obtain ownership of all works of authorship and inventions made by its employees, consultants and contractors during the time they were employed by or under contract with the Company or one or more of its subsidiaries and which relate to the Company's business, (3) to the Company's knowledge, no employee of the Company or any of its subsidiaries is in or has been in violation of any term of any patent disclosure agreement, invention assignment agreement or non-disclosure agreement and (4) all inventors of the Company's patent applications or of any other inventions created on behalf of the Company have assigned or are obligated to assign their rights in such patent applications or other inventions to the Company, or one or more of its subsidiaries.

(ff) Privacy Laws. The Company and its subsidiaries are, and at all prior times have been, in material compliance with all applicable federal, state, local or foreign laws relating to privacy, data protection, and the collection and use of Personal Data collected, used, or held for use by the Company in the conduct of the Company's business, including, without limitation, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act") (42 U.S.C. Section 17921 et seq.), the European Union General Data Protection Regulation ("GDPR") (EU 2016/679), and the California Consumer Privacy Act ("CCPA") (collectively, "Privacy Laws"). The Company and its subsidiaries take commercially reasonable steps to ensure compliance with its external privacy policy relating to the collection, storage, use, disclosure, security, handling and analysis of Personal Data (as defined below). As used herein, "Personal Data" means (i) a natural persons' name, street address, telephone number, email address, photograph, social security number, bank information, or customer or account number; (ii) any information which would qualify as "personally identifying information" under the Federal Trade Commission Act, as amended; (iii) "protected health information" as defined by HIPAA; (iv) "personal data" as defined by GDPR; and (v) any other piece of information that allows the identification of such natural person, or his or her family, or permits the collection or analysis of any data related to an identified person's health or sexual orientation. To the Company's knowledge, (i) none of the disclosures made or contained in its external privacy policy have been inaccurate, misleading, deceptive or in violation of any Privacy Laws in any material respect and (ii) the execution, delivery and performance of this Agreement or any other agreement referred to in this Agreement will not result in a breach of any Privacy Laws in any material respect. Except as would not reasonably be excepted to have, singly or in the aggregate, a Material Adverse Effect, neither the Company nor any of its subsidiaries, (i) has received written notice of any actual or potential liability under or relating to, or actual or potential violation of, any of the Privacy Laws, and has no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement that imposed any obligation or liability under any Privacy Law.

(gg) IT Systems. Except as would not reasonably be excepted to have, singly or in the aggregate, a Material Adverse Effect, (i)(x) there has been no actual or alleged security breach or attack or other compromise of or relating to any of the Company's and its subsidiaries' information technology and computer systems, networks, hardware, software, data (including any Personal Data and any other confidential or proprietary information in possession of the Company and its subsidiaries), equipment or technology (collectively, "IT Systems and Data"), and (y) the Company and its subsidiaries have not been notified in writing of, and have no knowledge of any event or condition that would reasonably be expected to result in, any security breach, attack or compromise to their IT Systems and Data, (ii) the Company and its subsidiaries have taken commercially reasonable steps to comply with, and to the Dompany's knowledge, are presently in compliance with, all applicable laws, regulations and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification and (iii) the Company and its subsidiaries have implemented commercially reasonable backup and disaster recovery technology consistent with industry standards and practice.

(hh) <u>Title to Real and Personal Property</u>. The Company and each of its subsidiaries have good and marketable title in and (in the case of real property) to, or have valid and marketable rights to lease or otherwise use, all items of real or personal property (other than intellectual property, which is addressed exclusively in Section 1(ee)) which are material to the business of the Company and its subsidiaries taken as a whole, in each case free and clear of all liens, encumbrances, security interests, claims and defects that (i) do not, singularly or in the aggregate, materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company or any of its subsidiaries or (ii) could not reasonably be expected singularly or in the aggregate, to have a Material Adverse Effect; and all of the leases and subleases material to the business of the Company, and under which the Company holds properties described in the General Disclosure Package and the Prospectus, are in full force and effect and the Company has not received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company to the continued possession of the leased or subleased premises under any such lease or sublease.

(ii) <u>No Labor Dispute</u>. There is (A) no significant unfair labor practice complaint pending against the Company, or any of its subsidiaries, nor to the Company's knowledge, threatened against it or any of its subsidiaries, before the National Labor Relations Board, any state or local labor relation board or any foreign labor relations board, and no significant grievance or significant arbitration proceeding arising out of or under any collective bargaining agreement is so pending against the Company or any of its subsidiaries, or, to the Company's knowledge, threatened against it and (B) no labor disturbance by or dispute with, employees of the Company or any of its subsidiaries exists or, to the Company's knowledge, is contemplated or threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or any of its subsidiaries, customers or contractors, that could reasonably be expected, singularly or in the aggregate, to have a Material Adverse Effect. The Company is not aware that any key employee or significant group of employees of the Company or any subsidiary plans to terminate employment with the Company or any such subsidiary.

(jj) <u>Compliance with ERISA</u>. No "prohibited transaction" (as defined in Section 406 of the Employee Retirement Income Security Act of 1974, as amended, including the regulations and published interpretations thereunder ("*ERISA*"), or Section 4975 of the Internal Revenue Code of 1986, as amended from time to time (the "*Code*")) or "accumulated funding deficiency" (as defined in Section 302 of ERISA) or any of the events set forth in Section 4043(b) of ERISA (other than events with respect to which the thirty (30)-day notice requirement under Section 4043 of ERISA has been waived) has occurred or could reasonably be expected to occur with respect to any employee benefit plan of the Company or any of its subsidiaries is in compliance in all material respects with applicable law, including ERISA and the Code. The Company or any of its subsidiaries have not incurred and could not reasonably be expected to incur liability under Title IV of ERISA with respect to the termination of, or withdrawal from, any pension plan (as defined in ERISA). Each pension plan for which the Company or any of its subsidiaries would have any liability that is intended to be qualified under Section 401(a) of the Code, to the Company's knowledge, is so qualified, and, to the Company's knowledge, nothing has occurred, whether by action or by failure to act, which could, singularly or in the aggregate, reasonably or in the aggregate, reasonably be expected to cause the loss of such qualification.

(kk) Environmental Laws and Hazardous Materials. The Company and its subsidiaries are in compliance with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to their businesses ("Environmental Laws"). There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company or any of its subsidiaries (or, to the Company's knowledge, any other entity for whose acts or omissions the Company or any of its subsidiaries, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability; and there has been no disposal, discharge, emission or other release of any kind onto such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances with respect to which the Company or any of its subsidiaries has knowledge.

(ll) <u>Taxes</u>. The Company and its subsidiaries each (i) have timely filed all necessary U.S. federal, state, local and non-U.S. tax returns, and all such returns were true, complete and correct, (ii) have timely paid all U.S. federal, state, local and non-U.S. taxes, for which it is liable, including, without limitation, all sales and use taxes and all taxes which the Company or any of its subsidiaries is obligated to withhold from amounts owing to current or former employees, officers, creditors and third parties and no penalties, fines, surcharges or interest have been incurred, and (iii) do not have any tax deficiency or claims outstanding or assessed or, to its knowledge, proposed against any of them which is reasonably expected to be determined adversely to the Company or its subsidiaries, except those, in each of the cases described in clauses (i), (ii) and (iii) above, that (i) would not, singularly or in the aggregate, have a Material Adverse Effect or (ii) are currently being contested in good faith and adequate reserves are being maintained for those taxes and the costs required to contest them which have been disclosed in its latest financial statements.

(mm) <u>Transfer Taxes</u>. No stamp duty, stamp duty reserve tax, registration, documentary, issue, transfer or other similar taxes or duties ("**Transfer Taxes**") are payable in Ireland by or on behalf of the Underwriters, the Company or any of its subsidiaries in connection with (i) the issuance and delivery of the Shares by the Company in the manner contemplated by this Agreement; (ii) the issuance and delivery of the Shares to or for the account of the Underwriters, in each case in the manner contemplated by this Agreement; (iii) the sale and delivery by the Underwriters of the Shares to purchasers thereof in the manner contemplated by this Agreement; or (iv) the execution and delivery of this Agreement.

(nn) <u>United States and Irish Tax Considerations</u>. The statements contained in the General Disclosure Package and the Prospectus under the headings Material Tax Considerations," insofar as they purport to describe the provisions of the laws and documents referred to therein, are accurate and fair in all material respects and are a complete summary description of the material Irish tax consequences for certain beneficial holders of Ordinary Shares.

(oo) <u>DAC6</u>. No transaction contemplated by this Agreement nor any transaction to be carried out in connection with any transaction contemplated by this Agreement meets any hallmark set out in Annex IV of the Council Directive of 25 May 2018 (2018/822/EU) amending Council Directive 2011/16/EU.

(pp) Insurance. The Company and each of its subsidiaries carry or are covered by, insurance in such amounts and covering such risks as the Company reasonably believes is adequate for the conduct of their respective businesses and the value of their respective properties, except where the failure to be so insured would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole. Neither the Company nor any of its subsidiaries has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received written notice from any insurer, agent of such insurer or the broker of the Company or any of its subsidiaries that any material capital improvements or any other material expenditures (other than premium payments) are required or necessary to be made in order to continue such insurance.

Accounting Controls. The Company and each of its subsidiaries maintains a system of "internal (qq)control over financial reporting" (as such term is defined in Rule 13a-15(f) of the General Rules and Regulations under the Securities Exchange Act of 1934, as amended (such act, the "Exchange Act," and such rules and regulations, the "Exchange Act **Rules**")) that is designed to comply with the requirements of the Exchange Act and has been designed by their respective principal executive and principal financial officers, or under their supervision, to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with IFRS and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (v) interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the Commission's rules and guidelines applicable thereto. The Company's internal control over financial reporting is effective. Except as described in the General Disclosure Package, since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(rr) <u>Disclosure Controls</u>. The Company and its subsidiaries maintain disclosure controls and procedures (as such is defined in Rule 13a-15(e) of the Exchange Act Rules) that are designed to comply with the requirements of the Exchange Act applicable to the Company and its subsidiaries; such disclosure controls and procedures have been designed to ensure that information required to be disclosed by the Company and its subsidiaries in reports that they file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management to allow timely decisions regarding disclosures.

(ss) <u>Minute Books</u>. The minute books of the Company and each of its subsidiaries have been made available to the Underwriters and counsel for the Underwriters, and such books (i) contain a complete summary of all meetings and actions of the Board (including each Board committee) and shareholders of the Company (or analogous governing bodies and interest holders, as applicable) and each of its subsidiaries since the time of its respective incorporation or organization through the date of the latest meeting and action, and (ii) accurately in all material respects reflect all transactions referred to in such minutes.

(tt) <u>Material Agreements</u>. There is no license, lease, contract, or other agreement or document required by the Securities Act or by the Rules and Regulations to be described in the General Disclosure Package or to be filed as an exhibit to the Registration Statement which is not so described therein or filed therewith as required; and all descriptions of any such licenses, leases, contracts, or other agreements or documents contained in the General Disclosure Package are accurate and complete descriptions of such documents in all material respects. Other than as described in the General Disclosure Package, no such license, lease, contract or other agreement has been suspended or terminated for convenience or default by the Company or any of the other parties thereto, and the Company and its subsidiaries have not received notice of and the Company does not have knowledge of any such pending or threatened suspension or termination.

(uu) <u>No Undisclosed Relationships</u>. No relationship, direct or indirect, exists between or among the Company or any of its subsidiaries on the one hand, and the directors, officers, shareholders (or analogous interest holders), customers or suppliers of the Company or any of its affiliates on the other hand, which is required to be described in the General Disclosure Package and the Prospectus and which is not so described.

(vv) <u>No Registration Rights</u>. No person or entity has the right to require registration of shares of Ordinary Shares or other securities of the Company or any of its subsidiaries because of the filing or effectiveness of the Registration Statement, or otherwise, except for persons and entities who have expressly waived such right in writing or who have been given timely and proper written notice and have failed to exercise such right within the time or times required under the terms and conditions of such right. Except as described in the General Disclosure Package, there are no persons with registration rights or similar rights to have any securities registered by the Company or any of its subsidiaries under the Securities Act.

(ww) <u>Margin Rules</u>. The application of the proceeds received by the Company from the issuance, sale and delivery of the Stock as described in the General Disclosure Package and the Prospectus will not violate Regulation T, U or X of the Board of Governors of the Federal Reserve system or any other regulation of such Board of Governors.

(xx) <u>No Broker's Fees</u>. Neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against the Company or any of its subsidiaries or the Underwriters for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares or any transaction contemplated by this Agreement, the Registration Statement, the General Disclosure Package or the Prospectus.

(yy) <u>No Restrictions on Subsidiaries</u>. Except as described in the General Disclosure Package and the Prospectus, no subsidiary of the Company is currently prohibited, directly or indirectly, under any agreement or other instrument to which it is a party or is subject, from paying any dividends to the Company, from making any other distribution on such subsidiary's capital stock, from repaying to the Company any loans or advances to such subsidiary from the Company or from transferring any of such subsidiary's properties or assets to the Company or any other subsidiary of the Company.

(zz) <u>Dividends.</u> Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, no approvals are currently required in Ireland in order for the Company to pay dividends or other distributions declared by the Company to the holders of Ordinary Shares. Under current laws and regulations of Ireland and any political subdivisions thereof, any amount payable with respect to the Ordinary Shares upon liquidation of the Company or upon redemption thereof and dividends and other distributions declared and payable on the share capital of the Company and its subsidiaries may be paid by the Company or the relevant subsidiary in United States dollars or euros and freely transferred out of Ireland, subject to applicable anti-money laundering laws or sanctions and except as set forth or contemplated in the Pricing Prospectus, no such payments made to the holders thereof or therein who are either the Company, or any subsidiary, or non-residents of Ireland who hold their Ordinary Shares as an investment and not in connection with any trade carried on by them, will be subject to income, withholding or other taxes under laws and regulations of Ireland or any political subdivision or taxing authority thereof or therein and without the necessity of obtaining any governmental authorization in Ireland or any political subdivisions or taxing authorities thereof or therein.

(aaa) <u>Insolvency</u>. No order has been made or petition or application presented or resolution passed by the Company or any of its subsidiaries or any of their respective directors for the winding up of the Company or any of its subsidiaries or for the appointment of a liquidator or examiner to the Company or any of its subsidiaries or for an administration order in respect of the Company or any of its subsidiaries; no receiver or examiner has been appointed by any person of the whole or any part of the business or assets of the Company or any of its subsidiaries; and, to the Company's knowledge, no equivalent steps or action are being undertaken, or equivalent circumstances exist, in any jurisdiction outside Ireland.

(bbb) <u>PFIC and Foreign Personal Holding Company Status</u>. Based on the Company's current operations, income, assets and certain estimates and projections, including as to the relative values of our assets, including goodwill, the Company does not expect to be a Passive Foreign Investment Company ("**PFIC**") within the meaning of Section 1297 of the Code for its current taxable year.

(ccc) <u>Forward-Looking Statements</u>. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) contained in either the General Disclosure Package or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(ddd) <u>Listing.</u> The Shares have been approved for listing subject to notice of issuance on the Exchange. A registration statement has been filed on Form 8-A pursuant to Section 12 of the Exchange Act, which registration statement complies in all material respects with the Exchange Act.

(eee) <u>Sarbanes-Oxley Act</u>. There is and has been no failure on the part of the Company or, to the Company's knowledge, any of the Company's officers or directors, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "*Sarbanes-Oxley Act*") that are applicable to the Company as of the date hereof and as of the Closing Date, including Section 402 related to loans.

(fff) <u>No Unlawful Payments</u>. Neither the Company nor its subsidiaries nor any, to the Company's knowledge, director, officer, employee, agent, affiliate or other person acting on behalf of the Company or any subsidiary, has (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity, (ii) made or taken an act in furtherance of an offer, promise, or authorization of any direct or indirect unlawful payment to any foreign or domestic government official or employee, including of any government-owned or controlled entity or of any of the foregoing, or any political party or party official, or candidate for political office, (iii) violated or is in violation of any applicable provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, or any applicable anti-corruption laws, rules, or regulations of Ireland, including, without limitation, the UK Bribery Act 2010, as amended, the Criminal Justice (Corruption Offences) Act 2018 of Ireland or any other applicable anti-corruption or anti-bribery laws, rules, or regulations (iv) made, offered, authorized, requested, or taken an act in furtherance of any other unlawful bribe, rebate, payoff, influence payment, kickback, or other unlawful or improper payment or benefit to any person. The Company and its subsidiaries have instituted, maintain and enforce, and will continue to maintain and enforce policies and procedures designed to promote and ensure compliance with all applicable anti-corruption laws.

(ggg) Loans. There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees of indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of their respective family members, except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus. All transactions by the Company with office holders or control persons of the Company have been duly approved by the Board, or duly appointed committees or officers thereof, if and to the extent required under U.S. law.

(hhh) <u>Statistical and Market Data</u>. The statistical and market related data included in the Registration Statement, the General Disclosure Package and the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate, and such data agree with the sources from which they are derived.

(iii) <u>Compliance with Money Laundering Laws</u>. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with all applicable financial recordkeeping and reporting requirements, including those of the U.S. Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "*Anti-Money Laundering Laws*"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

## (jjj) <u>Compliance with OFAC.</u>

(i) Neither the Company, its subsidiaries nor any directors, officers or employees nor, to the Company's knowledge, any agent or controlled affiliate acting on behalf of the Company or its subsidiaries is an individual or entity ("*Person*") that is, or is owned or controlled by a Person that is: (i) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("*OFAC*"), the United Nations Security Council ("*UNSC*"), the European Union ("*EU*"), Her Majesty's Treasury ("HMT"), or other relevant sanctions authority (collectively, "Sanctions"), nor (ii) located, organized or resident in a country or territory that is the subject of a U.S. government embargo (including, without limitation, Cuba, Iran, North Korea, Syria and the Crimea).

(ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person: (i) to fund or facilitate any activities or business of or with any Person that, at the time of such funding or facilitation, is the subject of Sanctions, or in any country or territory that, at the time of such funding or facilitation, is the subject of a U.S. government embargo; or (ii) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) Since incorporation, the Company and its subsidiaries have not knowingly engaged in, are not now knowingly engaged in, and will not knowingly engage in, any direct or indirect dealings or transactions with any Person that at the time of the dealing or transaction is or was the subject of Sanctions or any country or territory that, at the time of the dealing or transaction is or was the subject of a U.S. government embargo.

(kkk) <u>No Associated Persons; FINRA Matters</u>. Neither the Company nor any of its affiliates (within the meaning of FINRA Rule 5121(f)(1)) directly or indirectly controls, is controlled by, or is under common control with, or is an associated person (within the meaning of Article I, Section 1(rr) of the By-laws of FINRA) of, any member firm of FINRA.

(lll) <u>Certification Regarding Beneficial Owners</u>. The Company has delivered to the Representatives a properly completed and executed Certification Regarding Beneficial Owners of Legal Entity Customers, and, if required, copies of identifying documentation.

(mmm) <u>No Acquisitions or Dispositions</u>. Except as are described in the Registration Statement, the General Disclosure Package and the Prospectus, there are no contracts, letters of intent, term sheets, agreement, arrangements or understandings with respect to the direct or indirect acquisition or disposition by the Company of material interests in real or personal property.

(nnn) <u>Choice of Law</u>. The choice of the laws of the State of New York as the governing law of this Agreement is a valid choice of law under the laws of Ireland and will be honored by courts in Ireland except as may be limited by general principles of equity. The Company has the corporate power to submit, and pursuant to Section 17 of this Agreement, has legally, validly, effectively and irrevocably submitted, to the personal jurisdiction of each New York State and United States federal court sitting in The City of New York, New York (each, a "*New York Court*") and has validly and irrevocably waived any objection to the laying of venue of any suit, action or proceeding brought in any such court; and the Company has the power to designate, appoint and empower an authorized agent for service of process in any action arising out of or relating to this Agreement, the Registration Statement, the General Disclosure Package, the Prospectus or the offering of the Shares in any New York Court and service of process effected on such authorized agent will be effective to notify the Company of any action under this Agreement.

(ooo) <u>Enforceability</u>. Upon execution and delivery this Agreement will be in proper legal form to be enforceable under the laws of Ireland in accordance with its terms; to ensure the legality, validity, enforceability or admissibility into evidence in Ireland of this Agreement it is not necessary that this Agreement be filed or recorded with any court or other authority in Ireland (other than court filings in the ordinary course of proceedings).

(a) <u>Final Judgment</u>. Any final judgment for a fixed or readily calculable sum of money rendered by a New York Court having jurisdiction under its own domestic laws and recognized by the Irish courts as having jurisdiction (according to Irish conflicts of laws principles and rules of Irish private international laws at the time when proceedings were initiated) to give such final judgment in respect of any suit, action or proceeding against the Company based upon this Agreement and any instruments or agreements entered into for the consummation of the transactions contemplated herein and therein would be declared enforceable against the Company, without re-examination or review of the merits of the cause of action in respect of which the original judgment was given or re-litigation of the matters adjudicated upon, by the courts of Ireland; *provided*, *however*, (i) adequate service of process has been effected and the defendant has had a reasonable opportunity to be heard, (ii) such judgments or the enforcement thereof are not contrary to the law, public policy, security or sovereignty of Ireland, (iii) such judgments were not obtained by fraudulent means and do not conflict with any other valid judgment in the same matter between the same parties, (iv) an action between the same parties in the same matter is not pending in any Irish court at the time the lawsuit is instituted in the foreign court and (v) the procedural rules of the court giving the judgment have been observed. The Company is not aware of any reason why the enforcement in Ireland of such a New York Court judgment would be, as of the date hereof, contrary to public policy of Ireland.

(b) <u>Immunity</u>. Except as provided by laws or statutes generally applicable to transactions of the type described in this Agreement, neither the Company nor any of its respective properties, assets or revenues has any right of immunity under the laws of Ireland, New York or the United States, from any legal action, suit or proceeding, from the giving of any relief in any such legal action, suit or proceeding, from set-off or counterclaim, from the jurisdiction of any court in Ireland, or, New York or United States federal court, from service of process, attachment upon or prior judgment, or attachment in aid of execution of judgment, or from execution of a judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of a judgment, in any such court, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with this Agreement . To the extent that the Company or any of its respective properties, assets or revenues may have or may hereafter become entitled to any such right of immunity in any such court in which proceedings may at any time be commenced, the Company waives or will waive such right to the extent permitted by law and has consented to such relief and enforcement as provided in Section 17 of this Agreement.

Any certificate signed by or on behalf of the Company and delivered to the Representatives or to counsel for the Underwriters shall be deemed to be a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

3. *ISSUE AND DELIVERY OF SHARES.* On the basis of the representations, warranties and agreements herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue to the Underwriters, and the Underwriters agree, severally and not jointly, to purchase by way of subscription from the Company the respective numbers of Firm Shares set forth opposite the names of the Underwriters in <u>Schedule A</u> hereto.

The purchase price per share to be paid by the Underwriters to the Company for the Shares will be \$[•] per Share (the "*Purchase Price*").

The Company will deliver the Firm Shares to the Representatives for the respective accounts of the several Underwriters, through the facilities of The Depository Trust Company, issued in such names and in such denominations as the Representatives may direct by notice in writing to the Company given at or prior to 12:00 Noon, New York time, on the second (2nd) full business day preceding the Closing Date against payment of the aggregate Purchase Price therefor by wire transfer in federal (same day) funds to an account at a bank specified by the Company payable to the order of the Company for the Firm Shares sold by them all at the offices of Cooley LLP, 55 Hudson Yards, New York, New York 10001. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligations of each Underwriter hereunder. The time and date of the delivery and closing shall be at 10:00 A.M., New York time, on [•], 2021, in accordance with Rule 15c6-1 of the Exchange Act. The time and date of such payment and delivery are herein referred to as the "*Closing Date*". The Closing Date and the location of delivery of, and the form of payment for, the Firm Shares may be varied by agreement among the Company and the Representatives.

The Underwriters may subscribe for all or less than all of the Optional Shares. The price per Share to be paid for the Optional Shares shall be the Purchase Price, *provided*, *however*, that the amount paid by the Underwriters for any Optional Shares shall be reduced by an amount per Share equal to any dividends declared by the Company and payable on the Firm Shares but not payable on such Optional Shares. The Company agrees to issue to the Underwriters the number of Optional Shares specified in the written notice delivered by the Representatives to the Company described below and the Underwriters agree, severally and not jointly, to purchase such Optional Shares. Such Optional Shares shall be purchased from the Company by way of subscription for the account of each Underwriter in the same proportion as the number of Firm Shares set forth opposite such Underwriter's name on <u>Schedule A</u> bears to the total number of Firm Shares (subject to adjustment by the Representatives to eliminate fractions). The option granted hereby may be exercised as to all or any part of the Optional Shares at any time, and from time to time, *provided however*, that notice of such exercise must be delivered not more than thirty (30) days subsequent to the date of this Agreement. No Optional Shares shall be issued and delivered unless the Firm Shares previously has been, or simultaneously is sold and delivered. The right to subscribe for the Optional Shares or any portion thereof may be surrendered and terminated at any time upon notice by the Representatives to the Company.

The option granted hereby shall be exercised by written notice being given to the Company by Representatives setting forth the number of Optional Shares to be purchased by the Underwriters and the date and time for delivery of and payment for the Optional Shares. Each date and time for delivery of and payment for the Optional Shares (which may be the Closing Date, but not earlier) is herein called the "*Option Closing Date*" and shall in no event be earlier than two (2) business days nor later than five (5) business days after written notice is given. The Option Closing Date and the Closing Date are herein called the "*Closing Dates*."

The Company will deliver the Optional Shares to the Representatives for the respective accounts of the several Underwriters through the facilities of The Depository Trust Company issued in such names and in such denominations as the Representatives may direct by notice in writing to the Company given at or prior to 12:00 Noon, New York time, on the second (2nd) full business day preceding the Option Closing Date against payment of the aggregate Purchase Price therefor by wire transfer in federal (same day) funds to an account at a bank acceptable to the Representatives payable to the order of the Company, at the offices of Cooley LLP, 1114 Avenue of the Americas, New York, New York, 10036-7798. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligations of each Underwriter hereunder. The Company of the certificates through the facilities of The Depository Trust Company, shall make the certificates for the Optional Stock available to the Representatives for examination on behalf of the Underwriters in New York, New York not later than 10:00 A.M., New York Time, at least one (1) full business day prior to the Option Closing Date. The Option Closing Date and the location of delivery of, and the form of payment for, the Optional Shares may be varied by agreement between the Company and the Representatives.

The several Underwriters propose to offer the Shares for sale upon the terms and conditions set forth in the Prospectus.

4. *FURTHER AGREEMENTS OF THE COMPANY.* The Company agrees with the several Underwriters:

<u>Required Filings; Amendments or Supplements; Notice to the Representative</u>. To prepare the Rule (a) 462(b) Registration Statement, if necessary, in a form approved by the Representatives and file such Rule 462(b) Registration Statement with the Commission by 10:00 P.M., New York time, on the date hereof, and the Company shall at the time of filing either pay to the Commission the filing fee for the Rule 462(b) Registration Statement or give irrevocable instructions for the payment of such fee pursuant to Rule 111(b) under the Rules and Regulations; to prepare the Prospectus in a form approved by the Representatives containing information previously omitted at the time of effectiveness of the Registration Statement in reliance on Rules 430A, 430B or 430C of the Rules and Regulations and to file such Prospectus pursuant to Rule 424(b) of the Rules and Regulations not later than the second business (2<sup>nd</sup>) day following the execution and delivery of this Agreement or, if applicable, such earlier time as may be required by the Securities Act; to notify the Representatives immediately of the Company's intention to file or prepare any supplement or amendment to the Registration Statement, or to the Prospectus and to make no amendment or supplement to the Registration Statement, the General Disclosure Package or to the Prospectus to which the Representatives shall reasonably object by notice to the Company after a reasonable period to review; to advise the Representatives, promptly after it receives notice thereof, of the time when any amendment to the Registration Statement has been filed or becomes effective or any supplement to the General Disclosure Package or the Prospectus or any amended Prospectus or any Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication has been filed and to furnish the Underwriters with copies thereof; to file promptly all material required to be filed by the Company with the Commission pursuant to Rules 433(d) or 163(b)(2) of the Rules and Regulations, as the case may be; to advise the Representatives, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus, the Prospectus or any Written Testing-the-Waters Communication, of the suspension of the qualification of the Shares for offering or sale in any jurisdiction or, to the Company's knowledge, of the initiation or threatening of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the Registration Statement, the General Disclosure Package or the Prospectus or for additional information including, but not limited to, any request for information concerning any Testing-the-Waters Communication; and, in the event of the issuance of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus, any Issuer Free Writing Prospectus or the Prospectus or suspending any such qualification, and promptly to use its best efforts to obtain the withdrawal of such order.

(b) <u>Emerging Growth Company</u>. The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (a) the completion of the distribution of the Firm Shares within the meaning of the Securities Act and (b) completion of the Lock-Up Period (as defined below).

If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

(c) Permitted Free Writing Prospectus. The Company represents and agrees that, unless it obtains the prior consent of the Representatives, and each Underwriter represents and agrees that, unless it obtains the prior consent of the Company and the Representatives, it has not made and will not, other than the final term sheet prepared and filed pursuant to Section 4(d) hereof, make any offer relating to the Shares that would constitute a "free writing prospectus" as defined in Rule 405 of the Rules and Regulations unless the prior written consent of the Representatives has been received (each, a "**Permitted Free Writing Prospectus**"); provided that the prior written consent of the Representatives hereto shall be deemed to have been given in respect of the Issuer Free Writing Prospectuses included in <u>Schedule B</u> hereto. The Company represents that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus, including the requirements relating to timely filing with the Commission, legending and record keeping and will not take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) of the Rules and Regulations a free writing prospectus prepared by or on behalf of such Underwriter that such Underwriter otherwise would not have been requirement to file with the Commission any electronic road show.

(d) <u>Ongoing Compliance</u>. If at any time prior to the date when a prospectus relating to the Shares is required to be delivered (or in lieu thereof, the notice referred to in Rule 173(a) under the Securities Act) any event occurs or condition exists as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact, or omit to state any material fact necessary to make the statements therein, in light of the circumstances under which they were made when the Prospectus is delivered (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations), not misleading, or if it is necessary at any time to amend or supplement the Registration Statement, or the Prospectus to comply with the Securities Act, that the Company will promptly notify the Representatives thereof and upon their request will prepare an appropriate amendment or supplement or upon their request make an appropriate filing pursuant to Section 13 or 14 of the Exchange Act in form and substance satisfactory to the Representatives which will correct such statement or omission or effect such compliance and will use its reasonable best efforts to have any amendment to the Registration Statement or declared effective as soon as possible. The Company will furnish without charge to each Underwriter and to any dealer in securities as many copies as the Representatives may from time to time reasonably request of such amendment or supplement. In case any Underwriter is required to deliver a prospectus (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules and Regulations) relating to the Shares, the Company upon the request of the Representatives will prepare promptly an amended or supplemented Prospectus as may be necessary to permit compliance with the requirements of Section 10(a)(3) of the Securities Act and deliver to such Underwriter as many copies as such Underwriter may request of such amended or supplemented Prospectus complying with Section 10(a)(3) of the Securities Act.

(e) <u>Amendment to General Disclosure Package</u>. If the General Disclosure Package is being used to solicit offers to buy the Shares at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur as a result of which, in the judgment of the Company or in the reasonable opinion of the Underwriters, it becomes necessary to amend or supplement the General Disclosure Package in order to make the statements therein, in the light of the circumstances then prevailing, not misleading, or to make the statements therein not conflict with the information contained in the Registration Statement then on file and not superseded or modified, or if it is necessary at any time to amend or supplement the General Disclosure Package to comply with any law, the Company promptly will either (i) prepare, file with the Commission (if required) and furnish to the Underwriters and any dealers an appropriate amendment or supplement to the General Disclosure Package or (ii) prepare and file with the Commission an appropriate filing under the Exchange Act which shall be incorporated by reference in the General Disclosure Package so that the General Disclosure Package as so amended or supplemented will not, in the light of the circumstances then prevailing, be misleading or conflict with the Registration Statement then on file, or so that the General Disclosure Package will comply with law.

(f) <u>Amendment to Issuer Free Writing Prospectus</u>. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or will conflict with the information contained in the Registration Statement, Pricing Prospectus or Prospectus and not superseded or modified or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading, the Company has promptly notified or supplemented and has promptly amended or will promptly amended or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus in reliance upon, and in conformity with, written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information the parties hereto agree is limited to the Underwriters' Information.

(g) <u>Delivery of Registration Statement</u>. To the extent not available on the Commission's Electronic Data Gathering, Analysis and Retrieval system or any successor system ("*EDGAR*"), upon the request of the Representatives, to furnish promptly to the Representatives and to counsel for the Underwriters a signed copy of each of the Registration Statement as originally filed with the Commission, and of each amendment thereto filed with the Commission, including all consents and exhibits filed therewith.

(h) <u>Delivery of Copies</u>. Upon request of the Representatives, to the extent not available on EDGAR, to deliver promptly to the Representatives in New York City such number of the following documents as the Representatives shall reasonably request: (i) conformed copies of the Registration Statement as originally filed with the Commission (in each case excluding exhibits), (ii) each Preliminary Prospectus, (iii) any Issuer Free Writing Prospectus, (iv) the Prospectus (the delivery of the documents referred to in clauses (i), (ii), (iii) and (iv) of this paragraph (h) to be made not later than 10:00 A.M., New York City time, on the business day following the execution and delivery of this Agreement), (v) conformed copies of any amendment to the Registration Statement (in each case excluding exhibits), and (vi) any amendment or supplement to the General Disclosure Package or the Prospectus (the delivery of the documents referred to in clauses (v) and (vi) of this paragraph (h) to be made not later than 10:00 A.M., New York City time, on the business day following the documents referred to in clauses (v) and (vi) of this paragraph (h) to be made not later than 10:00 A.M., New York City time, on the business day following the date of such amendment or supplement).

(i) <u>Earnings Statement</u>. To make generally available to its shareholders as soon as reasonably practicable, but in any event not later than sixteen (16) months after the effective date of the Registration Statement (as defined in Rule 158(c) of the Rules and Regulations), an earnings statement of the Company and its subsidiaries (which need not be audited) complying with Section 11(a) of the Securities Act (including, at the option of the Company, Rule 158); and to furnish to its shareholders as soon as practicable after the end of each fiscal year an annual report (including a balance sheet and statements of income, shareholders' equity and cash flows of the Company and its consolidated subsidiaries certified by independent public accountants) and as soon as possible after the second fiscal quarter of each fiscal year (beginning with the second fiscal quarter after the effective date of such Registration Statement), consolidated summary financial information of the Company and its subsidiaries for such semi-annual period in reasonable detail.

(j) <u>Blue Sky Compliance</u>. To take promptly from time to time such commercially reasonable actions as the Representatives may reasonably request, with the Representatives' cooperation, if necessary, to qualify the Shares for offering and sale under the securities or Blue Sky laws of such jurisdictions (domestic or foreign) as the Representatives may reasonably designate and to use its commercially reasonable efforts, with the Representatives' cooperation, if necessary, to continue such qualifications in effect, and to comply with such laws, for so long as required to permit the offer and sale of Shares in such jurisdictions; *provided* that the Company and its subsidiaries shall not be obligated to (i) qualify as foreign corporations in any jurisdiction in which they are not so qualified, (ii) file a general consent to service of process in any jurisdiction or (iii) subject itself to taxation in any such jurisdiction if it is not otherwise so subject.

(k) <u>Reports</u>. Upon request, during the period of five (5) years from the date hereof, to deliver to each of the Underwriters, (i) as soon as they are available, copies of all reports or other communications (financial or other) furnished to shareholders of the Company, and (ii) as soon as they are available, copies of any reports and financial statements furnished or filed with the Commission or any national securities exchange on which the Shares are listed. However, so long as the Company is subject to the reporting requirements of either Section 13 or Section 15(d) of the Exchange Act and is timely filing reports EDGAR, it is not required to furnish such reports or statements to the Underwriters.

Lock-Up. During the period commencing on and including the date hereof and ending on and including (1)the 180th day following the date of this Agreement, (the "Lock-Up Period") the Company will not, without the prior written consent of the Representatives (which consent may be withheld at the sole discretion of the Representatives), directly or indirectly offer, sell (including, without limitation, any short sale), assign, transfer, pledge, contract to sell, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act, or otherwise dispose of, or announce the offering of, or submit or file any registration statement under the Securities Act in respect of, any Ordinary Shares, options, rights or warrants to acquire Ordinary Shares or securities exchangeable or exercisable for or convertible into Ordinary Shares (other than is contemplated by this Agreement with respect to the Shares) or publicly announce any intention to do any of the foregoing; provided, however, that the Company may (i) issue Ordinary Shares and options to purchase Ordinary Shares pursuant to any director or employee incentive plan, stock ownership plan or dividend reinvestment plan of the Company in effect on the date hereof and described in the General Disclosure Package; (ii) issue Ordinary Shares pursuant to the conversion of securities or the exercise of warrants, which securities or warrants are outstanding on the date hereof and described in the General Disclosure Package; (iii) adopt a new equity incentive plan, and file a registration statement on Form S-8 under the Securities Act to register the offer and sale of securities to be issued pursuant to such new equity incentive plan, and issue securities pursuant to such new equity incentive plan (including, without limitation, the issuance of Ordinary Shares upon the exercise of options or other securities issued pursuant to such new equity incentive plan), provided that (1) such new equity incentive plan satisfies the transaction requirements of General Instruction A.1 of Form S-8 under the Securities Act and (2) this clause (iii) shall not be available unless each recipient of Ordinary Shares, or securities exchangeable or exercisable for or convertible into Ordinary Shares, pursuant to such new equity incentive plan shall be contractually prohibited from selling, offering, disposing of or otherwise transferring any such shares or securities during the remainder of the Lock-Up Period; and (iv) Ordinary Shares or other securities issued in connection with a transaction with an unaffiliated third party that includes a bona fide commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or intellectual property license agreements) or any acquisition of assets or acquisition of not less than a majority or controlling portion of the equity of another entity, provided that (x) the aggregate number of shares issued pursuant to this clause (iv) shall not exceed seven and a half percent (7.5%) of the total number of outstanding Ordinary Shares immediately following the issuance and sale of the Shares pursuant hereto and (y) the recipient of any such Ordinary Shares and securities issued pursuant to this clause (iv) during the 180day restricted period described above shall enter into an agreement substantially in the form of Exhibit I hereto. The Company will cause each officer, director and all securityholders of the Company to furnish to the Representatives, prior to the Closing Date, a "lock-up" agreement, substantially in the form of Exhibit I hereto. In addition, the Company will direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such "lock-up" agreements.

(m) <u>Release of Lock-Up</u>. If the Representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up letter described in Section 6(r) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of <u>Exhibit II</u> hereto through a major news service at least two business days before the effective date of the release or waiver.

(n) <u>Delivery of SEC Correspondence</u>. To supply the Representatives with copies of all correspondence to and from, and all documents issued to and by, the Commission in connection with the registration of the Shares under the Securities Act or any of the Registration Statement, any Preliminary Prospectus or the Prospectus, or any amendment or supplement thereto or document incorporated by reference therein.

(o) <u>Press Releases</u>. Prior to the Closing Date, not to issue any press release or other communication directly or indirectly or hold any press conference with respect to the Company, its condition, financial or otherwise, or earnings, business affairs or business prospects (except for routine oral marketing communications in the ordinary course of business and consistent with the past practices of the Company and of which the Representatives are notified), without the prior consent of the Representatives, unless in the judgment of the Company and its counsel, and after notification to the Representatives, such press release or communication is required by law.

(p) <u>Compliance with Regulation M</u>. Until the Representatives shall have notified the Company of the completion of the resale of the Shares, that the Company will not, and will use its reasonable best efforts to cause its affiliated purchasers (as defined in Regulation M under the Exchange Act) not to, either alone or with one or more other persons, bid for or purchase, for any account in which it or any of its affiliated purchasers has a beneficial interest, any Shares, or attempt to induce any person to purchase any Shares; and not to, and to use its reasonable best efforts to cause its affiliated purchasers not to, make bids or purchase for the purpose of creating actual, or apparent, active trading in or of raising the price of the Shares.

(q) <u>Registrar and Transfer Agent</u>. To maintain, at its expense, a registrar and transfer agent for the Shares.

(r) <u>Use of Proceeds</u>. To apply the net proceeds from the sale of the Shares in all material respects as set forth in the Registration Statement, the General Disclosure Package and the Prospectus under the heading "Use of Proceeds," and except as disclosed in the General Disclosure Package, the Company does not intend to use any of the proceeds from the sale of the Shares hereunder to repay any outstanding debt owed to any affiliate of any Underwriter.

(s) <u>Exchange Listing</u>. To use its reasonable best efforts to list, subject to notice of issuance, the Shares on the Exchange.

(t) <u>Performance of Covenants and Satisfaction of Conditions</u>. To use its reasonable best efforts to do and perform all things required to be done or performed under this Agreement by the Company prior to each Closing Date and to satisfy all conditions precedent to the delivery of the Firm Shares and the Optional Shares.

PAYMENT OF EXPENSES. The Company agrees to pay, or reimburse if paid by any Underwriter, whether or not the 5. transactions contemplated hereby are consummated or this Agreement is terminated: (a) the costs incident to the authorization, issuance, sale, preparation and delivery of the Shares and any issuance taxes payable in that connection; (b) the costs incident to the registration of the Shares under the Securities Act and the Exchange Act; (c) the costs incident to the preparation, printing and distribution of the Registration Statement, any Preliminary Prospectus, any Issuer Free Writing Prospectus, the General Disclosure Package, the Prospectus, any amendments, supplements and exhibits thereto and the costs of printing, reproducing and distributing the "Agreement Among Underwriters" between the Representatives and the Underwriters, the Master Selected Dealers' Agreement, the Underwriters' Questionnaire, this Agreement, and any closing documents by mail, telex or other means of communications; (d) the fees and expenses (including related fees and expenses of counsel for the Underwriters) incurred in connection with securing any required review by FINRA of the terms of the sale of the Shares and any filings made with FINRA; (e) any applicable listing or other fees; (f) the reasonable, documented fees and expenses (including related fees and expenses of counsel to the Underwriters) of qualifying the Shares under the securities laws of the several jurisdictions as provided in Section 4(k) and the reasonable, documented cost of preparing, printing and distributing wrappers, Blue Sky Memoranda and Legal Investment Surveys (provided that the amount payable by the Company with respect to fees and disbursements of counsel for the Underwriters pursuant to subsections (d), (e) and (f) shall not exceed \$40,000); (g) the cost of preparing and printing stock certificates; (h) all fees and expenses of the registrar and transfer agent and agent for service of process; (i) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the officers of the Company and such consultants, including fifty percent (50%) of the cost of any aircraft chartered in connection with the road show to be used by both the Company and Underwriters (the remaining fifty percent (50%) of the cost of such aircraft to be paid by the Underwriters) and (j) all other costs and expenses incident to the offering of the Shares or the performance of the obligations of the Company under this Agreement (including, without limitation, the fees and expenses of the Company's counsel and the Company's independent accountants) provided that, except to the extent otherwise provided in this Section 5 and in Sections 9 and 10, the Underwriters shall pay their own costs and expenses, including the fees and expenses of their counsel not contemplated herein and the expenses of advertising any offering of the Shares made by the Underwriters.

(a) The Company will indemnify and hold harmless the Underwriters against any transfer taxes, including any interest and penalties, on or in connection with (i) the creation, issuance and delivery of the Shares by the Company in the manner contemplated by this Agreement and the Prospectus, (ii) the issuance, sale and delivery of the Shares to or for the account of the Underwriters, in each case in the manner contemplated by this Agreement; (iii) the sale and delivery by the Underwriters of the Shares to purchasers thereof in the manner contemplated by this Agreement and the Prospectus; and (iv) the execution, delivery and performance by the Company or the Underwriters of this Agreement. All payments to be made by the Company under this Agreement shall be made without withholding or deduction for or on account of any present or future taxes, levies, imposts, duties, fees, assessments or other charges whatsoever, and all interest, penalties or similar liabilities with respect thereto ("**Taxes**") unless the Company is compelled by law to deduct or withhold such Taxes. In that event, the Company shall pay such additional amounts as may be necessary in order to ensure that the net amounts received after such withholding or deduction shall equal the amounts that would have been received if no withholding or deduction had been made.

(b) If the performance by the Underwriters of any of their obligations under this Agreement shall represent for VAT purposes under any applicable law the making by the Underwriters of any supply of goods or services to the Company and the Underwriters are required to account to the relevant tax authority for VAT (to the extent applicable), the Company shall pay to the Underwriters, in addition to the amounts otherwise payable by the Company pursuant to this Agreement, an amount equal to the VAT chargeable on any such supply of goods and services and the Underwriters shall issue the Company (to the extent applicable) with an appropriate VAT invoice in respect of the supply to which the payment relates. Where a sum (a "*Relevant Sum*") is paid or reimbursed to the Underwriters pursuant to this Agreement in respect of any cost, expense or other amount and that cost, expense or other amount includes an amount in respect of VAT (the "*VAT Element*"), then the Company, to the extent applicable, shall, in addition, pay an amount equal to the VAT Element to the Underwriters. For the purposes of this Agreement, "*VAT*" means value added tax as provided for in the Value-Added Tax Consolidation Act 2010 ("*VATA*") and subordinate legislation made under VATA as amended, modified or re-enacted (whether before or after the date of this Agreement) and any similar sales, consumption, use or turnover tax whether within Ireland or elsewhere in the world.

6. *CONDITIONS OF UNDERWRITERS' OBLIGATIONS.* The respective obligations of the several Underwriters hereunder are subject to the accuracy, when made and as of the Applicable Time and on each Closing Date, of the representations and warranties of the Company contained herein, to the accuracy of the statements of the Company made in any certificates pursuant to the provisions hereof, to the performance by the Company of its obligations hereunder, and to each of the following additional terms and conditions:

(a) <u>Registration Compliance; No Stop Orders</u>. The Registration Statement has become effective under the Securities Act, and no stop order suspending the effectiveness of the Registration Statement or any part thereof, preventing or suspending the use of any Preliminary Prospectus, the Prospectus or any Permitted Free Writing Prospectus or any part thereof shall have been issued and no proceedings for that purpose or pursuant to Section 8A under the Securities Act shall have been initiated or, to the Company's knowledge, threatened by the Commission, and all requests for additional information on the part of the Commission (to be included in the Registration Statement or the Prospectus or otherwise) shall have been complied with to the reasonable satisfaction of the Representatives; the Rule 462(b) Registration Statement, if any, each Issuer Free Writing Prospectus and the Prospectus shall have been filed with, the Commission within the applicable time period prescribed for such filing by, and in compliance with, the Rules and Regulations and in accordance with Section 4(b), and the Rule 462(b) Registration Statement, if any, shall have become effective immediately upon its filing with the Commission and FINRA shall have raised no unresolved objection to the fairness and reasonableness of the terms of this Agreement or the transactions contemplated hereby.

(b) <u>No Material Misstatements</u>. None of the Underwriters shall have discovered and disclosed to the Company on or prior to such Closing Date that the Registration Statement or any amendment or supplement thereto contains an untrue statement of a fact which, in the opinion of counsel for the Underwriters, is material or omits to state any fact which, in the opinion of such counsel, is material and is required to be stated therein or is necessary to make the statements therein not misleading, or that the General Disclosure Package, any Issuer Free Writing Prospectus or the Prospectus or any amendment or supplement thereto contains an untrue statement of fact which, in the opinion of such counsel, is material or omits to state any fact which, in the opinion of such counsel, is material and is necessary in order to make the statements, in the light of the circumstances in which they were made, not misleading.

(c) <u>Corporate Proceedings</u>. All corporate proceedings incident to the authorization, form and validity of each of this Agreement, the Shares, the Registration Statement, the General Disclosure Package, each Issuer Free Writing Prospectus and the Prospectus and the transactions contemplated hereby shall be reasonably satisfactory in all material respects to counsel for the Underwriters, and the Company shall have furnished to such counsel all documents and information that they may reasonably request to enable them to pass upon such matters.

(d) <u>Opinion and 10b-5 Statement of Counsel for the Company</u>. Davis, Polk and Wardwell, LLP U.S. counsel to the Company, shall have furnished to the Representatives such counsel's written opinion and 10b-5 Statement, as counsel to the Company, addressed to the Underwriters and dated such Closing Date, in form and substance reasonably satisfactory to the Representatives.

(e) <u>Opinion of Irish Counsel for the Company</u>. Dentons, Irish counsel to the Company, shall have furnished to the Representatives such counsel's written opinion, addressed to the Underwriters and dated such Closing Date, in form and substance reasonably satisfactory to the Representatives.

(f) <u>Opinion of Regulatory Counsel for the Company</u>. Hyman, Phelps & McNamara, P.C., regulatory counsel to the Company, shall have furnished to the Representatives such counsel's written opinion, as regulatory counsel to the Company, addressed to the Underwriters and dated such Closing Date, in form and substance reasonably satisfactory to the Representatives.

(g) <u>Opinion of Intellectual Property Counsel for the Company.</u> Breuer Friedrich Hahner, intellectual property counsel to the Company, shall have furnished to the Representatives such counsel's written opinion, as intellectual property counsel to the Company, addressed to the Underwriters and dated such Closing Date, in form and substance reasonably satisfactory to the Representatives.

(h) <u>Opinion and 10b-5 Statement of Counsel for the Underwriters.</u> The Representatives shall have received from Cooley LLP, as U.S. counsel for the Underwriters, such opinion or opinions, dated such Closing Date, with respect to such matters as the Underwriters may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

(i) <u>Comfort Letter</u>. At the time of the execution of this Agreement, the Representatives shall have received from PricewaterhouseCoopers Ltd, a letter, addressed to the Underwriters, executed and dated such date, in form and substance satisfactory to the Representatives (i) confirming that they are an independent registered accounting firm with respect to the Company and its subsidiaries within the meaning of the Securities Act and the Rules and Regulations and PCAOB and (ii) stating the conclusions and findings of such firm, of the type ordinarily included in accountants' "comfort letters" to underwriters, with respect to the financial statements and certain financial information contained or incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus.

(j) <u>Bring Down Comfort</u>. On the effective date of any post-effective amendment to the Registration Statement and on such Closing Date, the Representatives shall have received a letter (the "*bring-down letter*") from PricewaterhouseCoopers Ltd addressed to the Underwriters and dated such Closing Date confirming, as of the date of the bring-down letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the General Disclosure Package and the Prospectus, as the case may be, as of a date not more than three (3) business days prior to the date of the bring-down letter), the conclusions and findings of such firm, of the type ordinarily included in accountants' "comfort letters" to underwriters, with respect to the financial information and other matters covered by its letter delivered to the Representatives concurrently with the execution of this Agreement pursuant to paragraph (j) of this Section 6.

(k) Officer's Certificate. The Company shall have furnished to the Representatives a certificate, dated as of such Closing Date, of its Chief Financial Officer (or officer with a reasonably equivalent role) and one additional senior executive officer of the Company who is satisfactory to the Representatives, stating in their respective capacities as officers of the Company on behalf of the Company that (i) no stop order suspending the effectiveness of the Registration Statement (including, for avoidance of doubt, any Rule 462(b) Registration Statement), or any post-effective amendment thereto, shall be in effect and no proceedings for such purpose shall have been instituted or, to their knowledge, threatened by the Commission, (ii) for the period from and including the date of this Agreement through and including such Closing Date, there has not occurred any Material Adverse Effect, (iii) to their knowledge, after reasonable investigation, as of such Closing Date, the representations and warranties of the Company in this Agreement are true and correct and the Company has complied in all material respects with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to such Closing Date, and (iv) there has not been, subsequent to the date of the most recent audited financial statements included or incorporated by reference in the General Disclosure Package, any Material Adverse Effect in the financial position or results of operations of the Company, or any change or development that, singularly or in the aggregate, would reasonably be expected to involve a Material Adverse Effect, except as set forth in the General Disclosure Package and the Prospectus.

No Material Adverse Effect. Since the date of the latest audited financial statements included in the (l) General Disclosure Package, (i) neither the Company nor any of its subsidiaries shall have sustained any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth in the General Disclosure Package, and (ii) there shall not have been any change in the capital stock or long-term debt of the Company or any of its subsidiaries, or any change, or any development involving a prospective change, in or affecting the business, general affairs, management, financial position, shareholders' equity or results of operations of the Company and its subsidiaries, otherwise than as set forth in the General Disclosure Package (including, but not limited to, as a result of (1) the exercise, if any, of options, restricted share units or other equity awards, or the award of any options, restricted share units or restricted shares in the ordinary course of business pursuant to the Company's equity plans that are described in the Pricing Prospectus and the Prospectus, (2) the repurchase of shares by the Company pursuant to any contractual arrangement that provides for the repurchase of the Company securities as described in the Pricing Prospectus and the Prospectus, or (3) the issuance, if any, of shares upon conversion of Company securities as described in the Pricing Prospectus and the Prospectus) or (4) any transactions effected in connection with the Corporate Reorganization) the effect of which, in any such case described in clause (i) or (ii) of this paragraph 6(l), is, in the judgment of the Representatives, so material and adverse as to make it impracticable or inadvisable to proceed with the sale or delivery of the Shares on the terms and in the manner contemplated in the General Disclosure Package.

(m) <u>No Legal Impediment to Issuance</u>. No action shall have been taken and no law, statute, rule, regulation or order shall have been enacted, adopted or issued by any governmental or regulatory agency or body which would prevent the issuance or sale of the Shares; and no injunction, restraining order or order of any other nature by any foreign, federal or state court of competent jurisdiction shall have been issued which would prevent the issuance or sale of the Shares or materially and adversely affect or potentially materially and adversely affect the business or operations of the Company.

(n) <u>No Downgrade</u>. Subsequent to the execution and delivery of this Agreement (i) no downgrading shall have occurred in the Company's corporate credit rating or the rating accorded the Company's debt securities by any "nationally recognized statistical rating organization," as that term is defined by the Commission for purposes of Rule 436(g)(2) of the Rules and Regulations and (ii) no such organization shall have publicly announced that it has under surveillance or review (other than an announcement with positive implications of a possible upgrading), the Company's corporate credit rating or the rating of any of the Company's debt securities.

Market Conditions. Subsequent to the execution and delivery of this Agreement there shall not have (0)occurred any of the following: (i) trading in any of the Company's securities shall have been suspended or materially limited by the Commission or the Exchange, (ii) trading in securities generally on the New York Stock Exchange, Nasdaq Global Select Market, Nasdag Global Market, Nasdag Capital Market or the NYSE MKT LLC or in the over-the-counter market, or trading in any securities of the Company on any exchange or in the over-the-counter market, shall have been suspended or materially limited, or minimum or maximum prices or maximum range for prices shall have been established on any such exchange or such market by the Commission, by such exchange or market or by any other regulatory body or governmental authority having jurisdiction, (iii) a banking moratorium shall have been declared by Federal or state authorities in the United States or authorities in Ireland or a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States or Ireland, (iv) the United States or Ireland shall have become engaged in hostilities, or the subject of an act of terrorism, or there shall have been an outbreak of or escalation in hostilities involving the United States or Ireland, or there shall have been a declaration of a national emergency or war by the United States or Ireland or (v) there shall have occurred such a material adverse change in general economic, political or financial conditions (or the effect of international conditions on the financial markets in the United States or Ireland shall be such) as to make it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the sale or delivery of the Shares on the terms and in the manner contemplated in the General Disclosure Package and the Prospectus.

(p) <u>Exchange Listing</u>. The Exchange shall have approved the Shares for listing therein, subject only to official notice of issuance and evidence of satisfactory distribution; the Shares shall have been determined to be eligible for clearance and settlement through the facilities of the DTC.

(q) <u>Lock Up Agreements</u>. The Representatives shall have received the written agreements, substantially in the form of <u>Exhibit I</u> hereto, from all officers, directors, shareholders, optionholders and warrantholders of the Company.

(r) <u>Secretary's Certificate</u>. The Company shall have furnished to the Representatives a Secretary's Certificate of the Company, in form and substance reasonably satisfactory to counsel for the Underwriters and customary for the type of offering contemplated by this Agreement.

(s) <u>Chief Financial Officer Certificate</u>. The Company shall have furnished to the Representatives a certificate, dated such Closing Date, of its Chief Financial Officer (or officer with a reasonably equivalent role), in form and substance reasonably satisfactory to the Representatives.

(t) <u>Additional Document</u>. On or prior to such Closing Date, the Company shall have furnished to the Representatives such further certificates and documents as the Representatives may reasonably request.

All opinions, letters, evidence and certificates mentioned above or elsewhere in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in form and substance reasonably satisfactory to counsel for the Underwriters.

## 7. INDEMNIFICATION AND CONTRIBUTION.

Indemnification of Underwriters by the Company. The Company shall indemnify and hold harmless (a) each Underwriter, its affiliates, directors, officers, managers, members, employees, representatives and agents and each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (collectively the "Underwriter Indemnified Parties," and each, an "Underwriter Indemnified Party") against any loss, claim, damage, expense or liability whatsoever (or any action, investigation or proceeding in respect thereof), joint or several, to which such Underwriter Indemnified Party may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, expense, liability, action, investigation or proceeding arises out of or is based upon (A) any untrue statement or alleged untrue statement of a material fact contained in any Written Testing-the-Waters Communication, any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" filed or required to be filed pursuant to Rule 433(d) of the Rules and Regulations, the Registration Statement, the Prospectus, or in any amendment or supplement thereto or in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically) ("Marketing Materials") or (B) the omission or alleged omission to state in any Written Testing-the-Waters Communication, any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" filed or required to be filed pursuant to Rule 433(d) of the Rules and Regulations, the Registration Statement, the Prospectus, or in any amendment or supplement thereto or in any Marketing Materials, a material fact required to be stated therein or necessary to make the statements therein not misleading, and shall reimburse each Underwriter Indemnified Party promptly upon demand for any legal fees or other expenses reasonably incurred and documented by that Underwriter Indemnified Party in connection with investigating, or preparing to defend, or defending against, or appearing as a third party witness in respect of, or otherwise incurred in connection with, any such loss, claim, damage, expense, liability, action, investigation or proceeding, as such fees and expenses are incurred; provided, however, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage, expense or liability arises out of or is based upon an untrue statement or alleged untrue statement in, or omission or alleged omission from any Preliminary Prospectus, the Registration Statement, the Prospectus, or any such amendment or supplement thereto, any Issuer Free Writing Prospectus or any Marketing Materials made in reliance upon and in conformity with written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for use therein, which information the parties hereto agree is limited to the Underwriters' Information. Each indemnity agreement in this Section 7(a) is not exclusive and is in addition to each other indemnity agreement in this Section 7(a) and each other liability which the Company might have under this Agreement or otherwise, and shall not limit any rights or remedies which may otherwise be available under this Agreement, at law or in equity to any Underwriter Indemnified Party.

Indemnification of Company by the Underwriters. Each Underwriter, severally and not jointly, shall (b)indemnify and hold harmless the Company and each of its directors, and each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (collectively the "Company Indemnified Parties" and each a "Company Indemnified Party") against any loss, claim, damage, expense or liability whatsoever (or any action, investigation or proceeding in respect thereof), joint or several, to which such Company Indemnified Party may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, expense, liability, action, investigation or proceeding arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" filed or required to be filed pursuant to Rule 433(d) of the Rules and Regulations, the Registration Statement, the Prospectus or in any amendment or supplement thereto, or (ii) the omission or alleged omission to state in any Preliminary Prospectus, any Issuer Free Writing Prospectus, any "issuer information" filed or required to be filed pursuant to Rule 433(d) of the Rules and Regulations, the Registration Statement, the Prospectus or in any amendment or supplement thereto, a material fact required to be stated therein or necessary to make the statements therein not misleading, but in each case only to the extent that the untrue statement or alleged untrue statement or omission or alleged omission was made in reliance upon and in conformity with written information furnished to the Company through the Representatives by or on behalf of that Underwriter specifically for use therein, which information the parties hereto agree is limited to the Underwriters' Information, and shall reimburse the Company Indemnified Parties for any legal or other expenses reasonably incurred by such party in connection with investigating or preparing to defend or defending against or appearing as third party witness in connection with any such loss, claim, damage, liability, action, investigation or proceeding, as such fees and expenses are incurred. This indemnity agreement is not exclusive and will be in addition to any liability which the Underwriters might otherwise have and shall not limit any rights or remedies which may otherwise be available under this Agreement, at law or in equity to the Company Indemnified Parties.

Promptly after receipt by an indemnified party under this Section 7 of notice of the commencement of (c) any action, the indemnified party shall, if a claim in respect thereof is to be made against an indemnifying party under this Section 7, notify such indemnifying party in writing of the commencement of that action; provided, however, that the failure to notify the indemnifying party shall not relieve it from any liability which it may have under this Section 7 except to the extent it has been materially prejudiced by such failure; and, provided, further, that the failure to notify an indemnifying party shall not relieve it from any liability which it may have to an indemnified party otherwise than under this Section 7. If any such action shall be brought against an indemnified party, and it shall notify the indemnifying party thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it wishes, jointly with any other similarly notified indemnifying party, to assume the defense of such action with counsel reasonably satisfactory to the indemnified party (which counsel shall not, except with the written consent of the indemnified party, be counsel to the indemnifying party). After notice from the indemnifying party to the indemnified party of its election to assume the defense of such action, except as provided herein, the indemnifying party shall not be liable to the indemnified party under Section 7 for any legal or other expenses subsequently incurred by the indemnified party in connection with the defense of such action other than reasonable costs of investigation; provided, however, that any indemnified party shall have the right to employ separate counsel in any such action and to participate in the defense of such action but the fees and expenses of such counsel (other than reasonable costs of investigation) shall be at the expense of such indemnified party unless (i) the employment thereof has been specifically authorized in writing by the Company in the case of a claim for indemnification under Section 7(a) or the Representatives in the case of a claim for indemnification under Section 7(b), (ii) such indemnified party shall have been advised by its counsel that there may be one or more legal defenses available to it which are different from or additional to those available to the indemnifying party, or (iii) the indemnifying party has failed to assume the defense of such action and employ counsel reasonably satisfactory to the indemnified party within a reasonable period of time after notice of the commencement of the action or the indemnifying party does not diligently defend the action after assumption of the defense, in which case, if such indemnified party notifies the indemnifying party in writing that it elects to employ separate counsel at the expense of the indemnifying party, the indemnifying party shall not have the right to assume the defense of (or, in the case of a failure to diligently defend the action after assumption of the defense, to continue to defend) such action on behalf of such indemnified party and the indemnifying party shall be responsible for legal or other expenses subsequently incurred by such indemnified party in connection with the defense of such action; provided, however, that the indemnifying party shall not, in connection with any one such action or separate but substantially similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances, be liable for the reasonable fees and expenses of more than one separate firm of attorneys at any time for all such indemnified parties (in addition to any local counsel), which firm shall be designated in writing by the Representatives if the indemnified parties under this Section 7 consist of any Underwriter Indemnified Party or by the Company if the indemnified parties under this Section 7 consist of any Company Indemnified Parties. Subject to this Section 7(c), the amount payable by an indemnifying party under Section 7 shall include, but not be limited to, (x) reasonable and documented legal fees and expenses of counsel to the indemnified party and any other expenses in investigating, or preparing to defend or defending against, or appearing as a third party witness in respect of, or otherwise incurred in connection with, any action, investigation, proceeding or claim, and (y) all amounts paid in settlement of any of the foregoing. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of judgment with respect to any pending or threatened action or any claim whatsoever, in respect of which indemnification or contribution could be sought under this Section 7 (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party in form and substance reasonably satisfactory to such indemnified party from all liability arising out of such action or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party. Subject to the provisions of the following sentence, no indemnifying party shall be liable for settlement of any pending or threatened action or any claim whatsoever that is effected without its written consent (which consent shall not be unreasonably withheld or delayed), but if settled with its written consent, if its consent has been unreasonably withheld or delayed or if there be a judgment for the plaintiff in any such matter, the indemnifying party agrees to indemnify and hold harmless any indemnified party from and against any loss or liability by reason of such settlement or judgment. In addition, if at any time an indemnified party shall have requested that an indemnifying party reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 7(a) effected without its written consent if (i) such settlement is entered into more than sixty (60) days after receipt by such indemnifying party of the request for reimbursement, (ii) such indemnifying party shall have received notice of the terms of such settlement at least forty-five (45) days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

If the indemnification provided for in this Section 7 is unavailable or insufficient to hold harmless an (d) indemnified party under Section 7(a) or 7(b), then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid, payable or otherwise incurred by such indemnified party as a result of such loss, claim, damage, expense or liability (or any action, investigation or proceeding in respect thereof), as incurred, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering of the Shares, or (ii) if the allocation provided by clause (i) of this Section 7(d) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) of this Section 7(d), but also the relative fault of the Company on the one hand and the Underwriters on the other with respect to the statements, omissions, acts or failures to act which resulted in such loss, claim, damage, expense or liability (or any action, investigation or proceeding in respect thereof) as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other with respect to such offering shall be deemed to be in the same proportion as the total net proceeds from the offering of the Shares purchased under this Agreement (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters with respect to the Shares purchased under this Agreement, in each case as set forth in the table on the cover page of the Prospectus. The relative fault of the Company on the one hand and the Underwriters on the other shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company on the one hand or the Underwriters on the other, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such untrue statement, omission, act or failure to act; provided that the parties hereto agree that the written information furnished to the Company through the Representatives by or on behalf of the Underwriters for use in the Preliminary Prospectus, the Registration Statement, the Prospectus, or in any amendment or supplement thereto, consists solely of the Underwriters' Information.

(e) The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to Section 7(d) above were to be determined by pro rata allocation or by any other method of allocation which does not take into account the equitable considerations referred to Section 7(d) above. The amount paid or payable by an indemnified party as a result of the loss, claim, damage, expense, liability, action, investigation or proceeding referred to in Section 7(d) above shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating, preparing to defend or defending against or appearing as a third party witness in respect of, or otherwise incurred in connection with, any such loss, claim, damage, expense, liability, action, investigation or proceeding. Notwithstanding the provisions of this Section 7, no Underwriters shall be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Shares exceeds the amount of any damages which the Underwriter has otherwise paid or become liable to pay by reason of any untrue or alleged untrue statement, omission or alleged omission, act or alleged act or failure to act or alleged failure to act. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribute as provided in this Section 7 are several in proportion to their respective underwriting obligations and not joint.

8. *TERMINATION.* The obligations of the Underwriters hereunder may be terminated by the Representatives, in their absolute discretion by notice given to the Company prior to delivery of and payment for the Firm Shares if, prior to that time, any of the events described in Section 6(o) have occurred or if the Underwriters shall decline to purchase the Shares for any reason permitted under this Agreement.

9. REIMBURSEMENT OF UNDERWRITERS' EXPENSES. Notwithstanding anything to the contrary in this Agreement, if (a) this Agreement shall have been terminated pursuant to Section 8 or 10, (b) the Company shall fail to tender the Shares for delivery to the Underwriters for any reason not permitted under this Agreement, (c) the Underwriters shall decline to purchase the Shares for any reason permitted under this Agreement or (d) the sale of the Shares is not consummated because any condition to the obligations of the Underwriters set forth herein is not satisfied or because of the refusal, inability or failure on the part of the Company to perform any agreement herein or to satisfy any condition or to comply with the provisions hereof, then, in addition to the payment of amounts in accordance with Section 5, the Company shall reimburse the Underwriters for the reasonably incurred and documented by them in connection with this Agreement and the proposed purchase of the Shares, including, without limitation, travel and lodging expenses of the Underwriters, and upon demand the Company shall pay the full amount thereof to the Representatives; provided that if this Agreement is terminated pursuant to Section 10 by reason of the default of one or more Underwriters, the Company shall not be obligated to reimburse any defaulting Underwriter on account of expenses to the extent incurred by such defaulting Underwriter, provided further that the foregoing shall not limit any reimbursement obligation of the Company to any non-defaulting Underwriter under this Section 9.

10. *SUBSTITUTION OF UNDERWRITERS.* If any Underwriter or Underwriters shall default in its or their obligations to purchase the Shares hereunder on any Closing Date ("Defaulting Securities"), the Representatives shall have the right, within 24 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or, after notice to the Company, any other underwriters, to purchase all, but not less than all, of the Defaulting Securities in such amounts as may be agreed upon and upon the terms herein set forth; if however, the Representatives shall not have completed such arrangements within such 24-hour period, then:

(a) if the aggregate number of Defaulting Securities does not exceed ten percent (10%) of the total number of Shares to be purchased by all Underwriters on such Closing Date, the other Underwriters shall be obligated severally, in proportion to their respective commitments hereunder, to purchase the Defaulting Securities; or

(b) if the aggregate number of Defaulting Securities is more than ten percent (10%) of the total number of shares to be purchased by all Underwriters on such Closing Date, and arrangements satisfactory to the Representatives and the Company for the purchase of such Shares by other persons are not made within forty-eight (48) hours after such default, this Agreement shall terminate.

If the remaining Underwriters or substituted Underwriters are required hereby or agree to take up all or part of the shares of Shares of a defaulting Underwriter or Underwriters on such Closing Date as provided in this Section 10, (i) the Company shall have the right to postpone such Closing Dates for a period of not more than five (5) full business days in order that the Company may effect whatever changes may thereby be made necessary in the Registration Statement or the Prospectus, or in any other documents or arrangements, and the Company agrees promptly to file any amendments to the Registration Statement or supplements to the Prospectus which may thereby be made necessary, and (ii) the respective numbers of shares to be purchased by the remaining Underwriters or substituted Underwriters shall be taken as the basis of their underwriting obligation for all purposes of this Agreement. Nothing herein contained shall relieve any defaulting Underwriter of its liability to the Company or the other Underwriters for damages occasioned by its default hereunder. Any termination of this Agreement pursuant to this Section 10 shall be without liability on the part of any non-defaulting Underwriter or the Company, except that the representations, warranties, covenants, indemnities, agreements and other statements set forth in Section 2, the obligations with respect to expenses to be paid or reimbursed pursuant to Sections 5 and 9 and the provisions of Section 7 and Sections 11 through 21, inclusive, shall not terminate and shall remain in full force and effect.

## 11. *ABSENCE OF FIDUCIARY RELATIONSHIP.* The Company acknowledges and agrees that:

(a) each Underwriter's responsibility to the Company is solely contractual in nature, the Representatives have been retained solely to act as underwriters in connection with the sale of the Shares and no fiduciary, advisory or agency relationship between the Company and the Representatives have been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether any of the Representatives has advised or is advising the Company on other matters;

(b) the price of the Shares set forth in this Agreement was established by the Company following discussions and arms-length negotiations with the Representatives, and the Company is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) it has been advised that the Representatives and their affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that the Representatives have no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) it waives, to the fullest extent permitted by law, any claims it may have against the Representatives for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that the Representatives shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including shareholders, employees or creditors of the Company.

12. *Successors; Persons Entitled to Benefit of Agreement.* This Agreement shall inure to the benefit of and be binding upon the several Underwriters, the Company, its Subsidiaries and their respective successors and assigns. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, other than the persons mentioned in the preceding sentence, any legal or equitable right, remedy or claim under or in respect of this Agreement, or any provisions herein contained, this Agreement and all conditions and provisions hereof being intended to be and being for the sole and exclusive benefit of such persons and for the benefit of no other person; except that the representations, warranties, covenants, agreements and indemnities of the Company contained in this Agreement shall also be for the benefit of the Underwriter Indemnified Parties, and the indemnities of the several Underwriters shall be for the benefit of the Company Indemnified Parties. It is understood that each Underwriter's responsibility to the Company is solely contractual in nature and the Underwriters do not owe the Company, or any other party, any fiduciary duty as a result of this Agreement. No purchaser of any of the Shares from any Underwriter shall be deemed to be a successor or assign by reason merely of such purchase.

13. *SURVIVAL OF INDEMNITIES, REPRESENTATIONS, WARRANTIES, ETC.* The respective indemnities, covenants, agreements, representations, warranties and other statements of the Company and the several Underwriters, as set forth in this Agreement or made by them respectively, pursuant to this Agreement, shall remain operative and in full force and effect, regardless of any investigation made by or on behalf of any Underwriter, the Company or any person controlling any of them and shall survive delivery of and payment for the Shares. Notwithstanding any termination of this Agreement, including without limitation any termination pursuant to Section 8 or Section 10, the indemnities, covenants, agreements, representations, warranties and other statements forth in Sections 2, 5, 7 and 9 and Sections 11 through 21, inclusive, of this Agreement shall not terminate and shall remain in full force and effect at all times.

## 14. RECOGNITION OF THE U.S. SPECIAL RESOLUTION REGIMES.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

15. *Notices.* All statements, requests, notices and agreements hereunder shall be in writing, and:

(a) if to the Underwriters, shall be delivered or sent by mail, telex, facsimile transmission or email to Cowen and Company, LLC, Attention: Head of Equity Capital Markets, Fax: 646-562-1249 with a copy to the General Counsel, Fax: 646-562-1124 Stifel, Nicolaus & Company, Incorporated, [-]; and Richard C. Segal, Cooley LLP, 1114 Avenue of the Americas, New York, New York 10036-7798; Fax: 212-479-6275 and (b) if to the Company shall be delivered or sent by mail, telex, facsimile transmission or email to GH Research PLC, Attention: [•], with a copy to Davis Polk & Wardwell LLP, 450 Lexington Avenue, New York, New York, Attention: Yasin Keshvargar; *provided, however*, that any notice to an Underwriter pursuant to Section 7 shall be delivered or sent by mail, or facsimile transmission to such Underwriter at its address set forth in its acceptance telex to the Representatives, which address will be supplied to any other party hereto by the Representatives upon request. Any such statements, requests, notices or agreements shall take effect at the time of receipt thereof.

16. *DEFINITION OF CERTAIN TERMS.* For purposes of this Agreement, (a) "*affiliate*" has the meaning set forth in Rule 405 under the Securities Act, (b) "*business day*" means any day on which the New York Stock Exchange, Inc. is open for trading (c) "*subsidiary*" has the meaning set forth in Rule 405 of the Rules and Regulations; (d) "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k); (e) "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or (iii) a "covered FSI" as that term is defined in accordance with, 12 C.F.R. § 382.2(b); (f) "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. § 252.81, 47.2 or 382.1, as applicable; and (g) "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

GOVERNING LAW JURISDICTION, WAIVER OF JURY TRIAL, AGENT FOR SERVICE. This Agreement shall be governed by 17. and construed in accordance with the laws of the State of New York, including without limitation Section 5-1401 of the New York General Obligations. The Company irrevocably (a) submits to the exclusive jurisdiction of the Federal and state courts in the Borough of Manhattan in The City of New York for the purpose of any suit, action or other proceeding arising out of this Agreement or the transactions contemplated by this Agreement, the Registration Statement, and any Preliminary Prospectus or the Prospectus, (b) agrees that all claims in respect of any such suit, action or proceeding may be heard and determined by any such court, (c) waives to the fullest extent permitted by applicable law, any immunity from the jurisdiction of any such court or from any legal process, (d) agrees not to commence any such suit, action or proceeding other than in such courts, and (e) waives, to the fullest extent permitted by applicable law, any claim that any such suit, action or proceeding is brought in an inconvenient forum. Each of the parties to this Agreement hereby waives any right to trial by jury in any suit or proceeding arising out of or relating to this Agreement. The Company and its subsidiaries irrevocably appoints Cogency Global Inc., with offices at 122 East 42<sup>nd</sup> Street, 18<sup>th</sup> Floor New York, NY 10168 (and its successors) as its authorized agent in the Borough of Manhattan in The City of New York upon which process may be served in any such suit or proceeding, and agrees that service of process upon such agent, and written notice of said service to the Company or its subsidiaries by the person serving the same to the address provided in Section 15(b), shall be deemed in every respect effective service of process upon the Company in any such suit or proceeding.

18. UNDERWRITERS' INFORMATION. The parties hereto acknowledge and agree that, for all purposes of this Agreement, the Underwriters' Information consists solely of the following information in the Prospectus: the statements concerning the Underwriters contained in the Prospectus under the heading "Underwriting."

19. *AUTHORITY OF THE REPRESENTATIVES.* In connection with this Agreement, the Representatives will act for and on behalf of the several Underwriters, and any action taken under this Agreement by the Representatives, will be binding on all of the Underwriters.

20. *PARTIAL UNENFORCEABILITY*. The invalidity or unenforceability of any section, paragraph, clause or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph, clause or provision hereof. If any section, paragraph, clause or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

21. *GENERAL*. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. In this Agreement, the masculine, feminine and neuter genders and the singular and the plural include one another. The section headings in this Agreement are for the convenience of the parties only and will not affect the construction or interpretation of this Agreement. This Agreement may be amended or modified, and the observance of any term of this Agreement may be waived, only by a writing signed by the Company and the Representatives.

22. *COUNTERPARTS.* This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com or www.echosign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes

23. JUDGMENT CURRENCY. The obligations of the Company pursuant to this Agreement in respect of any sum due to any Underwriter shall, notwithstanding any judgment in a currency other than United States dollars, not be discharged until the first (1<sup>st</sup>) business day, following receipt by such Underwriter of any sum adjudged to be so due in such other currency, on which (and only to the extent that) such Underwriter may in accordance with normal banking procedures purchase United States dollars with such other currency; if the United States dollars so purchased are less than the sum originally due to such Underwriter hereunder, the Company agrees, as a separate obligation and notwithstanding any such judgment, to indemnify such Underwriter against such loss.

# (Signature page follows)

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If the foregoing is in accordance with your understanding please indicate your acceptance of this Agreement by signing in the space provided for that purpose below.

Very truly yours,

GH RESEARCH PLC

By:

Name: Title:

Accepted as of the date first above written: Cowen and Company, LLC

Acting on their own behalf and as Representatives of several Underwriters listed on Schedule A to this Agreement.

By: Cowen and Company, LLC

By:

Name: Title:

By: STIFEL, NICOLAUS & COMPANY, INCORPORATED

By:

Name: Title:

(Signature Page to GH Research PLC Underwriting Agreement)

# **SCHEDULE A**

Number of Firm Shares

Name Cowen and Company, LLC Stifel, Nicolaus & Company, Incorporated

Total

Sch. A

Number of Optional Shares

# SCHEDULE B

General Use Free Writing Prospectuses

Sch. B

# **SCHEDULE C**

Pricing Information [•] Ordinary Shares \$[•] per Ordinary Share [•]% discounts and \$[•]

Sch. C

Firm Shares:[•] OrdiOffering Price:\$[•] perUnderwriting Discounts and Commissions:[•]%Estimated Net Proceeds to the Company (after underwriting discounts and \$[•]commissions, but before transaction expenses):

### Exhibit I

# Form of Lock-Up Agreement

[DATE], 2021

Cowen and Company, LLC Stifel, Nicolaus & Company, Incorporated

As Representatives of the several Underwriters

c/o Cowen and Company, LLC 599 Lexington Avenue, 25<sup>th</sup> Floor New York, New York 10022

c/o Stifel, Nicolaus & Company, Incorporated 787 7<sup>th</sup> Avenue, 11<sup>th</sup> Floor New York, New York 10019

Re: GH Research PLC – Registration Statement on Form F-1

Dear Sirs and Madams:

This letter agreement (the "Agreement") is being delivered to you in connection with the proposed Underwriting Agreement (the "Underwriting Agreement") between GH Research PLC, a public limited company under the laws of Ireland (together with any successor thereto, the "Company") and Cowen and Company, LLC ("Cowen") and Stifel, Nicolaus & Company, Incorporated ("Stifel"), as representatives (the "Representatives") of a group of underwriters (collectively, the "Underwriters"), to be named therein, and the other parties thereto (if any), relating to the proposed public offering (the "Offering") of ordinary shares, nominal value \$0.025 per share (the "Ordinary Shares") of the Company.

In order to induce the Underwriters to enter into the Underwriting Agreement, and in light of the benefits that the Offering of the Ordinary Shares will confer upon the undersigned in his, her or its capacity as a securityholder and/or an officer, director or employee of the Company, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each Underwriter that, during the period beginning on the date hereof through and including the date that is the 180th day after the date of the Underwriting Agreement (the "Lock-Up Period"), the undersigned will not, and will not cause or direct any of its affiliates to, without the prior written consent of the Representatives, directly or indirectly, (i) offer, sell, assign, transfer, pledge, contract to sell, lend or otherwise dispose of, or announce the intention to otherwise dispose of, any Ordinary Shares (including, without limitation, Ordinary Shares which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations promulgated under the Securities Act of 1933, as amended (the "Securities Act") as the same may be amended or supplemented from time to time (such Ordinary Shares, the "Beneficially Owned Ordinary Shares")) or securities convertible into or exercisable or exchangeable for Ordinary Shares, (ii) enter into, or announce the intention to enter into, any swap, hedge or similar agreement or arrangement (including, without limitation, the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) that transfers, is designed to transfer or reasonably could be expected to transfer (whether by the undersigned or someone other than the undersigned) in whole or in part, directly or indirectly, the economic risk of ownership of the Beneficially Owned Ordinary Shares or securities convertible into or exercisable or exchangeable for Ordinary Shares, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition, or (iii) engage in, or announce the intention to engage in, any short selling of the Ordinary Shares or securities convertible into or exercisable or exchangeable for Ordinary Shares (the "Prohibited Activities"). The undersigned represents and warrants that the undersigned is not, and has not caused or directed any of its affiliates to be or become, currently a party to any agreement or arrangement that is designed to or which reasonably could be expected to lead to or result in any Prohibited Activities during the Lock-Up Period.

If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any issuer-directed Ordinary Shares the undersigned may purchase in the Offering.

If the undersigned is an officer or director of the Company, (i) the Representatives agree that, at least three (3) business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of Ordinary Shares, the Representatives will notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two (2) business days before the effective date of the release or waiver. Any release or waiver granted by the Representatives hereunder to any such officer or director shall only be effective on the date that is two (2) business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this Agreement to the extent and for the duration that such terms remain in effect at the time of the transfer.

The restrictions set forth in this agreement shall not apply to:

- (a) transactions relating to Ordinary Shares or any security convertible into Ordinary Shares acquired in the Offering (other than any issuerdirected Ordinary Shares purchased in the Offering by an officer or director of the Company) or in open market transactions after the completion of the Offering;
- (b) transfers or dispositions of Ordinary Shares or any security convertible into Ordinary Shares as a bona fide gift or for bona fide estate planning purposes or to a charitable organization or educational institutional;
- (c) transfers or dispositions of Ordinary Shares or any security convertible into Ordinary Shares to any member of the immediate family of the undersigned, affiliate thereof, or any trust or trustee or beneficiary thereof for the direct or indirect benefit of the undersigned or the immediate family of the undersigned;
- (d) transfers or dispositions of Ordinary Shares or any security convertible into Ordinary Shares to any corporation, partnership, limited liability company or other entity or affiliate of the undersigned or the immediate family of the undersigned;
- (e) transfers or dispositions of Ordinary Shares or any security convertible into Ordinary Shares (x) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the undersigned upon the death of the undersigned, or (y) by operation of law pursuant to a domestic order or negotiated divorce settlement;

- (f) transfers or dispositions of Ordinary Shares or any security convertible into Ordinary Shares to another corporation, member, partnership, limited liability company, trust or other entity that is a direct or indirect affiliate (as defined under Rule 12b-2 of the Exchange Act) of the undersigned, or to an investment fund or other entity that controls or manages, or is under common control with, the undersigned, or distributions of Ordinary Shares or other securities to partners, members, stockholders, beneficiaries or other equity holders of the undersigned;
- (g) transfers or dispositions of Ordinary Shares or any security convertible into Ordinary Shares to the Company (i) in connection with the repurchase of such securities with respect to the termination of the undersigned's employment with the Company or (ii) pursuant to contractual arrangements described in the Prospectus;

provided that in the case of any transfer, disposition or distribution (i) pursuant to clause (b), (c), (d) or (f), each transferee, donee or distributee shall sign and deliver a lock-up letter substantially in the form of this letter and (ii) pursuant to clause (b), (c), (d), (e), (f) or (g), no public announcement or filing under Section 16(a) of the Exchange Act (or its foreign equivalent), reporting a reduction in beneficial ownership of Ordinary Shares, shall be required or shall be voluntarily made during the Restricted Period (other than, in the case of a transfer or other disposition pursuant to clause (e) or (g) above, any Form 4 or Form 5 required to be filed under the Exchange Act (or its foreign equivalent) if the undersigned is subject to Section 16 reporting with respect to the Company under the Exchange Act (or its foreign equivalent) and indicating by footnote disclosure or otherwise the nature of the transfer or disposition);

- (h) transfers or dispositions (including through a "cashless" exercise or on a "net exercise" basis) of Ordinary Shares or any security convertible into Ordinary Shares to the Company in connection with the conversion of any convertible security into, or the exercise of any option or warrant for Ordinary Shares (including to satisfy withholding obligations or the payment of taxes in connection therewith); *provided* that (i) any such Ordinary Shares received by the undersigned shall be subject to the terms of this agreement and (ii) no filing under Section 16(a) of the Exchange Act (or its foreign equivalent) reporting a reduction in beneficial ownership of Ordinary Shares shall be required or shall be voluntarily made during the Restricted Period;
- (i) transfers or dispositions of Ordinary Shares or any security convertible into Ordinary Shares prior to the date of the public filing of the Company's Registration Statement on Form F-1 in connection with the Offering (the "Registration Statement") and pursuant to the Shareholders' Agreement dated April 12, 2021 by and between GH Research Ireland Limited and the shareholders party thereto, as such agreement may be amended or superseded;
- (j) transfers or dispositions of Ordinary Shares or other securities to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (a) through (j) above, *provided* that any Ordinary Shares shall be subject to the terms of this agreement;
- (k) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act (or its foreign equivalent) for the transfer of Ordinary Shares, *provided* that (i) such plan does not provide for the transfer of Ordinary Shares during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act (or its foreign equivalent), if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Ordinary Shares may be made under such plan during the Restricted Period;

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- (1) transfers or dispositions of Ordinary Shares or any security convertible into Ordinary Shares pursuant to a bona fide tender offer for the Company's capital shares, merger, consolidation or other similar transaction made to all holders of the Company's securities involving a Change of Control (as defined below) of the Company (including without limitation, the entering into of any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of Ordinary Shares or any security convertible into Ordinary Shares in connection with such transaction) that has been approved by the board of directors of the Company; *provided* that, in the event that such Change of Control transaction is not consummated, this clause (n) shall not be applicable and the undersigned's shares and other securities shall remain subject to the restrictions contained in this agreement; or
- (m) the conversion, exercise or exchange of Preferred Shares, options to purchase Ordinary Shares, warrants or any security convertible into Ordinary Shares pursuant to any reorganization, conversion or share split, as such terms are described in the Prospectus; *provided* that any such securities shall remain subject to the terms of this agreement.

For purposes of this agreement, "immediate family" shall mean any relationship by blood, marriage, domestic partnership or adoption, not more remote than first cousin, and securities of the Company (for purposes of determining record or beneficial *ownership* of a shareholder, all shares or securities held by investment funds affiliated with such shareholder shall be aggregated) and "Change of Control" shall mean the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transactions or a series of related transactions, to a person or group of affiliated persons (other than an Underwriter pursuant to the Offering), of the Company's voting securities if, after such transfer, such person or group of affiliated persons would hold greater than 50% of the outstanding voting securities of the Company (or the surviving entity), *provided* that, for the avoidance of doubt, the Offering shall not constitute a Change of Control.

In order to enable this covenant to be enforced, the undersigned hereby consents to the placing of legends or stop transfer instructions with the Company's transfer agent with respect to any Ordinary Shares or securities convertible into or exercisable or exchangeable for Ordinary Shares.

The undersigned further agrees that it will not, during the Lock-Up Period, make any demand or request for or exercise any right with respect to the registration under the Securities Act, of any Ordinary Shares or other Beneficially Owned Ordinary Shares or any securities convertible into or exercisable or exchangeable for Ordinary Shares or other Beneficially Owned Ordinary Shares.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Agreement and that this Agreement has been duly authorized (if the undersigned is not a natural person), executed and delivered by the undersigned and is a valid and binding agreement of the undersigned. This Agreement and all authority herein conferred are irrevocable and shall survive the death or incapacity of the undersigned (if a natural person) and shall be binding upon the heirs, personal representatives, successors and assigns of the undersigned.

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The undersigned acknowledges and agrees that the Underwriters have not provided any recommendation or investment advice nor have the Underwriters solicited any action from the undersigned with respect to the Offering of Ordinary Shares and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate. The undersigned further acknowledges and agrees that, although the Representatives may be required or choose to provide certain Regulation Best Interest and Form CRS disclosures to you in connection with the Offering, the Representatives and the other Underwriters are not making a recommendation to you to enter into this Agreement and nothing set forth in such disclosures is intended to suggest that the Representatives or any Underwriter is making such a recommendation.

This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state.

This Agreement may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com or www.echosign.com) or other transmission method and any copy so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

If (i) the Company notifies Cowen in writing that it does not intend to proceed with the Offering, (ii) the Underwriting Agreement is not executed by September 30, 2021, or (iii) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated for any reason prior to payment for and delivery of any Ordinary Shares to be sold thereunder, then this Agreement shall immediately be terminated and the undersigned shall automatically be released from all of his, her or its obligations under this Agreement. The undersigned acknowledges and agrees that whether or not any public offering of Ordinary Shares actually occurs depends on a number of factors, including market conditions.

[Signature page follows]

Very truly yours,

(Name of Securityholder - Please Print)

(Signature)

(Name of Signatory if Securityholder is an entity - Please Print)

(Title of Signatory if Securityholder is an entity - Please Print)

Address:

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# Exhibit II

# **GH Research PLC**

# [Date]

GH Research PLC announced today that Cowen and Company, LLC and Stifel, Nicolaus & Company, Incorporated the lead book-running managers in the Company's recent public sale of [•] Shares, each representing [•] ordinary shares, is [waiving] [releasing] a lock-up restriction with respect to [•] of the Company's Shares held by [certain officers or directors][an officer or director] of the Company. The [waiver][release] will take effect on , 20 , and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or exemption from registration under the United States Securities Act of 1933, as amended.

# **Companies Act 2014**

# PUBLIC LIMITED COMPANY

# CONSTITUTION

### OF

### **GH RESEARCH PUBLIC LIMITED COMPANY**

### MEMORANDUM OF ASSOCIATION

- 1 The name of the Company is GH RESEARCH PUBLIC LIMITED COMPANY.
- 2 The Company is a public limited company registered under Part 17 of the Companies Act 2014.
- 3 The objects for which the Company is established are:
  - (a) To carry on the business of a holding company and to co-ordinate the administration, finances and activities of any subsidiary companies or associated companies, to do all lawful acts and things whatsoever that are necessary or convenient in carrying on the business of such a holding company and in particular to carry on business in all its branches, companies or locations related to biopharmaceutical research and the development of novel therapies for the management of mental diseases.
  - (b) To carry on the businesses of a researcher, developer, manufacturer, distributor, wholesaler, retailer, service provider, investor, trader and any other business which may seem to the Company's board of directors capable of being conveniently carried on in connection with these objects or calculated directly or indirectly to enhance the value of or render more profitable any of the Company's property.
  - (c) To carry on all or any of the businesses as aforesaid either as a separate business or as the principal business of the Company.
  - (d) To invest and deal with the property of the Company in such manner as may from time to time be determined by the Company's board of directors and to dispose of or vary such investments and dealings.
  - (e) To borrow or raise money or capital in any manner and on such terms and subject to such conditions and for such purposes as the Company's board of directors shall think fit or expedient, whether alone or jointly and/or severally with any other person or company, including, without prejudice to the generality of the foregoing, whether by the issue of debentures or debenture stock (perpetual or otherwise) or otherwise, and to secure, with or without consideration, the payment or repayment of any money borrowed, raised or owing or any debt, obligation or liability of the Company or of any other person or company whatsoever in such manner and on such terms and conditions as the Company's board of directors shall think fit or expedient and, in particular by mortgage, charge, lien, pledge or debenture or any other security of whatsoever nature or howsoever described, perpetual or otherwise, charged upon all or any of the Company's property, both present and future, and to purchase, redeem or pay off any such securities and also to accept capital contributions from any person or company in any manner and on such terms and conditions and for such purposes as the Company's board of directors shall think fit or expedient.

- (f) To lend and advance money or other property or give credit or financial accommodation to any company or person in any manner either with or without security and whether with or without the payment of interest and upon such terms and conditions as the Company's board of directors shall think fit or expedient.
- (g) To guarantee, indemnify, grant indemnities in respect of, enter into any suretyship or joint obligation, or otherwise support or secure, whether by personal covenant, indemnity or undertaking or by mortgaging, charging, pledging or granting a lien or other security over all or any part of the Company's property (both present and future) or by any one or more of such methods or any other method and whether in support of such guarantee or indemnity or suretyship or joint obligation or otherwise, on such terms and conditions as the Company's board of directors shall think fit, the payment of any debts or the performance or discharge of any contract, obligation or liability of any person or company (including, without prejudice to the generality of the foregoing, the payment of any capital, principal, dividends or interest on any stocks, shares, debentures, debenture stock, notes, bonds or other securities of any person, authority or company) including, without prejudice to the generality of the foregoing, any company which is for the time being the Company's holding company or another subsidiary (as defined by the Act) of the Company's holding company or a subsidiary of the Company.
- (h) To grant, convey, assign, transfer, exchange or otherwise alienate or dispose of any property of the Company of whatever nature or tenure for such price, consideration, sum or other return whether equal to or less than the market value thereof or for shares, debentures or securities and whether by way of gift or otherwise as the Company's board of directors shall deem fit or expedient.
- (i) To purchase, take on, lease, exchange, rent, hire or otherwise acquire any property and to acquire and undertake the whole or any part of the business and property of any company or person.
- (j) To engage in currency exchange, interest rate and commodity transactions including, but not limited to, dealings in foreign currency, spot and forward rate exchange contracts, futures, options, forward rate agreements, swaps, caps, floors, collars and any other foreign exchange, interest rate or commodity hedging arrangements and such other instruments as are similar to, or derived from, any of the foregoing whether for the purpose of making a profit or avoiding a loss or managing a currency, interest rate or commodity exposure or any other exposure or for any other purpose.
- (k) To apply for, establish, create, purchase or otherwise acquire, sell or otherwise dispose of and hold any patents, trade marks, copyrights, brevets d' invention, registered designs, licences, concessions and the like conferring any exclusive or non-exclusive or limited rights to use or any secret or other information and any invention and to use, exercise, develop or grant licences in respect of or otherwise turn to account or exploit the property, rights or information so held.

- (l) To enter into any arrangements with any governments or authorities, national, local or otherwise and to obtain from any such government or authority any rights, privileges and concessions and to carry out, exercise and comply with any such arrangements, rights, privileges and concessions.
- (m) To establish, form, register, incorporate or promote any company or companies or person, whether inside or outside of Ireland.
- (n) To remunerate any person or company for services rendered or to be rendered in placing or assisting to place or guaranteeing the placing of any of the shares of the Company's capital or any debentures, debenture stock or other securities of the Company or in or about the formation or promotion of the Company or the conduct of its business.
- (o) To adopt such means of making known the products of the Company as may seem expedient and in particular by advertising in the press, by circulars, by purchase and exhibition of works of art or interest, by publication of books and periodicals and by granting prizes, rewards and donations.
- (p) To pay all costs, charges, fees and expenses incurred or sustained in or about the promotion, establishment, formation and registration of the Company.
- (q) To do all or any of the above things in any part of the world, and as principals, agents, contractors, trustees or otherwise and by or through trustees, agents or otherwise and either alone or in conjunction with any person or company.
- (r) To do all such other things as the Company's board of directors may think incidental or conducive to the attainment of the above objects or any of them
- 4 The liability of the members is limited.
- 5 The share capital of the Company is €25,000.00 and US\$1,000,000,000.00 divided into 25,000 A Ordinary Shares of €1.00 each, 99,968,697,874 Ordinary Shares of US\$0.01 each, 5,923,079 Series A Preferred Shares of US\$0.01 each and 25,379,047 Series B Preferred Shares of US\$0.01 each.
- 6 The shares forming the capital, increased or reduced, may be increased or reduced and be divided into such classes and issued with any special rights, privileges and conditions or with such qualifications as regards preference, dividend, capital, voting or other special incidents, and be held upon such terms as may be attached thereto or as may from time to time be provided by the original or any substituted or amended articles of association and regulations of the Company for the time being, but so that where shares are issued with any preferential or special rights attached thereto such rights shall not be alterable otherwise than pursuant to the provisions of the Company's articles of association for the time being.

### **ARTICLES OF ASSOCIATION**

# Part 1 - Interpretation

#### 1. Interpretation and general

- 1.1 The "optional provisions" as defined by section 1007(2) of the Act shall apply to the Company save in so far as they are excluded or modified herein.
- 1.2 In these Articles, unless the context requires otherwise:

"A **Conversion Price**" means the conversion price of a Series A Preferred Share in effect at the relevant time of determination, which shall (unless adjusted in accordance with these Articles) be equal to the Original Issue Price of the Series A Preferred Share;

"A Conversion Rate" means the rate obtained by dividing the Original Issue Price of the Series A Preferred Share by the A Conversion Price in effect at the relevant time of determination in accordance with these Articles;

"A Ordinary Shares" means the A ordinary shares of €1.00 each in the capital of the Company;

"A Preferred Shareholders" means the holders of Series A Preferred Shares;

"Additional Shares" means all Shares issued (or deemed to be issued pursuant to these Articles) after the Date of Adoption, other than pursuant to an Excluded Issuance;

"Allocation Notice" has the meaning given to that term in Regulation 12.5;

"**Approved Sale**" means a Deemed Liquidation Event or a Sale which has been approved by the Board and the Majority Investors;

"As-Converted Fully-Diluted Basis" means on the basis that:

- (a) all Preferred Shares in issue (to the extent not otherwise converted) have been converted in accordance with Regulation 14.1 (*Voluntary Conversion*);
- (b) all other outstanding securities of whatever type convertible into Shares have been so converted in accordance with their respective terms; and
- (c) all options, warrants or similar rights to subscribe or call for the issue of Shares (whether or not granted or in being at Completion) have been exercised in accordance with their respective terms;

"Affiliate" means, with respect to any specified person, any other person who, directly or indirectly, controls, is controlled by, or is under common control with such person, including, without limitation, any general partner, managing member, officer, director or trustee of such person, or any venture capital fund or other investment fund now or hereafter existing that is controlled by one (1) or more general partners, managing members or investment adviser of, or shares the same management company or investment adviser with, such person;

"Auditors" means the auditors of the Company from time to time;

"Automatic Conversion Event" shall have the meaning given to that term in Regulation 14.2;

"**B** Conversion Price" means the conversion price of a Series B Preferred Share in effect at the relevant time of determination, which shall (unless adjusted in accordance with these Articles) be equal to the Original Issue Price of the Series B Preferred Share;

"**B** Conversion Rate" means the rate obtained by dividing the Original Issue Price of the Series B Preferred Share by the B Conversion Price in effect at the relevant time of determination in accordance with these Articles;

"B Preferred Shareholders" means the holders of Series B Preferred Shares;

"Board" means the board of Directors as constituted from time to time;

"**Business Day**" means a day except a Saturday, Sunday or public holiday, on which banks in Ireland and New York are generally open for business;

"**Co-Lead Investors**" means (1) RA Capital Healthcare Fund, L.P. and RA Capital NEXUS Fund II, L.P. acting together; and (2) RTW Master Fund, LTD., RTW Innovation Fund, LTD., and RTW Venture Fund Limited, acting together;

"**Companies Act**" means the Companies Act 2014 and all Acts of the Oireachtas and statutory instruments which are to be read as one with, or construed or read together as one with, the Companies Act, and every statutory modification or reenactment thereof for the time being in force (or, where the context so admits and requires, any one or more of such Acts and all orders and regulations made thereunder;

"Conversion Price" means the A Conversion Price or the B Conversion Price (as applicable);

"**Conversion Rate**" means the A Conversion Rate or the B Conversion Rate (as applicable);

"**Date of Adoption**" means the date of adoption of these Articles;

"Deed of Adherence" has the meaning given to that term in the Shareholders' Agreement;

"**Deemed Liquidation Event**" means (i) any liquidation, dissolution or winding up of the Company, (ii) a merger or consolidation in which a person, or a group of related persons, acquires from shareholders of the Company shares representing more than fifty percent (50%) of the outstanding voting power of the Company for cash, or (iii) a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company; provided, however, that a transaction shall not constitute a Deemed Liquidation Event if its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately prior to such transaction or if the shareholders of the Company prior to such transaction own a majority by voting power of the issued shares of the surviving or acquiring corporation or other body corporate);

"**Defaulting Shareholder(s)**" has the meaning given to that term in Regulation 17.4;

"Directors" means the directors of the Company from time to time;

"document" includes, unless otherwise specified, any document sent or supplied in electronic form;

"Drag Notice" has the meaning given to that term in Regulation 17.1;

"**Drag Deadline Date**" has the meaning given to that term in Regulation 17.3;

"**Equity Securities**" means the Shares or any securities conferring the right to purchase Shares or securities directly or indirectly convertible into, or exchangeable for (with or without additional consideration), the Shares;

"Excess Offer Round Shares" has the meaning given to that term in Regulation 16.2;

"Excluded Issuance" means:

- (d) the issuing of Shares and/or granting of options to subscribe for Shares pursuant to the Share Option Plan and the allotment and issue of Shares upon exercise of any such options;
- (e) the conversion, pursuant to the provisions of Regulation 14 (*Conversion Rights: Preferred Shares*) of Preferred Shares into Ordinary Shares by: (i) re-designation and variation of the rights attaching thereto; and (ii) the issue of any additional Ordinary Shares as may be necessary to effect such conversion (and, in the event that Preferred Shares are automatically converted, in accordance with the provisions of these Articles, into Ordinary Shares immediately prior to an anticipated Qualified IPO and such Qualified IPO does not occur, the re-conversion of the resulting Ordinary Shares into Preferred Shares in accordance with the provisions of these Articles);
- (f) the allotment and issue of shares in connection with a pre-IPO reorganisation of the entire issued share capital of the Company made in accordance with these Articles;
- (g) the allotment and issue of Shares, with the prior written consent of the Majority Investors, by way of share dividend, as bonus shares in accordance with section 126(4) of the Companies Act;
- (h) the allotment and issue of shares pursuant to an effective registration statement in connection with a Qualified IPO; and
- (i) the allotment and issue of Shares upon a share split or subdivision;

"**Expert**" means: (i) an individual or firm, the identity of which has been approved in writing by the Majority Investors (such approval not to be unreasonably withheld or delayed), and which is appointed by the Board; or (b) in the case of an IPO only, the lead investment bank or banks advising the Company on the IPO;

"**Family Trust**" means in relation to an individual, a trust (whether arising under a settlement, declaration of trust or other instrument by whomsoever or wheresoever made or under a testamentary disposition or on an intestacy) under which no immediate beneficial interest in any of the Shares in question is for the time being vested in any person other than that individual and/or Privileged Relations of that individual; and so that for this purpose a person shall be considered to be beneficially interested in a share if such share or the income therefrom is or may become liable to be transferred or paid or applied or appointed to or for the benefit of such person or any voting or other rights attaching thereto are or may become liable to be exercisable by or as directed by such person pursuant to the terms of the relevant trusts or in consequence of an exercise of a power or discretion conferred thereby on any person or persons;

"Fair Value" means at any time and from time to time:

- (a) the average price per Share issued in the most recent investment round undertaken by the Company provided that such investment round completed in the immediately preceding twelve (12) months; or if none,
- (b) the average price per Share paid by a transferee on the most recent arm's-length market-value transfer of any such Shares completed in the immediately preceding twenty-four (24) months; or if none,
- (c) the fair value of the relevant Shares based on the open market price between a willing buyer and a willing seller as at the relevant date on which the relevant Shares are offered for sale, as determined by an independent expert appointed by agreement between the affected parties (or, in the absence of such agreement, appointed by the President for the time being of Chartered Accountants Ireland on the application of any affected party) who shall act as an expert and not as an arbitrator and whose decision shall, absent fraud or manifest error, be final and binding on all persons interested;

"Group" means the Company and its Subsidiaries;

"Investor Observer" has the meaning given to that term in Regulation 5.1;

"**IPO**" means the admission of any Shares to trading on any recognised stock exchange or regulated securities market in the Company's first public offering;

"**Majority Investors**" means the holders of a majority of the issued Series B Preferred Shares, voting together as a separate class;

"Non-Voting Ordinary Shares" has the meaning given to that term in Regulation 14.3;

"Offer Notice" has the meaning given to that term in Regulation 16.2;

"**Offer Period**" has the meaning given to that term in Regulation 16.2;

"Offer Round Shares" has the meaning given to that term in Regulation 16.1;

"Ordinary Shareholders" means the holders of Ordinary Shares;

"Ordinary Shares" means the ordinary shares of US\$0.01 each in the capital of the Company;

"Original Issue Price" means in the case of:

(j) the Series A Preferred Shares, US\$0.928571 per Series A Preferred Share; and

(k) the Series B Preferred Shares, US\$4.933204 per Series B Preferred Share.

"Other Shareholders" has the meaning given to that term in Regulation 17.1;

"Permitted Transfer" means any transfer of Shares to a Permitted Transferee;

"Permitted Transferee" means an Affiliate, Family Trust or Privileged Relation of the relevant transferor;

"Preferred Shares" means the Series A Preferred Shares and the Series B Preferred Shares;

"**Privileged Relation**" means in relation to an individual, a spouse, civil partner, child or grandchild (including step or adopted children and their issue) of that individual;

"Proportionate Offer Round Entitlement" has the meaning given to that term in Regulation 16.1;

"**Proposed Purchaser**" has the meaning given to that term in Regulation 17.1;

"Qualified IPO" means an IPO for gross proceeds to the Company of at least USD\$50 million;

"Redeemable Shares" means redeemable shares as defined by section 64 of the Act.

"Relevant Shares" has the meaning given to that term in Regulation 12.1;

"**Sale**" means the completion of any transaction whereby any person or group of persons Acting in Concert (as defined in the Irish Takeover Panel Act 1997 as amended) purchases the whole or a majority of the entire issued share capital of the Company or the whole or substantially the whole of the business and assets of the Company; provided, however, that a transaction shall not constitute a Sale if its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately prior to such transaction or if the shareholders of the Company prior to such transaction own a majority by voting power of the issued shares of the surviving or acquiring corporation or other body corporate);

"Sellers" has the meaning given to that term in Regulation 17.1;

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"Selling Shares" has the meaning given to that term in Regulation 17.1;

"Series A Preferred Shares" means the Series A Preferred Shares of US\$0.01 each in the capital of the Company;

"Series B Preferred Shares" means the Series B Preferred Shares of US\$0.01 each in the capital of the Company;

"**Shareholders**" means the Ordinary Shareholders, the A Preferred Shareholders, the B Preferred Shareholders and any other holder of Shares from time to time;

"**Shareholders Agreement**" means the shareholders' agreement in respect of the Company dated on or about the Date of Adoption between (i) the persons whose names and addresses are set out in Schedule 1 (ii) the person whose names and addresses are set out in Schedule 2 and (iii) the Company;

"**Shares**" means the Ordinary Shares, the Series A Preferred Shares, the Series B Preferred Shares and any other shares in the capital of the Company from time to time;

"**Share Option Plan**" means share option plan of the Company adopted in accordance with Clause 6.2 of the Shareholders Agreement pursuant to which up to three percent (3%) of the issued equity share capital of the Company on an As-Converted Fully-Diluted Basis as at the Date of Adoption may be put under option in favour of employees, officers, directors and consultants of the Group in such number as may be decided by the Board;

"Subsidiary" means any subsidiary of the Company, as defined in section 7 of the Companies Act;

"Threshold Investor" has the meaning given to that term in Regulation 14.3;

"**Transfer Notice**" has the meaning given to that term in Regulation 12.1;

"**Transferor**" has the meaning given to that term in Regulation 12.1.

- 1.3 It is hereby declared that in these Articles:
  - (a) the word "company", except where used in reference to this Company, shall be deemed to include a body corporate, whether a company (wherever formed, registered or incorporated), a corporation aggregate, a corporation sole and a national or local government or other legal entity;
  - (b) the word "person", shall be deemed to include any individual, firm, body corporate, association or partnership, government or state or agency of a state, local authority or government body or any joint venture association or partnership (whether or not having a separate legal personality) and that person's personal representatives, successors or permitted assigns;

- (c) the word "property", shall be deemed to include, where the context permits, real property, personal property including choses or things in action and all other intangible property and money and all estates, rights, titles and interests therein and includes the Company's uncalled capital and future calls and all and every other undertaking and asset;
- (d) a word or expression used in these Articles which is not otherwise defined and which is also used in the Companies Act shall have the same meaning here, as it has in the Companies Act;
- (e) any phrase introduced by the terms "including", "include" and "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms, whether or not followed by the phrases "but not limited to", "without prejudice to the generality of the foregoing" or any similar expression; and
- (f) words denoting the singular number only shall include the plural number and vice versa and references to one gender includes all genders.

# Part 2 - Corporate Capacity and Authority

#### 2. The common seal

- 2.1 The Company's seal shall be used only by the authority of its directors, or by a committee authorised by its directors or by any one or more persons severally or jointly so authorised by the directors or such a committee. Any instrument to which the Company's seal shall be affixed shall be signed by:
  - (a) a director and be countersigned by the secretary or by a second (if any) director or by some other person appointed for the purpose by its directors or by a committee; or
  - (b) a person (including a director) appointed for the purpose by its directors or a committee of its directors authorised by its directors in that behalf.
- 2.2 Section 43(2) and 43(3) of the Companies Act do not apply.

### 3. Official seal for use abroad

The Company may exercise the powers conferred by Section 44 of the Companies Act with regard to having an official seal for use abroad and such powers shall be vested in the directors.

# Part 3 - Directors

### 4. Directors

The Company shall have at least one director and not more than 5 directors. If at any time there is no director appointed to the Company, the members of the Company shall pass an ordinary resolution appointing a person to act as director.

#### 5. Methods of appointing Directors

- 5.1 The Company may by ordinary resolution appoint a person to be a Director either to a fill a vacancy or as an additional Director who are appointed without a term.
- 5.2 Each Co-Lead Investor shall be entitled to appoint one representative to attend as an observer at each and any meeting of the Board who will be entitled to speak at any such meetings but will not be entitled to vote (the **Investor Observers** and each an **Investor Observer**) and to remove any observer so appointed and upon his removal whether by the relevant Co-Lead Investor or otherwise, to appoint another observer in his place provided, however, that such Investor Observer shall agree to hold in confidence all information so provided in accordance with Clause 12 of the Shareholders' Agreement; and provided further, that the Company reserves the right to withhold any information and to exclude such Investor Observer from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in disclosure of trade secrets or a conflict of interest, or if such Investor or its such Investor Observer is a competitor of the Company.
- 5.3 Appointment and removal of a Director or an Investor Observer in accordance shall be by written notice from the relevant appointer to the Company or notified at any meeting of the Board or committee thereof and such appointment and/or removal shall take effect on the delivery of such notice or such later time as may be set out in the notice.
- 5.4 The Company will reimburse the Directors and the Investor Observers with the reasonable and vouched costs and out of pocket expenses incurred by them in respect of attending meetings of the Board or its committees.

### 6. Meetings of the Board

The Company shall send to each Director and the Investor Observers (if appointed) (in electronic form if so required):

- (a) reasonable advance notice of each meeting of the Board and each meeting of any committee of the Board specifying the date and time and place of the meeting, the notice to be accompanied by a written agenda specifying the business to be transacted at the meeting together with all papers to be circulated or presented to the meeting (except where the consent in writing of the Majority Investors is obtained); and
- (b) as soon as practicable after each meeting of the Board and each meeting of any committee of the Board, a copy of the minutes.

### 7. Directors' general authority

The business of the Company shall be managed by its directors, who may exercise all such powers of the Company as are not, by the Companies Act or by these Articles, required to be exercised by the Company in general meeting.

#### 8. Directors' power to delegate

- 8.1 Subject to these Articles, the directors may delegate any of their powers:
  - (a) to such person or committee;
  - (b) by such means (including by power of attorney);
  - (c) to such an extent;
  - (d) in relation to such matters or territories; and
  - (e) on such terms and conditions;

as they think fit.

- 8.2 If the directors so specify, any such delegation may authorise further delegation of the directors' powers by any person to whom they are delegated.
- 8.3 The directors may revoke any delegation in whole or part, or alter its terms and conditions.

#### 9. Committees

- 9.1 Committees to which the directors delegate any of their powers must follow procedures which are based as far as they are applicable on those provisions of these Articles which govern the taking of decisions by directors.
- 9.2 The directors may make rules of procedure for all or any committees, which prevail over rules derived from these Articles if they are not consistent with them.

#### 10. Quorum for directors' meetings

The quorum for directors' meetings shall be two. At a directors' meeting, unless a quorum is participating, no proposal is to be voted on, except a proposal to call another meeting.

# Part 4 - Appointment of directors

#### 11. Methods of appointing directors

- 11.1 The Company may by ordinary resolution appoint a person to be a director either to a fill a vacancy or as an additional director who are appointed without a term.
- 11.2 When forming a committee of the directors, the directors may authorise, or may authorise such committee to authorise, any person who is not a director to attend all or any meetings of any such committee on such terms as the directors (or as the case may be such committee) shall think fit, but any person so authorised shall not be entitled to vote at any such meetings.

# Part 5 – Shares Rights

11.3 Save as set out hereunder, the A Ordinary Shares, the Ordinary Shares, the Series A Preferred Shares and the Series B Preferred Shares shall rank *pari passu* with one another in all respects.

### 11.4 Voting Rights

The Ordinary Shareholders, the A Preferred Shareholders and the B Preferred Shareholders shall be entitled to receive notice of, and to attend and vote at, general meetings of the Company. Each Ordinary Shareholder, A Preferred Shareholder and B Preferred Shareholder shall have one vote on a show of hands and, on a poll:

- (a) each Ordinary Shareholder shall have one vote for each Ordinary Share held by him/her;
- (b) each A Preferred Shareholder shall have such number of votes for each Series A Preferred Share of which he/she/it is the holder equal to the number of Ordinary Shares into which a holder of Series A Preferred Shares is entitled, at the relevant time, to convert an Series A Preferred Share in accordance with these Articles; and
- (c) each B Preferred Shareholder shall have such number of votes for each Series B Preferred Share of which he/she/it is the holder equal to the number of Ordinary Shares into which a holder of Series B Preferred Shares is entitled, at the relevant time, to convert a Series B Preferred Share in accordance with these Articles.

The A Ordinary Shareholders shall be not entitled to receive notice of, and to attend and vote at, general meetings of the Company.

# 11.5 Dividends

The Ordinary Shareholders, A Preferred Shareholders and the B Preferred Shareholders shall be entitled to the payment of dividends on a pari passu basis to be paid in proportion to their shareholding on an As-Converted Fully-Diluted Basis. In any case, the Company may not declare any dividend on the Ordinary Shares in preference to the Preferred Shares.

The A Ordinary Shareholders shall not be entitled to any dividends.

11.6 Return of Capital - Order of Priority

In the event of any return of capital of the Company (including a Deemed Liquidation Event), the assets of the Company available for distribution to the Shareholders shall be distributed among the Shareholders as follows:

- (a) first, the A Preferred Shareholders and the B Preferred Shareholders shall be entitled to receive an amount per Series A Preferred Share and Series B Preferred Share (as applicable) equal to the Original Issue Price of such Share plus any declared but unpaid dividends;
- (b) thereafter, the balance of any assets of the Company shall to be distributed to the Ordinary Shareholders pro rata to the number of Ordinary Shares held by each of them.

For the avoidance of doubt, the entitlement of the holders of Preferred Shares to their liquidation preferences set out above shall not be abrogated or diminished in the event part of the consideration is subject to escrow or indemnity holdback in connection with a Deemed Liquidation Event. The A Ordinary Shareholders shall not be entitled to any return of capital.

#### 11.7 Valuation of Non-Cash Consideration

- (a) If any assets of the Company to be distributed to Shareholders, including in connection with a Deemed Liquidation Event, are other than cash then the value of such assets shall be their fair market value as determined by the Auditors (or, in circumstances where the Auditors are unwilling to act, the Expert) except that any publicly-traded securities to be distributed to Shareholders in a liquidation, dissolution or winding-up of the Company shall be valued as follows:
  - (i) if the securities are then traded on a securities exchange or quotation system, then the value of the securities shall be deemed to be the average of the closing prices of the securities on such exchange or system over the fifteen (15) trading day period ending on the day prior to the distribution date; or
  - (ii) if the securities are actively traded over-the-counter, then the value of the securities shall be deemed to be the average of the closing bid prices of the securities over the fifteen (15) trading day period ending on the day prior to the distribution date.
- (b) In the event of a sale, merger or other acquisition of the Company by another person or entity, the distribution date shall be deemed to be the date such transaction closes.
- (c) In the event of a pre-IPO reorganisation of the entire issued share capital of the Company into a single class of shares, the IPO valuation of the Group shall be the value determined by the Expert.

# Part 6 – Transfers

#### 12. Offer round

- 12.1 Save in the case of a Permitted Transfer, if any Shareholder proposes at any time to transfer any Shares (the **Transferor**) or any rights or interests therein or thereon, it shall notify the Board in writing that it proposes to do so. Such notification (the **Transfer Notice**) shall constitute the Board the agent of the Transferor for the sale of each of the Shares specified in the Transfer Notice (the **Relevant Shares**) at the price specified in the Transfer Notice (the **Specified Price**). The Specified Price shall consist of cash consideration only. The Transfer Notice shall also specify the name of the proposed transferee and may contain a provision that unless all the Relevant Shares are sold by the Company pursuant to this Regulation 12.1 none shall be so sold and any such provision shall be binding on the Company. A Transfer Notice shall be irrevocable save with the consent of the Board. The Transferor shall at the same time deposit with the Company the share certificate(s) in respect of the Relevant Shares.
- 12.2 Upon the receipt of a Transfer Notice (whether deemed or otherwise), the Directors shall decide whether it is in the best interests of the Company that the Company should purchase the Relevant Shares at the Specified Price, and shall communicate their decision within fifteen (15) Business Days of such receipt to the Transferor. If their decision is negative, the provisions of Regulation 12.3 shall apply with effect from the communication thereof to the Transferor. If such decision is positive, the communication thereof to the Transferor shall constitute a contract for the purchase of the Relevant Shares by the Company at the Specified Price, conditional upon the compliance by the Company with the statutory requirements for such purchase within thirty (30) Business Days, including in particular, the approval of the members by written resolution or at an Extraordinary General Meeting. Subject to the fulfilment of the said condition, the succeeding provisions of this Regulation 12.3, shall apply mutatis mutandis to the purchase of the Relevant Shares by the Company. If the said condition shall not be fulfilled, the contract for the purchase of the Relevant Shares by the Company shall lapse, and the provisions of Regulation 12.3 shall apply with effect from such lapse.

- 12.3 Within two (2) Business Days of this Regulation 12.3 having effect, the Board shall inform the Ordinary Shareholders (other than the Transferor), the A Preferred Shareholders and the B Preferred Shareholders (the **Other Shareholder(s)**) by notice in writing of the number of Relevant Shares and of the Specified Price and invite the Other Shareholder(s) to apply in writing irrevocably to the Board within twenty (20) Business Days from the date of dispatch of such notice to purchase some or all of the Relevant Shares at the Specified Price. If a member or members shall within the said period of twenty (20) Business Days apply for all or (except where the Transfer Notice provides otherwise) any of the Relevant Shares the Directors shall allocate the Relevant Shares (or so many of them as shall be applied for as aforesaid) to or amongst the applicants and in case of competition pro rata (as nearly as possible) according to the number of Shares of which they are registered as holders or unconditionally entitled to be registered as holders on an As-Converted Fully-Diluted Basis, provided that no applicant shall be obliged to take more than the maximum number of Relevant Shares specified by him as aforesaid.
- 12.4 If, pursuant to any offer under the provisions of the preceding sub-paragraphs of this Regulation, all of the Relevant Shares are not applied for, the Directors may allocate the Relevant Shares or the balance thereof (as the case may be) to any other person or persons who is or are willing to purchase same at the Specified Price.
- 12.5 Forthwith upon any allocation pursuant to Regulation 12.3 and/or Regulation 12.4 the Company shall give written notice of such allocation(s) to the Transferor and the persons to whom the Relevant Shares (or so many of them as aforesaid) shall have been allocated (the **Allocation Notice**) and shall specify in the Allocation Notice the place in the State and time (being not earlier than seven (7) and not later than fourteen (14) Business Days after the date of the Allocation Notice but in any event not being earlier than twenty (20) Business Days after the notice in writing referred to in Regulation 12.3 is given) at which the sale of the Relevant Shares so allocated shall be completed.
- 12.6 The Transferor shall be bound to transfer the Shares comprised in an Allocation Notice to the purchaser named therein at the time and place therein specified and if he shall fail to do so any Director or some other person appointed by the Directors for the purpose shall be deemed to have been appointed attorney of the Transferor with full power to execute, complete and deliver, in the name and on behalf of the Transferor, transfers of such of the Relevant Shares as aforesaid to each purchaser against payment to the Company of the Specified Price in respect of each such Share. Each purchaser, on payment of such price to the Company in respect of each of the Relevant Shares so transferred to him, shall be deemed to have obtained a good discharge for such payment and, on execution and delivery of the said transfers duly stamped, each purchaser shall be entitled to insist upon his name being entered in the register of members of the Company as the holder by transfer of such of the Relevant Shares as shall have been transferred to him. The Company shall forthwith pay any such amount received by it hereunder into a separate bank account in the name of the Company and shall hold any such amount in trust for the Transferor.

- 12.7 If the purchaser shall fail to complete a transfer of Relevant Shares, the Relevant Shares in question shall, without prejudice to any claim the Transferor may have against such purchaser, be re-allocated by the Directors as soon as may be among other holders of Shares or other applicants willing to acquire same. The procedures set out aforesaid in Regulation 12.3, Regulation 12.4 and Regulation 12.5 shall apply to any such re-allocation save that the defaulting purchaser shall not be permitted to participate in any further offer.
- 12.8 If the Directors do not dispose of all of the Relevant Shares comprised in any Transfer Notice in accordance with the foregoing provisions of this Regulation 12 they shall so notify the Transferor forthwith and during the period of forty (40) Business Days next following the despatch of such notice the Transferor shall be at liberty to transfer all or any of the Relevant Shares which are not required to be allocated by the Directors in accordance with this Regulation 12 to any person on a bona fide sale at any price not being less than the Specified Price (after deducting, where appropriate, any dividend or other distribution declared or made after the date of the Transfer Notice and to be retained by the Transferor) provided that:-
  - (a) if the Transfer Notice shall state that unless all the Relevant Shares are sold none of them shall be sold, the Transferor shall not be entitled hereunder to transfer any of the Relevant Shares unless in aggregate the whole of such Shares are allocated in accordance with the preceding provisions of this Regulation 12 or transferred under this sub-paragraph;
  - (b) the Directors may require to be satisfied that such Shares are being transferred in pursuance of a bona fide sale for the consideration stated in the transfer without any deduction, rebate or allowance whatsoever to the purchaser and (without prejudice to the Directors' general rights to refuse to register any transfer) if not so satisfied may refuse to register the instrument of transfer; and
  - (c) any such transferee shall enter into and lodge with the Company a binding and legal commitment to the effect that such person or persons thereby accepts and shall jointly and severally be bound by such of the terms of any shareholders agreement then in place as shall apply to the transferor.
- 12.9 For the purpose of ensuring that a transfer of Shares is a Permitted Transfer or that no circumstances have arisen whereby a Transfer Notice is required to be given hereunder the Directors may from time to time (and shall if required to do so by any member on reasonable grounds) require any member, the legal personal representatives of any deceased member, the liquidator or receiver of any corporate member or any person named as transfere in any transfer lodged for registration to furnish to the Company such information and evidence as the Directors may think fit regarding any matter which they may deem relevant to such purpose. Failing such information or evidence being furnished to the satisfaction of the Directors within a reasonable time after request the Directors shall (without prejudice to the Directors' general rights to refuse to register any transfer) be entitled to refuse to register the transfer in question or (in case no transfer is in question) to require by notice in writing that a Transfer Notice be given in respect of the Shares concerned. If such information or evidence discloses that a Transfer Notice ought to have been given in respect of any Shares the Directors may require that a Transfer Notice be given in respect of the Shares concerned.

- 12.10 In any case where the Directors have duly required a Transfer Notice to be given in respect of any Shares and such Transfer Notice is not duly given within a period of one month, or such longer period as the Directors may, if they think fit, reasonably allow for the purpose, such Transfer Notice shall (except and to the extent that a Permitted Transfer of any of such Shares shall have been lodged) be deemed to have been given or received on such date after the expiration of the said period as the Directors may by resolution determine and the provisions of this Regulation 12 relating to Transfer Notices shall take effect accordingly.
- 12.11 If any member attempts to deal with or dispose of any Shares or interest in Shares otherwise than in accordance with the provisions of these Articles, the Directors may require a Transfer Notice to be given in respect of such Shares to which the provisions of this Regulation 12 shall apply save that the Specified Price of such Shares shall be deemed to be the lower of the Fair Value of those Shares and the price at which the relevant Shareholder has subscribed for those Shares.
- 12.12 The Auditors in assessing the amount of Fair Value shall value the Shares on the basis of an open market price on a going concern basis as between a willing seller and a willing buyer. The Auditors decision as to Fair Value shall be final and binding.
- 12.13 Where any person has become unconditionally entitled to be registered as the holder of a Share, he and not the registered holder of the Share, shall be deemed to be a member of the Company in respect of that Share for the purposes of the operation of this Regulation 12.
- 12.14 The provisions of this Regulation 12 shall not apply in circumstances where the provisions of Regulation 17 (*Drag Along Rights*) are validly invoked.
- 12.15 The Company undertakes to the Investors that no person shall be registered as the holder of any Shares whether upon transfer or transmission except where such transfer or transmission is made in accordance with these Articles.

#### 13. Permitted Transfers

- 13.1 A Shareholder (who is not a Permitted Transferee) (the **Original Shareholder**) may transfer all or any of his or its Shares to a Permitted Transferee without restriction as to price or otherwise, provided such Permitted Transferee has executed and delivered to the Company a Deed of Adherence.
- 13.2 Shares previously transferred as permitted by Regulation 13.1 may be transferred by the transferee to any other Permitted Transferee of the Original Shareholder without restriction as to price or otherwise, provided such Permitted Transferee has executed and delivered a to the Company a Deed of Adherence.

- 13.3 If a Permitted Transferee who was an Affiliate of the Original Shareholder ceases to be an Affiliate of the Original Shareholder, the Permitted Transferee must not later than five (5) Business Days after the date on which the Permitted Transferee so ceases, transfer the Shares held by it to the Original Shareholder or an Affiliate of the Original Shareholder (which in either case is not in liquidation) without restriction as to price or otherwise failing which it will be deemed to have given a Transfer Notice in respect of those Shares.
- 13.4 Sale of Shares in GH Research Ireland Limited
  - (a) Subject to Regulation 13.4(b) below, no Shares held by the Company in GH Research Ireland Limited may be sold unless the consent in writing of 90% of the Shareholders of the Company is obtained, such consent to be obtained in a general meeting of the Company.
  - (b) The restriction contained in Regulation 13.4(a) shall only apply to:
    - (i) the sale of Shares in GH Research Ireland Limited and shall not apply in respect of any divestments;
    - (ii) the sale of Shares in GH Research Ireland Limited which takes place at any time before 1 June 2028; and
    - (iii) the sale of Shares in GH Research Ireland Limited and shall not apply in respect of the sale of Shares in other Subsidiary of the Company.

# Part 7 – Conversion

#### 14. Conversion Rights: Preferred Shares

#### 14.1 Voluntary Conversion

Each Series A Preferred Share and Series B Preferred Share shall be convertible, at the option of the holder, at any time after the Date of Adoption into one fully paid Ordinary Share subject to adjustment in accordance with the provisions of Regulation 15 (*Conversion Price Adjustment*); provided that such holder may waive such option to convert upon written notice to the Company.

### 14.2 Automatic Conversion

- (a) All Preferred Shares in issue (to the extent not otherwise converted) shall automatically be converted into fully paid Ordinary Shares, at the then applicable Conversion Rate, upon the earliest to occur of the following:
  - (i) immediately prior to a Qualified IPO; or
  - upon the receipt by the Company of a written request for such conversion from the holders of a majority of the issued Series A Preferred Shares, voting together as a separate class and the Majority Investors;

The events referred to in this paragraph are hereinafter referred, in this Regulation 14 (*Conversion Rights: Preferred Shares*), as **Automatic Conversion Events**, and each an **Automatic Conversion Event**.

- (b) The number of Ordinary Shares to which a holder of Series A Preferred Shares shall be entitled upon conversion shall be the product (rounded to the nearest whole number) obtained by multiplying the A Conversion Rate then in effect by the number of Series A Preferred Shares being converted. The A Conversion Rate in effect shall be the quotient obtained by dividing the Original Issue Price of the Series A Preferred Shares by the A Conversion Price in effect at the relevant time of determination. The A Conversion Price (which at the Date of Adoption is equal to the Original Issue Price of the Series A Preferred Shares) is subject to adjustment in accordance with the provisions of the below Regulation 15 (Conversion Price Adjustment).
- (c) The number of Ordinary Shares to which a holder of Series B Preferred Shares shall be entitled upon conversion shall be the product (rounded to the nearest whole number) obtained by multiplying the B Conversion Rate then in effect by the number of Series B Preferred Shares being converted. The B Conversion Rate in effect shall be the quotient obtained by dividing the Original Issue Price of the Series B Preferred Shares by the B Conversion Price in effect at the relevant time of determination. The B Conversion Price (which at the Date of Adoption is equal to the Original Issue Price of the Series B Preferred Shares) is subject to adjustment in accordance with the provisions of Regulation 15 (*Conversion Price Adjustment*).
- (d) Upon conversion, each Preferred Share shall convert:
  - (i) by an automatic process of re-designation into Ordinary Shares; and
  - (ii) if required (by virtue of the A Conversion Rate or the B Conversion Rate being adjusted (as applicable)), by the issue of additional Ordinary Shares.
- (e) In the event that additional Ordinary Shares are required to be issued to effect the conversion:
  - (i) all appropriate adjustments shall be made to the Company's undenominated capital, profits available for distribution, unrealised revaluation reserves and/or other applicable reserves to ensure the issue to the A Preferred Shareholder(s) and B Preferred Shareholder(s), as fully paid-up bonus shares, of the relevant number of additional Ordinary Shares without the requirement of any approval by the Shareholders, and the Company shall be bound to allot and issue such bonus shares; and
  - (ii) in the event that sufficient capital reserves are unavailable for capitalisation or in order to meet any company law requirement, the A Preferred Shareholder(s) and B Preferred Shareholder(s) shall be entitled to subscribe at par for Ordinary Shares in the capital of the Company to ensure the issue to the A Preferred Shareholder(s) and B Preferred Shareholder(s) of the relevant number of additional Ordinary Shares, and the Company shall be bound to allot and issue such additional Ordinary Shares.

- (f) In the event that any Preferred Shares are converted into Ordinary Shares pursuant to this Regulation 14 (*Conversion Rights: Preferred Shares*) immediately prior to an anticipated Qualified IPO and such Qualified IPO does not close within seven days of conversion, the Ordinary Shares into which such Preferred Shares are converted shall be re-converted into the number of Preferred Shares as they were originally converted from (by a process of: (i) re-designating the required number of such Ordinary Shares as Preferred Shares; and (ii) in the event that additional Ordinary Shares were issued in order to give effect to a conversion, by the surrender of the balance of such Ordinary Shares to the Company for no valuable consideration) upon notice to that effect being received by the Company from the holder of the Preferred Shares originally converted, provided that such notice is received by the Company within thirty (30) days of the date the Qualified IPO was scheduled to have occurred.
- (g) Before any holder of Preferred Shares shall be entitled to convert any Preferred Shares into Ordinary Shares and to receive certificates in respect of the Ordinary Shares to be so converted, he/it shall deliver the relevant share certificate or certificates in respect of the Preferred Shares to be converted or an indemnity in lieu thereof in a form reasonably satisfactory to the Company at its registered office, provided that, in the case of an Automatic Conversion Event, the relevant Preferred Shares shall be converted automatically without any further action by the holders of the Preferred Shares and whether or not the share certificates representing such Preferred Shares are delivered to the Company. However, no new share certificates in respect of the Ordinary Shares arising from an Automatic Conversion Event shall be issued by the Company to any person until delivery by that person of the relevant share certificates in respect of his/its Preferred Shares automatically converted to the Company (or an indemnity in lieu thereof).
- (h) A conversion of Preferred Shares pursuant to this Regulation 14 (*Conversion Rights: Preferred Shares*) shall be deemed to have been made immediately prior to the close of business on the date of surrender of the share certificate or certificates (or an indemnity in lieu thereof) in respect of the Preferred Shares to be converted, or, if appropriate, the date of the Automatic Conversion Event and the person or persons entitled to receive the Ordinary Shares arising upon such conversion shall be treated for all purposes as the registered holder of such Ordinary Shares from such time, provided that, if the conversion is made in connection with a Sale, the conversion may (at the option of any holder of the Preferred Shares to be converted) be made conditional upon the closing of the Sale, in which event the conversion of any such holder's Preferred Shares shall instead be deemed to have been made immediately prior to the closing of the Sale.
- (i) Subject to the above paragraph, the Company shall, as soon as practicable following conversion of any Preferred Shares pursuant to this Regulation 14 (*Conversion Rights: Preferred Shares*), forward to each relevant holder, share certificates in respect of the resultant Ordinary Shares to which he/it is entitled.
- (j) The Company shall at all times keep available out of its authorised but unissued share capital solely for the purpose of effecting the conversion of Preferred Shares, such number of Ordinary Shares as shall from time to time be sufficient to effect the conversion of all Preferred Shares, and if at any time the number of authorised but unissued Ordinary Shares shall not be sufficient to effect the conversion of all Preferred Shares, the Company and the Shareholders will take such corporate action as may be necessary to increase its authorised but unissued Ordinary Shares to such number of shares as shall be sufficient for such purpose.

#### 14.3 Non-Voting Ordinary Shares

In the event of an IPO (including a Qualified IPO), Investors who, together with any purchase of shares in an IPO by such Investor and its Affiliates would otherwise own greater than 9.9% of the Company's Ordinary Shares (a **Threshold Investor**), may convert all or a portion of the Preferred Shares held by such Threshold Investors into Ordinary Shares or into non-voting Ordinary Shares (the **Non-Voting Ordinary Shares**) with the election as to which security to convert into made by each Threshold Investor, at such Investor's sole discretion. The Non-Voting Ordinary Shares shall in all respects be identical to the Ordinary Shares, except that the Non-Voting Ordinary Shares shall be non-voting and convertible on a one-to-one basis into Ordinary Shares, subject to a beneficial ownership limitation, initially 9.9% (which may be increased or decreased at Threshold Investor's election on sixty-one (61) days' notice by the holder) with respect to the Threshold Investor's ownership of Ordinary Shares immediately prior to and following such conversion.

### 15. Conversion Price Adjustment

- 15.1 In the event the Company shall issue, or shall be deemed to issue, Additional Shares without consideration or for a consideration per Share less than the A Conversion Price and/or the B Conversion Price in effect on the date of, and immediately prior to, such issue, then the relevant Conversion Price(s) shall be adjusted downwards to a price determined by multiplying (as applicable):
  - (a) the A Conversion Price by a fraction, the numerator of which shall be the sum of: (a) the aggregate number of Shares (determined on an As-Converted Fully-Diluted Basis) in issue immediately prior to the issue of the Additional Shares; and (b) the number of Ordinary Shares that the aggregate consideration received, receivable, or deemed to be received or receivable, by the Company for the issue of the Additional Shares would purchase at the A Conversion Price in effect on the date of, and immediately prior to, such issue, and the denominator of which shall be the sum of: (a) the aggregate number of Shares (determined on an As-Converted Fully-Diluted Basis) in issue immediately prior to the issue of Additional Shares; and (b) the number of the Additional Shares (as assumes, if applicable, that such shares have converted into Ordinary Shares in accordance with their terms); and
  - (b) the B Conversion Price by a fraction, the numerator of which shall be the sum of: (a) the aggregate number of Shares (determined on an As-Converted Fully-Diluted Basis) in issue immediately prior to the issue of the Additional Shares; and (b) the number of Ordinary Shares that the aggregate consideration received, receivable, or deemed to be received or receivable, by the Company for the issue of the Additional Shares would purchase at the B Conversion Price in effect on the date of, and immediately prior to, such issue, and the denominator of which shall be the sum of: (a) the aggregate number of Shares (determined on an As-Converted Fully-Diluted Basis) in issue immediately prior to the issue of Additional Shares; and (b) the number of the Additional Shares (as assumes, if applicable, that such shares have converted into Ordinary Shares in accordance with their terms).

This adjustment mechanism is summarised in the following formula:

 $X = A \times (\underline{B+C})$ (B+D)

where:

- X means the adjusted Conversion Price
- A means the relevant Conversion Price in effect on the date of, and immediately prior to, the issue of the Additional Shares
- B means the aggregate number of Shares (determined on an As-Converted Fully-Diluted Basis) in issue immediately prior to the issue of the Additional Shares
- C means the number of Ordinary Shares that the aggregate consideration received, receivable, or deemed to be received or receivable, by the Company for the issue of the Additional Shares would purchase at the relevant Conversion Price in effect on the date of, and immediately prior to, the issue of the Additional Shares
- D means the number of the Additional Shares (as assumes, if applicable, that such shares have converted into Ordinary Shares in accordance with their terms).
- 15.2 Downward Adjustment Only

No adjustment of a Conversion Price shall be made pursuant to this Regulation 15 (*Conversion Price Adjustment*) in respect of the issue, or deemed issue, of Additional Shares unless the consideration per Share for an Additional Share issued, or deemed to be issued by the Company, is less than the A Conversion Price and/or B Conversion Price in effect on the date of, and immediately prior to, such issue, or deemed issue, of Additional Shares.

#### 15.3 Deemed Issue of Additional Shares

In the event that the Company at any time or from time to time after the Date of Adoption grants or issues any options, options for convertible securities or convertible securities, then the maximum number of Additional Shares issuable upon the exercise of such options or, in the case of convertible securities, the conversion or exchange of such convertible securities or in the case of options for convertible securities the exercise of such options and the conversion or exchange of the underlying convertible securities, shall be deemed, for the purposes of this Regulation 15 (*Conversion Price Adjustment*) to have been issued as of the time of such issue for such consideration as is determined in accordance with paragraph (c) of Regulation 15.4 (*Determination of Consideration*). No further adjustment to the A Conversion Price and/or the B Conversion Price shall be made upon the subsequent issue of Ordinary Shares or convertible securities into, or for, Ordinary Shares.

#### 15.4 Determination of Consideration

- (a) If any Additional Shares are issued, or deemed to have been issued, for cash, the consideration received, or receivable, by the Company therefor, shall be deemed to be the amount received, or receivable, by the Company therefor (net of discounts, commissions and related expenses).
- (b) If any Additional Shares are issued, or deemed to have been issued, for consideration other than cash, the value of the consideration other than cash received, or receivable, by the Company therefor, shall be determined on a basis consistent with Regulation 11.7 (*Valuation of Non-Cash Consideration*).
- (c) The consideration per share received, receivable, or deemed to be received or receivable, by the Company for Additional Shares deemed to have been issued pursuant to Regulation 15.3 (*Deemed Issue of Additional Shares*) in relation to the grant or issue of options, convertible securities or options for convertible securities shall be the quotient obtained by dividing:
  - (i) the total amount (if any) received, or receivable, by the Company as consideration for the issue of such options, convertible securities or options for convertible securities plus the minimum aggregate amount of additional consideration (as set forth in the instruments relating thereto without regard to any provision contained therein for a subsequent adjustment of such consideration) payable to the Company upon the exercise of such options or the conversion or exchange of such convertible securities, the exercise of such options for convertible securities and the subsequent conversion or exchange of such convertible securities; by
  - (ii) the maximum number of Additional Shares (as set out in the instruments relating thereto, without regard to any provision contained therein for a subsequent adjustment of such number) issuable upon the exercise of such options or the conversion or exchange of such convertible securities or, in the case of options for convertible securities, the exercise of such options for convertible securities and the subsequent conversion or exchange of convertible securities.
- (d) In the event the consideration for Additional Shares received, receivable or valued (as the case may be) is in a currency other than US Dollars, for the purpose of determining whether the Company has issued (or is deemed to have issued) such Additional Shares for a consideration per share less than the A Conversion Price and/or the B Conversion Price, the consideration shall be notionally converted to US Dollars at the average of the applicable foreign exchange rates for the five (5) Business Days ending on the date of issue (or deemed issue) of the Additional Shares (calculated by reference to the daily 10:00 am foreign exchange spot rates published by the Federal Reserve Bank of New York).

#### 15.5 Share Capital Reorganisation

If there is a reorganisation of the Company's share capital (whether by way of share split, consolidation or otherwise) or if there is a bonus issue of shares (other than a bonus issue to effect a conversion of Preferred Shares pursuant to Regulation 14 (*Conversion Rights: Preferred Shares*) above) or other adjustment (including, without limitation, the granting of share appreciation rights, phantom share rights or other rights with equity features) to the Company's share capital, the Original Issue Price of the Series A Preferred Shares, the A Conversion Price, the Original Issue Price of the Series B Preferred Shares and the B Conversion Price shall be automatically adjusted (either upwards or downwards as the case may be) to take account of the reorganisation, bonus issue or other adjustment (the intention being that: (i) upon conversion of the Series A Preferred Shares, the A Preferred Shareholders would hold the same proportion of issued Ordinary Shares as they would have held had the reorganisation, bonus issue or other adjustment not occurred; and (ii) upon conversion of the Series B Preferred Shareholders would hold the same proportion of issued Ordinary Shares as they would have held had the reorganisation, bonus issue or other adjustment not occurred; and (ii) upon conversion of the Series B Preferred Shares, the B Preferred Shareholders would hold the same proportion of issued Ordinary Shares as they would have held had the reorganisation, bonus issue or other adjustment not occurred.

### 15.6 Protection Against Impairment

The Company will not through any reorganisation, re-capitalisation, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid, or seek to avoid, the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at all times in good faith assist in the carrying out of all the provisions of this Regulation 15 (*Conversion Price Adjustment*) and in the taking of all such action as may be necessary or appropriate in order to protect the conversion rights of the A Preferred Shareholders and the B Preferred Shareholders against impairment.

#### 15.7 Notice of Adjustment

Immediately upon any adjustment of a Conversion Price pursuant to any provision of this Regulation 15 (*Conversion Price Adjustment*), the Board shall give written notice thereof to all holders of the relevant Preferred Shares setting forth details, and certifying the calculation, of such adjustment.

#### 15.8 Independent Certification

(a) In the event that any of the A Preferred Shareholders are not satisfied with any certificate of the A Conversion Price issued by the Board pursuant to this Regulation 15 (*Conversion Price Adjustment*), or if the Board does not issue such a certificate, any A Preferred Shareholder may request the Auditors (or in circumstances where the Auditors are unwilling to act, the Expert) to independently certify the A Conversion Price. If the price certified by the Auditor or Expert as the case may be differs from the A Conversion Price issued by the Board the Auditors' or Expert's (as the case may be) costs shall be borne by the Company. If the price certified by the Auditor or Expert as the case may be is the same as the A Conversion Price issued by the Board the Auditors' or Expert's (as the case may be) costs shall be borne by the requesting A Preferred Shareholder(s). The Auditors' or Expert's (as the case may be) certificate shall, except in the case of manifest error, be binding on the Company and each of the Shareholders.

- (b) In the event that any of the B Preferred Shareholders are not satisfied with any certificate of the B Conversion Price issued by the Board pursuant to this Regulation 15 (Conversion Price Adjustment), or if the Board does not issue such a certificate, any B Preferred Shareholder may request the Auditors (or in circumstances where the Auditors are unwilling to act, the Expert) to independently certify the B Conversion Price. If the price certified by the Auditor or Expert as the case may be differs from the B Conversion Price issued by the Board the Auditors' or Expert's (as the case may be) costs shall be borne by the Company. If the price certified by the Auditor or Expert as the case may be is the same as the B Conversion Price issued by the Board the Auditors' or Expert's (as the case may be) costs shall be borne by the requesting B Preferred Shareholder(s). The Auditors' or Expert's (as the case may be) certificate shall, except in the case of manifest error, be binding on the Company and each of the Shareholders.
- 15.9 Waiver of Rights
  - (a) The rights of all A Preferred Shareholders to have the A Conversion Price adjusted in accordance with the provisions of this Regulation 15 may be waived with the written consent of the holders of a majority of the issued Series A Preferred Shares. Such waiver may be given in advance of, or following, an issue (or deemed issue) of Additional Shares, and shall be binding on all Shareholders of that class.
  - (b) The rights of all B Preferred Shareholders to have the B Conversion Price adjusted in accordance with the provisions of this Regulation 15 may be waived with the written consent of the holders of a majority of the issued Series B Preferred Shares. Such waiver may be given in advance of, or following, an issue (or deemed issue) of Additional Shares, and shall be binding on all Shareholders of that class.

## Part 8 – Share Issues

## 16. Allotment of Shares

- 16.1 Until the earlier of: (i) a Qualified IPO; or (ii) a Deemed Liquidation Event, all Equity Securities which the Directors propose to allot and issue (other than any Equity Securities the subject of an Excluded Issuance) (the **Offer Round Shares**) shall first be offered to each of the Ordinary Shareholders and the holders of Preferred Shares, in the respective proportions, as nearly as may be, that the number of Ordinary Shares and Preferred Shares (determined on an As-Converted Fully-Diluted Basis) held by each of them individually bears to the total number of Ordinary Shares and Preferred Shares (determined on an As-Converted Fully-Diluted Basis) held by all of them (their **Proportionate Offer Round Entitlements** and each **a Proportionate Offer Round Entitlement**), at the same price and on the same terms.
- 16.2 The offer shall be made by notice in writing (the **Offer Notice**) specifying the number of Offer Round Shares offered and the price, and limiting a period (not being less than ten (10) Business Days) within which the offer, if not accepted in writing, will be deemed to be declined (the **Offer Period**). The terms of the offer, to be set out in the Offer Notice, shall also provide that it shall be open to each offeree Shareholder to specify if he, or it, is willing to subscribe for Offer Round Shares in excess of his, or its, Proportionate Offer Round Entitlement (the **Excess Offer Round Shares**) and, if an offeree Shareholder does so specify, he, or it, shall state the number of Excess Offer Round Shares that he, or it is willing to subscribe for.

### 16.3 *Procedure for Acceptance*

An offeree Shareholder who wishes to accept the offer in respect of any Offer Round Shares (including any Excess Offer Round Shares) shall be required to notify the Company, by notice in writing, of his, or its, acceptance prior to the expiry of the Offer Period, specifying the number of Offer Round Shares (including Excess Offer Round Shares) he, or it, wishes to apply for. An offeree Shareholder who does not so notify the Company within the Offer Period shall be deemed to have declined the offer.

### 16.4 Allocation of Offer Round Shares

As soon as practicable following the expiry of the Offer Period (or, if earlier, upon notification of acceptance or nonacceptance having been received, in writing, from all offerees), the Company shall allocate the Offer Round Shares in the following manner:

- (c) if the total number of Offer Round Shares applied for is equal to or less than the available number of Offer Round Shares, in accordance with the applications of the accepting Shareholders; or
- (d) if the total number of Offer Round Shares applied for is greater than the total number of Offer Round Shares offered:
  - (i) first, each accepting Shareholder shall be allocated his, or its, Proportionate Offer Round Entitlement (or such lesser number of Offer Round Shares for which he, or it, has applied); and
  - (ii) secondly, each accepting Shareholder shall be allocated such number of Excess Offer Round Shares, if any, in accordance with his, or its, application or, in the event of competition, as nearly as may be to the proportion that the number of Ordinary Shares and Preferred Shares (determined on an As-Converted Fully-Diluted Basis) held by him, or it, individually bears to the total number of Ordinary Shares and Preferred Shares (determined on an As-Converted Fully-Diluted Basis) held by all accepting Shareholders applying for Excess Offer Round Shares, provided that no accepting Shareholder shall be allocated more Excess Offer Round Shares than he, or it, shall have stated himself, or itself, willing to take,

and, in either case, the Company shall, as soon as practicable thereafter, give notice of each such allocation (an **Allocation Notice**) to the applicant Shareholders and shall specify, in the Allocation Notice, the place and time (being not earlier than five (5) Business Days and not later than ten (10) Business Days after the date of the Allocation Notice) at which the allotment and issue of the Offer Round Shares shall be completed (the **Allotment Completion Date**). On the Allotment Completion Date, each accepting Shareholder will be obliged to complete the subscription for the relevant number of Offer Round Shares (including any Excess Offer Round Shares) allocated in accordance with this Regulation 16.4 (*Allocation of Offer Round Shares*) and to pay the relevant subscription monies to the Company.

#### 16.5 Directors' Discretion

After the expiry of the Offer Period (or, if earlier, upon notification of acceptance or non-acceptance having been received, in writing, from all offeree Shareholders), any remaining Offer Round Shares not required to be allotted to Ordinary Shareholders pursuant to the above Regulation 16.4 (*Allocation of Offer Round Shares*) shall be at the disposal of the Directors who -may allot such Equity Securities to such person, or persons, as they so determine, provided that:

- (e) such Equity Securities are allotted at no less than the price per Equity Securities and otherwise on no better terms than were offered to the Ordinary Shareholders and/or the holders of Preferred Shares; and
- (f) if required by the Board, any allottee which is not party to the Shareholders' Agreement shall first have agreed to adhere to the provisions of the Shareholders' Agreement by executing a Deed of Adherence.
- 16.6 Non-Assignability

The benefit of an offer to allot Equity Securities or the benefit of the contract arising out of the acceptance thereof cannot be assigned or transferred by the offeree.

# Part 9 – Drag

# 17. Drag-along Rights

- 17.1 If Shareholders (to always include the Majority Investors) (for the purposes of this Regulation 17.1, collectively, the **Sellers**) intend to sell as part an Approved Sale all of their Shares (the **Selling Shares**) the Sellers shall have the right to give to the Company not less than twenty (20) Business Days' advance notice before the completion of the Approved Sale requiring all (but not some only) of the other Shareholders (the **Other Shareholders**) to sell all (but not some only) of their Shares in accordance with this Regulation 17.1. The notice given to the Company (the **Drag Notice**) shall include:
  - (a) the identity of the proposed purchaser (the **Proposed Purchaser**);
  - (b) details of the Selling Shares and the price per share for each class of Selling Share and all other Shares which the Proposed Purchaser is proposing to pay;
  - (c) the manner in which the consideration is to be paid;
  - (d) specifying that the Other Shareholders are required to transfer their Shares pursuant to this Regulation 17.1;

- (e) the place, date and time of completion, being a date not less than twenty (20) Business Days from the date of the Drag Notice;
- (f) the form of the documentation referred to in Regulation 17.3 which the Other Shareholders are required to sign in connection with the sale of their Shares to the Proposed Purchaser and the date by which the Other Shareholders shall have delivered such duly executed documentation; and
- (g) such other particulars of the proposed Approved Sale as the Sellers consider to be materially relevant to the other Shareholders.
- 17.2 The Board shall, within five (5) Business Days of receipt of a Drag Notice, send a copy of the Drag Notice to each of the Other Shareholders.
- 17.3 Every Other Shareholder who has been sent a copy Drag Notice pursuant to Regulation 17.2 shall be required to sell all of its Shares to the Proposed Purchaser within ten (10) Business Days of the date of dispatch of the copy Drag Notice by the Board pursuant to Regulation 17.2, or such longer period as shall be stipulated by the Board at the direction of the Sellers, (the final day of either such period being the **Drag Deadline Date**) and shall execute the necessary documentation to transfer the relevant Shares (including any agreements required to be entered into by all Shareholders in relation to the Approved Sale) in favour of the Proposed Purchaser provided that:
  - (a) the terms, including price, of such sale shall, subject as hereafter provided in this Regulation 17.3, be the same (to the extent applicable) in all respects as those applicable to the Sellers pursuant to the Approved Sale;
  - (b) the price payable to the Other Shareholders shall be payable entirely in cash;
  - (c) the net proceeds of the Approved Sale shall be distributed to the Shareholders in accordance with Regulation 11.6 (*Return of Capital*);
  - (d) the liability of the Other Shareholders pursuant to the terms of the Approved Sale shall be several and not joint and shall not exceed such Other Shareholder's pro rata portion of the consideration received by the Other Shareholder;
  - (e) the Other Shareholders shall not be required to enter into any indemnities or warranties in favour of the Proposed Purchaser save warranties as to their title to their Shares and their capacity to enter into any documents in respect of the sale of their Shares and shall not be required to participate in any scheme for the avoidance of tax by the Proposed Purchaser;
  - (f) such Other Shareholder is not required to agree (unless such Other Shareholder is a Company officer or employee) to any restrictive covenant in connection with the Approved Sale (including, without limitation, any covenant not to compete or covenant not to solicit customers, employees or suppliers of any party to the Approved Sale) or any release of claims other than a release in customary form of claims arising solely in such Other Shareholder's capacity as a shareholder of the Company;

- (g) the Proposed Purchaser completes the purchase of all of the Selling Shares simultaneously.
- 17.4 If any of the parties hereto, other than the Company (the **Defaulting Shareholder(s)**) fail to comply with any of the terms of this Regulation 17 by the Drag Deadline Date, such Defaulting Shareholder shall be deemed to have irrevocably appointed the Chairman (if appointed) (or failing him the company secretary of the Company) to be his agent and attorney for the sale of his Shares in accordance with the Drag Notice (together with all rights then attached thereto) and to execute and deliver all necessary documentation to transfer the Relevant Shares on his behalf and the Company may receive the purchase money in trust for each of the Defaulting Shareholders. With effect from the day after the Drag Deadline Date, the voting and other rights attaching to those Shares may not be exercised by such Defaulting Shareholder and payment of any dividends declared on such Shares shall be withheld and held in trust for such Defaulting Shareholder until such time as the requisite transfer is effected. The Company shall, subject to the relevant share transfer forms of the Shares being duly stamped, register the name of the transferee of such Shares in the register of shareholders of the Company. The receipt by the Company of the purchase money, pursuant to such transfers, shall constitute a good and valid discharge to the Proposed Purchaser (who shall not be bound to see to the application thereof) and after the Proposed Purchaser has been registered in purported exercise of the aforesaid powers the validity of the proceedings shall not be questioned by any person. The Company shall not pay the purchase money to a Defaulting Shareholder until he shall, in respect of the Shares being the subject of the Drag Notice, have delivered his share certificates or a suitable indemnity and any other necessary documentation to the Company.
- 17.5 On any person, following the issue of a Drag Notice, becoming a holder of Shares, including but not limited to pursuant to the exercise of a preexisting option or warrant to acquire Shares or pursuant to the conversion of any convertible security of the Company (a **New Other Shareholder**), a Drag Notice shall be deemed to have been served on the New Other Shareholder on the same terms as the previous Drag Notice who shall then be bound to sell and transfer all Shares so acquired to the Proposed Purchaser and the provisions of this Regulation 17 shall apply with the necessary changes to the New Other Shareholder except that completion of the sale of the Shares shall take place immediately on the Drag Notice being deemed served on the New Other Shareholder.
- 17.6 Notwithstanding the foregoing, if the Proposed Purchaser fails to complete the Approved Sale, the Drag Notice shall no longer be binding and cease to have effect. The Selling Shareholders shall be entitled to serve further Drag Notices following the lapse of any particular Drag Notice.

## Part 5 – Shares - General

#### 18. Share capital

The share capital of the Company is €25,000.00 and US\$1,000,000,000.00 divided into 25,000 A Ordinary Shares of €1.00 each, 99,968,697,874 Ordinary Shares of US\$0.01 each, 5,923,079 Series A Preferred Shares of US\$0.01 each and 25,379,047 Series B Preferred Shares of US\$0.01 each.

#### 19. Shares - General

- 19.1 Shares in the capital of the Company shall have nominal values.
- 19.2 The Company may allot shares:
  - (a) of different nominal values;
  - (b) of different currencies;
  - (c) with different amounts payable on them; or
  - (d) with a combination of two or more of the foregoing characteristics.
- 19.3 Any share in the Company may be issued with such preferred, deferred or other special rights or such restrictions, whether in regard to dividend, voting, return of capital or otherwise, as the Company may from time to time by ordinary resolution determine.
- 19.4 Unless the Board determines otherwise, any share in the capital of the Company shall be deemed to be a Redeemable Share on, and from the time of, the existence or creation of an agreement, transaction or trade between the Company and any person (who may or may not be a member) pursuant to which the Company acquires or will acquire a share in the capital of the Company, or an interest in shares in the capital of the Company, from the relevant person, save for an acquisition for nil consideration pursuant to section 102(1)(a) of the Act. In these circumstances, the acquisition of such shares by the Company, save where acquired for nil consideration in accordance with the Act, shall constitute the redemption of a Redeemable Share in accordance with Chapter 6 of Part 3 of the Act. No resolution, whether special or otherwise, shall be required to be passed to deem any share in the capital of the Company a Redeemable Share.
- 19.5 The Shares shall entitle the holders thereof to the same rights and privileges and subject them to the same restrictions and provisions.

#### 20. Authority to allot Shares

- 20.1 Subject to Regulation 16, the Directors are hereby generally and unconditionally authorised to exercise all the powers of the Company to allot relevant securities within the meaning of section 1021 of the Act. The maximum amount of relevant securities which may be allotted under the authority hereby conferred shall be the amount of the authorised but unissued share capital of the Company at the date on which the resolution adopting these Articles takes effect.
- 20.2 The Directors are hereby empowered pursuant to sections 1022 and 1023(1) of the Companies Act to allot equity securities within the meaning of the said section 1022 pursuant to the authority conferred by Regulation 20.1 as if section 1022(1) of the Companies Act did not apply to any such allotment.

## 21. Lien on Shares

The Company shall have a first and paramount lien on every share (not being a fully paid share) for all moneys (whether immediately payable or not) called, or payable at a fixed time, in respect of that share. The directors may at any time declare any share in the Company to be wholly or in part exempt from this regulation.

#### 22. Variation of Rights attached to Special Classes of Shares

If at any time the share capital is divided into different classes of shares, the rights attached to any class (unless otherwise provided by the terms of issue of the shares of that class) may, in accordance with section 88 of the Act, whether or not the Company is being wound up, be varied or abrogated (a) with the consent in writing of the holders of 75 per cent, in nominal value, of the issued shares of that class, or , (b) with the sanction of a special resolution passed at a separate general meeting of the holders of the shares of that class but not otherwise.

## 23. Variation of company capital

- 23.1 The Company may, by ordinary resolution and in accordance with section 83 of the Act, do any one or more of the following, from time to time:
  - (a) consolidate and divide all or any of its shares into shares of a larger nominal value than its existing shares;
  - (b) subdivide its shares, or any of them, into shares of a smaller nominal value, so however, that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced share shall be the same as it was in the case of the share from which the reduced share is derived;
  - (c) increase the nominal value of any of its shares by the addition to them of any undenominated capital;
  - (d) reduce the nominal value of any of its shares by the deduction from them of any part of that value, subject to the crediting of the amount of the deduction to undenominated capital, other than the share premium account;
  - (e) convert any undenominated capital into shares for allotment as bonus shares to holders of existing shares;
  - (f) increase its share capital by new shares of such amount as it thinks expedient; or cancel shares of its share capital which, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person, and diminish the amount of its share capital by the amount of the shares so cancelled.
- 23.2 The rights conferred upon the holders of the shares of any class issued by the Company with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking pari passu therewith.

#### 24. Reduction of company capital

- 24.1 The Company may, in accordance with the provisions of sections 84 to 87 of the Act, reduce its company capital in any way it thinks expedient and, without prejudice to the generality of the foregoing, may thereby:
  - (a) extinguish or reduce the liability on any of its shares in respect of share capital not paid up;
  - (b) either with or without extinguishing or reducing liability on any of its shares, cancel any paid up company capital which is lost or unrepresented by available assets; or
  - (c) either with or without extinguishing or reducing liability on any of its shares, pay off any paid up company capital which is in excess of the wants of the Company.

#### 25. Acquisition of own shares

The Company is authorised to acquire its own shares by purchase, or in the case of redeemable shares, by redemption or purchase in accordance with section 105 of the Act.

## Part 6

# **General Meetings** — General

- 26. Subject to Regulation 27, the Company shall in each year hold a general meeting as its annual general meeting in addition to any other meeting in that year, and shall specify the meeting as such in the notices calling it; and not more than 15 months shall elapse between the date of one annual general meeting of the Company and that of the next.
- 27. So long as the Company holds its first annual general meeting within 18 months of its incorporation, it need not hold it in the year of its incorporation or in the year following.
- 28. The annual general meeting shall be held at such time and place as the Directors shall determine.
- 29. All general meetings of the Company other than annual general meetings shall be called extraordinary general meetings.
- 30. The Directors may, whenever they think fit, convene an extraordinary general meeting and extraordinary general meetings shall also be convened by the Directors, on such requisition, or in default, may be convened by such requisitionists, as provided by section 178(3) to (7) of the Act.
- 31. An annual general meeting or extraordinary general meeting of the Company may be held outside Ireland. The Company shall make, at its expense, all necessary arrangements to ensure that members can by technological means participate in any such meeting without leaving Ireland.
- 32. A general meeting of the Company may be held in two or more venues (whether inside or outside of Ireland) at the same time using any technology that provides members, as a whole, with a reasonable opportunity to participate, and such participation shall be deemed to constitute presence in person at the meeting.

#### 33. Notice of general meetings

- 33.1 The only persons entitled to notice of general meetings of the Company are:
  - (a) the members;
  - (b) the personal representatives of a deceased member, which member would but for his death be entitled to vote;
  - (c) the assignee in bankruptcy of a bankrupt member of the Company (being a bankrupt member who is entitled to vote at the meeting);
  - (d) the Directors and secretary of the Company; and
  - (e) unless the Company is entitled to and has availed itself of the audit exemption under the Act, the statutory auditors (who shall also be entitled to receive other communications relating to any general meeting which a member is entitled to receive).
- 33.2 A meeting of the Company, other than an adjourned meeting, shall be called:
  - (a) in the case of the annual general meeting or an extraordinary general meeting for the passing of a special resolution, by not less than 21 days' notice;
  - (b) in the case of any other extraordinary general meeting, by not less than fourteen days' notice; or
  - (c) in either case, on such shorter notice as all of the members and, unless the Company has availed of the audit exemption under the Companies Act (and, where relevant, section 399 of the Companies Act has been complied with in that regard), the statutory auditors of the Company agree.
- 33.3 In determining the correct period of notice for a general meeting, neither the day on which the notice is served nor the day of the meeting for which it is given shall be counted.

#### 34. Unanimous written resolutions

- 34.1 In accordance with section 193(1) of the Companies Act (as modified in its application to a PLC by section 1093 of the Act), notwithstanding any provision to the contrary in the Act:
  - (a) a resolution in writing signed by all the members of the Company for the time being entitled to attend and vote on such resolution at a general meeting (or being bodies corporate by their duly appointed representatives) shall be as valid and effective for all purposes as if the resolution had been passed at a general meeting of the Company duly convened and held (a "unanimous written resolution");
  - (b) if described as a special resolution a unanimous written resolution shall be deemed to be a special resolution within the meaning of the Act, and
  - (c) a unanimous written resolution may consist of several documents in like form each signed by one or more members.
- 34.2 A unanimous written resolution shall be deemed to have been passed at a meeting held on the date on which it was signed by the last member to sign, and, where the resolution states a date as being the date of his or her signature thereof by any member, it shall be taken that it was signed by him or her on that date.

- 34.3 Where a unanimous written resolution is not contemporaneously signed, the Company shall notify the members, within 21 days after the date of delivery to it of the document or documents constituting the unanimous written resolution of the fact that the resolution has been passed.
- 34.4 The signatories of unanimous written resolution shall, within 14 days after the date of its passing, procure delivery to the Company of the documents constituting the unanimous written resolution and without prejudice to the use of the other means of delivery generally permitted by the Act, such delivery may be effected by electronic mail or the use of a facsimile machine and the Company shall retain those documents as if they constituted the minutes of a-general meeting of the Company.

#### 35. Written decision of sole member

35.1 At any time that the Company is a single-member company, its sole member may pass any resolution as a written decision in accordance with section 196 of the Act.

#### **36.** Quorum for general meetings

- 36.1 Two members of the Company present in person or by proxy and having the right to attend and vote at the meeting and holding shares representing more than 50 per cent of the votes that may be cast by all members at the relevant time shall be a quorum at a general meeting; provided that at any time when the Company is a single-member company, one member of the Company present in person or by proxy at a general meeting of it shall be a quorum.
- 36.2 If within 15 minutes after the time appointed for a general meeting a quorum is not present, then:
  - (a) the meeting shall stand adjourned to the same day in the next week, at the same time and place or to such other day and at such other time and place as the Directors may unanimously determine; and
  - (b) if at the adjourned meeting a quorum is not present within half an hour after the time appointed for the meeting, the members present shall be a quorum.

### Part 7 - Officers' indemnity and insurance

#### 37. Indemnity for officers

- 37.1 Subject to the provisions of the Act, the Company may indemnify any officer of the Company against any liability incurred by him or her in defending proceedings, whether civil or criminal, in which judgment is given in his or her favour or in which he or she is acquitted, or in connection with any proceedings or application referred to in, or under, section 233 or 234 of the Companies Act in which relief is granted to him or her by the court.
- 37.2 Every officer of the Company shall be entitled to be indemnified out of the assets of the Company against all losses or liabilities which he or she may sustain or incur in or about the execution of the duties of his or her office or otherwise in relation thereto and no officer shall be liable for any loss, damage or misfortune which may happen to or be incurred by the Company in the execution of the duties of his or her office or in relation thereto. This regulation shall only have effect in so far as its provisions are not void under section 235 of the Companies Act.

# **Companies Act 2014**

# PUBLIC LIMITED COMPANY

# CONSTITUTION

# OF

# GH RESEARCH PUBLIC LIMITED COMPANY

## MEMORANDUM OF ASSOCIATION

- 1 The name of the Company is GH RESEARCH PUBLIC LIMITED COMPANY.
- 2 The Company is a public limited company registered under Part 17 of the Companies Act 2014 (the Act).
- 3 The objects for which the Company is established are:
  - (a) To carry on the business of a holding company and to co-ordinate the administration, finances and activities of any subsidiary companies or associated companies, to do all lawful acts and things whatsoever that are necessary or convenient in carrying on the business of such a holding company and in particular to carry on business in all its branches, companies or locations related to biopharmaceutical research and the development of novel therapies for the management of mental diseases.
  - (b) To carry on the businesses of a researcher, developer, manufacturer, distributor, wholesaler, retailer, service provider, investor, trader and any other business which may seem to the Company's board of directors capable of being conveniently carried on in connection with these objects or calculated directly or indirectly to enhance the value of or render more profitable any of the Company's property.
  - (c) To carry on all or any of the businesses as aforesaid either as a separate business or as the principal business of the Company.
  - (d) To invest and deal with the property of the Company in such manner as may from time to time be determined by the Company's board of directors and to dispose of or vary such investments and dealings.
  - (e) To borrow or raise money or capital in any manner and on such terms and subject to such conditions and for such purposes as the Company's board of directors shall think fit or expedient, whether alone or jointly and/or severally with any other person or company, including, without prejudice to the generality of the foregoing, whether by the issue of debentures or debenture stock (perpetual or otherwise) or otherwise, and to secure, with or without consideration, the payment or repayment of any money borrowed, raised or owing or any debt, obligation or liability of the Company or of any other person or company whatsoever in such manner and on such terms and conditions as the Company's board of directors shall think fit or expedient and, in particular by mortgage, charge, lien, pledge or debenture or any other security of whatsoever nature or howsoever described, perpetual or otherwise, charged upon all or any of the Company's property, both present and future, and to purchase, redeem or pay off any such securities and also to accept capital contributions from any person or company in any manner and on such terms and conditions and for such purposes as the Company's board of directors shall think fit or expedient.

- (f) To lend and advance money or other property or give credit or financial accommodation to any company or person in any manner either with or without security and whether with or without the payment of interest and upon such terms and conditions as the Company's board of directors shall think fit or expedient.
- (g) To guarantee, indemnify, grant indemnities in respect of, enter into any suretyship or joint obligation, or otherwise support or secure, whether by personal covenant, indemnity or undertaking or by mortgaging, charging, pledging or granting a lien or other security over all or any part of the Company's property (both present and future) or by any one or more of such methods or any other method and whether in support of such guarantee or indemnity or suretyship or joint obligation or otherwise, on such terms and conditions as the Company's board of directors shall think fit, the payment of any debts or the performance or discharge of any contract, obligation or liability of any person or company (including, without prejudice to the generality of the foregoing, the payment of any capital, principal, dividends or interest on any stocks, shares, debentures, debenture stock, notes, bonds or other securities of any person, authority or company) including, without prejudice to the generality of the foregoing, any company which is for the time being the Company's holding company or another subsidiary (as defined by the Act) of the Company's holding company or a subsidiary of the Company.
- (h) To grant, convey, assign, transfer, exchange or otherwise alienate or dispose of any property of the Company of whatever nature or tenure for such price, consideration, sum or other return whether equal to or less than the market value thereof or for shares, debentures or securities and whether by way of gift or otherwise as the Company's board of directors shall deem fit or expedient.
- (i) To purchase, take on, lease, exchange, rent, hire or otherwise acquire any property and to acquire and undertake the whole or any part of the business and property of any company or person.
- (j) To engage in currency exchange, interest rate and commodity transactions including, but not limited to, dealings in foreign currency, spot and forward rate exchange contracts, futures, options, forward rate agreements, swaps, caps, floors, collars and any other foreign exchange, interest rate or commodity hedging arrangements and such other instruments as are similar to, or derived from, any of the foregoing whether for the purpose of making a profit or avoiding a loss or managing a currency, interest rate or commodity exposure or any other exposure or for any other purpose.
- (k) To apply for, establish, create, purchase or otherwise acquire, sell or otherwise dispose of and hold any patents, trade marks, copyrights, brevets d' invention, registered designs, licences, concessions and the like conferring any exclusive or non-exclusive or limited rights to use or any secret or other information and any invention and to use, exercise, develop or grant licences in respect of or otherwise turn to account or exploit the property, rights or information so held.
- (l) To enter into any arrangements with any governments or authorities, national, local or otherwise and to obtain from any such government or authority any rights, privileges and concessions and to carry out, exercise and comply with any such arrangements, rights, privileges and concessions.
- (m) To establish, form, register, incorporate or promote any company or companies or person, whether inside or outside of Ireland.

- (n) To remunerate any person or company for services rendered or to be rendered in placing or assisting to place or guaranteeing the placing of any of the shares of the Company's capital or any debentures, debenture stock or other securities of the Company or in or about the formation or promotion of the Company or the conduct of its business.
- (o) To adopt such means of making known the products of the Company as may seem expedient and in particular by advertising in the press, by circulars, by purchase and exhibition of works of art or interest, by publication of books and periodicals and by granting prizes, rewards and donations.
- (p) To pay all costs, charges, fees and expenses incurred or sustained in or about the promotion, establishment, formation and registration of the Company.
- (q) To do all or any of the above things in any part of the world, and as principals, agents, contractors, trustees or otherwise and by or through trustees, agents or otherwise and either alone or in conjunction with any person or company.
- (r) To do all such other things as the Company's board of directors may think incidental or conducive to the attainment of the above objects or any of them.

#### NOTE: it is hereby declared that in this memorandum of association:

- (a) the word "company", except where used in reference to this Company, shall be deemed to include a body corporate, whether a company (wherever formed, registered or incorporated), a corporation aggregate, a corporation sole and a national or local government or other legal entity; and
- (b) the word "person", shall be deemed to include any individual, firm, body corporate, association or partnership, government or state or agency of a state, local authority or government body or any joint venture association or partnership (whether or not having a separate legal personality) and that person's personal representatives, successors or permitted assigns; and
- (c) the word "property", shall be deemed to include, where the context permits, real property, personal property including choses or things in action and all other intangible property and money and all estates, rights, titles and interests therein and includes the Company's uncalled capital and future calls and all and every other undertaking and asset; and
- (d) a word or expression used in this memorandum of association which is not otherwise defined and which is also used in the Companies Act 2014 shall have the same meaning here, as it has in the Companies Act 2014; and
- (e) any phrase introduced by the terms "including", "include" and "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms, whether or not followed by the phrases "but not limited to", "without prejudice to the generality of the foregoing" or any similar expression; and
- (f) words denoting the singular number only shall include the plural number and vice versa and references to one gender includes all genders; and

- (g) it is intended that the objects specified in each paragraph in this clause shall, except where otherwise expressed in such paragraph, be separate and distinct objects of the Company and shall not be in any way limited or restricted by reference to or inference from the terms of any other paragraph or the order in which the paragraphs of this clause occur or the name of the Company.
- 4 The liability of the members is limited.
- 5 The share capital of the Company is US\$1,000,000,000 divided into 40,000,000 Ordinary Shares of US\$0.025 each.
- 6 The shares forming the capital, may be increased or reduced and be divided into such classes and issued with any special rights, privileges and conditions or with such qualifications as regards preference, dividend, capital, voting or other special incidents, and be held upon such terms as may be attached thereto or as may from time to time be provided by the original or any substituted or amended articles of association and regulations of the Company for the time being, but so that where shares are issued with any preferential or special rights attached thereto such rights shall not be alterable otherwise than pursuant to the provisions of the Company's articles of association for the time being.

# **GH RESEARCH PUBLIC LIMITED COMPANY**

# **ARTICLES OF ASSOCIATION**

# Part 1 - Interpretation

## 1. Interpretation and general

- 1.1 The "optional provisions" as defined by section 1007(2) of the Companies Act (as defined below) shall apply to the Company save in so far as they are excluded or modified herein.
- 1.2 In these Articles, unless the context requires otherwise:

**1990 Regulations** means the Companies Act 1990 (Uncertificated Securities) Regulations 1996 (SI No. 68 of 1996) as may be amended from time to time.

**address** includes any number or address used for the purposes of communication by way of electronic mail or other Electronic Communication.

Advanced Electronic Signature has the same meaning as under the Electronic Commerce Act, 2000 (as amended or supplemented from time to time).

**Approved Nominee** means a person appointed under contractual arrangements with the Company to hold shares or rights or interests in shares of the Company on a nominee basis.

Articles means these articles of association as from time to time and for the time being in force.

Associated Company means any company which for the time being is a Subsidiary or a holding company of the Company, is a subsidiary of a holding company of the holding company of the Company or is a company in which the Company or any of such companies as aforesaid shall for the time being hold shares entitling the holder thereof to exercise at least one-fifth of the votes at any general meeting of such company (not being voting rights which arise only in specified circumstances.

Auditors means the auditors of the Company from time to time.

**Board** means the board of Directors as constituted from time to time.

**Business Day** means a day except a Saturday, Sunday or public holiday, on which banks in Ireland and New York are generally open for business.

Chairman means the person occupying the position of Chairman of the Board from time to time.

Chief Executive Officer shall include any equivalent office.

**Clear Days** means, in relation to a period of notice, that period excluding the day when the notice is given or deemed to be given and excluding the day for which notice is being given or on which an action or event for which notice is being given is to occur or take effect.

**Companies Act** means the Companies Act 2014 and all Acts of the Oireachtas and statutory instruments which are to be read as one with, or construed or read together as one with, the Companies Act, and every statutory modification or reenactment thereof for the time being in force (or, where the context so admits and requires, any one or more of such Acts and all orders and regulations made thereunder. **Company** means the company whose name appears in the heading to these Articles.

**Company Secretary** means the person or persons appointed as company secretary or joint company secretary of the Company from time to time and shall include any assistant or deputy secretary.

Date of Adoption means the date of adoption of these Articles.

**Directors** means the directors of the Company from time to time.

document includes, unless otherwise specified, any document sent or supplied in electronic form.

**Electronic Communication** has the same meaning as under the Electronic Commerce Act, 2000 (as amended or supplemented from time to time) and in addition includes in the case of notices or documents issued on behalf of the Company, such documents being made available or displayed on a website of the Company (or a website designated by the Board) and **electronic** and **electronically** shall be construed accordingly.

**Electronic Signature** has the same meaning as under the Electronic Commerce Act, 2000 (as amended or supplemented from time to time).

**Equity Securities** means the Shares or any securities conferring the right to purchase Shares or securities directly or indirectly convertible into, or exchangeable for (with or without additional consideration), the Shares.

**Euro** or **€** shall mean the Euro, the lawful currency of the State.

**Exchange Act** means the United States Securities Exchange Act of 1934, as amended from time to time and the rules and regulations of the SEC promulgated thereunder.

**Group** means the Company and its Subsidiaries from time to time and for the time being.

**member** means in relation to any Share, the member whose name is entered in the Register as the holder of the Share or, where the context permits, the members whose names are entered in the Register as the joint holders of Shares and shall include a member's personal representatives in consequence of his or her death or bankruptcy.

Memorandum means the memorandum of association of the Company.

Office means the registered office for the time being of the Company.

Ordinary Shareholders means the holders of Ordinary Shares.

**Ordinary Shares** means the ordinary shares of US\$0.025 each in the capital of the Company.

Redeemable Shares means redeemable shares as defined by section 64 of the Companies Act.

Register means the register of members of the Company to be kept as required by the Companies Act.

**Regulation** means an article of these Articles.

**SEC** means the U.S. Securities and Exchange Commission.

**Securities Act** means the United States Securities Act of 1933, as amended from time to time and the rules and regulations of the SEC promulgated thereunder.

Shareholders means the Ordinary Shareholders and any other holder of Shares from time to time.

Shares means the Ordinary Shares any other shares in the capital of the Company from time to time.

**State** means the Republic of Ireland.

**Stock Exchange** means any securities exchange or other system on which the Shares may be listed or otherwise authorised for trading from time to time in circumstances where the Company has approved such listing or trading.

Subsidiary means any subsidiary of the Company, as defined in section 7 of the Companies Act.

- 1.3 It is hereby declared that in these Articles:
  - (a) the word "company", except where used in reference to this Company, shall be deemed to include a body corporate, whether a company (wherever formed, registered or incorporated), a corporation aggregate, a corporation sole and a national or local government or other legal entity;
  - (b) the word "person", shall be deemed to include any individual, firm, body corporate, association or partnership, government or state or agency of a state, local authority or government body or any joint venture association or partnership (whether or not having a separate legal personality) and that person's personal representatives, successors or permitted assigns;
  - (c) the word "property", shall be deemed to include, where the context permits, real property, personal property including choses or things in action and all other intangible property and money and all estates, rights, titles and interests therein and includes the Company's uncalled capital and future calls and all and every other undertaking and asset;
  - (d) a word or expression used in these Articles which is not otherwise defined and which is also used in the Companies Act shall have the same meaning here, as it has in the Companies Act;
  - (e) any phrase introduced by the terms "including", "include" and "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms, whether or not followed by the phrases "but not limited to", "without prejudice to the generality of the foregoing" or any similar expression; and

(f) words denoting the singular number only shall include the plural number and vice versa and references to one gender includes all genders.

# Part 2 – Share Capital and Rights

### 2. Authorised share capital

The share capital of the Company is US\$1,000,000,000 divided into 40,000,000,000 Ordinary Shares of US\$0.025 each.

#### 3. Rights attaching to Ordinary Shares

- 3.1 The Ordinary Shares shall entitle the holders thereof to the following rights:
  - (a) subject to the right of the Company to set record dates for the purposes of determining the identity of members entitled to notice of and/or to vote at a general meeting and the authority of the Board and chairperson of the meeting to maintain order and security, the right to attend any general meeting of the Company and to exercise one vote per Ordinary Share held at any general meeting of the Company;
  - (b) the right to participate pro rata in all dividends declared by the Company; and
  - (c) the right, in the event of the Company's winding up, to participate pro rata in the total assets of the Company.

#### 4. Redeemable Shares

- 4.1 Unless the Board determines otherwise, any Share shall be deemed to be a Redeemable Share on, and from the time of, the existence or creation of an agreement, transaction or trade between the Company (including any agent or broker acting on behalf of the Company) and any person (who may or may not be a member) pursuant to which the Company acquires or will acquire a Share, or an interest in Shares, from the relevant person, save for an acquisition for nil consideration pursuant to section 102(1)(a) of the Companies Act. In these circumstances, the acquisition of such Shares by the Company, save where acquired for nil consideration in accordance with the Companies Act, shall constitute the redemption of a Redeemable Share in accordance with Chapter 6 of Part 3 of the Companies Act. No resolution, whether special or otherwise, shall be required to be passed to deem any Share a Redeemable Share.
- 4.2 The Company may by special resolution, and subject to the provisions of the Companies Act governing the variation of rights attached to classes of Shares and the amendment of these Articles, convert any of its Shares into Redeemable Shares.

#### 5. Variation of rights

5.1 Whenever the share capital is divided into different classes of Shares, the rights attaching to a class of Shares may only be varied or abrogated if (a) the holders of 75% in nominal value of the issued Shares of that class consent in writing to the variation, or (b) a special resolution, passed at a separate general meeting of the holders of that class, sanctions the variation. The quorum at any such separate general meeting, other than an adjourned meeting, shall be one person holding or representing by proxy at least a majority in nominal value of the class in question and the quorum at an adjourned meeting shall be one person holding or representing by proxy Shares of the class in question or that person's proxy.

5.2 The rights conferred upon the holders of any class of Shares issued with preferred or other rights shall not, unless otherwise expressly provided by the terms of issue of the Shares of that class, be deemed to be varied by a purchase or redemption by the Company of its own Shares or by the creation or issue of further Shares ranking pari passu therewith or subordinate thereto.

#### 6. Trust not recognised

Except as required by law, no person shall be recognised by the Company as holding any Share upon any trust, and the Company shall not be bound by or be compelled in any way to recognise (even when having notice thereof) any equitable, contingent, future or partial interest in any Share or any interest in any fractional part of a Share or (except only as by these Articles or by law otherwise provided) any other rights in respect of any Share except an absolute right to the entirety thereof in the member. This shall not preclude (i) the Company from requiring the members or a transferee of Shares to furnish the Company with information as to the beneficial ownership of any Share when such information is reasonably required by the Company, or (ii) the Directors, where they consider it appropriate, providing the information given to the members of Shares to the holders of depositary instruments in such Shares.

#### 7. Allotment and acquisition of Shares

- 7.1 The following provisions shall apply:
  - (a) Subject to the provisions of these Articles relating to new Shares, the Shares shall be at the disposal of the Directors, and they may (subject to the provisions of the Companies Act) allot, grant options over or otherwise dispose (with or without conferring a right of renunciation) of them to such persons, on such terms and conditions and at such times as they may consider to be in the best interests of the Company and its members, but so that no Share shall be issued at a discount to the nominal value thereof (except in accordance with the provisions of the Companies Act) and so that, unless otherwise permitted under the Companies Act, in the case of Shares offered to the public for subscription, the amount payable on application on each Share shall not be less than one-quarter of the nominal amount of the Share and the whole of any premium thereon.
  - (b) Without prejudice to the generality of the powers conferred on the Directors by other paragraphs of these Articles, and subject to any requirement to obtain the approval of the members under any laws, regulations or the rules of any Stock Exchange, the Directors may grant from time to time options to subscribe for the unallotted Shares to Directors and other persons in the service or employment of the Company or any Subsidiary or Associated Company on such terms and subject to such conditions as may be approved from time to time by the Directors or by any committee thereof appointed by the Directors for the purpose of such approval and on the terms and conditions required to obtain the approval of any statutory authority in any jurisdiction.
  - (c) The Directors are hereby generally and unconditionally authorised to exercise all the powers of the Company to allot relevant securities within the meaning of section 1021 of the Companies Act. The maximum amount of relevant securities which may be allotted under the authority hereby conferred shall be the amount of the authorised but unissued share capital of the Company at the Date of Adoption. The authority hereby conferred shall expire on the date which is five (5) years after the Date of Adoption unless and to the extent that such authority is renewed, revoked or extended prior to such date. The Company may before such expiry make an offer or agreement which would or might require relevant securities to be allotted after such expiry and the Directors may allot relevant securities in pursuance of such offer or agreement, notwithstanding that the authority hereby conferred has expired.

- (d) The Company may issue permissible letters of allotment (as defined by section 1019 of the Companies Act) to the extent permitted by the Companies Act.
- (e) The Directors are hereby empowered pursuant to sections 1022 and 1023(1) of the Companies Act to allot Equity Securities within the meaning of the said section 1022 for cash pursuant to the authority conferred by Regulation 7.1(c) as if section 1022(1) of the Companies Act did not apply to any such allotment. The Company may before the expiry of such authority make an offer or agreement which would or might require Equity Securities to be allotted after such expiry and the Directors may allot Equity Securities in pursuance of such an offer or agreement as if the power conferred by this Regulation 7.1(e) had not expired.
- (f) Unless otherwise determined by the Directors or the rights attaching to or by the terms of issue of any particular Shares, or to the extent required by the Companies Act, any Stock Exchange, depository or any operator of any clearance or settlement system, no person whose name is entered as a member in the Register shall be entitled to receive a share certificate for any Shares of any class held by him or her in the capital of the Company (nor on transferring part of a holding, to a certificate for the balance).
- (g) Any share certificate, if issued, shall specify the number of Shares in respect of which it is issued and the amount paid thereon or the fact that they are fully paid, as the case may be, and may otherwise be in such form as shall be determined by the Directors. Such certificates may be under seal. All certificates for Shares shall be consecutively numbered or otherwise identified and shall specify the Shares to which they relate. The name and address of the person to whom the Shares represented thereby are issued, with the number of Shares and date of issue, shall be entered in the Register. All certificates surrendered to the Company for transfer shall be cancelled and no new certificate shall be issued until the former certificate for a like number of Shares in the capital of the Company shall have been surrendered and cancelled. The Directors may authorise certificates to be issued with the seal and authorised signature(s) affixed by some method or system of mechanical process. In respect of a Share or Shares held jointly by several persons, the Company shall not be bound to issue a certificate or certificates to each such person, and the issue and delivery of a certificate or certificates to one of several joint holders shall be sufficient delivery to all such holders. If a share certificate is defaced, worn out, lost or destroyed, it may be renewed on such terms (if any) as to evidence and indemnity and on the payment of such expenses reasonably incurred by the Company in investigating such evidence, as the Directors may prescribe, and, in the case of defacement or wearing out, upon delivery of the old certificate.
- 7.2 The Directors (and any committee established under Regulation 58.1 and so authorised by the Directors and any person so authorised by the Directors or such committee) may without prejudice to Regulation 56.1:
  - (a) allot, issue, grant options over and otherwise dispose of Shares in the Company; and
  - (b) exercise the Company's powers under Regulation 7.1,

on such terms and subject to such conditions as they think fit, subject only to the provisions of the Companies Act and these Articles.

#### 8. Payment of commission

The Company may exercise the powers of paying commissions conferred or permitted by the Companies Act. Subject to the provisions of the Companies Act, any such commission may be satisfied by the payment of cash or by the allotment of fully or partly paid Shares or partly in one way and partly in the other. On any issue of Shares the Company may also pay such brokerage as may be lawful.

### 9. Disclosure of interests

- 9.1 For the purposes of this Regulation:-
  - (a) Deemed Voting Concert Party Interest means an agreement or arrangement between two or more persons with respect to, or to the exercise of, voting rights attaching to Shares and which is likely to result in those rights being exercised so as to influence or to control the policy of the Company or the management of its affairs which the Directors have deemed to be a Deemed Voting Concert Party Interest for the purposes of this Regulation 9 and, where the Directors so resolve, each of the persons who is party to such agreement or arrangement shall be deemed (for the purposes of this Regulation 9) to be interested in all the Shares to which the voting rights in question are attached and, in this definition, references to an arrangement include references to an understanding or mutual expectation, whether formal or informal and whether or not legally binding.
  - (b) **Disclosure Notice** means a notice served pursuant to Regulation 9.2 below.
  - (c) Interest means an interest (of any size) in the Relevant Share Capital which would be taken into account in deciding whether a notification to the Company would be required under Chapter 4 of Part 17 of the Companies Act) but shall for all purposes include (the Included Interests) (i) rights to subscribe for or convert into, or entitlements to acquire rights to subscribe for or convert into, shares which would on issue or conversion (as the case may be) be comprised in the Relevant Share Capital; (ii) the interests referred to in Section 260 (a), (c) and (h) of the Companies Act) except (in any case) those of a bare or custodian trustee and of a simple trustee and (iii) any Deemed Voting Concert Party Interest; and interested shall be construed accordingly.
  - (d) **Relevant Share Capital** means the relevant share capital of the Company (as that expression is defined in Section 1047(1) of the Companies Act).
  - (e) **Share** means any share comprised in Relevant Share Capital.
- 9.2 The Directors may by notice in writing require any member, or other person appearing to be interested or to have been interested in Shares, to disclose to the Company in writing such information as the Directors shall require relating to the ownership of or any Interest in Shares as lies within the knowledge of such member or other person (supported if the Directors so require by a statutory declaration and/or by independent evidence) including (without prejudice to the generality of the foregoing):-
  - (a) any information which the Company is entitled to seek pursuant to Section 1062 of the Companies Act.
- 9.3 The Directors may give any number of Disclosure Notices pursuant to Regulation 9.2 above to the same member or other person in respect of the same Shares.

- 9.4 The Directors may serve notice pursuant to the terms of this Regulation irrespective of whether or not the person on whom it shall be served may be dead, bankrupt, insolvent or otherwise incapacitated and no such incapacity or any unavailability of information or inconvenience or hardship in obtaining the same shall be a satisfactory reason for failure to comply with any such notice, provided that if the Directors in their absolute discretion think fit, they may waive compliance in whole or in part with any notice given under this Regulation in respect of a Share in any case of bona fide unavailability of information or genuine hardship or where they otherwise think fit but no such waiver shall prejudice or affect in any way any non-compliance not so waived whether by the person concerned or any other person appearing to the Directors to be interested in the Shares or by any person to whom a notice may be given at any time.
- 9.5 The provisions of Regulations 82 to 89 inclusive shall apply to the service of notices required by this Regulation to be served.
- 9.6 If at any time the Directors are satisfied that any member, or any other person appearing to be interested in Shares held by such member, has been duly served with a Disclosure Notice and is in default for the prescribed period (as defined in Regulation 9.11(b)) in supplying to the Company the information thereby required, or, in purported compliance with such a notice, has made a statement which is false or inadequate in a material particular, then the Directors may, in their absolute discretion at any time thereafter by notice (a **Direction Notice**) to such member direct that:
  - (a) in respect of the Shares in relation to which the default occurred (the **Default Shares**) the member shall not be entitled to attend or to vote at a general meeting either personally or by proxy or to exercise any other right conferred by membership in relation to meetings of the Company;
  - (b) where the nominal value of the Default Shares represents at least 0.25 per cent of the nominal value of the issued shares of the class concerned, then the Direction Notice may additionally direct that:
    - (i) except in a liquidation of the Company, no payment shall be made of any sums due from the Company on the Default Shares, whether in respect of capital or dividend or otherwise, and the Company shall not have any liability to pay interest on any such payment when it is finally paid to the member (but the provisions of this Regulation 9.6(b)(i) shall apply only to the extent permitted from time to time by Stock Exchange rules);
    - (ii) no other distribution shall be made on the Default Shares;
    - (iii) no transfer of any of the Default Shares held by such member shall be registered unless:
      - (A) the member is not himself or herself in default as regards supplying the information requested and the transfer when presented for registration is accompanied by a certificate by the member in such form as the Directors may in their absolute discretion require to the effect that after due and careful enquiry the member is satisfied that no person in default as regards supplying such information is interested in any of the shares the subject of the transfer; or
      - (B) the transfer is an approved transfer (as defined in Regulation 9.11(c)).

The Company shall send to each other person appearing to be interested in the Shares the subject of any Direction Notice a copy of the notice, but the failure or omission by the Company to do so shall not invalidate such notice.

- 9.7 Where any person appearing to be interested in the Default Shares has been duly served with a Direction Notice and the Default Shares which are the subject of such Direction Notice are held by an Approved Nominee, the provisions of this Regulation shall be treated as applying only to such Default Shares held by the Approved Nominee and not (insofar as such person's apparent interest is concerned) to any other shares held by the Approved Nominee.
- 9.8 Where the member on which a Disclosure Notice is served is an Approved Nominee acting in its capacity as such, the obligations of the Approved Nominee as a member of the Company shall be limited to disclosing to the Company such information relating to any person appearing to be interested in the Shares held by it as has been recorded by it pursuant to the arrangements entered into by the Company or approved by the Directors pursuant to which it was appointed as an Approved Nominee.
- 9.9 Any Direction Notice shall cease to have effect:
  - (a) in relation to any Shares which are transferred by such member by means of an approved transfer; or
  - (b) when the Directors are satisfied that such member and any other person appearing to be interested in Shares held by such member, has given to the Company the information required by the relevant Disclosure Notice.
- 9.10 The Directors may at any time give notice cancelling a Direction Notice.
- 9.11 For the purposes of this Regulation:
  - (a) a person shall be treated as appearing to be interested in any Shares if the member holding such Shares has given to the Company a notification under the said section 1062 which either (i) names such person as being so interested or (ii) fails to establish the identities of all those interested in the Shares and (after taking into account the said notification and any other relevant disclosure notification) the Company knows or has reasonable cause to believe that the person in question is or may be interested in the Shares;
  - (b) the prescribed period is 28 days from the date of service of the said Disclosure Notice unless the nominal value of the Default Shares represents at least 0.25 per cent of the nominal value of the issued Shares of that class, when the prescribed period is 14 days from that date;
  - (c) a transfer of Shares is an approved transfer if but only if:
    - (i) it is a transfer of Shares to an offeror by way or in pursuance of acceptance of an offer made to all the members (or all the members other than the person making the offer and his nominees) of the Shares to acquire those Shares or a specified proportion of them; or
    - (ii) the Directors are satisfied that the transfer is made pursuant to a sale of the whole of the beneficial ownership of the Shares the subject of the transfer to a party unconnected with the member and with other persons appearing to be interested in such Shares; or

- (iii) the transfer results from a sale made through a Stock Exchange on which the Shares are normally traded.
- 9.12 Any resolution or determination of, or decision or exercise of any discretion or power by the Directors under or pursuant to the provisions of this Regulation shall be final and conclusive and things done by or on behalf of, or on the authority of, the Directors pursuant to the foregoing provisions of this Regulation shall be conclusive and binding on all persons concerned and shall not be open to challenge, whether as to validity or otherwise on any ground whatsoever. The Directors shall not be required to give any reasons for any decision, determination or declaration taken or made in accordance with this Regulation.
- 9.13 The provisions of this Regulation are in addition to, and do not limit, any other right or power of the Company or the Directors, including any right vested in the Company or the Directors by the Companies Act including under section 1066 of the Companies Act or otherwise under Irish law.

#### 10. Calls on Shares

- 10.1 The Directors may from time to time make calls upon the members in respect of any consideration unpaid on their Shares (whether on account of the nominal value of the Shares or by way of premium), provided that in the case where the conditions of allotment or issuance of Shares provide for the payment of consideration in respect of such Shares at fixed times, the Directors shall only make calls in accordance with such conditions.
- 10.2 Each member shall (subject to receiving at least thirty days' notice specifying the time or times and place of payment, or such lesser or greater period of notice provided in the conditions of allotment or issuance of the Shares) pay to the Company, at the time or times and place so specified, the amount called on the Shares.
- 10.3 A call may be revoked or postponed, as the Directors may determine.
- 10.4 A person upon whom a call is made shall remain liable for such call notwithstanding the subsequent transfer of the Shares in respect of which the call was made.
- 10.5 Subject to the conditions of allotment or issuance of the Shares, a call shall be deemed to have been made at the time when the resolution of the Directors authorising the call was passed and may be required to be paid by instalments if specified in the call.
- 10.6 The joint holders of a Share shall be jointly and severally liable to pay all calls in respect of it.
- 10.7 If the consideration called in respect of a Share or in respect of a particular instalment is not paid in full before or on the day appointed for payment of it, the person from whom the sum is due shall pay interest in cash on the unpaid value from the day appointed for payment of it to the time of actual payment of such rate, not exceeding five per cent per annum or such other rate as may be specified by an order under section 2(7) of the Companies Act, as the Directors may determine, but the Directors may waive payment of such interest wholly or in part.
- 10.8 Any consideration which, by the terms of issue of a Share, becomes payable on allotment or issuance or at any fixed date (whether on account of the nominal value of the Share or by way of premium) shall, for the purposes of these Articles, be deemed to be a call duly made and payable on the date on which, by the terms of issue, that consideration becomes payable, and in the case of non-payment of such a consideration, all the relevant provisions of these Articles as to payment of interest and expenses, forfeiture or otherwise, shall apply as if such consideration had become payable by virtue of a call duly made and notified.

- 10.9 The Directors may, on the issue of Shares, differentiate between the holders of different classes as to the amount of calls to be paid and the times of payment.
- 10.10 The Directors may, if they think fit:
  - (a) receive from any member willing to advance such consideration, all or any part of the consideration uncalled and unpaid upon any Shares held by him or her; and/or
  - (b) pay, upon all or any of the consideration so advanced (until the amount concerned would, but for such advance, become payable) interest at such rate (not exceeding, unless the Company in a general meeting otherwise directs, five per cent per annum or such other rate as may be specified by an order under section 2(7) of the Companies Act) as may be agreed upon between the Directors and the member paying such consideration in advance.
- 10.11 The Company may:
  - (a) acting by its Directors, make arrangements on the issue of Shares for a difference between the members in the amounts and times of payment of calls on their Shares;
  - (b) acting by its Directors, accept from any member the whole or a part of the amount remaining unpaid on any Shares held by him or her, although no part of that amount has been called up;
  - (c) acting by its Directors and subject to the Companies Act, pay a dividend in proportion to the amount paid up on each Share where a larger amount is paid up on some Shares than on others; and
  - (d) by special resolution determine that any portion of its share capital which has not been already called up shall not be capable of being called up except in the event and for the purposes of the Company being wound up; upon the Company doing so, that portion of its share capital shall not be capable of being called up except in that event and for those purposes.

#### 11. Lien

- 11.1 The Company shall have a first and paramount lien on every Share (not being a fully paid Share) for all consideration (whether immediately payable or not) called, or payable at a fixed time, in respect of that Share.
- 11.2 The Directors may at any time declare any Share to be wholly or in part exempt from Regulation 11.1.
- 11.3 The Company's lien on a Share shall extend to all dividends payable on it.
- 11.4 The Company may sell, in such manner as the Directors think fit, any Shares on which the Company has a lien, but no sale shall be made unless (i) a sum in respect of which the lien exists is immediately payable; and (ii) the following conditions are satisfied:
  - (a) a notice in writing, stating and demanding payment of such part of the amount in respect of which the lien exists as is immediately payable, has been given to the registered holder of the Share for the time being, or the person entitled thereto by reason of his or her death or bankruptcy; and
  - (b) a period of 14 days after the date of giving of that notice has expired.

- 11.5 The following provisions apply in relation to a sale referred to in Regulation 11.4:
  - (a) to give effect to any such sale, the Directors may authorise some person to transfer the Shares sold to the purchaser of them;
  - (b) the purchaser shall be registered as the holder of the Shares comprised in any such transfer;
  - (c) the purchaser shall not be bound to see to the application of the purchase consideration, nor shall his or her title to the Shares be affected by any irregularity or invalidity in the proceedings in reference to the sale;
  - (d) after the name of the purchaser has been entered in the Register, the remedy of any person aggrieved by the sale shall be in damages only and against the Company exclusively; and
  - (e) the proceeds of the sale shall be received by the Company and applied in payment of such part of the amount in respect of which the lien exists as is immediately payable, and the residue, if any, shall (subject to a like lien for sums not immediately payable as existed upon the Shares before the sale) be paid to the person entitled to the Shares at the date of the sale.

# 12. Liability of the Company to make payment

- 12.1 Whenever any law for the time being of any country, state or place imposes or purports to impose any immediate or future or possible liability upon the Company (or any Subsidiary) to make any payment or empowers any government or taxing authority or government official to require the Company to make any payment in respect of any Shares registered in the Register as held either jointly or solely by any members or in respect of any dividends, bonuses or other monies due or payable or accruing due or which may become due or payable to such member by the Company on or in respect of any Shares registered as mentioned above or for or on account or in respect of any member and whether in consequence of:
  - (a) the death of such member;
  - (b) the non-payment of any income tax or other tax by such member;
  - (c) the non-payment of any estate, probate, succession, death, stamp or other duty by the executor or administrator of such member or by or out of her estate; or
  - (d) any other act or thing;

## in every such case:

- (a) the Company shall be fully indemnified by such member or her executor or administrator from all liability;
- (b) the Company shall have a lien upon all dividends and other monies payable in respect of the Shares registered in the Register as held either jointly or solely by such member for all monies paid or payable by the Company as referred to above in respect of such Shares or in respect of any dividends or other monies thereon or for or on account or in respect of such member under or in consequence of any such law, together with interest at the rate of fifteen per cent annum (or such other rate as the Board may determine) thereon from the date of payment to date of repayment, and the Company may deduct or set off against such dividends or other monies so payable any monies paid or payable by the Company as referred to above together with interest at the same rate;

- (c) the Company may recover as a debt due from such member or her executor or administrator (wherever constituted) any monies paid by the Company under or in consequence of any such law and interest thereon at the rate and for the period referred to above in excess of any dividends or other monies then due or payable by the Company; and
- (d) the Company may if any such money is paid or payable by it under any such law as referred to above refuse to register a transfer of any Shares by any such member or her executor or administrator until such money and interest is set off or deducted as referred to above or in the case that it exceeds the amount of any such dividends or other monies then due or payable by the Company, until such excess is paid to the Company.

Subject to the rights conferred upon the holders of any class of Shares, nothing in this Regulation 12 will prejudice or affect any right or remedy which any law may confer or purport to confer on the Company. As between the Company and every such member as referred to above (and, her executor, administrator and estate, wherever constituted), any right or remedy which such law shall confer or purport to confer on the Company shall be enforceable by the Company.

## 13. Forfeiture

- 13.1 If a member of the Company fails to pay any call or instalment of a call on the day appointed for payment of it, the Directors may, at any time thereafter during such time as any part of the call or instalment remains unpaid, serve a notice on the member requiring payment of so much of the call or instalment as is unpaid, together with any interest which may have accrued.
- 13.2 The notice referred to in Regulation 13.1 shall:
  - (a) specify a further day (not earlier than the expiration of 14 days after the date of service of the notice) on or before which the payment required by the notice is to be made; and
  - (b) state that, if the amount concerned is not paid by the day so specified, the shares in respect of which the call was made will be liable to be forfeited.
- 13.3 If the requirements of the notice referred to in Regulation 13.2 are not complied with, any Share in respect of which the notice has been served may at any time after the day so specified (but before, should it occur, the payment required by the notice has been made) be forfeited by a resolution of the Directors to that effect. The forfeiture shall include all dividends or other moneys payable in respect of the forfeited Shares and not paid before forfeiture.
- 13.4 On the trial or hearing of any action for the recovery of any money due for any call, it shall be sufficient to prove that the name of the member sued is entered in the Register as the holder, or one of the holders, of the Shares in respect of which such debt accrued, that the resolution making the call is duly recorded in the minute book and that notice of such call was duly given to the member sued, in pursuance of these Articles, and it shall not be necessary to prove the appointment of the Directors who made such call nor any other matters whatsoever, but the proof of the matters aforesaid shall be conclusive evidence of the debt.

- 13.5 A forfeited Share may be sold or otherwise disposed of on such terms and in such manner as the Directors think fit, and at any time before a sale or disposition the forfeiture may be cancelled on such terms as the Directors think fit. Where for the purposes of its disposal such a Share is to be transferred to any person, the Directors may take such steps as the Directors consider are necessary or desirable in order to effect such sale and, for this purpose, may authorise some person to execute an instrument of transfer of the Share to that person. The Company may receive the consideration, if any, given for the Share on any sale or disposal thereof and may execute a transfer of the Share in favour of the person to whom the Share is sold or disposed of and thereupon he shall be registered as the holder of the Share and shall not be bound to see to the application of the purchase moneys, nor shall his title to the Share be affected by any irregularity or invalidity in the proceedings in reference to the forfeiture, sale or disposal of the Share and after the name of the transferee has been entered in the Register the remedy of any person aggrieved by the sale shall be in damages only and against the Company exclusively.
- 13.6 A person whose Shares have been forfeited shall cease to be a member of the Company in respect of the forfeited Shares, but shall, notwithstanding, remain liable to pay to the Company all consideration which, at the date of forfeiture, were payable by him or her to the Company in respect of the Shares, without any deduction or allowance for the value of the Shares at the time of the forfeiture but his or her liability shall cease if and when the Company shall have received payment in full of all such consideration in respect of the Shares.
- 13.7 A statement in writing that the maker of the statement is a Director or the Company Secretary, and that a Share has been duly forfeited on a date stated in the statement, shall be conclusive evidence of the facts stated in it as against all persons claiming to be entitled to the Share.
- 13.8 The following provisions apply in relation to a sale or other disposition of a Share referred to in Regulation 13.5:
  - (a) the Company may receive the consideration, if any, given for the Share on the sale or other disposition of it and may execute a transfer of the Share in favour of the person to whom the Share is sold or otherwise disposed of (the **disponee**);
  - (b) upon such execution, the disponee shall be registered as the holder of the Share; and
  - (c) the disponee shall not be bound to see to the application of the purchase consideration, if any, nor shall his or her title to the Share be affected by any irregularity or invalidity in the proceedings in reference to the forfeiture, sale or disposal of the Share.
- 13.9 The provisions of these Articles as to forfeiture shall apply in the case of non-payment of any sum which, by the terms of issue of a Share, becomes payable at a fixed time, whether on account of the nominal value of the Share or by way of premium, as if the same had been payable by virtue of a call duly made and notified.
- 13.10 The Directors may accept the surrender of any Share which the Directors have resolved to have been forfeited upon such terms and conditions as may be agreed and, subject to any such terms and conditions, a surrendered Share shall be treated as if it has been forfeited.

#### 14. Payment by instalments

If by the conditions of allotment of any Share the whole or part of the amount or issue price thereof shall be payable by instalments, every such instalment when due shall be paid to the Company by the person who for the time being shall be the holder of the Share.

#### 15. Conversion of Shares into Stock

- 15.1 The Company by ordinary resolution may convert any paid up Shares into stock and reconvert any stock into paid up Shares of any denomination.
- 15.2 The holders of stock may transfer the same or any part thereof, in the same manner, and subject to the same regulations, as and subject to which the Shares from which the stock arose might have been transferred before conversion, or as near thereto as circumstances admit; and the Directors may fix from time to time the minimum amount of stock transferable but so that such minimum shall not exceed the nominal amount of each Share from which the stock arose.
- 15.3 The holders of stock shall have, according to the amount of stock held by them, the same rights, privileges and advantages in relation to dividends, voting at meetings of the Company and other matters as if they held the Shares from which the stock arose, but no such right, privilege or advantage (except participation in the dividends and profits of the Company and in the assets on winding up) shall be conferred by an amount of stock which, if existing in Shares, would not have conferred that right, privilege or advantage.
- 15.4 Such of these Articles as are applicable to paid up Shares shall apply to stock, and the words "Share" and "Shareholder" therein shall include "stock" and "stockholder".

## Part 3 – Alteration of Share Capital

#### 16. Increase of capital

- 16.1 The Company from time to time by ordinary resolution may increase the share capital by such sum, to be divided into Shares of such amount, as the resolution shall prescribe.
- 16.2 Subject to the provisions of the Companies Act, the new Shares shall be issued to such persons, upon such terms and conditions and with such rights and privileges annexed thereto as the general meeting resolving upon the creation thereof shall direct and, if no direction be given, as the Directors shall determine and in particular such Shares may be issued with a preferential or qualified right to dividends and in the distribution of the assets of the Company and with a special, or without any, right of voting.
- 16.3 Except so far as otherwise provided by the conditions of issue or by these Articles, any capital raised by the creation of new Shares shall be considered part of the pre-existing ordinary capital and shall be subject to the provisions herein contained with reference to calls and instalments, transfer and transmission, forfeiture, lien and otherwise.

#### 17. Variation of capital

- 17.1 The Company, by ordinary resolution, may:-
  - (a) consolidate and divide all or any of its share capital into Shares of larger amount;
  - (b) subject to Section 83(1)(b) of the Companies Act, subdivide its Shares, or any of them, into Shares of smaller amount, so however that in the sub-division the proportion between the amount paid and the amount, if any, unpaid on each reduced Share shall be the same as it was in the case of the Share from which the reduced Share is derived (and so that the resolution whereby any Share is sub-divided may determine that, as between the holders of the Shares resulting from such sub-division, one or more of the Shares may have, as compared with the others, any such preferred, deferred or other rights or be subject to any such restrictions as the Company has power to attach to unissued or new Shares); or

(c) cancel any Shares which, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person and reduce the amount of its authorised share capital by the amount of the Shares so cancelled.

#### **18.** Fractions on consolidation

Subject to the provisions of these Articles, whenever as a result of a consolidation of Shares any members would become entitled to fractions of a Share, the Directors may sell, on behalf of those members, the Shares representing the fraction for the best price reasonably obtainable to any person and distribute the proceeds of sale in due proportion among those members, and the Directors may take such steps as the Directors consider are necessary or desirable in order to effect such sale and, for this purpose, may authorise any person to execute an instrument of transfer of the Shares to, or in accordance with the directions of, the purchaser. The transferee shall not be bound to see to the application of the purchase money nor shall his title to the Shares be affected by any irregularity in or invalidity of the proceedings in reference to the sale.

#### 19. Reduction of capital

Subject to the provisions of the Companies Act, the Company, by special resolution, may reduce its share capital, any capital redemption reserve fund, any undenominated capital and/or any share premium account in any manner and with, and subject to, any incident authorised, and consent required, by law.

## 20. Purchase of own Shares

- 20.1 Subject to the provisions of Chapter 6 of Part 3 or Chapter 5 of Part 17 of the Companies Act and the other provisions of this Regulation 20, the Company may:
  - (a) pursuant to Section 66(4) of the Companies Act, issue any Shares which are to be redeemed or are liable to be redeemed at the option of the Company or the member on such terms and in such manner as may be determined by the Company in general meeting (by special resolution) on the recommendation of the Directors;
  - (b) redeem Shares on such terms as may be contained in, or be determined pursuant to the provisions of, these Articles. Subject as aforesaid, the Company may cancel any Shares so redeemed or may hold them as treasury shares and re-issue such treasury shares as Shares of any class or classes or cancel them;
  - (c) subject to or in accordance with the provisions of the Companies Act and without prejudice to any relevant special rights attached to any class of Shares, pursuant to Section 105 and Chapter 5 of Part 17 of the Companies Act, purchase any of its own Shares (including any Redeemable Shares and without any obligation to purchase on any pro rata basis as between members or members of the same class) whether in the market, by tender or by private arrangement at such prices and otherwise on such terms and conditions as the Board may from time to time determine and may cancel any shares so purchased or hold them as treasury shares (as defined by Section 109 of the Companies Act) and may reissue any such shares as shares of any class or classes or cancel them; or
  - (d) pursuant to Section 83(3) of the Companies Act convert any of its Shares into Redeemable Shares provided that the total number of Shares which shall be redeemable pursuant to this authority shall not exceed the limit in Section 1071(1)(b) of the Companies Act.

- 20.2 The Company may give financial assistance for the purpose of an acquisition of its Shares or, where the Company is a subsidiary, its holding company where permitted by sections 82 and 1043 of the Companies Act.
- 20.3 The Company may make a payment in respect of the redemption or purchase of its own Shares in any manner permitted by the Companies Act.
- 20.4 The holder of the Shares being purchased shall be bound to deliver up to the Company at its registered office or such other place as the Board shall specify, the certificate(s) (if any) thereof for cancellation and thereupon the Company shall pay to her the purchase or redemption monies or consideration in respect thereof.

## **Part 4 – Transfer of Shares**

#### 21. Transfer of Shares

- 21.1 Subject to the Companies Act and to such of the restrictions contained in these Articles as may be applicable, any member may transfer all or any of his Shares (of any class) by an instrument of transfer in the usual common form or in any other form which the Board may from time to time approve. The instrument of transfer may be endorsed on the certificate.
- 21.2 The instrument of transfer of a Share shall be signed by or on behalf of the transferor and, if the Share is not fully paid, by or on behalf of the transferee.
- 21.3 The instrument of transfer of any Share may be executed for and on behalf of the transferor by the Company Secretary or any other party designated by the Board for such purpose, and the Company Secretary or any other party designated by the Board for such purpose shall be deemed to have been irrevocably appointed agent for the transferor of such Share or Shares with full power to execute, complete and deliver in the name of and on behalf of the transferor of such Share or Shares all such transfers of Shares held by the members in the share capital of the Company. Any document which records the name of the transferor, the name of the transferee, the class and number of Shares agreed to be transferred, the date of the agreement to transfer Shares and the price per Share, shall, once executed by the transferor or the Company Secretary or any other party designated by the Board for such purpose as agent for the transferor, be deemed to be a proper instrument of transfer for the purposes of the Companies Act. The transferor shall be deemed to remain the member holding the Share until the name of the transferee is entered on the Register in respect thereof, and neither the title of the transferee nor the title of the transferor shall be affected by any irregularity or invalidity in the proceedings in reference to the sale should the Directors so determine. All instruments of transfer may be retained by the Company.
- 21.4 The Company, at its absolute discretion, may, or may procure that a Subsidiary shall, pay Irish stamp duty arising on a transfer of Shares on behalf of the transferee of such Shares of the Company. If stamp duty resulting from the transfer of Shares which would otherwise be payable by the transferee is paid by the Company or any Subsidiary on behalf of the transferee, then in those circumstances, the Company shall, on its behalf or on behalf of its Subsidiary (as the case may be), be entitled to (i) reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those Shares and (iii) to the extent permitted by section 1042 of the Companies Act, claim a first and paramount lien on the Shares on which stamp duty has been paid by the Company or its Subsidiary for the amount of stamp duty paid. The Company's lien shall extend to all dividends paid on those Shares.

- 21.5 Notwithstanding the provisions of these Articles and subject to the 1990 Regulations, or any regulations made under section 1086 of the Companies Act, title to any Shares may also be evidenced and transferred without a written instrument in accordance with section 239 of the Companies Act 1990 or section 1086 of the Companies Act or any regulations made thereunder. The Directors shall have power to permit any class of Shares to be held in uncertificated form and to implement any arrangements they think fit for such evidencing and transfer which accord with such regulations and in particular shall, where appropriate, be entitled to disapply or modify all or part of the provisions in these Articles with respect to the requirement for written instruments of transfer and share certificates (if any), in order to give effect to such regulations.
- 21.6 The Board may, in its absolute discretion and without assigning any reason for its decision, decline to register any transfer of any Share which is not a fully-paid Share save and however, that in the case of such a Share which is admitted to listing on any of the Stock Exchanges such restriction shall not operate so as to prevent dealings in such a Share from taking place on an open and proper basis.
- 21.7 The Directors shall not register any person as a holder of any Share (other than an allottee under an issue of Shares by way of capitalisation of profits or reserves made pursuant to these Articles) unless such person has furnished to the Directors a declaration (in such form as the Directors may from time to time prescribe) signed by him or on his behalf (or, in the case of a corporation, sealed by the corporation or signed on its behalf by an attorney or duly authorised officer of the corporation), together with such evidence as the Directors may require of the authority of any signatory on behalf of such person, stating (i) the name and nationality of any person who has an interest in any such Share and (if such declaration or the Directors so require) the nature and extent of the interest of each such person or (ii) such other information as the Directors may from time to time determine. The Directors shall in any case where they may consider it appropriate require such person to provide such evidence or give such information as to the matters referred to in the declaration as they think fit. The Directors shall decline to register any person as a holder of a Share if such further evidence or information is not provided or given. The Directors shall, so long as they act reasonably and in good faith, be under no liability to the Company or to any other person if they register any person as the holder of a Share on the basis of a declaration or other evidence or information provided pursuant to this Regulation which declaration, evidence or information appears on its face to be correct.
- 21.8 The Board may also decline to register any transfer if:
  - (a) the instrument of transfer is not duly stamped, if required, and lodged at the Office or any other place as the Board may from time to time specify for the purpose, accompanied by the certificate (if any) for the Shares to which it relates and such other evidence as the Board may reasonably require to show the right of the transferor to make the transfer;
  - (b) the instrument of transfer is in respect of more than one class of Share;
  - (c) the instrument of transfer is in favour of more than four persons jointly;
  - (d) a registration statement under the Securities Act is not in effect with respect to such transfer or such transfer is not exempt from registration;
  - (e) it is not satisfied that all applicable consents, authorisations, permissions or approvals of any governmental body or agency in Ireland or any other applicable jurisdiction required to be obtained under relevant law prior to such transfer have been obtained; or

- (f) it is not satisfied that the transfer would not violate the terms of any agreement to which the Company (or any of its Subsidiaries) and the transferor are party or subject.
- 21.9 The Company shall not be obligated to make any transfer to an infant or to a person in respect of whom an order has been made by a competent court or official on the grounds that she is or may be suffering from mental disorder or is otherwise incapable of managing her affairs or under other legal disability.
- 21.10 Subject to any directions of the Board from time to time in force, the Company Secretary or any other party designated by the Board for such purpose may exercise the powers and discretions of the Board under Regulation 21.8, Regulation 27, Regulation 32 and Regulation 34.2.
- 21.11 If the Board declines to register a transfer it shall, within two months after the date on which the instrument of transfer was lodged with the Company, send to the transferee notice of such refusal.
- 21.12 No fee shall be charged by the Company for registering any transfer or for making any entry in the Register concerning any other document relating to or affecting the title to any Share (except that the Company may require payment of a sum sufficient to cover any tax or other governmental charge that may be imposed on it in connection with such transfer or entry).
- 21.13 The Company shall be entitled to retain any instrument of transfer which is registered, but any instrument of transfer which the Directors refuse to register shall be returned to the person lodging it when notice of the refusal is given.
- 21.14 Nothing in these Articles shall preclude the Directors from recognising a renunciation of the allotment of any Shares by the allottee in favour of some other person.

## 22. Transmission of Shares

- 22.1 In the case of the death of a member, the survivor or survivors, where the deceased was a joint holder, and the personal representatives of the deceased where he or she was a sole holder, shall be the only persons recognised by the Company as having any title to his or her interest in the Shares; but nothing herein contained shall release the estate of a deceased member from any liability in respect of any Share which had been held by him (whether jointly or otherwise).
- 22.2 A person becoming entitled to a Share in consequence of the death, bankruptcy, liquidation or insolvency of a member, or otherwise becoming entitled to a Share by operation of any law, directive or regulation (whether of the State, the European Union, or any other jurisdiction) may elect, upon such evidence of title being produced as the Directors may reasonably require at any time and from time to time, and subject as further provided in this Regulation, either to become the holder of the Share or to have some person nominated by him registered as the transferee. If he elects to become the holder he shall give notice to the Company to that effect and, where the Directors are satisfied with the evidence of title produced to them, they may register such person as the holder of the Share, subject to the other provisions of these Articles and of the Companies Act. If he elects to have another person registered, he shall execute an instrument of transfer of the Share to that person. All of the provisions of these Articles relating to the transfer of Shares shall apply to any notice or instrument of transfer given under this Regulation as if it were an instrument of transfer executed by the member and the event giving rise to the entitlement of the relevant person to the Shares had not occurred.

- 22.3 The Directors shall, in either of those cases, have the same right to decline or suspend registration as they would have had in the case of a transfer of the Share by that member before the event giving rise to the entitlement of the relevant person to the Shares.
- 22.4 A person becoming entitled to a Share by any of the circumstances set out in Regulation 22.2 shall, upon supplying to the Company such evidence as the Directors may reasonably require to show his title to the Share (notwithstanding that he is not entered on the Register as the holder of the Share), have the rights to which he would be entitled if he were the holder of the Share, except that, before being registered as the holder of the Share, he shall not be entitled in respect of it to receive notices of, or to attend or vote at any meeting of the Company or at any separate meeting of the holders of any class of Shares, so, however, that the Directors, at any time, may give notice requiring any such person to elect either to be registered himself or to transfer the Share and, if the notice is not complied with within ninety days, the Directors thereupon may withhold payment of all dividends, bonuses or other moneys payable in respect of the Share until the requirements of the notice have been complied with.
- 22.5 The Company may charge a fee not exceeding €10.00 on the registration of every probate, letters of administration, certificate of death, power of attorney, notice as to stock or other instrument or order.
- 22.6 The Directors may determine such procedures as they shall think fit regarding the transmission of shares in the Company held by a body corporate that are transmitted by operation of law in consequence of a merger or division.

### 23. Closing Register or Fixing Record Date

- 23.1 For the purpose of determining members entitled to notice of or to vote at any meeting of members or any adjournment thereof, or members entitled to receive payment of any dividend, or in order to make a determination of members for any other proper purpose, the Board may provide, subject to the requirements of section 174 of the Companies Act, that the Register shall be closed for transfers at such times and for such periods, not exceeding in the whole thirty days in each year. If the Register shall be so closed for the purpose of determining members entitled to notice of, or to vote at, a meeting of members, such Register shall, subject to applicable law and Stock Exchange rules, be so closed for at least five days immediately preceding such meeting and the record date for such determination shall be the date of the closure of the Register.
- 23.2 In lieu of, or apart from, closing the Register, the Board may fix in advance a date as the record date (a) for any such determination of members entitled to notice of or to vote at a meeting of the members, which record date shall not, subject to applicable law and Stock Exchange rules, be more than sixty days before the date of such meeting, and (b) for the purpose of determining the members entitled to receive payment of any dividend or other distribution, or in order to make a determination of members for any other proper purpose, which record date shall not, subject to applicable law and Stock Exchange rules, be more than sixty days prior to the date of payment of such dividend or other distribution or the taking of any action to which such determination of members is relevant.
- 23.3 If the Register is not so closed and no record date is fixed for the determination of members entitled to notice of or to vote at a meeting of members, the date immediately preceding the date on which notice of the meeting is deemed given under these Articles shall be the record date for such determination of members. Where a determination of members entitled to vote at any meeting of members has been made as provided in these Articles, such determination shall apply to any adjournment thereof; provided, however, that the Directors may fix a new record date of the adjourned meeting, if they think fit.

# Part 5 – Dividends, Reserves and Capitalisation of Profits and Reserves

#### 24. Declaration of Dividends

- 24.1 Subject to the provisions of the Companies Act, the Company by ordinary resolution may declare dividends in accordance with the respective rights of the members, but no dividend shall exceed the amount recommended by the Directors. Dividends may be declared or paid in any currency.
- 24.2 The Directors may at their discretion make provision to enable any holder of Ordinary Shares as they shall from time to time determine to receive dividends duly declared in a currency or currencies other than Euro. For the purposes of the circulation of the amount receivable in respect of any dividend, the rate of exchange to be used to determine the foreign currency equivalent of any sum payable as a dividend shall be such market rate selected by the Directors as they shall consider appropriate ruling at the close of business in Dublin on the date which is the business day last preceding (i) in the case of a dividend to be declared by the Company in general meeting, the date on which the Directors publicly announce their intention to recommend that specific dividend; and (ii) in the case of any other dividend, the date on which the Directors publicly announce their intention to pay that specific dividend.
- 24.3 Where a holder of Ordinary Shares has elected or agreed pursuant to provision made under these Articles to receive dividends in a currency other than Euro the Directors may at their discretion make such arrangements as they deem necessary to enable payment of the dividend to be made to such holders in such currency for value on the date on which the relevant dividend is paid, or such later date as the Directors may determine.
- 24.4 Subject to the rights of persons, if any, entitled to Shares with special rights as to dividend (and to the rights of the Company under Regulation 12 and Regulation 27) all dividends shall be declared and paid such that Shares of the same class shall rank equally irrespective of the premium credited as paid up on such Shares.
- 24.5 If any Share is issued on terms providing that it shall rank for a dividend as from a particular date, such Share shall rank for dividend accordingly.

## 25. Interim and fixed dividends

25.1 Subject to the provisions of the Companies Act, the Directors may declare and pay interim dividends if it appears to them that they are justified by the profits of the Company available for distribution. If the share capital is divided into different classes, the Directors may declare and pay interim dividends on Shares which confer deferred or non-preferred rights with regard to dividend as well as on Shares which confer preferential rights with regard to dividend, but subject always to any restrictions for the time being in force (whether under these Articles, under the terms of issue of any Shares or under any agreement to which the Company is a party, or otherwise) relating to the application, or the priority of application, of the Company's profits available for distribution or to the declaration or as the case may be the payment of dividends by the Company. Subject as aforesaid, the Directors may also pay at intervals settled by them any dividend payable at a fixed rate if it appears to them that the profits available for distribution justify the payment. Provided the Directors act in good faith they shall not incur any liability to the holders of Shares conferring preferred rights for any loss they may suffer by the lawful payment of an interim dividend on any Shares having deferred or non-preferred rights.

- 25.2 The Directors may from time to time:
  - (a) before declaring any dividend, set aside out of the profits of the Company such sums as they think proper as a reserve or reserves which shall, at the discretion of the Directors, be applicable for any purpose to which the profits of the Company may be properly applied, and pending such application may, at the like discretion either be employed in the business of the Company or be held as cash or cash equivalents or invested in such investments as the Directors may lawfully determine; and
  - (b) without placing the profits of the Company to reserve, carry forward any profits which they may think prudent not to distribute.
- 25.3 Unless otherwise specified by the Directors at the time of declaring a dividend, the dividend shall be a final dividend.
- 25.4 Where the Directors specify that a dividend is an interim dividend at the time it is declared, such interim dividend shall not constitute a debt recoverable against the Company and the declaration may be revoked by the Directors at any time prior to its payment provided that the holders of the same class of share are treated equally on any revocation.

### 26. Payment of dividends

- 26.1 Except as otherwise provided by the rights attached to Shares, all dividends shall be declared and paid according to the amounts paid up on the Shares on which the dividend is paid. Subject as aforesaid, all dividends shall be apportioned and paid proportionately to the amounts paid or credited as paid on the Shares during any portion or portions of the period in respect of which the dividend is paid; but, if any Share is issued on terms providing that it shall rank for dividend as from a particular date, such Share shall rank for dividend accordingly. For the purposes of this Regulation, no amount paid on a Share in advance of calls shall be treated as paid on a Share.
- 26.2 Any one of two or more joint holders may give valid receipts for any dividends, bonuses or other moneys payable in respect of the Shares held by them as joint holders, whether paid by cheque or negotiable instrument or direct transfer.

## 27. Deductions from dividends

The Directors may deduct from any dividend or other moneys payable to any member in respect of a Share any moneys presently payable by him to the Company in respect of that Share.

#### 28. Dividends in specie

- 28.1 A general meeting declaring a dividend may direct, upon the recommendation of the Directors, that it shall be satisfied wholly or partly by the distribution of assets (and, in particular, of paid up Shares, debentures or debenture stock of any other company or in any one or more of such ways) and the Directors shall give effect to such resolution.
- 28.2 Where any difficulty arises in regard to a distribution, the Directors may settle the matter as they think expedient and, in particular, may:
  - (a) issue fractional certificates (subject always to the restriction on the issue of fractional shares) and fix the value for distribution of such specific assets or any part of them;
  - (b) determine that cash payments shall be made to any members upon the footing of the value so fixed, in order to adjust the rights of all the parties; and

(c) vest any such specific assets in trustees as may seem expedient to the Directors.

# 29. Payment of dividends by post

Any dividend or other moneys payable in respect of any Share may be paid by cheque or warrant sent by post, at the risk of the person or persons entitled thereto, to the registered address of the holder or, where there are joint holders, to the registered address of that one of the joint holders who is first named on the Register or to such person and to such address as the holder or joint holders may in writing direct. Every such cheque or warrant shall be made payable to the order of the person to whom it is sent and payment of the cheque or warrant shall be a good discharge to the Company. Any joint holder or other person jointly entitled to a Share as aforesaid may give receipts for any dividend or other moneys payable in respect of the Share. The Directors may also, in circumstances which they consider appropriate, arrange for payment of dividends by electronic funds transfer, bank transfer or by any other method selected by the Directors from time to time and in such event the debiting of the Company's account in respect of the appropriate amount shall be deemed a good discharge of the Company's obligations in respect of any payment made by any such method.

# **30.** Dividends not to bear interest

No dividend or other moneys payable by the Company on or in respect of any Shares shall bear interest against the Company unless otherwise provided by the rights attached to the Shares.

# 31. Payment to holders on a particular date

Any resolution declaring a dividend on Shares of any class, whether a resolution of the Company in general meeting or a resolution of the Directors, may specify that the same may be payable to the persons registered as the holders of such Shares at the close of business on a particular date, notwithstanding that it may be a date prior to that on which the resolution is passed, and thereupon the dividend shall be payable to them in accordance with their respective holdings so registered, but without prejudice to the rights inter se of transferors and transferees of any such Shares in respect of such dividend. The provisions of this Regulation shall apply, mutatis mutandis, to capitalisations to be effected in pursuance of these Articles.

# 32. Unclaimed dividends

If the Directors so resolve, any dividend or distribution which has remained unclaimed for twelve years from the date of its declaration shall be forfeited and cease to remain owing by the Company. The payment by the Directors of any unclaimed dividend, distribution or other moneys payable in respect of a Share into a separate account shall not constitute the Company a trustee in respect thereof. Any dividend, interest or other sum payable which remains unclaimed for one year after having been declared may be invested or otherwise made use of by the Directors for the benefit of the Company until claimed.

# 33. Reserves

Before recommending any dividend, whether preferential or otherwise, the Directors may carry to reserve out of the profits of the Company such sums as they think proper. All sums standing to reserve may be applied from time to time at the discretion of the Directors for any purpose to which the profits of the Company may be properly applied and at the like discretion may be either employed in the business of the Company or invested in such investments as the Directors may lawfully determine. The Directors may divide the reserve into such special funds as they think fit and may consolidate into one fund any special funds or any parts of any special funds into which the reserve may have been divided as they may lawfully determine. Any sum which the Directors may carry to reserve out of the unrealised profits of the Company shall not be mixed with any reserve to which profits available for distribution have been carried. The Directors may also carry forward, without placing the same to reserve, any profits which they may think it prudent not to divide.

### 34. Capitalisation of profits and reserves

- 34.1 Any capitalisation provided for in Regulations 34.2 to 34.5 inclusive will not require approval or ratification by the members.
- 34.2 The Directors may resolve to capitalise any part of a relevant sum (within the meaning of Regulation 34.3) by applying such sum in paying up in full unissued shares of a nominal value or nominal value and premium, equal to the sum capitalised, to be allotted and issued as fully paid bonus shares, to those members of the Company who would have been entitled to that sum if it were distributed by way of dividend (and in the same proportions).
- 34.3 For the purposes of Regulation 34.2, "relevant sum" means: (a) any sum for the time being standing to the credit of the Company's undenominated capital; (b) any of the Company's profits available for distribution; (c) any sum representing unrealised revaluation reserves; or (d) a merger reserve or any other capital reserve of the Company.
- 34.4 The Directors may in giving effect to any resolution under Regulation 34.2 make: (a) all appropriations and applications of the undivided profits resolved to be capitalised by the resolution; and (b) all allotments and issues of fully paid Shares or debentures, if any, and generally shall do all acts and things required to give effect to the resolution with full power to the Directors to make such provisions as they shall think fit for the case of Shares or debentures becoming distributable in fractions (and, in particular, without prejudice to the generality of the foregoing, either to disregard such fractions or to sell the Shares or debentures represented by such fractions and distribute the net proceeds of such sale to and for the benefit of the Company or to and for the benefit of the members otherwise entitled to such fractions in due proportions) and to authorise any person to enter on behalf of all the members concerned into an agreement with the Company providing for the allotment to them respectively, credited as fully paid up, of any further Shares or debentures to which they may become entitled on such capitalisation or, as the case may require, for the payment up by the application thereto of their respective proportions of the profits resolved to be capitalised of the amounts remaining unpaid on their existing Shares and any agreement made under such authority shall be binding on all such members.
- 34.5 Where the Directors have resolved to approve a bona fide revaluation of all the fixed assets of the Company, the net capital surplus in excess of the previous book value of the assets arising from such revaluation may be: (a) credited by the Directors to undenominated capital, other than the share premium account; or (b) used in paying up unissued shares of the Company to be issued to members as fully paid bonus shares.

# Part 6 – General Meetings

## 35. General Meetings — General

35.1 Subject to Regulation 35.2, the Company shall in each year hold a general meeting as its annual general meeting in addition to any other meeting in that year, and shall specify the meeting as such in the notices calling it; and not more than 15 months shall elapse between the date of one annual general meeting of the Company and that of the next.

- 35.2 So long as the Company holds its first annual general meeting within 18 months of its incorporation, it need not hold it in the year of its incorporation or in the year following.
- 35.3 The annual general meeting shall be held at such time and place as the Directors shall determine.
- 35.4 All general meetings of the Company other than annual general meetings shall be called extraordinary general meetings.
- 35.5 The Directors may, whenever they think fit, convene an extraordinary general meeting. An extraordinary general meeting shall also be convened by the Directors on the requisition of members, or if the Directors fail to so convene an extraordinary general meeting, such extraordinary general meeting may be convened by the requisitioning members, in each case in accordance with section 178(3) to (7) of the Companies Act.
- 35.6 If at any time the number of Directors is less than four, any Director or, subject to section 1104 of the Companies Act, any member that satisfies the criteria thereunder, may convene an extraordinary general meeting in the same manner as nearly as possible as that in which meetings may be convened by the Directors.
- 35.7 An annual general meeting or extraordinary general meeting of the Company may be held outside Ireland. The Company shall make, at its expense, all necessary arrangements to ensure that members can by technological means participate in any such meeting without leaving Ireland.
- 35.8 A general meeting of the Company may be held in two or more venues (whether inside or outside of Ireland) at the same time using any technology that provides members, as a whole, with a reasonable opportunity to participate, and such participation shall be deemed to constitute presence in person at the meeting.

#### 36. Notice of general meetings

- 36.1 The only persons entitled to notice of general meetings of the Company are:
  - (a) the members;
  - (b) the personal representatives of a deceased member, which member would but for his death be entitled to vote;
  - (c) the assignee in bankruptcy of a bankrupt member of the Company (being a bankrupt member who is entitled to vote at the meeting);
  - (d) the Directors and Company Secretary; and
  - (e) the Auditors (who shall also be entitled to receive other communications relating to any general meeting which a member is entitled to receive).
- 36.2 Subject to the provisions of the Companies Act allowing a general meeting to be called by shorter notice, an annual general meeting and an extraordinary general meeting called for the passing of a special resolution shall be called by at least twenty-one days' notice. Any other extraordinary general meeting shall also be called by at least twenty-one days' notice, except that it may be called by fourteen days' notice where:
  - (a) all members, who hold Shares that carry rights to vote at the meeting, are permitted to vote by electronic means at the meeting; and

- (b) a special resolution reducing the period of notice to fourteen days has been passed at the immediately preceding annual general meeting, or at a general meeting held since that meeting.
- 36.3 Any notice convening a general meeting shall specify the time and place of the meeting and, in the case of special business, the general nature of that business and, in reasonable prominence, that a member entitled to attend, speak, ask questions and vote is entitled to appoint a proxy to attend, speak, ask questions and vote in his place and that a proxy need not be a member of the Company. It shall also give particulars of any Directors who are to retire by rotation or otherwise at the meeting and of any persons who are recommended by the Directors for appointment or reappointment as Directors at the meeting, or in respect of whom notice has been duly given to the Company of the intention to propose them for appointment or re-appointment as Directors at the meeting. Every notice shall specify such other details as are required by applicable law or the relevant code, rules and regulations applicable to the listing of the shares on any Stock Exchange. Subject to any restrictions imposed on any shares, the notice shall be given to all the members and to the Directors and Auditors.
- 36.4 The accidental omission to give notice of a meeting to, or the non-receipt of notice of a meeting by, any person entitled to receive notice shall not invalidate the proceedings at the meeting.
- 36.5 In cases where instruments of proxy are sent out with notices, the accidental omission to send such instrument of proxy to, or the non-receipt of such instrument of proxy by, any person entitled to receive such notice shall not invalidate any resolution passed or any proceeding at any such meeting. A member present, either in person or by proxy, at any general meeting of the Company or of the holders of any class of Shares will be deemed, subject to Regulation 36.8, to have received notice of that meeting and, where required, of the purpose for which it was called.
- 36.6 Where, by any provision contained in the Companies Act, extended notice is required of a resolution, the resolution shall not be effective (except where the Directors have resolved to submit it) unless notice of the intention to move it has been given to the Company not less than twenty-eight days (or such shorter period as the Companies Act permits) before the meeting at which it is moved, and the Company shall give to the members notice of any such resolution as required by and in accordance with the provisions of the Companies Act.
- 36.7 In determining the correct period of notice for a general meeting, neither the day on which the notice is served nor the day of the meeting for which it is given shall be counted.
- 36.8 Whenever any notice is required to be given by law or by these Articles to any person or persons, a waiver thereof in writing, signed by the person or persons entitled to the notice whether before or after the time stated therein, shall be deemed equivalent thereto. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened.

36.9 The Directors may, for the purpose of controlling the level of attendance at any place specified for the holding of a general meeting, from time to time make such arrangements whether involving the issue of tickets (on a basis intended to afford to all members otherwise entitled to attend such meeting an equal opportunity of being admitted to the meeting) or the imposition of some random means of selection or otherwise as they shall in their absolute discretion consider to be appropriate, and may from time to time vary any such arrangements or make new arrangements in place therefor and the entitlement of any member or proxy to attend a general meeting at such place shall be subject to any such arrangements as may be for the time being in force and by the notice of meeting stated to apply to that meeting. In the case of any general meeting to which such arrangements apply the Directors shall, and in the case of any other general meeting the Directors may, when specifying the place of the general meeting, direct that the meeting shall be held at a place specified in the notice at which the chairman of the meeting shall preside (the Principal Place) and make arrangements for simultaneous attendance and participation at other places by members otherwise entitled to attend the general meeting but excluded therefrom under the provisions of this Regulation or who wish to attend at any of such other places provided that persons attending at the Principal Place and at any of such other places shall be able to see and hear and be seen and heard by persons attending at the Principal Place and at such other places. Such arrangements for simultaneous attendance may include arrangements for controlling the level of attendance in any manner aforesaid at such other places provided that they shall operate so that any such excluded members as aforesaid are able to attend at one of such other places. For the purposes of all other provisions of these Articles any such meeting shall be treated as being held and taking place at the Principal Place.

## 37. Written decision of sole member

At any time that the Company is a single-member company, its sole member may pass any resolution as a written decision in accordance with section 196 of the Companies Act.

## 38. Quorum for general meetings

- 38.1 One member present in person or by proxy and having the right to attend and vote at the meeting and together holding Shares representing more than 25% of the votes that may be cast by all members at the relevant time shall be a quorum at a general meeting; for the avoidance of doubt, at any time when the Company is a single-member company, one member of the Company present in person or by proxy at a general meeting of it shall be a quorum.
- 38.2 If within 15 minutes (or such greater time determined by the chairperson) after the time appointed for a general meeting a quorum is not present, then the meeting shall stand adjourned to the same day in the next week, at the same time and place or to such other day and at such other time and place as the Directors may determine.

### 39. Proxies

39.1 Every member entitled to attend, speak, ask questions and vote at a general meeting may appoint a proxy or proxies to attend, speak, ask questions relating to items on the agenda subject to section 1107 of the Companies Act and vote on his behalf and may appoint more than one proxy to attend, speak, ask questions and vote at the same general meeting provided that, where a member appoints more than one proxy in relation to a general meeting, each proxy must be appointed to exercise the rights attached to different shares held by that member.

- 39.2 The appointment of a proxy shall be in writing in any usual form as set out in Section 184 of the Companies Act or in any other form which the Directors may approve and shall be signed by or on behalf of the appointor. The signature on such appointment need not be witnessed. A body corporate may sign a form of proxy under its common seal or under the hand of a duly authorised officer thereof or in such other manner as the Directors may approve. A proxy need not be a member of the Company. A member shall be entitled to appoint a proxy by electronic means, to an address specified by the Company. The proxy form must make provision for three-way voting (i.e., to allow votes to be cast for or against a resolution or to be withheld) on all resolutions intended to be proposed, other than resolutions which are merely procedural. An instrument or other form of communication appointing or evidencing the appointment of a proxy or a corporate representative (other than a standing proxy or representative) together with such evidence as to its due execution as the Board may from time to time require, may be returned to the address or addresses stated in the notice of meeting or adjourned meeting or any other such information or communication by such time or times as may be specified in the notice of meeting or adjourned meeting or in any other such information or communication (which times may differ when more than one place is so specified) or, if no such time is specified, at any time prior to the holding of the relevant meeting or adjourned meeting at which the appointment of a proxy shall be valid after twelve months have elapsed from the date named in it as the date of its execution.
- 39.3 Without limiting the foregoing, in relation to any Shares which are held in uncertificated form, the Directors may from time to time permit appointments of a proxy to be made by means of an Electronic Communication in the form of an Uncertificated Proxy Instruction, (that is, a properly authenticated dematerialised instruction, and/or other instruction or notification, which is sent by means of the relevant system concerned and received by such participant in that system acting on behalf of the Company as the Directors may prescribe, in such form and subject to such terms and conditions as may from time to time be prescribed by the Directors (subject always to the facilities and requirements of the relevant system concerned)); and may in a similar manner permit supplements to, or amendments or revocations of, any such Uncertificated Proxy Instruction to be made by like means. The Directors may in addition prescribe the method of determining the time at which any such properly authenticated dematerialised instruction (and/or other instruction or notification) is to be treated as received by the Company or such participant. The Directors may treat any such Uncertificated Proxy Instruction which purports to be or is expressed to be sent on behalf of a member of a Share as sufficient evidence of the authority of the person sending that instruction to send it on behalf of that member.

## 40. Bodies corporate acting by representatives at meetings

Any body corporate which is a member, or a proxy for a member, of the Company may by resolution of its directors or other governing body authorise such person or persons as it thinks fit to act as its representative or representatives at any meeting of the Company or of any class of members of the Company and, subject to evidence being furnished to the Company of such authority as the Directors may reasonably require, any person(s) so authorised shall be entitled to exercise the same powers on behalf of the body corporate which he represents as that body corporate could exercise if it were an individual member of the Company or, where more than one such representative is so authorised, all or any of the rights attached to the Shares in respect of which he is so authorised. Where a body corporate appoints more than one representative in relation to a general meeting, each representative must be appointed to exercise the rights attached to different shares held by that body corporate.

### 41. Receipt of proxy appointments

- 41.1 Where the appointment of a proxy and any authority under which it is signed or a copy certified notarially or in some other way approved by the Directors is to be received by the Company:
  - (a) in physical form, it shall be deposited at the Office or (at the option of the member) at such other place or places (if any) as may be specified for that purpose in or by way of note to the notice convening the meeting;
  - (b) in electronic form, it may be so received where an address has been specified by the Company for the purpose of receiving Electronic Communications:

- (i) in the notice convening the meeting; or
- (ii) in any appointment of proxy sent out by the Company in relation to the meeting; or
- (iii) in any invitation contained in an Electronic Communication to appoint a proxy issued by the Company in relation to the meeting;

provided that it is so received by the Company no later than 3 hours, or such other time as may be communicated to the members, before the time for holding the meeting or adjourned meeting or (in the case of a poll taken otherwise than at or on the same day as the meeting or adjourned meeting) for the taking of the poll at which it is to be used, at which the person named in the proxy proposes to vote and in default shall not be treated as valid or, in the case of a meeting which is adjourned to, or a poll which is to be taken on, a date not later than the record date applicable to the meeting which was adjourned or the poll, it shall be sufficient if the appointment of a proxy and any such authority and certification thereof as aforesaid is so received by the Company at the commencement of the adjourned meeting shall, unless the contrary is stated, be valid for any adjournment of the meeting. An appointment of a proxy relating to more than one meeting (including any adjournment thereof) having once been so received for the purposes of any meeting shall not be required to be delivered, deposited or received again for the purposes of any subsequent meeting to which it relates.

- 41.2 For the avoidance of doubt, such appointments of proxy made by electronic or intend communications (as permitted by the Directors) would be deemed to be deposited at the place specified for such purpose once received by the Company.
- 41.3 When two or more valid but differing appointments of a proxy are received in respect of the same Shares for use at the same meeting, the one bearing the later date shall be treated as replacing and revoking the other; if the appointments are undated the last one received shall be treated as valid; and if the Company is unable to determine which was the last received, none shall be treated as valid, and a certificate endorsed by the Company Secretary stating that the appointment is valid or invalid, as the case may be, shall be conclusive for all purposes.

## 42. Effect of proxy appointments

- 42.1 Effect of proxy appointments:
  - (a) Receipt by the Company of an appointment of a proxy in respect of a meeting shall not preclude a member from attending and voting at the meeting or at any adjournment thereof. However, if that member votes at the meeting or at any adjournment thereof, then as regards to the resolution(s) any proxy notice delivered to the Company by or on behalf of that same member shall on a poll, be invalid to the extent that such member votes in respect of the shares to which the proxy notice relates.
  - (b) A proxy shall have the right unless the contrary is stated in his appointment to exercise all or any of the rights of his appointer, or (where more than one proxy is appointed) all or any of the rights attached to the Shares in respect of which he has been appointed the proxy to attend, to demand or join in demanding a poll and to speak and vote at a general meeting of the Company. Unless his appointment provides otherwise, a proxy may vote or abstain in his discretion on any resolution put to the vote. An appointment of a proxy shall be valid, unless the contrary is stated therein, as well for any adjournment of the meeting as for the meeting to which it relates.

(c) Subject always to the provisions of the Companies Act, the appointment, and notification of any revocation of appointment of, a proxy, and the giving of voting instructions to a proxy shall be subject to such formal requirements as the Directors from time to time in their absolute discretion may consider necessary in order to ensure the correct identification of a member's appointment, to ensure the correct identification of a member's voting instructions.

#### 43. Effect of revocation of proxy or of authorisation

- 43.1 A vote given or poll demanded in accordance with the terms of an appointment of a proxy or a resolution authorising a representative to act on behalf of a body corporate shall be valid notwithstanding the previous death, insanity or winding up of the principal, or the revocation of the appointment of a proxy or of the authority under which the proxy was appointed or of the resolution authorising the representative to act or the transfer of the Share in respect of which the proxy was appointed or the authorisation of the representative to act was given, provided that no notice in writing (whether in electronic form or otherwise) of such death, insanity, winding up, revocation or transfer is received by the Company at the Office before the commencement of the meeting or adjourned meeting at which the appointment of a proxy is used or at which the representative acts provided however that where such intimation is given in electronic form, it shall have been received by the Company before the commencement of the meeting at which the appointment of a proxy is used or at which the representative acts.
- 43.2 The Directors may send to the members, at the expense of the Company, by post, electronic mail or otherwise, forms for the appointment of a proxy (subject to the applicable requirements of the Companies Act and with or without reply paid envelopes for their return) for use at any general meeting or at any class meeting, either in blank or nominating any one or more of the Directors or any other persons in the alternative. If, for the purpose of any meeting, invitations to appoint as proxy a person or one of a number of persons specified in the invitations are issued at the expense of the Company, such invitations shall be issued to all (and not to some only) of the members entitled to be sent a notice of the meeting and to vote thereat by proxy, but the accidental omission to issue such invitations to, or the non-receipt of such invitations by, any member shall not invalidate the proceedings at any such meeting.

#### 44. The business of general meetings

- 44.1 All business shall be deemed to be special business that is transacted at an extraordinary general meeting or that is transacted at an annual general meeting other than, in the case of an annual general meeting, the business specified in Regulation 44.5 which shall be ordinary business.
- 44.2 At any meeting of the members, only such business shall be conducted as shall have been properly brought before such meeting. To be properly brought before an annual general meeting, business must be:
  - (a) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board;
  - (b) otherwise properly brought before the meeting by or at the direction of the Board; or
  - (c) otherwise properly brought before the meeting by a member.

- 44.3 Without prejudice to any procedure which may be permitted under the Companies Act, for business to be properly brought before an annual general meeting by a member, the member must have given timely notice thereof in writing to the Company Secretary. To be timely, a member's notice must be received not less than sixty days nor more than ninety days prior to the first anniversary of the preceding year's annual general meeting; provided, however, that in the event that the date of the annual general meeting is advanced by more than thirty days or delayed by more than sixty days from such anniversary, notice by the member to be timely must be so received not earlier than the ninetieth day prior to such annual general meeting and not later than the close of business on the later of (i) the sixtieth day prior to such annual general meeting or (ii) the tenth day following the date on which notice of the date of the annual general meeting was mailed or public disclosure thereof was made by the Company, whichever event in this clause (ii) first occurs. For the avoidance of doubt, in no event shall the adjournment or postponement of any general meeting, or the public announcement of such an adjournment or postponement, commence a new time period (or extend any time period) for the giving of a member's notice to the Company Secretary pursuant to this Regulation 44.3. Each such notice shall set forth as to each matter the member proposes to bring before the annual general meeting (other than a nomination for election as a director):
  - (a) a brief description of the business desired to be brought before the annual general meeting and the reasons for conducting such business at the meeting;
  - (b) the name and address, as they appear on the Register, of the member proposing such business;
  - (c) the class, series and number of Shares which are beneficially owned by the member;
  - (d) whether and the extent to which any hedging, derivative or other transaction is in place or has been entered into within the prior six months preceding the date of delivery of the notice by or for the benefit of the member with respect to the Company or its Subsidiaries or any of their respective securities, debt instruments or credit ratings, the effect or intent of which transaction is to give rise to gain or loss as a result of changes in the trading price of such securities or debt instruments or changes in the credit ratings for the Company, its Subsidiaries or any of their respective securities or debt instruments (or, more generally, changes in the perceived creditworthiness of the Company or its Subsidiaries), or to increase or decrease the voting power of the member, and if so, a summary of the material terms thereof; and
  - (e) any material interest of the member in such business.

To be properly brought before an extraordinary general meeting, other than pursuant to Regulation 44.2, business must be (i) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board or by the Company Secretary pursuant to the applicable provisions of these Articles or (ii) otherwise properly brought before the meeting by or at the direction of the Board.

- 44.4 The chairperson of the meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting and in accordance with the provisions of these Articles, and if he or she should so determine, any such business not properly brought before the meeting shall not be transacted.
- 44.5 Without prejudice to the powers of the Directors to include on the agenda of any annual general meeting of the Company such other matters as they may, in their absolute discretion, think fit, the business of the annual general meeting shall include:

- (a) the consideration of the Company's statutory financial statements and the report of the Directors and the report of the Auditors on those statements and that report;
- (b) the review by the members of the Company's affairs;
- (c) the declaration of a dividend (if any) of an amount not exceeding an amount recommended by the Directors from time to time;
- (d) the election and re-election of Directors in the place of those retiring (whether by rotation or otherwise);
- (e) the authorisation of the Directors to approve the remuneration of the Auditors; and
- (f) the appointment or re-appointment of Auditors.

## 45. Proceedings at general meetings

- 45.1 The Chairman, if any, shall preside as chairperson at every general meeting of the Company, or if there is no such Chairman, or if he or she is not present at the time appointed for the holding of the meeting or is unwilling to act, the Directors present shall elect one of their number to be chairperson of the meeting.
- 45.2 If at any meeting no Director is willing to act as chairperson or if no Director is present at the time appointed for holding the meeting, the members present shall choose one of their number to be chairperson of the meeting.
- 45.3 At each meeting of members, the chairperson of the meeting shall fix and announce the date and time of the opening and the closing of the polls for each matter upon which the members will vote at the meeting and shall determine the order of business and all other matters of procedure.
- 45.4 The Directors may adopt such rules, regulations and procedures for the conduct of any meeting of the members as they deem appropriate. Except to the extent inconsistent with any applicable rules, regulations and procedures adopted by the Board, the chairperson of any meeting may adopt such rules, regulations and procedures for the meeting, which need not be in writing, and take such actions with respect to the conduct of the meeting, as the chairperson of the meeting deems appropriate, to maintain order and safety and for the conduct of the meeting. Without limiting the foregoing, he or she may:
  - (a) limit attendance at or participation in the meeting to members of record of the Company, their duly authorised proxies or such other persons as the chairperson of the meeting shall determine;
  - (b) restrict dissemination of materials and use of audio or visual recording devices at the meeting;
  - (c) take steps to maintain order and safety at the meeting;
  - (d) establish seating arrangements;
  - (e) restrict entry to the meeting after the time fixed for its commencement;
  - (f) establish an agenda or order of business;

- (g) adjourn the meeting without a vote of the members, whether or not there is a quorum present;
- (h) limit the time allotted to member questions or comments; and
- (i) make rules governing speeches and debate including time limits and access to microphones.

The chairperson of the meeting acts in his or her absolute discretion and his or her rulings are not subject to appeal.

- 45.5 The chairperson of the meeting may, with the consent of any meeting at which a quorum is present, and shall if so directed by the meeting, adjourn the meeting from time to time and from place to place.
- 45.6 No business shall be transacted at any adjourned meeting other than the business left unfinished at the meeting from which the adjournment took place.
- 45.7 Where a meeting is adjourned, the time and place for the adjourned meeting shall be fixed by the Directors. When a meeting is adjourned for thirty days or more, notice of the adjourned meeting shall be given as in the case of an original meeting but, subject to that, it shall not be necessary to give any notice of an adjournment or of the business to be transacted at an adjourned meeting.
- 45.8 A Director shall be entitled, notwithstanding that he is not a member, to attend and speak at any general meeting and at any separate meeting of the holders of any class of Shares in the Company. The Auditors shall be entitled to attend any general meeting and to be heard on any part of the business of the meeting which concerns them as the Auditors.

45.9

- (a) No amendment may be made to a resolution, at or before the time when it is put to a vote, unless the chairperson of the meeting decides that the amendment or the amended resolution may properly be put to a vote at that meeting.
- (b) If the chairperson of the meeting rules a resolution or an amendment to a resolution admissible or out of order (as the case may be), the proceedings of the meeting or on the resolution in question shall not be invalidated by any error in his or her ruling. Any ruling by the chairperson of the meeting in relation to a resolution or an amendment to a resolution shall be final and conclusive.

45.10

- (a) For business to be properly requested by a member to be brought before a general meeting, the member must comply with the requirements of the Companies Act or:
  - (i) be a member at the time of the giving of the notice for such general meeting;
  - (ii) be entitled to vote at such meeting; and
  - (iii) have given timely and proper notice in writing to the Company Secretary in accordance with Regulation 44.3.
- 45.11 Except where a greater majority is required by the Companies Act or these Articles, any question proposed for a decision of the members at any general meeting of the Company or a decision of any class of members at a separate meeting of any class of shares shall be decided by an ordinary resolution.

### 46. Voting

- 46.1 At any general meeting, a resolution put to the vote of the meeting shall be decided on a poll.
- 46.2 Save as provided in Regulation 46.3 of these Articles, a poll shall be taken in such manner (including by the use of a ballot, electronic devices, voting papers or tickets) as the chairperson of the meeting directs and he or she may appoint scrutineers (who need not be members) and fix a time and place for declaring the result of the poll. The result of the poll shall be deemed to be the resolution of the meeting at which the poll was demanded.
- 46.3 A poll demanded on the election of a chairperson of the meeting or on a question of adjournment shall be taken forthwith. A poll demanded on any other question shall be taken either forthwith or at such time (not being more than thirty days after the poll is demanded) and place as the chairperson of the meeting may direct. The demand for a poll shall not prevent the continuance of a meeting for the transaction of any business other than the question on which the poll was demanded.
- 46.4 No notice need be given of a poll not taken forthwith if the time and place at which it is to be taken are announced at the meeting at which it is demanded. In any other case at least seven Clear Days' notice shall be given specifying the time and place at which the poll is to be taken.
- 46.5 If authorised by the Directors, any vote taken by written ballot may be satisfied by a ballot submitted by electronic and/or telephonic transmission, provided that any such electronic or telephonic submission must either set forth or be submitted with information from which it can be determined that the electronic or telephonic submission has been authorised by the member or proxy.

## 47. Votes of Members

- 47.1 Subject to the provisions of these Articles and any rights or restrictions for the time being attached to any class or classes of Shares in the capital of the Company, every member of record present in person or by proxy shall have one vote for each share registered in his or her name in the Register.
- 47.2 Where there are joint holders of a Share, the vote of the senior who tenders a vote, whether in person or by proxy, shall be accepted to the exclusion of the votes of the other joint holder or holders; and for this purpose, seniority shall be determined by the order in which the names of the joint holders stand in the Register.
- 47.3 A member of unsound mind, a member who has made an enduring power of attorney, or in respect of whom an order has been made by any court having jurisdiction (whether in the State or elsewhere) in matters concerning mental disorder, may vote by his or her committee, donee of an enduring power of attorney, receiver, guardian or other person appointed by that court and any such committee, donee of an enduring power of attorney, receiver, guardian or other person appointed by that court and any such committee, donee of an enduring power of attorney, receiver, guardian or other person may vote by proxy. Evidence to the satisfaction of the Directors of the authority of the person claiming to exercise the right to vote pursuant to this Regulation shall be deposited at the Office or at such other place as is specified in accordance with these Articles for the deposit of instruments of proxy, before the time appointed for holding the meeting or adjourned meeting at which the right to vote is to be exercised and in default the right to vote shall not be exercisable.

- 47.4 No objection shall be raised to the qualification of any voter except at the general meeting or adjourned general meeting at which the vote objected to is given or tendered and every vote not disallowed at such general meeting shall be valid for all purposes. Any such objection made in due time shall be referred to the chairperson of the general meeting whose decision shall be final and conclusive.
- 47.5 In relation to any general meeting of the Company or of any class of Shareholders or to any adjourned meeting of which notice is given, the Board may specify in the notice of meeting or adjourned meeting or in any document sent to Shareholders by or on behalf of the Board in relation to the meeting, a time and date (a **Record Date)** which is not more than 60 days before the date fixed for the meeting.
- 47.6 A person shall be entered on the Register by the Record Date specified in respect of a general meeting in order to exercise the right of a member to participate and vote at the general meeting and any change to an entry on the Register after the record date shall be disregarded in determining the right of any person to attend and vote at the meeting.
- 47.7 Votes may be given either personally (including by a duly authorised representative of a corporate member) or by proxy. On a poll taken at a meeting of the members of the Company or a meeting of any class of members of the Company, a member, whether present in person or by proxy, entitled to more than one vote need not, if he votes, use all his votes or cast all the votes he uses in the same way.
- 47.8 Subject to such requirements and restrictions as the Directors may specify, the Company may permit members to vote by correspondence in advance of a general meeting in respect of one or more of the resolutions proposed at a meeting. Where the Company permits members to vote by correspondence, it shall only count votes cast in advance by correspondence, where such votes are received at the address and before the date and time specified by the Company, provided the date and time is no more than 24 hours before the time at which the vote is to be concluded.
- 47.9 Subject to such requirements and restrictions as the Directors may specify, the Company may permit members who are not physically present at a meeting to vote by electronic means at the general meeting in respect of one or more of the resolutions proposed at a meeting.
- 47.10 Where a member requests a full account of a vote before or on the declaration of the result of a vote at a general meeting, then with respect to each resolution proposed at a general meeting the Company shall establish:
  - (a) the number of Shares for which votes have been validly cast;
  - (b) the proportion of the Company's issued share capital at close of business on the record date before the meeting represented by those votes;
  - (c) the total number of votes validly cast; and
  - (d) the number of votes cast in favour of and against each resolution and, if counted, the number of abstentions.
- 47.11 Where no member requests a full account of the voting before or on the declaration of the result of a vote at a general meeting, it shall be sufficient for the Company to establish the voting results only to the extent necessary to ensure that the required majority is reached for each resolution. The Company shall ensure that a voting result established in accordance with this Regulation is published on its internet site or the site of the SEC not later than the end of the fifteenth day after the date of the meeting at which the voting result was obtained.

- 47.12 Where there is an equality of votes, the chairperson of the meeting shall not have a second or casting vote.
- 47.13 Unless the Directors otherwise determine, no member shall be entitled to vote at any general meeting or any separate meeting of the holders of any class of Shares, either in person or by proxy, or to exercise any privilege as a member in respect of any Share held by him unless all moneys then payable by him in respect of that Share have been paid.

## 48. Class meetings

The provisions of these Articles relating to general meetings shall, as far as applicable, apply in relation to any meeting of any class of member of the Company.

# Part 7 – Directors

#### 49. Number of Directors

- 49.1 The number of Directors shall be fixed from time to time by the Board, provided that in no case shall the number fixed by the Board be less than two nor more than nine unless this is approved by an ordinary resolution passed in accordance with Regulation 49.5.
- 49.2 The continuing Directors may act notwithstanding any vacancy in their body, provided that if the number of the Directors is reduced below the prescribed minimum the remaining Director or Directors shall appoint forthwith an additional Director or additional Directors to make up such minimum or shall convene a general meeting of the Company for the purpose of making such appointment. If there be no Director or Directors able or willing to act then any two members may summon a general meeting for the purpose of appointing Directors. Any additional Director so appointed shall hold office (subject to the provisions of the Companies Act and these Articles) only until the conclusion of the annual general meeting of the Company next following such appointment unless he is re-elected during such meeting.
- 49.3 The Directors may from time to time appoint any person to be a Director, either to fill a casual vacancy or as an addition to the existing Directors, provided that the total number of Directors shall not at any time exceed the number as may be provided for in these Articles. A Director who is appointed pursuant to this Regulation shall be required to retire at the next following annual general meeting. If not re-appointed at such annual general meeting, such Director shall vacate office at the conclusion thereof.
- 49.4 The Board, upon recommendations of the nomination and governance committee (or equivalent committee established by the Board), shall propose nominees for election to the office of Director at each annual general meeting.
- 49.5 The Company may from time to time, by ordinary resolution, increase or reduce the number of Directors provided that any resolution to appoint a Director approved by the members that would result in the maximum number of Directors being exceeded shall be deemed to constitute an ordinary resolution increasing the maximum number of Directors to the number that would be in office following such a resolution of appointment.
- 49.6 The Company may, by ordinary resolution, appoint another person in place of a Director removed from office under section 146 of the Companies Act and, without prejudice to the powers of the Directors under Regulation 49.3, the Company in a general meeting may appoint any person to be a Director either to fill a casual vacancy or as an additional Director.

### 50. Share qualification

A Director shall not require a Share qualification.

## 51. Ordinary remuneration of Directors

- 51.1 The remuneration to be paid to the Directors shall be such remuneration as the Board shall determine from time to time. Such remuneration shall be deemed to accrue from day to day. The Board may from time to time determine that, subject to the requirements of the Companies Act, all or part of any fees or other remuneration payable to any Director shall be provided in the form of Shares or other securities of the Company or any Subsidiary, or options or rights to acquire such Shares or other securities, on such terms as the Board may decide.
- 51.2 A Director is expressly permitted (for the purposes of section 228(1)(d) of the Companies Act) to use the Company's property pursuant to or in conjunction with the exercise or performance of his duties, functions and powers as Director or employee; the terms of any conditions of service or employment or letter of appointment; and, or in the alternative, any other usage authorised by the Directors (or a person authorised by the Directors) from time to time; and including in each case for a Director's own benefit or for the benefit of another person.

## 52. Special remuneration of Directors

Any Director who holds any executive office (including for this purpose the office of Chairman or deputy chairman) or who serves on any committee, or who otherwise performs services which in the opinion of the Directors are outside the scope of the ordinary duties of a Director, may be paid such extra remuneration by way of salary, commission or otherwise as the Board may determine from time to time.

## 53. Expenses of Directors

The Directors may be paid all travelling, hotel and other expenses properly incurred by them in connection with their attendance at meetings of Directors or committees of Directors or general meetings or separate meetings of the holders of any class of Shares or of debentures of the Company or otherwise in connection with the discharge of their duties.

## 54. Alternate Directors

- 54.1 Any Director may appoint by writing under his hand any person (including another Director) to be his alternate provided always that no such appointment of a person other than a Director as an alternate shall be operative unless and until such appointment shall have been approved by resolution of the Directors.
- 54.2 An alternate Director shall be entitled to receive notices of all meetings of the Directors and of all meetings of committees of Directors of which his appointor is a member, to attend and vote at any such meeting at which the Director appointing him is not personally present and in the absence of his appointor to exercise all the powers, rights, duties and authorities of his appointor as a Director (other than the right to appoint an alternate hereunder).

- 54.3 Save as otherwise provided in these Articles, an alternate Director shall be deemed for all purposes to be a Director and shall alone be responsible for his own acts and defaults and he shall not be deemed to be the agent of the Director appointing him. The remuneration of any such alternate Director shall be payable out of the remuneration paid to the Director appointing him and shall consist of such portion of the last mentioned remuneration as shall be agreed between the alternate and the Director appointing him.
- 54.4 A Director may revoke at any time the appointment of any alternate appointed by him. If a Director shall die or cease to hold the office of Director the appointment of his alternate shall thereupon cease and determine but if a Director retires by rotation or otherwise but is reappointed or deemed to have been reappointed at the meeting at which he retires, any appointment of an alternate Director made by him which was in force immediately prior to his retirement shall continue after his re-appointment.
- 54.5 Any appointment or revocation pursuant to this Regulation may be sent to the Company by delivery, post, cable, telegram, telex, telefax, electronic mail or any other means of communication approved by the Directors and may bear a printed or facsimile signature of the Director making such appointment or revocation or in any other manner approved by the Directors.

#### 55. Vacation of office by Directors

- 55.1 In addition to the circumstances described in sections 146, 148(1) and 196(2) of the Companies Act, the office of Director shall be vacated:
  - (a) ipso facto, if that Director:
    - (i) resigns his or her office by notice in writing to the Company;
    - (ii) he ceases to be a Director by virtue of any provision of the Companies Act or he becomes prohibited by law from being a Director;
    - (iii) becomes subject to a declaration of restriction under section 819 of the Companies Act and the Directors, at any time during the currency of the declaration, resolve that his or her office be vacated;
    - (iv) resigns his office by spoken declaration at any Board meeting and such resignation is accepted by resolution of that meeting, in which case such resignation shall take effect at the conclusion of such meeting unless otherwise resolved;
    - (v) is adjudicated insolvent or bankrupt or makes any arrangement or compromise with his creditors generally (in any jurisdiction);
    - (vi) is removed from office by notice in writing served upon him signed by not less than 75% of his co-Directors;
    - (vii) is removed from office by notice in writing to the Company: where there is a sole member, by the sole member or where there is more than one member, by any member or members having the right to attend and vote at a general meeting of the Company on a resolution to remove a Director and holding for the time being not less than 90% in nominal value of the shares giving that right; and

- (b) by resolution of the Board:
  - (i) where that Director can no longer be reasonably regarded as possessing an adequate decision making capacity by reason of his or her health;
  - (ii) where that Director is sentenced to a term of imprisonment (whether or not the term is suspended) following conviction of a criminal offence in any jurisdiction;
  - (iii) where that Director is for more than six months absent, without the permission of the Directors, from meetings of the Directors held during that period and his alternate Director (if any) shall not have attended any such meeting in his place during such period and the Directors pass a resolution that by reason of such absence he has vacated office; or
  - (iv) where that Director is in employment of the Company, the Company's holding company or a subsidiary of the Company's holding company, upon the termination of such employment;

and a Director so removed shall have no right to prior notice or to raise any objection to his or her removal from office but any removal (other than one initiated by the Director) shall be without prejudice to any claim for compensation or damages payable as a result of the removal also terminating any contract of service. If the relevant Director holds an appointment to an executive office which thereby automatically determines, such removal shall be deemed an act of the Company and shall have effect without prejudice to any claim for damages for breach of any contract of service between him and the Company.

55.2 The Company may, in accordance with Section 146 of the Companies Act, remove any Director before the expiry of his period of office notwithstanding anything in these Articles or in any agreement between the Company and such Director and may if thought fit, by ordinary resolution appoint another Director in his stead. The person appointed shall be subject to retirement at the same time as if he had become a Director on the date on which the Director in whose place he is appointed was last appointed a Director. Nothing in this Regulation shall be taken as depriving a person removed hereunder of compensation or damages payable to him in respect of the termination of his appointment as Director or of any appointment terminating with that of Director.

## 56. Directors' powers

- 56.1 Subject to the provisions of the Companies Act, the Memorandum and these Articles and to any directions by the members given in a general meeting, not being inconsistent with these Articles or with the Companies Act, the business of the Company shall be managed by the Directors who may do all such acts and things and exercise all the powers of the Company as are not by the Companies Act or by these Articles required to be done or exercised by the Company in general meeting. No alteration of the Memorandum or of these Articles and no such direction by the members given in a general meeting shall invalidate any prior act of the Directors which would have been valid if that alteration had not been made or that direction had not been given. The powers given by this Regulation shall not be limited by any special power given to the Directors by these Articles and a meeting of Directors at which a quorum is present may exercise all powers exercisable by the Directors.
- 56.2 Any reference to a power of the Company required to be exercised by the Company in a general meeting includes a reference to a power of the Company that, but for the power of the members to pass a written resolution to effect the first-mentioned power's exercise, would be required to be exercised by the Company in a general meeting.

## 57. Power to delegate

- 57.1 Without prejudice to the generality of the last preceding Regulation, the Directors may delegate (with power to sub-delegate) any of their powers to any managing director of the Company or any other Director holding any other executive office or to any committee consisting of one or more Directors together with such other persons (if any) as may be appointed to such committee by the Directors provided that a majority of the members of each committee appointed by the Directors shall at all times consist of Directors and that no resolution of any such committee shall be effective unless a majority of the members of the committee present at the meeting at which it was passed are Directors.
- 57.2 Insofar as any such power or discretion is delegated to a committee any reference in these Articles to the exercise by the Directors of the power or discretion so delegated shall be read and construed as if it were a reference to the exercise thereof by such a committee. Any such delegation may be made subject to any conditions the Directors may impose, and either collaterally with or to the exclusion of their own powers and may be revoked. Subject to any such conditions, the proceedings of a committee with two or more members shall be governed by the provisions of these Articles regulating the proceedings of Directors so far as they are capable of applying.
- 57.3 The acts of the Board or of any committee established by the Board or any delegee of the Board or any such committee shall be valid notwithstanding any defect which may afterwards be discovered in the appointment or qualification of any Director, committee member or delegee.

### 58. Committees

- 58.1 The Directors may establish one or more committees consisting in whole or in part of members of the Board. The composition, function, power and obligations of any such committee will be determined by the Board from time to time.
- 58.2 A committee established under Regulation 58.1 (a **committee**) may elect a chairperson of its meetings; if no such chairperson is elected, or if at any meeting the chairperson is not present after the time appointed for holding it, the members of the committee present may choose one of their number to be chairperson of the meeting.
- 58.3 A committee may meet and adjourn as it thinks proper. Committee meetings shall take place at such time and place as the relevant committee may determine. Questions arising at any meeting of a committee shall be determined (subject to Regulation 58.1) by a majority of votes of the members of the committee present, and where there is an equality of votes, the chairperson of the committee shall not have a second or casting vote.
- 58.4 Where any committee is established by the Directors :
  - (a) the meetings and proceedings of such committee shall be governed by the provisions of these Articles regulating the meetings and proceedings of the Directors so far as the same are applicable and are not superseded by any regulations imposed upon such committee by the Directors; and
  - (b) the Directors may authorise, or may authorise such committee to authorise, any person who is not a Director to attend all or any meetings of any such committee on such terms as the Directors or the committee think fit, provided that any such person shall not be entitled to vote at meetings of the committee.

## 59. Appointment of attorneys

The Directors, from time to time and at any time by power of attorney, may appoint any company, firm or person or fluctuating body of persons, whether nominated directly or indirectly by the Directors, to be the attorney or attorneys of the Company for such purposes and with such powers, authorities and discretions (not exceeding those vested in or exercisable by the Directors under these Articles) and for such period and subject to such conditions as they may think fit. Any such power of attorney may contain such provisions for the protection of persons dealing with any such attorney as the Directors may think fit and may authorise any such attorney to sub-delegate all or any of the powers, authorities and discretions vested in him.

## 60. Local management

Without prejudice to the generality of Regulations 57 and 59 the Directors may establish any committees, local boards or agencies for managing any of the affairs of the Company, either in the State or elsewhere, and may appoint any persons to be members of such committees, local boards or agencies and may fix their remuneration and may delegate to any committee, local board or agent any of the powers, authorities and discretions vested in the Directors with power to sub-delegate and any such appointment or delegation may be made upon such terms and subject to such conditions as the Directors may think fit, and the Directors may remove any person so appointed, and may annul or vary any such delegation, but no person dealing in good faith with any such committee, local board or agency, without notice of any such removal, annulment or variation shall be affected thereby.

# 61. Borrowing powers

The Directors may exercise all the powers of the Company to borrow or raise money, to indemnify and guarantee and to mortgage or charge its undertaking, property, assets, and uncalled capital or any part thereof subject to Part 3 of the Companies Act and to issue debentures, debenture stock and other securities whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party, without any limitation as to amount.

## 62. Execution of negotiable instruments

All cheques, promissory notes, drafts, bills of exchange and other negotiable instruments and all receipts for moneys paid to the Company shall be signed, drawn, accepted, endorsed or otherwise executed, as the case may be, by such person or persons and in such manner as the Directors shall determine from time to time by resolution.

## 63. Provision for employees

The Directors may exercise any power conferred by the Companies Act to make provision for the benefit of persons employed or formerly employed by the Company or any of its Subsidiaries in connection with the cessation or the transfer to any person of the whole or any part of the undertaking of the Company or that Subsidiary.

### 64. Retirement by Rotation

64.1 At each annual general meeting of the Company each Director shall retire from office.

64.2 A Director who retires at an annual general meeting may be reappointed, if willing to act. If he is not reappointed (or deemed to be reappointed pursuant to these Articles) he shall retain office until the meeting appoints someone in his place or, if it does not do so, until the end of the meeting.

#### 65. Deemed reappointment

If the Company, at the meeting at which a Director retires by rotation, does not fill the vacancy, the retiring Director, if willing to act, shall be deemed to have been re-appointed unless at the meeting it is resolved not to fill the vacancy or a resolution for the reappointment of the Director is put to the meeting and lost.

## 66. Eligibility for appointment as a Director

- 66.1 No person other than a Director retiring by rotation shall be appointed a Director at any annual general meeting unless he is recommended by the Directors or unless a draft resolution for the appointment of such person (accompanied by the particulars which would be required, if he were to be so appointed, to be included in the Company's register of Directors together with a notice executed by that person of his willingness to be appointed) shall have been proposed by a member or members holding not less than three per cent of the issued share capital of the Company, representing not less than three per cent of the total voting rights of all the members of the Company who have a right to vote at the meeting, received by the Company in hardcopy form or in electronic form at least forty-two days before the meeting to which it relates, and passed at that meeting in compliance with the Companies Act and these Articles.
- 66.2 In the case of a general meeting other than an annual general meeting, no person other than a Director retiring as aforesaid or a person recommended by the Directors shall be appointed unless not less than fourteen nor more than thirty Clear Days before the date appointed for the meeting, a draft resolution for the appointment of such person (accompanied by the particulars which would be required, if he were to be so appointed, to be included in the Company's register of Directors together with a notice executed by that person of his willingness to be appointed) shall have been proposed by a member or members holding not less than three per cent of the issued share capital of the Company, representing not less than three per cent of the total voting rights of all the members of the Company who have a right to vote at the meeting, received by the Company in hardcopy form or in electronic form, and passed at that meeting in compliance with the Companies Act and these Articles.
- 66.3 No Director shall be required to retire on account of age.

#### 67. Executive Offices

- 67.1 The Directors may appoint one or more of their body to the office of Chief Executive Officer (by whatever name called including managing director) or to any other executive office under the Company (including, where considered appropriate, the office of the Chairman) on such terms and for such period as they may determine and, without prejudice to the terms of any contract entered into in any particular case, may revoke any such appointment at any time.
- 67.2 A Director holding any such executive office shall receive such remuneration, whether in addition to or in substitution for his ordinary remuneration as a Director and whether by way of salary, commission, participation in profits or otherwise or in any combination of the foregoing as the Directors may determine.

- 67.3 The appointment of any Director to the office of Chairman or Chief Executive Officer shall determine automatically if he ceases to be a Director (other than where he is re-appointed as a Director at an annual general meeting of the Company having retired by rotation in accordance with these Articles) but without prejudice to any claim for damages for breach of any contract of service between him and the Company.
- 67.4 The appointment of any Director to any other executive office shall not determine automatically if he ceases from any cause to be a Director unless the contract or resolution under which he holds office shall expressly state otherwise, in which event such determination shall be without prejudice to any claim for damages for breach of any contract of service between him and the Company.
- 67.5 The Board may appoint any person whether or not he or she is a Director, to hold such executive or official position (except that of Auditor) as the Board may from time to time determine. The same person may hold more than one office of executive or official position.
- 67.6 A Director may hold any other office or place of profit under the Company (except that of Auditor) in conjunction with his office of Director, and may act in a professional capacity to the Company, on such terms as to remuneration and otherwise as the Directors shall arrange. Nothing in Section 228(1)(e) of the Companies Act shall restrict a Director from entering into any commitment which has been approved by the Board or has been approved pursuant to such authority as may be delegated by the Board in accordance with these Articles. It shall be the duty of each Director to obtain the prior approval of the Board, before entering into any commitment permitted by Sections 228(1)(e)(ii) and 228(2) of the Companies Act.
- 67.7 The Board shall determine from time to time, the powers and duties of any such office holder or official appointed under Regulation 67.1 and/or Regulation 67.5, and subject to the provisions of the Companies Act and these Articles, the Directors may confer upon an office holder or official any of the powers exercisable by them upon such terms and conditions and with such restrictions as they may think fit and in conferring any such powers, the Directors may specify that the conferral is to operate either: (a) so that the powers concerned may be exercised concurrently by them and the relevant office holder; or (b) to the exclusion of their own such powers.
- 67.8 The Directors may (a) revoke any conferral of powers under Regulation 67.7 or (b) amend any such conferral (whether as to the powers conferred or the terms, conditions or restrictions subject to which the conferral is made). The use or inclusion of the word "officer" (or similar words) in the title of any executive or other position shall not be deemed to imply that the person holding such executive or other position is an "officer" of the Company within the meaning of the Companies Act.

# 68. Disclosure of interests by Directors

A Director or shadow director of the Company who is in any way, whether directly or indirectly, interested in a contract or proposed contract with the Company shall comply with the provisions of Section 231 of the Companies Act, with regard to the disclosure of such interest by declaration.

## 69. Directors' interests

69.1 A Director may have regard to the interests of any other companies in the Group to the full extent permitted by the Companies Act.

- 69.2 The Directors may exercise the voting powers conferred by the shares of any other company held or owned by the Company in such manner in all respects as they think fit and, in particular, they may exercise the voting powers in favour of any resolution: (a) appointing the Directors or any of them as directors or officers of such other company; or (b) providing for the payment of remuneration or pensions to the directors or officers of such other company.
- 69.3 Any Director may vote in favour of the exercise of such voting rights notwithstanding that he or she may be or may be about to become a Director or officer of the other company referred to in Regulation 69.2 and as such or in any other way is or may be interested in the exercise of such voting rights in the foregoing manner.
- 69.4 A Director notwithstanding his office but subject to his having disclosed any interest which he is required to disclose whether by these Articles or the Companies Act in accordance with these Articles or the Companies Act as the case may be:-
  - (a) may be a party to, or otherwise interested in, any transaction or arrangement with the Company or any Subsidiary or Associated Company thereof or in which the Company or any Subsidiary or Associated Company thereof is otherwise interested;
  - (b) may be a Director or other officer of, or employed by, or a party to any transaction or arrangement with, or otherwise interested in, any body corporate promoted by the Company or in which the Company or any Subsidiary or Associated Company thereof is otherwise interested; and
  - (c) shall not be accountable, by reason of his office, to the Company for any benefit which he derives from any such office or employment or from any such transaction or arrangement or from any interest in any such body corporate and no such transaction or arrangement shall be liable to be avoided on the ground of any such interest or benefit.
- 69.5 No Director or intended Director shall be disqualified by his office from contracting with the Company either as vendor, purchaser or otherwise, nor shall any such contract or any contract or arrangement entered into by or on behalf of the other company in which any Director shall be in any way interested be avoided nor shall any Director so contracting or being so interested be liable to account to the Company for any profit realised by any such contract or arrangement by reason solely of such Director holding that office or of the fiduciary relationship thereby established. The nature of a Director's interest must be declared by him at the meeting of the Directors at which the question of entering into the contract or arrangement is first taken into consideration or, if the Director was not at the date of that meeting interested in the proposed contract or arrangements at the next meeting of the Directors held after he became so interested, and in a case where the Director becomes interested in a contract or arrangement after it is made at the first meeting of the Directors held after he becomes so interested.
- 69.6 A copy of every declaration made and notice given under this Regulation shall be entered within three days after the making or giving thereof in a book kept for this purpose. Such book shall be open for inspection without charge by any Director, Company Secretary, Auditor or member of the Company at the Office and shall be produced at every general meeting of the Company and at any meeting of the Directors if any Director so requests in sufficient time to enable the book to be available at the meeting.

- 69.7 For the purposes of this Regulation:-
  - (a) a general notice given to the Directors that a Director is to be regarded as having an interest of the nature and extent specified in the notice in any transaction or arrangement in which a specified person or class of persons or company is interested shall be deemed to be a disclosure that the Director has an interest in any such transaction of the nature and extent so specified with the relevant party; and
  - (b) an interest of which a Director has no knowledge and of which it is unreasonable to expect him to have knowledge shall not be treated as an interest of his.

### 70. Restriction on Directors' voting

- 70.1 Save as otherwise provided by these Articles, a Director shall not vote at a meeting of the Directors or a committee of Directors on any resolution concerning a matter in which he has, directly or indirectly or together with any person or persons connected with him an interest which is material or a duty which conflicts or may conflict with the interests of the Company. A Director shall not be counted in the quorum present at a meeting in relation to any such resolution on which he is not entitled to vote.
- 70.2 A Director shall be entitled (unless he has some material interest or duty which conflicts or may conflict with the interests of the Company which is not indicated below) to vote (and be counted in the quorum) in respect of any resolutions concerning any of the following matters, namely:-
  - (a) the giving of any security, guarantee or indemnity to him in respect of money lent by him or by any other person at the request of or for the benefit of the Company or any of its Subsidiaries or obligations incurred by him or any other person on behalf of the Company or any of its Subsidiaries at the request of or for the benefit of the Company or any of its Subsidiaries;
  - (b) the giving of any security, guarantee or indemnity to a third party in respect of a debt or obligation of the Company or any of its Subsidiaries for which he himself has assumed responsibility in whole or in part and whether alone or jointly with others under a guarantee or indemnity or by the giving of security;
  - (c) the subscription or purchase of shares, debentures or other securities of the Company or any of its Subsidiaries pursuant to an offer or invitation to members or debenture holders of the Company or any of its Subsidiaries or any class of them, or to the public or any section of the public in which offer or invitation he is or may be entitled to participate as a holder of securities or in which he is or is to be interested as a participant in the underwriting or sub-underwriting thereof;
  - (d) any proposal concerning any other company in which he is interested, directly or indirectly or together with any person or persons connected with him and whether as an officer or shareholder or otherwise howsoever, provided that he is not the holder of or beneficially interested, directly or indirectly in one per cent. or more of the issued shares of any class of such company or of the voting rights available to members of such company (any such interest being deemed for the purposes of this Regulation to be a material interest in all circumstances);
  - (e) any proposal concerning the adoption, modification or operation of a superannuation fund or retirement benefits scheme under which he may benefit and which has been approved by or is subject to and conditional upon approval for taxation purposes by the appropriate Revenue authorities which does not award the Director any privilege or benefit not generally awarded to the employees to whom such arrangement or scheme relates;

- (f) any proposal concerning the adoption, modification or operation of any scheme for enabling employees (including full time executive Directors) of the Company and/or any Subsidiary to acquire Shares or any arrangement for the benefit of employees of the Company or any of its Subsidiaries which does not award the Director any privilege or benefit not generally awarded to the employees to whom such scheme or arrangement relates; or
- (g) any proposal concerning insurance which the Company proposes to maintain or purchase for the benefit of the Directors or for the benefit of persons including the Directors.
- 70.3 Where proposals are under consideration concerning the appointment (including fixing or varying the terms of appointment) of two or more Directors to offices or employments with the Company or any company in which the Company is interested such proposals may be divided and considered in relation to each Director separately and in such case each of the Directors concerned (if not debarred from voting thereon), shall be entitled to vote (and be counted in the quorum) in respect of each resolution except that concerning his own appointment.
- 70.4 If a question arises at a meeting of Directors or of a committee of Directors as to the materiality of a Director's interest or as to the right of any Director to vote and such question is not resolved by his voluntarily agreeing to abstain from voting, such question may be referred, before the conclusion of the meeting, to the chairman of the meeting and his ruling in relation to any Director other than himself shall be final and conclusive except in a case where the nature or extent of the interest of such Director has not been fully and fairly disclosed; provided that, if such question arises in relation to the chairman of the meeting, he shall temporarily vacate the chair.
- 70.5 For the purposes of this Regulation, an interest of a person who is the spouse or a minor child of a Director shall be treated as an interest of the Director and in relation to an alternate Director, an interest of his appointor shall be treated as an interest of the alternate Director.

# 71. Entitlement to grant pensions

The Directors may provide benefits, whether by way of pensions, gratuities or otherwise, for any Director, former Director or other officer or former officer of the Company or to any person who holds or has held any employment with the Company or with any body corporate which is or has been a Subsidiary of or an Associated Company or a predecessor in business of the Company, any Subsidiary or of any such Associated Company and to any member of his family or any person who is or was dependent on him and may set up, establish, support, alter, maintain and continue any scheme for providing all or any such benefits and for such purposes any Director accordingly may be, become or remain a member of, or re-join, any scheme and receive or retain for his own benefit all benefits to which he may be or become entitled thereunder. The Directors may pay out of the funds of the Company any premiums, contributions or sums payable by the Company under the provisions of any such scheme in respect of any of the persons or class of persons above referred to who are or may be or become members thereof.

## 72. Convening and regulation of Directors' meetings

- 72.1 Subject to the provisions of these Articles, the Directors may regulate their proceedings as they think fit. A Director may, and the Company Secretary at the request of a Director shall, call a meeting of the Directors. Such meetings shall take place at such time and place as the Directors may determine.
- 72.2 Any Director may waive notice of any meeting and any such waiver may be retrospective. If the Directors so resolve, it shall not be necessary to give notice of a meeting of Directors to any Director who, being a resident of the State, is for the time being absent from the State.
- 72.3 The Directors may establish attendance and procedural guidelines from time to time about how their meetings are to be conducted consistent with good corporate governance and applicable tax requirements.
- 72.4 Notice of a meeting of the Directors shall be deemed to be duly given to a Director if it is given to him personally or by word of mouth or sent in writing by delivery, post, cable, telegram, telex, telefax, electronic mail or otherwise in electronic form, (whether as an Electronic Communication or otherwise) or by any other means of communication approved by the Directors to him at his last known address or any other address or number (including any address or number used for the purpose of communication by way of electronic mail or other Electronic Communication) given by him to the Company for this purpose.

## 73. Quorum for Directors' meetings

- 73.1 The quorum for the transaction of the business of the Directors may be fixed by the Directors and unless so fixed at any other number shall be two. For the purposes of this Regulation an alternate Director shall be counted in a quorum, but so that not less than two individuals shall constitute the quorum.
- 73.2 Any Director who ceases to be a Director at a meeting of the Directors may continue to be present and to act as a Director and to be counted in the quorum until the termination of the meeting provided no other Director objects and provided also that otherwise a quorum of Directors would not be present.
- 73.3 The continuing Directors or a sole Director may act notwithstanding any vacancies in their number but if the number of Directors is less than the number fixed as the quorum, they may act only for the purpose of filling vacancies or of calling a general meeting.

#### 74. Voting at Directors' meetings

- 74.1 Questions arising at any meeting of Directors shall be decided by a majority of votes. Where there is an equality of votes, the chairman of the meeting shall not have a second or casting vote.
- 74.2 Subject as hereinafter provided, each Director present and voting shall have one vote and in addition to his own vote shall be entitled to one vote in respect of each other Director not present at the meeting who shall have authorised him in respect of such meeting to vote for such other Director in his absence. Any such authority may relate generally to all meetings of the Directors or to any specified meeting or meetings and must be in writing and may be sent by delivery, post, cable, telegram, telex, telefax, or may be provided in electronic form (whether as an Electronic Communication or otherwise) or be sent by any other means of communication approved by the Directors and may bear a printed or facsimile signature of the Director giving such authority or may be otherwise authenticated in such manner as may be prescribed by the Directors. The authority must be delivered to the Company Secretary prior to or must be produced at the first meeting at which a vote is to be cast pursuant thereto provided that no Director shall be entitled to any vote at a meeting on behalf of another Director pursuant to this paragraph if the other Director shall have appointed an alternate Director and that alternate Director is present at the meeting at which the Director proposes to vote pursuant to this Regulation.

## 75. Telecommunication meetings

- 75.1 Any Director or alternate Director may participate in a meeting of the Directors or any committee of the Directors by means of conference telephone, or by video or other telecommunications equipment by means of which all persons participating in the meeting can hear each other speak and such participation in a meeting shall constitute presence in person at the meeting. Any such Director or alternate Director participating by means of conference telephone or other telecommunications equipment shall be counted in assessing whether any quorum is present at such meeting.
- 75.2 Such a meeting will be deemed to take place:
  - (b) where the largest group of those Directors participating in the conference is assembled;
  - (c) if there is no such group, where the chairperson of the meeting then is; or
  - (d) if neither subparagraph (a) or (b) applies, in such location as the meeting itself decides.

## 76. Chairman of the board of Directors

Subject to any appointment to the office of Chairman made pursuant to these Articles, the Directors may elect a chairman of their meetings and determine the period for which he is to hold office, but if no such chairman is elected or if at any meeting the chairman is unwilling to act or is not present within five minutes after the time appointed for holding the same the deputy chairman if any, shall be the chairman of the meeting or if he is unwilling to act or is not present within five minutes after the time appointed for holding the same the Directors present may choose one of their number to be chairman of the meeting.

# 77. Validity of acts of Directors

All acts done by any meeting of the Directors or of a committee of Directors or by any person acting as a Director, notwithstanding that it be afterwards discovered that there was some defect in the appointment of any such Director or person acting as aforesaid, or that they or any of them were disqualified from holding office or had vacated office, shall be as valid as if every such person had been duly appointed and was qualified to be a Director, had continued to be a Director and had been entitled to vote.

## 78. Directors' resolutions or other documents in writing

78.1 A resolution or other document in writing signed (or otherwise authenticated in a manner determined by the Directors) by all the Directors entitled to receive notice of a meeting of Directors or of a committee of Directors shall be as valid as if it had been passed at a meeting of Directors or (as the case may be) a committee of Directors duly convened and held and may consist of several documents in the like form each signed (or otherwise authenticated as aforesaid, as the case may be) by one or more Directors and a resolution signed by an alternate Director need not also be signed by his appointer and, if it is signed by a Director who has appointed an alternate Director, it need not be signed by the alternate Director in that capacity. Such resolution or other document or documents when duly signed (or otherwise authenticated as aforesaid, as the case may be) may be delivered or transmitted (unless the Directors shall otherwise determine either generally or in any specific case) by facsimile transmission or some other similar means of transmitting the contents of documents or may be delivered or transmitted in electronic form, whether as an Electronic Communication or otherwise provided such manner of delivery or transmission has been approved by the Directors.

- 78.2 Subject to Regulation 78.3, where one or more of the Directors (other than a majority of them) would not, by reason of:
  - (a) the Companies Act or any other enactment;
  - (b) these Articles; or
  - (c) an applicable rule of law or a Stock Exchange,

be permitted to vote on a resolution such as is referred to in Regulation 78.1, if it were sought to pass the resolution at a meeting of the Directors duly convened and held, then such a resolution, notwithstanding anything in Regulation 78.1, shall be valid for the purposes of that subsection if the resolution is signed by those of the Directors who would have been permitted to vote on it had it been sought to pass it at such a meeting.

- 78.3 In a case falling within Regulation 78.2, the resolution shall state the name of each Director who did not sign it and the basis on which he or she did not sign it.
- 78.4 For the avoidance of doubt, nothing in Regulations 78.1 to 78.3 dealing with a resolution that is signed by other than all of the Directors shall be read as making available, in the case of an equality of votes, a second or casting vote to the one of their number who would, or might have been, if a meeting had been held to transact the business concerned, chairperson of that meeting.

### 79. Appointment of Company Secretary

- 79.1 The Company Secretary shall be appointed by the Directors for such term, at such remuneration and upon such conditions as they may think fit and any Company Secretary so appointed may be removed by them. The Directors may appoint a sole or joint Company Secretary, an assistant Company Secretary and a deputy Company Secretary for such term, at such remuneration and upon such conditions as they may think fit; and any such person so appointed may be removed by them.
- 79.2 Anything required or authorised by the Companies Act or these Articles to be done by or to the Company Secretary may be done by or to any assistant or acting Company Secretary or, if there is no assistant or acting Company Secretary readily available and capable of acting, by or to any officer or employee of the Company authorised generally or specially in that behalf by the Directors provided that any provision of the Companies Act or these Articles requiring or authorising a thing to be done by or to a Director and the Company Secretary shall not be satisfied by its being done by or to the same person acting both as a Director and as, or in the place of, the Company Secretary.

# Part 8 - Corporate Capacity and Authority

## 80. The common seal

80.1 The Company's seal shall be used only by the authority of its Directors, or by a committee authorised by its Directors or by any one or more persons severally or jointly so authorised by the Directors or such a committee, and the use of the seal shall be deemed to be authorised for these purposes where the matter or transaction pursuant to which the seal is to be used has been so authorised.

- 80.2 Any instrument to which the Company's seal shall be affixed shall be signed by:
  - (a) a Director and be countersigned by the Company Secretary or by a second (if any) Director or by some other person appointed for the purpose by its Directors or by a committee; or
  - (b) a person (including a Director) appointed for the purpose by its Directors or a committee of its Directors authorised by its Directors in that behalf.
- 80.3 Section 43(2) and 43(3) of the Companies Act do not apply.
- 80.4 The Company may have one or more duplicate common seals or official seals for use in different locations including for use abroad.

#### 81. Official seal for use abroad

The Company may exercise the powers conferred by Section 44 of the Companies Act with regard to having an official seal for use abroad and such powers shall be vested in the directors.

# Part 9 – Notices

#### 82. Notices in writing

Any notice to be given, served or delivered -pursuant to these Articles shall be in writing or by sending the same by electronic mail or other form of Electronic Communication approved by the Directors to the address of any member notified to the Company by the member for such purpose.

## 83. Service of notices and documents

- 83.1 A notice or document (including a share certificate and a proxy appointment) to be given, served or delivered in pursuance of these Articles or otherwise may be given to, served on or delivered to any member by the Company:
  - (a) by handing same to him or his authorised agent;
  - (b) by leaving the same at his registered address;
  - (c) by sending the same by ordinary post in a pre-paid cover addressed to him at his registered address; or
  - (d) by delivering or making the same available in electronic form, whether as an Electronic Communication or otherwise subject to and in accordance with the provisions of these Articles.
- 83.2 Where a notice or document is given, served or delivered pursuant to Regulation 83.1(a) or 83.1(b), the giving, service or delivery thereof shall be deemed to have been effected at the time the same was handed to the member or his authorised agent, or left at his registered address (as the case may be).

- 83.3 Where a notice or document is given, served or delivered pursuant to Regulation 83.1(c), the giving, service or delivery thereof shall be deemed to have been effected at the expiration of twenty-four hours following posting and in the case of its being posted on a Friday seventy-two hours after despatch or on a Saturday or Sunday forty-eight hours after despatch. In proving service or delivery it shall be sufficient to prove that such cover was properly addressed, stamped and posted.
- 83.4 Where a notice, document or other information is given, served or delivered in electronic form whether as an Electronic Communication or otherwise pursuant to Regulation 83.1(d), it shall be treated as having been given, served or delivered:
  - (a) if given, served or delivered by electronic mail, at the time it was sent; or
  - (b) where any such notice or document is given, served or delivered by being made available or displayed on a website, when the recipient received or is deemed to have received notice of the fact that the notice, document or other information was available on the website.
- 83.5 Every legal personal representative, committee, receiver, curator bonis or other legal curator, assignee in bankruptcy or liquidator of a member shall be bound by a notice given as aforesaid if sent to the last registered address of such member or, in the event of notice given or delivered pursuant to Regulation 83.1(d), if sent to the address notified to the Company by the member for such purpose (or if otherwise delivered or made available in accordance with this Regulation 83), notwithstanding that the Company may have notice of the death, lunacy, bankruptcy, liquidation or disability of such member.
- 83.6 Where a member has elected to receive notices or other documents in electronic form, whether as an Electronic Communication or otherwise, the Company may notwithstanding such election and without giving advance notice to the member, provide such notices or documents in accordance with any of the methods allowed for in Regulation 83 and such provision shall satisfy the Company's obligations in this regard.
- 83.7 Without prejudice to the provisions of Regulation 83.1 and 83.2, if at any time by reason of:
  - (a) the suspension or curtailment of postal services within the State, the Company is unable effectively to convene a general meeting by notice sent through the post; or
  - (b) the occurrence of any event or thing as a consequence of which the Company is unable effectively to convene a general meeting by means of an Electronic Communication;

a general meeting may be convened by a notice advertised on the same day in at least one leading national daily newspaper published in the State (and one national daily newspaper published in the United States of America) and such notice shall be deemed to have been duly served on or delivered to all members entitled thereto at noon on the day on which the said advertisement or advertisements shall appear. In any such case the Company shall send confirmatory copies of the notice through the post to those members whose registered addresses are outside the State (if or to the extent that in the opinion of the Directors it is practical so to do) or are in areas of the State unaffected by such suspension or curtailment of postal services and if at least ninety-six hours prior to the time appointed for the holding of the meeting the posting of notices to members in the State, or any part thereof which was previously affected, has become practical in the opinion of the Directors, the Directors shall send forthwith confirmatory copies of the notice by post or electronic means, whether as an Electronic Communication or otherwise (as the case may be) to such members. The accidental omission to give any such confirmatory copy of a notice of a meeting to, or the non-receipt of any such confirmatory copy by, any person entitled to receive the same shall not invalidate the proceedings at the meeting. 83.8 Notwithstanding anything contained in this Regulation the Company shall not be obliged to take account of or make any investigations as to the existence of any suspension or curtailment of postal services within or in relation to all or any part of any jurisdiction or area other than the State and, in the case of Regulation 83.7(b), the Company shall not be obliged to carry out any tests or investigations into the causes of or circumstances surrounding the event or thing in question as a consequence of which the Company shall be unable effectively to convene a general meeting by means of an Electronic Communication other than such tests and investigations as may be used from time to time by the Company or its agents in relation to the use or operation of any systems for Electronic Communication.

### 84. Notices to members

Any member whose registered address is not within the State and who gives to the Company an address within the State at which notices may be served upon him shall be entitled to have notices served upon him at that address or shall be entitled to receive notices by electronic mail, or other formal Electronic Communication approved by the Directors, to be sent to an address notified to the Company by the member for such purpose but unless he does so shall not be entitled to receive any notice from the Company.

## 85. Service on joint holders

A notice may be given by the Company to the joint holders of a Share by giving the notice to the joint holder whose name stands first in the Register in respect of the Share or, in the case of a notice sent by electronic mail or other form of Electronic Communication approved by the Directors, to the address in respect of the joint holding notified to the Company by the joint holders for such purpose, and notice so given shall be sufficient notice to all the joint holders.

## 86. Service on transfer or transmission of Shares

- 86.1 Every person who becomes entitled to a Share shall before his name is entered in the Register in respect of the Share, be bound by any notice in respect of that Share which has been duly given to a person from whom he derives his title provided that the provisions of this Regulation shall not apply to any Disclosure Notice unless, under the provisions these Articles, it is a notice which continues to have effect notwithstanding the registration of a transfer of the Shares to which it relates.
- 86.2 Without prejudice to the provisions of these Articles allowing a meeting to be convened by newspaper advertisement, a notice may be given by the Company to the persons entitled to a Share in consequence of the death or bankruptcy of a member by sending or delivering it, in any manner authorised by these Articles for the giving of notice to a member, addressed to them at the address (inclusive of an electronic address), if any, supplied by them for that purpose. Until such an address has been supplied, a notice may be given in any manner in which it might have been given if the death or bankruptcy had not occurred.

### 87. Signature to notices

The signature to any notice to be given by the Company may be written or printed or, in the case of a notice in electronic form the signature may be an Electronic Signature, Advanced Electronic Signature or otherwise as the Directors may approve.

## 88. Deemed receipt of notices

A member present, either in person or by proxy, at any meeting of the Company or the holders of any class of Shares shall be deemed to have received notice of the meeting and, where requisite, of the purposes for which it was called.

# 89. Use of Electronic Communication

- 89.1 Notwithstanding any other provision of these Articles, whenever any person (including without limitation the Company, a Director, the Company Secretary, any officer of the Company, a member or any other person) is required or permitted by these Articles or otherwise to give or receive information in writing such information may be given or received in electronic form, whether as an Electronic Communication or otherwise in such manner or form and subject to such terms, conditions or restrictions as the Directors may, subject to the Companies Act, determine or approve from time to time in their absolute discretion.
- 89.2 Subject to the Companies Act, the Company and its Directors, Company Secretary or officers shall not be compelled to receive or to send Electronic Communications or information in electronic form under these Articles or otherwise until such time as the Directors shall have advised (pursuant to any terms and conditions of Electronic Communication or otherwise) the recipient or giver (as the case may be) in writing of the manner, form and restrictions (if any) by which such information may be sent or received.
- 89.3 Any requirement in these Articles for the consent of a member in regard to the receipt by such member of electronic mail or other means of Electronic Communications approved by the Directors, including the receipt of the Company's annual report, statutory financial statements and the Directors' and Auditor's reports thereon, shall be deemed to have been satisfied where the Company has written to the member informing him or her of its intention to use Electronic Communications for such purposes and the member has not, within four weeks of the issue of such notice, served an objection in writing on the Company. Where a member has given, or is deemed to have given, his/her consent to the receipt by such member of electronic mail or other means of Electronic Communications approved by the Directors, she/he may revoke such consent at any time by requesting the Company to communicate with him or her in documented form; provided, however, that such revocation shall not take effect until five days after written notice of the revocation is received by the Company. Notwithstanding anything to the contrary in this Regulation 89.3, no such consent shall be necessary, and to the extent it is necessary, such consent shall be deemed to have been given, if Electronic Communications are permitted to be used under the rules and regulations of any Stock Exchange or under the rules of the SEC.

### 90. Service of notices on the Company

In addition to the means of service of documents set out in section 51 of the Companies Act, a notice or other document may be served on the Company by an officer of the Company by email provided, however, that the Directors have designated an email address for that purpose and notified that email address to its officers for the express purpose of serving notices on the Company.

## 91. Sending statutory financial statements to members

- 91.1 Subject to Regulation 89.3, each of the members hereby agree and consent that copies of the documents referred to in section 338(2) of the Companies Act, are to be treated, for the purposes of section 338 of the Companies Act, as sent to a person where:
  - (a) the Company and that person have agreed to his or her having access to the documents on a website (instead of their being sent to him or her), provided such agreement shall be deemed to have been given, if Electronic Communications are permitted to be used under the rules and regulations of any Stock Exchange or under the rules of the SEC;

- (b) the documents are documents to which that agreement applies; and
- (c) that person is notified, in a manner for the time being agreed for the purpose between him or her and the Company, of:
  - (i) the publication of the documents on a website;
  - (ii) the address of that website; and
  - (iii) the place on that website where the documents may be accessed, and how they may be accessed. Documents treated in accordance with Regulation 91 as sent to any person are to be treated as sent to him or her not less than 21 days before the date of a meeting if, and only if:
    - (A) the documents are published on the website throughout a period beginning at least 21 days before the date of the meeting and ending with the conclusion of the meeting; and
    - (B) the notification given for the purposes of Regulation 91.1(c) is given not less than 21 days before the date of the meeting.
- 91.2 Any obligation by virtue of section 339(1) or (2) of the Companies Act to furnish a person with a document may, unless these Articles provide otherwise, be complied with by using Electronic Communications for sending that document to such address as may for the time being be notified to the Company by that person for that purpose.

# Part 10 – Accounting Records

## 92. Accounts

- 92.1 The Directors shall, cause the Company to keep accounting recording whether in the form of documents electronic form or otherwise, which are sufficient to:
  - (a) correctly record and explain the transactions of the Company;
  - (b) enable at any time, the assets, liabilities, the financial position and profit or loss of the Company to be determined with reasonable accuracy;
  - (c) enable the Directors to ensure that any financial statements and any Director's report of the Company, required to be prepared under the Companies Act, comply with the requirements of the Companies Act; and
  - (d) enable the financial statements of the Company to be audited.
- 92.2 The accounting records of the Company shall be kept on a continuous and consistent basis that is to say, the entries therein shall be made in a timely manner and be consistent from one year to the next. Adequate accounting records shall be deemed to have been maintained if they comply with the provisions of Chapter 2 of Part 6 of the Companies Act and explain the Company's transactions and facilitate the preparation of financial statements that give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and, if relevant, the Group and include any information and returns referred to in section 283(2) of the Companies Act.

- 92.3 The accounting records of the Company shall not be deemed to be kept if there are not kept such accounting records as comply with the Companies Act and as are necessary to give a true and fair view of the state of the Company's affairs and to explain its transactions.
- 92.4 The accounting records shall be kept at the Office or, subject to the provisions of the Companies Act, at such other place as the Directors think fit and shall be open at all reasonable times to the inspection of the Directors.
- 92.5 In accordance with the provisions of the Companies Act, the Directors shall cause to be prepared and to be laid before the annual general meeting of the Company from time to time statutory financial statements of the Company and such other reports and financial statements as are required by the Companies Act to be prepared and laid before such meeting.
- 92.6 A copy of every statutory financial statement (including every document required by law to be annexed thereto) which is to be laid before the annual general meeting of the Company together with a copy of the Directors' report and Auditors' report shall be sent by post, electronic mail or any other means of Electronic Communications, not less than twenty-one Clear Days before the date of the annual general meeting, to every person entitled under the provisions of the Companies Act to receive them; and the required number of copies of these documents shall be forwarded at the same time to the appropriate sections of the Stock Exchanges. For the purposes of this Regulation, sending by Electronic Communications includes the making available or displaying on the Company's website (or a website designated by the Board) or the website of the SEC, and each member is deemed to have irrevocably consented to receipt of every statutory financial statement of the Company (including every document required by law to be annexed thereto) and every copy of the Directors' report and the Auditors' report and every copy of any summary financial statements prepared in accordance with section 1119 of the Companies Act, by any such document being made so available or displayed.
- 92.7 Auditors shall be appointed and removed and their duties regulated in accordance with the Companies Act.

# Part 11 – Winding Up

### 93. Distribution on winding up

- 93.1 Subject to the provisions of the Companies Act as to preferential payments, the property of the Company on its winding up shall be distributed among the members according to their rights and interests in the Company.
- 93.2 Unless the conditions of issue of the Shares in question provide otherwise, dividends declared by the Company more than six years preceding the commencement date of a winding up of the Company, being dividends which have not been claimed within that period of six years, shall not be a claim admissible to proof against the Company for the purposes of the winding up.
- 93.3 If the Company shall be wound up and the assets available for distribution among the members as such shall be insufficient to repay the whole of the paid up or credited as paid up share capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members in proportion to the capital paid up or credited as paid up at the commencement of the winding up on the Shares held by them respectively. And if in a winding up the assets available for distribution among the members shall be more than sufficient to repay the whole of the share capital paid up or credited as paid up at the commencement of the winding up, the excess shall be distributed among the members in proportion to the capital at the commencement of the winding up or credited as paid up or the said Shares held by them respectively. Provided that this Regulation shall not affect the rights of the holders of Shares issued upon special terms and conditions.

- (a) In case of a sale by the liquidator under section 601 of the Companies Act, the liquidator may by the contract of sale agree so as to bind all the members, for the allotment to the members directly, of the proceeds of sale in proportion to their respective interests in the Company and may further, by the contract, limit a time at the expiration of which obligations or Shares not accepted or required to be sold shall be deemed to have been irrevocably refused and be at the disposal of the Company, but so that nothing herein contained shall be taken to diminish, prejudice or affect the rights of dissenting members conferred by the said section.
- (b) The power of sale of the liquidator shall include a power to sell wholly or partially for debentures, debenture stock, or other obligations of another company, either then already constituted or about to be constituted for the purpose of carrying out the sale.

### 94. Distribution in specie

If the Company is wound up, the liquidator, with the sanction of a special resolution of the Company and any other sanction required by the Companies Act, may divide among the members in specie or kind the whole or any part of the assets of the Company (whether they shall consist of property of the same kind or not) and, for such purpose, may value any assets and determine how the division shall be carried out as between the members or different classes of members. The liquidator, with the like sanction, may subject to the Companies Act vest the whole or any part of such assets in trustees upon such trusts for the benefit of the members as, with the like sanction, he determines, but so that no member shall be compelled to accept any assets upon which there is a liability.

# Part 12 – Miscellaneous

## 95. Minutes of meetings

The Directors shall cause minutes to be made and to be entered in books kept for that purpose of the following matters, namely:-

- (a) of all appointments of officers and committees made by the Directors and of their salary or remuneration;
- (b) of the names of Directors present at every meeting of the Directors and of the names of any Directors and of all other members thereof present at every meeting of any committee appointed by the Directors; and
- (c) of all resolutions and proceedings of all general meetings of the Company and of the holders of any class of Shares and of the Directors and of committees appointed by the Directors.

Any such minute as aforesaid, if purporting to be signed by the chairman of the meeting at which the proceedings were held, or by the chairman of the next succeeding meeting, shall be receivable as prima facie evidence of the matters stated in such minute without any further proof.

## 96. Inspection

The Directors shall determine from time to time whether and to what extent and at what times and places and under what conditions or regulations the accounts and books of the Company or any of them shall be open to the inspection of members, not being Directors. No member (not being a Director) shall have any right of inspecting any account or book or document of the Company except as conferred by the Companies Act or authorised by the Directors or by the Company in general meeting. No member shall be entitled to require discovery of or any information respecting any detail of the Company's trading, or any matter which is or may be in the nature of a trade secret, mystery of trade, or secret process which may relate to the conduct of the business of the Company and which in the opinion of the Directors it would be inexpedient in the interests of the members of the Company to communicate to the public.

# 97. Secrecy

Every officer of the Company or other person employed in the business of the Company shall, when required by the Directors before entering upon his duties, sign a declaration pledging himself to observe a strict secrecy respecting the business of the Company and all transactions of the Company with its customers and the state of accounts with individuals, and in matters relating thereto and shall by such declaration pledge himself not to reveal any of the matters which may come to his knowledge in the discharge of his duties, except when required to do so by the Directors or by any general meeting or by a court of law or by the person to whom such matters relate, and except so far as may be necessary in order to comply with any of the provisions of these Articles.

# 98. Destruction of records

The Company shall be entitled to destroy all instruments of transfer which have been registered at any time after the expiration of six years from the date of registration thereof, all notifications of change of address at any time after the expiration of two years from the date of recording thereof and all share certificates and dividend mandates which have been cancelled or ceased to have effect at any time after the expiration of one year from the date of such cancellation or cessation. It shall be presumed conclusively in favour of the Company that every entry in the Register purporting to have been made on the basis of an instrument of transfer or other document so destroyed was duly and properly made and every instrument duly and properly registered and every share certificate so destroyed was a valid and effective document duly and properly cancelled and every other document hereinbefore mentioned so destroyed was a valid and effective document in accordance with the recorded particulars thereof in the books or records of the Company. Provided always that:

- (a) the provision aforesaid shall apply only to the destruction of a document in good faith and without notice of any claim (regardless of the parties thereto) to which the document might be relevant;
- (b) nothing herein contained shall be construed as imposing upon the Company any liability in respect of the destruction of any document earlier than as aforesaid or in any other circumstances which would not attach to the Company in the absence of this Regulation; and
- (c) references herein to the destruction of any document include references to the disposal thereof in any manner.

#### 99. Untraced Shareholders

- 99.1 The Company may sell any Shares on behalf of a holder, or person entitled by transmission to, the Shares, if:-
  - (a) the Shares have been in issue throughout the qualifying period and at least three cash dividends have become payable on the Shares during the qualifying period;
  - (b) no cash dividend payable on the Shares has either been claimed by presentation to the paying bank of the relative cheque or warrant or been satisfied by the crediting of any account which the holder has with the Company, whether in the sole name of such holder or jointly with another person or persons, or by the transfer of funds to a bank account designated by the holder of, or person entitled by transmission to, the Shares at any time during the relevant period;
  - (c) the Company has not at any time during the relevant period received, so far as the Company at the end of the relevant period is then aware, any communication from the holder of, or person entitled by transmission to, the Shares;
  - (d) the Company has caused advertisements giving notice of its intention to sell the Shares to be published in a leading daily newspaper with a national circulation in the State and another in a newspaper circulating in the area of the address shown in the register of the holder of, or person entitled by transmission to, the untraced Shares, and (in either such case) a period of three months has elapsed from the date of publication of the advertisement; and
  - (e) the Company has given notice to the relevant departments of the Stock Exchanges of its intention to make the sale.
- 99.2 For the purposes of this Regulation 99:

**the qualifying period** means the period of twelve years immediately preceding the date of publication of the relevant advertisements referred to in Regulation 99.1(d) above;

**the relevant period** means the period beginning at the commencement of the qualifying period and ending on the date when all the requirements of Regulation 99.1 above have been satisfied.

- 99.3 For the purposes of Regulation 99.1(c), a statutory declaration that the declarant is a Director or the Company Secretary and that the Company was not aware at the end of the relevant period of having at any time during the relevant period received any communication from the holder of, or person entitled by transmission to, the Shares shall be conclusive evidence of the facts stated in it as against all persons claiming to be entitled to the Shares.
- 99.4 If, after the publication of the advertisement referred to in Regulation 99.1(d) but before the Company has become entitled to sell the Shares pursuant to this Regulation, the requirements of Regulation 99.1(b) or 99.1(c) above cease to be satisfied, the Company may nevertheless sell those Shares after the requirements of Regulation 99.1 above have been satisfied afresh in relation to them.
- 99.5 If during any relevant period further Shares have been issued in right of those held at the beginning of that relevant period or of any previously so issued during that relevant period and all the requirements of Regulation 99.1(b) to (e) above have been satisfied in regard to the further Shares, the Company may also sell the further Shares.

- 99.6 The manner, timing and terms of any sale of Shares pursuant to this Regulation (including but not limited to the price or prices at which the same is made) shall be such as the Directors determine, based upon advice from such bankers, brokers or other persons as the Directors consider appropriate which are consulted by it for the purposes, to be reasonably practicable having regard to all the circumstances including the number of Shares to be disposed of and the requirement that the disposal be made without delay; and the Directors shall not be liable to any person for any of the consequences of reliance on such advice.
- 99.7 To give effect to any sale of Shares pursuant to this Regulation the Directors may take such steps as the Directors consider are necessary or desirable in order to effect such sale and, for this purpose, may authorise some person to transfer the Shares in question and may enter the name of the transferee in respect of the transferred Shares in the register notwithstanding the absence of any share certificate being lodged in respect thereof and may issue a new certificate to the transferee and an instrument of transfer executed by that person or such other method of transfer as is employed by this person shall be as effective as if it had been executed or employed by the holder of, or person entitled by transmission to, the Shares. The purchaser shall not be bound to see to the application of the purchase moneys nor shall his title to the Shares be affected by any irregularity or invalidity in the proceedings relating to the sale.
- 99.8 The Company shall account to the holder or other person entitled to such Shares for the net proceeds of such sale by carrying all moneys in respect thereof to a separate account which shall be a permanent debt of the Company and the Company shall be deemed to be a debtor and not a trustee in respect thereof for such holder or other person. Moneys carried to such separate account may be either employed in the business of the Company or invested in such investments as the Directors may think fit, from time to time.

#### 100. Register of Shareholders

- 100.1 The Register shall be kept in the manner prescribed by the Companies Act at the Office or at such other place as may be authorised by the Board from time to time consistent with the Companies Act.
- 100.2 The Register may be closed at such times and for such periods as the Board may from time to time decide, subject to Section 174 of the Companies Act. Except during such time as it is closed, the Register shall be open to inspection in the manner prescribed by the Companies Act at such times as the Board may from time to time determine.
- 100.3 Unless the Board so determines, no Shareholder or intending Shareholder shall be entitled to have entered in the Register, or otherwise recognised by the Company, any indication of any trust or any equitable, beneficial, contingent, future, fractional or partial interest in any Share, and if any such entry exists or is permitted by the Board it shall not be deemed to abrogate any provision of these Articles provided that no interest will be entered in the Register unless permitted by the Companies Act.
- 100.4 If the Board considers it necessary or appropriate, the Company may establish and maintain a duplicate Register at such location or locations within or outside the State as the Board thinks fit. The original Register shall be treated as the register of members for the purposes of these Articles and the Companies Act.
- 100.5 The Company or any agent(s) appointed by it to maintain the duplicate Register in accordance with these Articles, shall as soon as practicable and on a regular basis record or procure the recording in the original Register in such manner as to show at all times the members for the time being and the shares respectively held by them, in all respects in accordance with the Companies Act.

#### 101. Shareholder Rights Plan

The Board is hereby expressly authorised to adopt any shareholder rights plan, upon such terms and conditions as the Board deems expedient and in the best interests of the Company, subject to applicable law.

#### 102. Sale of shares in GH Research Ireland Limited

- 102.1 Subject to Regulation 102.2 below, no shares held by the Company in GH Research Ireland Limited may be sold unless the consent in writing of 90% of the Shareholders is obtained, such consent to be obtained in a general meeting of the Company.
- 102.2 The restriction contained in Regulation 102.1 shall only apply to:
  - (a) the sale of shares in GH Research Ireland Limited and shall not apply in respect of any divestments;
  - (b) the sale of shares in GH Research Ireland Limited which takes place at any time before 1 June 2028; and
  - (c) the sale of shares in GH Research Ireland Limited and shall not apply in respect of the sale of shares in other Subsidiary.

#### Part 13 – Dispute Resolution

#### 103. Exclusive jurisdiction

- 103.1 Save in respect of any cause of action arising under the Securities Act or the Exchange Act, the courts of Ireland shall have exclusive jurisdiction to determine any and all disputes brought by a member in that member's capacity as such, or as a purported derivative claim in respect of a cause of action vested in the Company or seeking relief on behalf of the Company, against the Company or the Board or any of the Directors or officers individually (or against any combination of the foregoing persons), arising out of or connection with these Articles or any non-contractual obligations arising out of or in connection with these Articles.
- 103.2 Unless the Company by ordinary resolution consents in writing to the selection of an alternative forum in the United States, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the Exchange Act.

#### Part 14 – Officers' and employees indemnity and insurance

#### 104. Indemnity

- 104.1 Subject to the provisions of and so far as may be permitted by the Companies Act, each person who is or was:
  - (a) a Director;
  - (b) an officer of the Company;
  - (c) an employee of the Company;

- (d) a trustee, administrator, or policy committee member of a Company that is a corporate trustee of a pension plan established for the benefit of employees of the Company;
- (e) an official of a Company, including if organised or operated in a foreign jurisdiction, while serving in a functionally equivalent position to:
  - (i) a duly elected or appointed director, shadow director or a de facto director of a Company;
  - (ii) a prospective director as identified in a Company prospectus or similar offering document;
  - (iii) an officer, senior manager, in-house general counsel, company secretary, risk manager, controller, chancellor or governor of a Company, or any other natural person who:
    - (A) makes, or participates in making, decisions that affect the whole, or a substantial part, of the business of the Company; or
    - (B) has the capacity to significantly affect the Company's financial standing;
  - (iv) a trustee, administrator, or policy committee member of a Company that is a corporate trustee of a pension plan established for the benefit of employees of the Company; and
  - (v) an approved person under the United Kingdom Senior Managers & Certification Regime;
- (f) an individual described in the following sections while serving at the specific direction or request of the Company in a position functionally equivalent to those described in the following sections for an outside entity:
  - (i) a duly elected or appointed director, shadow director or a de facto director of a Company;
  - (ii) a prospective director as identified in a Company prospectus or similar offering document;
  - (iii) an officer, senior manager, in-house general counsel, company secretary, risk manager, controller, chancellor or governor of a Company, or any other natural person who:
    - (A) makes, or participates in making, decisions that affect the whole, or a substantial part, of the business of the Company; or
    - (B) has the capacity to significantly affect the Company's financial standing;
  - (iv) a trustee, administrator, or policy committee member of a Company that is a corporate trustee of a pension plan established for the benefit of employees of the Company; and
  - (v) an approved person under the United Kingdom Senior Managers & Certification Regime,

#### (together the **Indemnified Parties**),

shall be entitled to be indemnified by the Company against all costs, charges, losses, expenses and liabilities incurred by him or her in the execution and discharge of his or her duties or in relation thereto, including any liability incurred by him or her in defending any proceedings, civil or criminal, which relate to anything done or omitted or alleged to have been done or omitted by him or her in their capacity carrying out the roles specified in Regulation 104.1(a) to 104.1(f) and in which judgment is given in his or her favour (or the proceedings are otherwise disposed of without any finding or admission of any material breach of duty on his or her part) or in which he or she is acquitted or in connection with any application under any statute for relief from liability in respect of any such act or omission in which relief is granted to him or her by the court.

- 104.2 In the case of any threatened, pending or completed action, suit or proceeding by or in the right of the Company, the Company shall indemnify, to the fullest extent permitted by the Companies Act, each person indicated in Regulation 104.1 against expenses, including attorneys' fees actually and reasonably incurred in connection with the defence or the settlement thereof, except no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable for fraud or dishonesty in the performance of his or her duty to the Company unless and only to the extent that the courts of Ireland or the court in which such action or suit was brought shall determine upon application that despite the adjudication of liability, but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses as the court shall deem proper.
- 104.3 As far as permissible under the Companies Act, expenses, including attorneys' fees, incurred in defending any action, suit or proceeding referred to in this Regulation shall be paid by the Company in advance of the final disposition of such action, suit or proceeding upon receipt of a written affirmation by or on behalf of the Indemnified Party or other indemnitee of a good faith belief that the criteria for indemnification have been satisfied and a written undertaking to repay such amount if it shall ultimately be determined that such Indemnified Party or other indemnitee is not entitled to be indemnified by the Company as authorised by these Articles.
- 104.4 It being the policy of the Company that indemnification of the persons specified in this Regulation shall be made to the fullest extent permitted by law, the indemnification provided by this Regulation shall not be deemed exclusive of: (a) any other rights to which those seeking indemnification or advancement of expenses may be entitled under the Memorandum, these Articles, any agreement, any insurance purchased by the Company, any vote of members or disinterested Directors, or pursuant to the direction (however embodied) of any court of competent jurisdiction, or otherwise, both as to action in his or her official capacity and as to action in another capacity while holding such office, or (b) any amendments or replacements of the Companies Act which permit for greater indemnification of the persons specified in this Regulation and any such amendment or replacement of the Companies Act shall hereby be incorporated into these Articles. As used in this Regulation 104.4, references to the "Company" include all constituent companies in a consolidation or merger in which the Company or any predecessor to the Company by consolidation or merger was involved. The indemnification provided by this Regulation shall continue as to a person who has ceased to be an Indemnified Party and shall inure to the benefit of the heirs, executors, and administrators of such Indemnified Parties or other indemnitees.

- 104.5 To the extent permitted by law, the Directors may arrange insurance cover at the cost of the Company in respect of any liability, loss or expenditure incurred by any Indemnified Party in relation to anything done or alleged to have been done or omitted to be done by him in his capacity in carrying out the roles specified in Regulation 104.1(a) to 104.1(f) (as relevant).
- 104.6 The Company may additionally indemnify any agent of the Company or any director, officer, employee or agent of any of its Subsidiaries to the fullest extent provided by law, and purchase and maintain insurance for any such person as appropriate.
- 104.7 No person shall be personally liable to the Company or its members for monetary damages for breach of fiduciary duty as a Director, provided, however, that the foregoing shall not eliminate or limit the liability of a Director:
  - (a) for any breach of the Director's duty of loyalty to the Company or its members;
  - (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; or
  - (c) for any transaction from which the Director derived an improper personal benefit.

If any applicable law or the relevant code, rules and regulations applicable to the listing of the Shares on any Stock Exchange is amended hereafter to authorise corporate action further eliminating or limiting the personal liability of Directors, then the liability of a Director shall be eliminated or limited to the fullest extent permitted by the relevant law, as so amended. Any amendment, repeal or modification of this Regulation 104.7 shall not adversely affect any right or protection of a Director existing hereunder with respect to any act or omission occurring prior to such amendment, repeal or modification.

#### Exhibit 5.1



Dentons Ireland LLP 2nd Floor Joshua Dawson House Dawson Street Dublin 2 D02 RY95 Ireland

dentons.com

21 June 2021

To: Board of Directors GH Research plc 28 Baggot Street Lower Dublin 2 D02 NX43 Ireland

#### RE: GH Research Public Limited Company – Registration Statement on Form F-1 - Exhibit 5.1

Ladies and Gentlemen

We have acted as Irish legal advisers to GH Research plc, a public limited company incorporated in Ireland with registered number 691405 (the "**Company**"), in connection with the proposed initial public offering by the Company of up to 9,583,333 ordinary shares of nominal value \$0.025 each in the capital of the Company (the "**Ordinary Shares**") (the "**Offering**"), including 1,250,000 Ordinary Shares subject to the underwriters' over-allotment option, as described in the Registration Statement (as defined below).

The Company's registration statement on Form F-1 (File No. 333-256796) filed by the Company with the Securities and Exchange Commission (the "**SEC**") on 4 June 2021, as subsequently amended, in the form in which it is to become effective, including the information deemed to be included in it at the time of effectiveness pursuant to Rule 430A under the Securities Act of 1933, as amended (the "**Securities Act**"), is referred to in this letter as the "**Registration Statement**", and the prospectus included in it is referred to in this letter as the "**Prospectus**".

#### 1 INTRODUCTION

#### 1.1 Purpose

In connection with the preparation and filing of the Registration Statement we have been asked to provide opinions on certain matters, as set out below. We have taken instructions in this regard solely from the Company.

#### 1.2 Defined terms and headings

In this letter:

- (a) capitalised terms used without definition in this letter or the schedules hereto have the meanings assigned to them in the Registration Statement unless a contrary indication appears; and
- (b) headings are for ease of reference only and shall not affect interpretation.

Davis Brown ► East African Law Chambers ► Eric Silwamba, Jalasi and Linyama ► Durham Jones & Pinegar ► LEAD Advogados ► Rattagan Macchiavello Arocena ► Jiménez de Aréchaga, Viana & Brause ► Lee International ► Kensington Swan ► Bingham Greenebaum ► Cohen & Grigsby ► Sayarh & Menjra ► Larraín Rencoret ► For more information on the firms that have come together to form Dentons, go to dentons.com/legacyfirms

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## 1.3 Legal Review

For the purpose of issuing this letter, we have examined such questions of law as we have considered appropriate to give the opinions set forth in this letter. We have reviewed:

- (a) the documents listed in schedule 1 (*Documents*) to this letter (the "**Documents**");
- (b) legal searches against the Company on 18 June 2021 on the file of the Company maintained by the Registrar of Companies in Dublin, the Judgments Office of the High Court and the Central Office of the High Court (the "**Searches**"); and
- (c) such other corporate records of the Company as we have deemed necessary as a basis for the opinions hereinafter expressed.

#### 1.4 Applicable Law

This letter, the opinions given in it, and any non-contractual obligations arising out of or in connection with this letter and / or the opinions given in it, are governed by, and are to be construed in accordance with, the laws of Ireland (meaning Ireland exclusive of Northern Ireland) and relate only to Irish law as applied by the Irish courts. In particular:

- (a) we have not investigated the laws of any country other than Ireland (meaning Ireland exclusive of Northern Ireland) and we express no opinion in this letter on the laws of any jurisdiction other than Ireland (meaning Ireland exclusive of Northern Ireland) and we assume that no foreign law effects any of the opinions given below. It is assumed that no foreign law which may apply to the matters contemplated by the Registration Statement, the Offering, the Company, any document or any other matter contemplated by any document would or might affect this letter and / or opinions given in it; and
- (b) we do not undertake or accept any obligation to update this letter and / or opinions given in it to reflect subsequent changes in Irish law or factual matters.

#### 1.5 Assumptions

- (a) The opinions given in this letter are given on the basis of each of the assumptions set out in schedule 2 (*Assumptions*) to this letter.
- (b) The opinions given in this letter are strictly limited to the matters stated in paragraph 2 (*Opinion*) below and do not extend, and should not be read as extending, by implication or otherwise, to any other matters.

#### 2 OPINION

Subject to paragraph 1 (*Introduction*), the other matters set out in this letter and its schedules and to any matters not disclosed to us, it is our opinion that, the Ordinary Shares, when issued in accordance with the terms of the Registration Statement and the Prospectus, will have been duly authorised and will be validly issued, fully paid and will be non-assessable (which term means that no further sums are required to be paid by the holders thereof in connection with the issue of such Ordinary Shares).

# 3 EXTENT OF OPINIONS

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- 3.1 We express no opinion as to any agreement, instrument or other document other than as specified in this letter or as to any liability to tax or duty which may arise or be suffered as a result of or in connection with the Offering or the transactions contemplated thereby.
- 3.2 This letter only applies to those facts and circumstances which exist as at today's date and we assume no obligation or responsibility to update or supplement this letter to reflect any facts or circumstances which may subsequently come to our attention, any changes in laws which may occur after today, or to inform the addressee of any change in circumstances happening after the date of this letter which would alter our opinion.

# 4 DISCLOSURE AND RELIANCE

- 4.1 This letter is addressed to you in connection with the Registration Statement. We consent to the filing of this letter with the SEC as an exhibit to the Registration Statement and any amendments thereto. We also hereby consent to the reference to our Firm under the caption "Legal Matters" in the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.
- 4.2 Other than for the purpose set out in the prior paragraph, this letter may not be relied upon, or assigned, for any purpose, without our prior written consent, which may be granted or withheld in our discretion.

Yours faithfully

/s/ Dentons Ireland LLP DENTONS IRELAND LLP

## Schedule 1

#### Documents

1. A copy of the Registration Statement.

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- 2. The results of the Searches.
- 3. A copy of the certificate of incorporation of the Company dated 29 March 2021.
- 4. A copy of the constitution of the Company adopted by the resolution of the shareholders of the Company on 27 May 2021 (the "Constitution").
- 5. A copy of the constitution of the Company exhibited to the Registration Statement and proposed to be effective immediately prior to completion of the Offering (the "**Completion Constitution**").
- 6. A copy of the resolutions of the shareholders of the Company dated 18 June 2021 approving amongst other things the adoption of the Completion Constitution, the redemption of the 25,000 A ordinary shares of €1.00 each from Florian Schönharting out of the proceeds of the Offering and subsequent cancellation, the conversion of 5,923,079 Series A preferred shares of \$0.01 each into 5,923,079 ordinary shares of \$0.01 each, the conversion of 25,379,047 Series B preferred shares of \$0.01 each into 25,379,047 ordinary shares of \$0.01 each and the subsequent consolidation of the ordinary shares of \$0.01 each into ordinary shares of \$0.025 each.
- 7. A copy of the resolution of the board of the Company approving, amongst other things, the Offering and the filing of the Registration Statement dated 4 June 2021.

## Schedule 2

#### Assumptions

The opinions in this letter have been given on the basis of the following assumptions:

- (i) the genuineness of all signatures, stamps and seals on all documents, the authenticity and completeness of all documents submitted to us as originals, and the conformity to original documents of all documents submitted to us as copies;
- (ii) that, where a document has been examined by us in draft or specimen form, it will be or has been duly executed in the form of that draft or specimen, and that each of the signed documents examined by us has been duly executed and, where applicable, delivered on behalf of the Company;
- (iii) that the Completion Constitution will be so effective immediately prior to the issuance of the Ordinary Shares and will not have been amended or superseded and that there will be no other terms governing the Ordinary Shares other than those set out in the Completion Constitution;
- (iv) on the date of allotment and issue of the Ordinary Shares (the "Allotment Date") the Company will comply with all applicable laws to allot and issue the Ordinary Shares;
- (v) that all documents, forms and notices which should have been delivered to the Registrar of Companies in respect of the Company have been so delivered, that information revealed by the Searches was complete and accurate in all respects and has not, since the time of the Searches, been altered and that the results of the Searches will remain complete and accurate as at the Allotment Date;
- (vi) that the minutes of the meetings of the board of directors of the Company and the written resolutions of the board of directors of the Company provided to us in connection with the giving of the opinions in this letter reflect a true record of the proceedings described in them in duly convened, constituted and quorate meetings in which all constitutional, statutory and other formalities were duly observed, and the resolutions set out in the minutes were validly passed and have not been and will not be revoked or varied and remain in full force and effect and will remain so as at the Allotment Date;
- (vii) that none of the resolutions of the shareholders of the Company upon which we have relied have been or will be varied, amended or revoked in any respect and remain in full force an effect;
- (viii) that, in relation to each meeting of the board of directors of the Company, each provision contained in the Companies Act 2014 (as amended (the "Companies Act") or the Constitution relating to the declaration of the directors' interests or the power of the interested directors to vote and to count in the quorum was or will be duly observed;
- (ix) that there is, at Allotment Date, no matter affecting the authority of the directors to issue and allot the Ordinary Shares, not disclosed by the Constitution or the Completion Constitution or the resolutions produced to us, which would have any adverse implications in relation to the opinions expressed in this letter;
- (x) that the Ordinary Shares offered under the Registration Statement will be in consideration of the receipt by the Company prior to the issue of the Ordinary Shares pursuant thereto of either cash or the release of a liability of the Company for a liquidated sum, at least equal to the nominal value of such Ordinary shares and any premium required to be paid up on the Ordinary Shares pursuant to their terms is issue;

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- (xi) that neither the Registration Statement nor the Prospectus constitutes (and is not intended/required to constitute) a prospectus within the meaning of Part 23 of the Companies Act and that no offer of securities to the public is made, or will be made, that requires the publication of a prospectus pursuant to Irish prospectus law in general, or in particular pursuant to the Prospectus (Directive 2017/1129) Regulations (EU) 2017/2019;
- (xii) that each party, to the extent that its activities in relation to the Offering will constitute the provision of an investment service operating in Ireland and require authorisation, is acting under and within the terms of an authorisation to do so (which authorisation has been given by the supervisory authority under the European Communities (Markets in Financial Instruments) Regulations (Nos. 1 to 3) 2007 or a competent authority for the purposes of Directive 2004/39/EC of 10 May 1993, as amended or extended from time to time, in another Member State) or is exempt from the requirement to have such authorisation;
- (xiii) that (i) the Company is at the date of this letter, and immediately after the issue of the Ordinary Shares will be, able to pay its debts within the meaning of Sections 570 of the Companies Act or any analogous provisions under any applicable laws (ii) no liquidator, receiver or examiner or other similar or analogous officer has been appointed in relation to the Company any of the assets or undertakings; and (iii) no petition for the making of a winding-up order or the appointment of an examiner or any similar officer or any similar or analogous procedure in any jurisdiction has been presented in relation to the Company;
- (xiv) the accuracy and completeness of the information disclosed in the Searches and that such information is accurate as of the date of this letter and has not since the time of such search been altered. It should be noted that:
  - (A) the matters disclosed in the Searches may not present a complete summary of the actual position on the matters we have caused searches to be conducted for;
  - (B) the position reflected by the Searches may not be fully up-to-date (and this risk may be higher while emergency measures introduced by the Irish Government in light of the COVID-19 pandemic remain in place); and
  - (C) searches at the Companies Registration Office, Dublin do not necessarily reveal whether or not a prior charge has been created or a resolution has been passed or a petition presented or any other action taken for the winding-up of, or the appointment of a receiver or an examiner to, the Company or its assets;
- (xv) the truth, completeness and accuracy of all representations and statements as to factual matters contained in the Documents; and
- (xvi) that all securities issued and sold under the Registration Statement will be issued and sold in compliance with all applicable laws (other than Irish law), including applicable federal and state securities laws, in the manner stated in the Registration Statement.

Exhibit 10.1

#### **REGISTRATION RIGHTS AGREEMENT**

## dated as of [•], 2021

#### among

#### **GH RESEARCH PLC**

#### and

## THE HOLDERS NAMED HEREIN

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This Registration Rights Agreement dated as of [•], 2021 (this "**Agreement**"), is by and among GH Research PLC (the "**Company**") and the Holders listed in Schedule A hereto. Capitalized terms used but not defined elsewhere herein have the meanings assigned to them in Section 1.1.

WHEREAS, the Holders are currently party to that certain Shareholders' Agreement relating to GH Research Ireland Limited, a wholly-owned subsidiary of the Company dated April 12, 2021 (the "**Shareholders' Agreement**") that provides for, among other things, the Company and the Holders to enter into a registration rights agreement, effective no later than the closing of an IPO (as defined in the Shareholders' Agreement);

WHEREAS, the Company will adopt a new Constitution (as defined below) in connection with an IPO; and

WHEREAS, as part of the arrangements to enable the Company to consummate an IPO, the Holders and the Company desire to enter into this Agreement to set forth the registration rights of the Holders with respect to any Registrable Securities held by them.

WHEREAS, the Holders acknowledge that the registration rights of the Holders shall not apply to the IPO.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

Section 1. DEFINED TERMS; RULES OF CONSTRUCTION.

1.1 <u>DEFINED TERMS</u>. Capitalized terms used and not otherwise defined in this Agreement have the meanings ascribed to them below:

"Affiliate" means, in relation to one Person, any Person that is, directly or indirectly, (i) Controlled by, (ii) Controlling, or (iii) under common Control with such other Person, as of the date on which, or at any time during the period in which, such affiliate status is determined.

"Agreement" has the meaning set forth in the preamble hereof.

"Asset Sale" means the disposal (in one transaction or a series of connected transactions) by the Company of all or substantially all of its undertaking and assets (which shall include, without limitation, the grant by the Company of an exclusive license over all or substantially all of the commercially valuable intellectual property of the Company not entered into in the ordinary course of business);

"Board" means the board of directors of the Company as constituted from time to time.

"**Business Day**" means any day other than Saturday, Sunday or a day on which commercial banks are required or authorized by law to remain closed in Dublin, Ireland or New York, New York.

"**Company**" has the meaning set forth in the preamble hereof.

"Company Notice" has the meaning set forth in Section 2(a) hereof.

"Constitution" means the constitution of the Company as amended or superseded from time to time.

"**Control**" shall have the meaning ascribed in Rule 405 of the Securities Act. The terms "Controlled" and "Controlling" shall be construed accordingly with this definition.

"Deemed Liquidation Event" means a merger or consolidation of the Company involving the cessation of the Company's existence as an independent body corporate (other than a merger or consolidation in which the Company's shareholders immediately prior to completion of the merger or consolidation continue to be entitled to exercise a majority of the voting rights attaching to the shares or securities of the merged or consolidated entity immediately following completion of the merger or consolidation and in substantially the same proportions between them as they were entitled to exercise those voting rights in the share capital of the Company immediately prior to such merger or consolidation).

"Delay/Suspension Period" has the meaning set forth in Section 10 hereof.

"Demand Notice" has the meaning set forth in Section 2(a) hereof.

"**Demand Registration**" has the meaning set forth in Section 2(a) hereof.

"Eligible Holders" has the meaning set forth in Section 2(a) hereof.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

**"F-3**" means such form under the Securities Act as in effect on the date of this Agreement or any successor registration form under the Securities Act subsequently adopted by the SEC that permits inclusion or incorporation of substantial information by reference to other documents filed by the Company with the SEC in a similar or comparable manner.

**"Family Trust**" means in relation to an individual, a trust (whether arising under a settlement, declaration of trust or other instrument by whomsoever or wheresoever made or under a testamentary disposition or on an intestacy) under which no immediate beneficial interest in any of the Ordinary Shares in question is for the time being vested in any person other than that individual and/or Privileged Relations of that individual; and so that for this purpose a person shall be considered to be beneficially interested in a share if such share or the income therefrom is or may become liable to be transferred or paid or applied or appointed to or for the benefit of such person or any voting or other rights attaching thereto are or may become liable to be exercisable by or as directed by such person pursuant to the terms of the relevant trusts or in consequence of an exercise of a power or discretion conferred thereby on any person or persons.

"FINRA" means the Financial Industry Regulatory Authority, Inc.

"Governmental Authority" means (i) the federal government, any state or municipal government or other national or foreign political subdivision with jurisdiction over the applicable Person; (ii) an executive, regulatory, legislative, judicial or administrative government entity or authority with jurisdiction over the applicable Person, whether national or foreign, which includes, with respect to items (i) and (ii) above, their respective bodies, autonomous government entities, self-regulatory entities, divisions, departments, boards, representation offices, agencies or commissions, including the SEC; (iii) a single court, tribunal or judicial, administrative or arbitration body; or (iv) any stock exchange or organized over-the-counter market to which the applicable Person is subject.

"**Holder**" shall mean the Investors or any of their Affiliates, so long as such Person holds any Registrable Securities and any Person owning Registrable Securities who is a Permitted Transferee of rights under Section 14.2.

"**Holder Majority**" means, (i) with respect to a particular Registration Statement, Holder(s) holding more than 70% of the Registrable Securities then-held by Holder(s) who are participating in such Registration Statement and (ii) for all other purposes, Holder(s) holding more than 70% of the Registrable Securities then-held by Holder(s);.

"Initiating Holder" has the meaning set forth in Section 2(a) hereof.

"**Insolvency Proceedings**" means any insolvency related proceedings, whether in or out of court, including proceedings or steps leading to any form of bankruptcy, liquidation, administration, receivership, arrangement or scheme with creditors, moratorium, stay or limitation of creditors' rights, interim or provisional supervision by a court or court appointee, winding up or striking off, or any distress, execution, commercial rent arrears recovery or other process levied or exercised, or any event similar to any such events in any jurisdiction outside England and Wales.

"**Investors**" means each Party listed in Schedule A hereto, and any other person who becomes a party to the Shareholders' Agreement as an "Investor" by signing a Deed of Adherence in accordance with clause 7.7 of the Shareholders' Agreement and is named in that Deed of Adherence as an "Investor".

"**IPO**" means the Company's firm commitment underwritten initial public offering of Ordinary Shares representing Ordinary Shares of the Company under the Securities Act, consummated on or about the date hereof, for listing on Nasdaq.

"**Material Adverse Change**" means (1) in the opinion of a Holder Majority, there has been a material adverse change in the position or prospects of the Company; or (2) the Company has entered into any Insolvency Proceedings.

"**Material Transaction**" means any material transaction in which the Company or any of its subsidiaries proposes to engage or is engaged, including a material purchase or sale of assets or securities, financing, merger, consolidation, reorganization, tender offer or any other material transaction that would require disclosure pursuant to the Exchange Act, and with respect to which the board of directors of the Company reasonably has determined in good faith that compliance with this Agreement may reasonably be expected to either materially interfere with the Company's or such subsidiary's ability to consummate such transaction in a timely fashion or require the Company to disclose material, non-public information prior to such time as it would otherwise be required to be disclosed.

"Ordinary Shares" refer to the ordinary shares in the issued share capital of the Company following the closing of the IPO.

"**Original Shareholder**" means in relation to a Permitted Transfer of Ordinary Shares, the transferor or (in the case of a series of Permitted Transfers) the first transferor in the series.

"**Other Securities**" means with respect to a particular registration statement, any of the Ordinary Shares or Ordinary Shares that are to be included in such registration statement that are not Primary Securities or Registrable Securities.

"Permitted Transfers" means an Affiliate, Family Trust or Privileged Relation of the relevant transferor.

"**Person**" means an individual, company (whether incorporated or not), general or limited partnership, association, foundation, condominium, fund, consortia, joint venture, entity, trust, international or multilateral organization or other public, private or semi-public entity and any Governmental Authority as well as the successors thereof.

"**Primary Securities**" means, with respect to a particular registration statement, any of the Ordinary Shares or Ordinary Shares, which may be sold by the Company in a registered offering pursuant to such registration statement.

"**Privileged Relation**" means in relation to an individual, a spouse, civil partner, child or grandchild (including step or adopted children and their issue) of that individual.

"**Prospectus**" means the prospectus included in a Registration Statement filed with the SEC, including any prospectus subject to completion, and any such prospectus as amended or supplemented by any prospectus supplement with respect to the terms of the offering of any portion of the Registrable Securities and, in each case, by all other amendments and supplements to such prospectus, including post-effective amendments, and in each case including all material incorporated by reference therein.

"**Registrable Securities**" means, at any time, and with respect to any Holder, all Ordinary Shares without designation issued or issuable upon conversion or exchange of the series A preferred shares and the series B preferred shares of the Company previously held by such Holder; <u>provided</u> that "Registrable Securities" shall exclude (i) any Ordinary Shares without designation sold by a person to the public pursuant either to an effective registration statement under the Securities Act or Rule 144 under the Securities Act, and (ii) any Ordinary Shares without designation sold by a person in a transaction in which the applicable rights under clause 7 of the Shareholders' Agreement are not assigned to a Permitted Transferee in accordance with the terms of this Agreement or for which registration rights have terminated.

"**Registration**" means a registration with the SEC of the offer and sale to the public of Ordinary Shares under a Registration Statement. The terms "**Register,**" "**Registered**" and "**Registering**" shall have a correlative meaning.

"**Registration Statement**" means any registration statement of the Company that registers any of the Registrable Securities under the Securities Act, and all amendments and supplements to any such Registration Statement, including post-effective amendments, in each case including the Prospectus contained therein, all exhibits thereto and all material incorporated by reference therein.



"Rule 144" means Rule 144 promulgated under the Securities Act or any successor rule thereto.

**"S-3**" means such form under the Securities Act as in effect on the date of this Agreement or any successor registration form under the Securities Act subsequently adopted by the SEC that permits inclusion or incorporation of substantial information by reference to other documents filed by the Company with the SEC in a similar or comparable manner.

"SEC" means the United States Securities and Exchange Commission.

"Securities Act" the United States Securities Act of 1933, as amended.

"**Shareholders Agreement**" means the Shareholders Agreement dated as of April 12, 2021, among the Company and the Holders.

"**Subsidiary**", "**Subsidiary Undertaking**" and "**Parent Undertaking**" have the respective meanings set out in sections 1159 and 1162 of the Act;

"Holders' Counsel" has the meaning set forth in Section 6(a)(ii) hereof.

"**Takedown Notice**" has the meaning set forth in Section 3(a) hereof.

**"Transaction Documents**" means this Agreement and the other agreements, instruments and documents contemplated hereby and thereby, including each exhibit hereto and thereto.

"Trustees" in relation to a Holder means the trustee or the trustees of a Family Trust.

"**Underwritten Offering**" means a Registration in which securities of the Company (including as may be represented by Ordinary Shares) are sold to an underwriter or underwriters on a firm commitment basis for reoffering to the public in a widely distributed offering.

"\$" means the lawful currency of the United States of America.

1.2 <u>RULES OF CONSTRUCTION</u>. The term "**this Agreement**" means this registration rights agreement together with all schedules and exhibits hereto, as the same may from time to time be amended, modified, supplemented or restated in accordance with the terms hereof. The use in this Agreement of the term "including" means "including, without limitation." The words "herein," "hereof," "hereunder" and other words of similar import refer to this Agreement as a whole, including the schedules and exhibits, as the same may from time to time be amended, modified, supplemented or restated, and not to any particular section, subsection, paragraph, subparagraph or clause contained in this Agreement. All references to sections, schedules and exhibits mean the sections of this Agreement and the schedules and exhibits attached to this Agreement, except where otherwise stated. The title of and the section and paragraph headings in this Agreement are for convenience of reference only and shall not govern or affect the interpretation of any of the terms or provisions of this Agreement. Where specific language is used to clarify by example a general statement contained herein, such specific language shall not be deemed to modify, limit or restrict in any manner the construction of the general statement to which it relates. Unless expressly provided otherwise, the measure of a period of one month or year for purposes of this Agreement shall be that date of the following month or year corresponding to the starting date. For example, one month following February 18 is March 18, and one month following March 31 is May 1.

## Section 2. DEMAND REGISTRATION.

(a) At any time after one hundred eighty (180) days following the consummation of the IPO, for so long as any Registrable Securities are then outstanding, a Holder or Holders holding in the aggregate at least ten percent (10%) of the Registrable Securities then outstanding shall have the right to request that the Company file and cause to become effective a Registration Statement on Form F-1 with the SEC on the appropriate registration form for all or part of the Registrable Securities held by such Holder(s) once such Holder(s) are no longer subject to the lock-up applicable to them entered into in connection with the IPO (which may be due to the expiration or waiver of such lock-up with respect to such Registrable Securities) (a "Demand Notice") by delivering a written request to the Company specifying the number of Registrable Securities such Holder(s) wish to Register and the intended method of distribution thereof (a "Demand Registration" and the Holder(s) submitting such Demand Registration, the "Initiating Holder" or "Initiating Holders", collectively). The Company shall (i) within twenty (20) days of the receipt of such request, give written notice of such Demand Registration (the "Company Notice") to all Holders other than the Initiating Holder(s) (the "Eligible Holders"), (ii) as soon as practicable, and in any event within forty-five (45) days of receipt of such request, file a Registration Statement in respect of such Demand Registration, provided that all necessary documents for the registration can be obtained and prepared within such 45-day period; and (iii) use its reasonable best efforts to cause such Registration Statement to become effective as soon as practicable thereafter. The Company shall include in such Registration all Registrable Securities that the Eligible Holders request to be included within the twenty (20) days following their receipt of the Company Notice. If the method of distributing the offering is an Underwritten Offering, the Company shall include such information in the Company Notice, and the managing underwriter for such offering will be designated by the Board and shall reasonably acceptable to a majority in interest of the Initiating Holders.

(b) The Company shall not be obligated to file and use its reasonable best efforts to cause to become effective: (i) more than one Registration Statement initiated pursuant to Section 2(a); (ii) any Registration Statement pursuant to Section 2(a) (A) if the Company believes, in good faith, that it will file and cause to be effective a registration statement with respect to Primary Securities (other than on Form F-4 or Form S-8 promulgated under the Securities Act or any successor forms thereto) within 60 days of such a demand or (B) if a registration statement with respect to Primary Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities Act or any successor forms thereto) has been declared effective in the prior 180 days; provided that in connection with any such registration statement that has not been declared effective. The Registrable Securities requested to be Registered pursuant to Section 2(a) (including, for the avoidance of doubt, the Registrable Securities of Eligible Holders requested to be registered) must represent an aggregate price to the public of Registrable Securities that is reasonably expected to equal at least \$50,000,000; or (iii) a Registration Statement initiated pursuant to Section 2(a) if the Holders propose to dispose of Registrable Securities that may be immediately registered on Form F-3 pursuant to a request made pursuant to Section 3(a).

(c) With respect to any registration pursuant to Section 2(a), the Company may include in such registration any Primary Securities or Other Securities; <u>provided</u>, <u>however</u>, that if the managing underwriter or underwriters formally advise(s) the Company in writing and with sufficient explanation that the inclusion of all Registrable Securities, Primary Securities and Other Securities proposed to be included in such registration would interfere with the successful marketing (including, but not limited to, pricing) of all such securities, then the number of Registrable Securities, Primary Securities and Other Securities proposed to be included in the following order:

(i) first, the Registrable Securities held by the Holders requesting that their Registrable Securities be included in such registration pursuant to Section 2(a), <u>pro rata</u> based upon the number of Registrable Securities owned by each such Holder at the time of such registration; <u>provided</u>, <u>however</u>, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all Primary Securities and Other Securities are first entirely excluded from the underwriting, provided that for purposes of this Subsection 2(c) concerning apportionment, any selling Holder and all Affiliates of that selling Holder shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all persons included in such "selling Holder," as defined in this sentence;

- (ii) second, the Primary Securities; and
- (iii) third, the Other Securities.

To facilitate the allocation of Ordinary Shares in accordance with the above provisions, the Company or the underwriters may round the number of Shares allocated to any Holder to the nearest one hundred (100) shares.

(d) A requested registration under this Section 2 may be rescinded at any time prior to such registration being declared effective by the SEC by written notice to the Company from those Holders who initiated the request, at their discretion; <u>provided</u>, <u>however</u>, that such rescinded registration shall not count as a registration initiated pursuant to this Section 2 for purposes of Section 2(b)(i) above if (i) such request to rescind the registration is during a period the Company has deferred taking action pursuant to Section 2(b)(ii) above or Section 10 below or (ii) if the Company shall have been reimbursed (<u>pro rata</u> by the Holders requesting registration or in such other proportion as they may agree) for all reasonable and documented out-of-pocket expenses incurred by the Company in connection with such rescinded registration; <u>provided</u>, <u>further</u>, <u>however</u>, that if, at the time of such rescission, the Holders who initiated the request shall have learned of an event that is, or is reasonably likely to result in, a Material Adverse Change from that known to such Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to reimburse the Company for any out-of-pocket expenses incurred by the Company in connection with such rescinded registration and such rescinded registration shall not count as a registration initiated pursuant to this Section 2 for purposes of clause (i) of subsection (b).

(e) The Company shall be deemed to have effected a Registration for purposes of Section 2(a) only if the applicable Registration Statement (i) is declared effective by the SEC or becomes effective upon filing with the SEC, or (ii) is withdrawn at the request of the requesting Holders (other than as a result of a Material Adverse Change to the Company).

(f) In the event that the Company intends to effect a Registration for purposes of Section 2(a) by means of an Underwritten Offering, no Holder may include Registrable Securities in such Registration unless such Holder, subject to the limitations set forth in Section 9, (i) agrees to sell its Registrable Securities on the basis provided in the applicable underwriting arrangements; (ii) completes and executes all questionnaires, powers of attorney, indemnities, underwriting agreements and other documents reasonably required and in customary form under the terms of such underwriting arrangements and (iii) cooperates with the Company's reasonable and customary requests in connection with such Registration (it being understood that the Company's failure to perform its obligations hereunder, which failure is caused by such Holder's failure to cooperate, will not constitute a breach by the Company of this Agreement).

(f) For purposes of Section 2, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in Section 2(c), fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

## Section 3. REGISTRATIONS ON FORM S-3 OR F-3.

(a) Subject to Section 3(b), at any time after the date hereof when the Company is eligible to Register the applicable Registrable Securities on Form S-3 or Form F-3 (or a successor form), a Holder or Holders holding in the aggregate at least twenty percent (20%) of the Registrable Securities then outstanding is entitled to request a Demand Registration pursuant to which the Company shall, as soon as practicable and in any event within forty-five (45) days after the date such request is given, file and use its commercially reasonable efforts to cause to become effective as soon as practicable thereafter a registration statement on Form S-3 or Form F-3 (or a successor thereto) for all or part of the Registrable Securities on such Form S-3 or Form F-3 (or a successor thereto) pursuant to this Section 3 (a "Shelf Registration"). For the avoidance of doubt, the requirement that (i) the Company deliver a Company Notice within 10 days in connection with a Demand Registration and (ii) the right of Eligible Holders to request that their Registrable Securities be included in a Registration Statement filed in connection with a Demand Registration, each as set forth in Section 2(a), shall apply to a Demand Registration that is effected as a Shelf Registration. There shall be no limitations on the number of Shelf Registration or shelf takedowns pursuant to such Shelf Registrations; provided, however, that the Holders may not require the Company to effect more than two Shelf Registrations or cooperate in more than two shelf takedowns pursuant to this Section 3 in a 12-month period. If any Initiating Holder holds Registrable Securities included on a Shelf Registration, it shall have the right to request that the Company cooperate in a shelf takedown at any time, including an Underwritten Offering, by delivering a written request thereof to the Company specifying the kind and number of Registrable Securities such Initiating Holder wishes to include in the shelf takedown ("Takedown Notice"). The Company shall (i) within five (5) Business Days of the receipt of a Takedown Notice, give written notice of such Takedown Notice to all Holders of Registrable Securities included on such Shelf Registration (the "Company Takedown Notice"), and (ii) take all actions reasonably requested by the Initiating Holder who submitted the Takedown Notice, including the filing of a prospectus supplement and the other actions described in Section 6, in accordance with the intended method of distribution set forth in the Takedown Notice as expeditiously as practicable, and in any case, within 45 days of receipt of such Takedown Notice. If the shelf takedown is an Underwritten Offering, the Company shall include in such Underwritten Offering all Registrable Securities that the Holders of Registrable Securities included in the Registration Statement for such Shelf Registration request be included within the five Business Days following such Holders' receipt of the Company Takedown Notice. If the method of distributing the offering is an Underwritten Offering, the Company shall include such information in the Company Takedown Notice, and the managing underwriter for such offering will be designated by the Board and shall reasonably acceptable to a majority in interest of the Initiating Holders. The Registrable Securities requested to be included in a Shelf Registration or in a Takedown Notice must represent a price to the public of Registrable Securities that is reasonably expected to equal at least \$5,000,000. With respect to any Shelf Registration and subsequent shelf takedown pursuant to this Section 3(a), the Company may include in such Shelf Registration or shelf takedown any Primary Securities or Other Securities; provided, however, that if in connection with any shelf takedown the managing underwriter or underwriters formally advise(s) the Company in writing and with sufficient explanation that the inclusion of all Registrable Securities, Primary Securities and Other Securities proposed to be included in such shelf takedown would interfere with the successful marketing (including, but not limited to, pricing) of all such securities, then the number of Registrable Securities, Primary Securities and Other Securities proposed to be included in such shelf takedown shall be included in the following order:

(i) first, the Registrable Securities held by the Holders requesting that their Registrable Securities be included in such shelf takedown pursuant to Section 3(a), <u>pro rata</u> based upon the number of Registrable Securities owned by each such Holder and included in the Shelf Registration at the time of such shelf takedown; <u>provided</u>, <u>however</u>, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all Primary Securities and Other Securities are first entirely excluded from the underwriting, provided that for purposes of this Subsection 3(a) concerning apportionment, any selling Holder and all Affiliates of that selling Holder shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities included in the Shelf Registration owned by all persons included in such "selling Holder," as defined in this sentence;

(ii) second, the Primary Securities; and

(iii) third, the Other Securities.

To facilitate the allocation of Ordinary Shares in accordance with the above provisions, the Company or the underwriters may round the number of Shares allocated to any Holder to the nearest one hundred (100) shares.

(b) The Company shall not be obligated file and use its commercially reasonable efforts to cause to become effective any Shelf Registration Statement or to cooperate in any shelf takedown pursuant to Section 3(a) (i) if the Company believes, in good faith, that it will file and cause to be effective a registration statement with respect to Primary Securities (other than on Form F-4 or Form S-8 promulgated under the Securities Act or any successor forms thereto) within 30 days of such a demand or (ii) if a registration statement with respect to Primary Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities (other than on Form F-4 or Form S-8 promulgated under the Securities Act or any successor forms thereto) has been declared effective and not withdrawn in the prior 90 days; provided that in connection with any such registration statement that has not been declared effective, the Company is in good faith using commercially reasonable efforts to cause such registration statement to become effective.

(c) A requested registration under this Section 3 may be rescinded at any time prior to such registration being declared effective by the SEC by written notice to the Company from those Holders who initiated the request, at their discretion; <u>provided</u>, <u>however</u>, that such rescinded registration shall not count as a registration initiated pursuant to this Section 3 for purposes of this subsection (c) if (i) such request to rescind the registration is during a period the Company has deferred taking action pursuant to Section 3(b) above or Section 10 below or (ii) if the Company shall have been reimbursed (<u>pro rata</u> by the Holders requesting registration or in such other proportion as they may agree) for all reasonable and documented out-of-pocket expenses incurred by the Company in connection with such rescinded registration; <u>provided</u>, <u>further</u>, <u>however</u>, that if, at the time of such rescission, the Holders who initiated the request shall have learned of an event that is, or is reasonably likely to result in, a Material Adverse Change from that known to such Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to reimburse the Company for any out-of-pocket expenses incurred by the Company in connection with such rescinded registration and such rescinded registration shall not count as a registration initiated pursuant to this Section 3 for purposes of subsection (c).

(d) For purposes of Section 3, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in Section 3(a), fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

## Section 4. PIGGYBACK REGISTRATION.

(a) If the Company at any time proposes, for any reason, to file a Registration Statement on Form S-1, F-1, F-3 or S-3 promulgated under the Securities Act or any successor forms thereto, to register any Primary Securities or Other Securities under the Securities Act (other than (i) on Form F-4 or Form S-8 promulgated under the Securities Act or any successor forms thereto or (ii) to register any Primary Securities in connection with the IPO), it shall promptly give written notice to each holder of its intention so to register such Primary Securities or Other Securities and, upon the written request, given no later than twenty (20) days prior to such registration of Primary Securities or Other Securities, of any such Holder to include in such registration Registrable Securities owned by such Holder (which request shall specify the number of the Registrable Securities proposed to be included in such registration), the Company shall cause all such Registrable Securities to be included in such registration on the same terms and conditions as the securities otherwise being sold in such registration (such registration, a "**Piggyback Registration**"); provided, however, that if such registration is an Underwritten Offering and the managing underwriter formally advises the Company in writing and with sufficient explanation that the inclusion of all Primary Securities, Registrable Securities and Other Securities proposed to be registered by the Company, then the number of Primary Securities, Registrable Securities and Other Securities proposed to be included in such registration shall be included in the following order:

(i) first, Primary Securities;

(ii) second, Registrable Securities held by the Holders requesting that Registrable Securities be included in such registration, <u>pro rata</u> based upon the number of Registrable Securities owned by each such Holder at the time of such registration, provided that for purposes of this Section 4(a) concerning apportionment, any selling Holder and all Affiliates of that selling Holder shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all persons included in such "selling Holder," as defined in this sentence; <u>provided</u>, <u>however</u> that the Company and the underwriters in such a transaction may reduce the number of Registrable Securities proposed to be registered to a minimum of 20% of the total number of securities to be registered pursuant to any such Piggyback Registration; and

(iii) third, the Other Securities held by shareholders requesting that Other Securities be included in such registration, <u>pro</u> <u>rata</u> based on the number of Other Securities owned by each such shareholder at the time of such registration of Other Securities (or among such shareholders in such other proportion as they shall otherwise agree).

To facilitate the allocation of Ordinary Shares in accordance with the above provisions, the Company or the underwriters may round the number of Shares allocated to any Holder to the nearest one hundred (100) shares.

<u>provided, further, however</u>, that if, at any time after giving written notice of its intention to Register any securities pursuant to this Section 4 and prior to the effective date of the Registration Statement filed in connection with such Registration, the Company shall determine for any reason not to Register or to delay Registration of such securities, the Company may, at its election, give written notice of such determination to each such Holder and, thereupon, (i) in the case of a determination not to Register, shall be relieved of its obligation to Register any Registrable Securities in connection with such Registration and shall have no liability to any Holder in connection with such termination, and (ii) in the case of a determination to delay Registration, shall be permitted to delay Registering any Registrable Securities for the same period as the delay in Registering such other Registrable Securities.

(b) For the avoidance of doubt, no Registration effected under this Section 4 shall relieve the Company of its obligations to effect any Demand Registration under Section 2 or 3 (for the avoidance of doubt, subject to the limitations on registration set forth in Sections 2(b), 3(b) and 10 hereof). If the offering pursuant to a Registration Statement pursuant to this Section 4 is to be an Underwritten Offering, then each Holder making a request for a Piggyback Registration pursuant to this Section 4 shall, and the Company shall use reasonable best efforts to coordinate arrangements with the underwriters so that each such Holder may, participate in such Underwritten Offering. If the offering pursuant to such Registration Statement is to be on any other basis, then each Holder making a request for a Piggyback Registration pursuant to this Section 4 shall, and the Company shall use reasonable best efforts to coordinate arrangements so that each such Holder may, participate in such offering on such basis. If the Company files a Shelf Registration for its own account and/or for the account of any other Persons, the Company agrees that it shall use its reasonable best efforts to include in such Registration Statement such disclosures as may be required by Rule 430B under the Securities Act in order to ensure that the Holders may be added to such Shelf Registration at a later time through the filing of a Prospectus supplement rather than a posteffective amendment. Any such Holder may withdraw its request for inclusion at any time prior to executing the underwriting agreement, or if none, prior to the applicable registration statement or prospectus supplement, as applicable, being filed publicly with the SEC. For certainty, any such Holder who has withdrawn its request for inclusion shall nevertheless continue to have the right to include any Registrable Securities in any subsequent registration statement or registration statements as may be filed by the Company with respect to offerings of its securities, all upon the terms and conditions set forth herein.

## Section 5. RULE 144 REPORTING.

With a view to making available to the Holders the benefits of Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3 or Form F-3 (or a successor thereto), the Company shall use commercially reasonable efforts to:

(a) make and keep available adequate current public information, as those terms are understood and defined in Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;

(b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 or Form F-3 (or a successor thereto) (at any time after the Company so qualifies).

#### Section 6. PREPARATION AND FILING.

(a) If and whenever the Company is under an obligation pursuant to the provisions of this Agreement to effect the registration of Registrable Securities, the Company shall, as expeditiously as practicable, and to the fullest extent permitted by applicable law:

(i) prepare and file with the SEC a Registration Statement that registers such Registrable Securities and use its commercially reasonable efforts to cause such Registration Statement (or any post-effective amendment thereto) to become effective as promptly as practicable, and remain effective for a period of 120 days or until the distribution contemplated in such Registration Statement of all of such Registrable Securities have been completed (if earlier); provided, however, that: such 120 day period shall be extended for a period of time equal to the period a Holder refrains, at the request of an underwriter of the Company, from selling any securities included in such registration; provided, further, in the case of any registration of Registrable Securities on Form S-3 or Form F-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such Registration Statement shall be kept effective until the earlier of such time as all such Registrable Securities are sold or such time as all Registrable Securities registered on such Registration Statement are eligible to be sold pursuant to Rule 144 without limitation thereunder as to volume or manner of sale;

(ii) prepare and file with the SEC such amendments and supplements to such Registration Statement and the Prospectus used in connection therewith as may be necessary to keep such Registration Statement effective for the lesser of the period required pursuant to clause (i) of this Section 6(a) or until all of the Registrable Securities have been disposed of (if earlier) and to comply with the provisions of the Securities Act with respect to the sale or other disposition of such Registrable Securities;

(iii) furnish, in reasonable advance of any public filing, drafts of a Registration Statement that registers Registrable Securities, a Prospectus relating thereto and any amendments or supplements relating to such Registration Statement or Prospectus, to one special counsel selected by a Holder Majority (the "**Holders' Counsel**") copies of all such documents proposed to be filed and such other documents as the Holders may reasonably request, and consider in good faith any comments of any Holder selling Registrable Securities and their respective counsel on such documents;

(iv) use its commercially reasonable efforts to register or qualify, or obtain exemption from the registration or qualification requirements for, Registrable Securities under such other securities or blue sky laws of such jurisdictions as any seller of the Registrable Securities reasonably requests and take any and all other measures and do all other things which may be reasonably necessary or advisable to enable such seller of the Registrable Securities to consummate the disposition thereof in such jurisdictions; <u>provided</u>, <u>however</u>, that the Company will not be required to qualify generally to do business, subject itself to general taxation or consent to general service of process in any jurisdiction where it would not otherwise be required so to do but for this clause (iv), unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(v) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering

(vi) use its commercially reasonable efforts to cause all Registrable Securities covered by such registration statement on any United States national securities exchange on which any Ordinary Shares are listed;

(vii) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and request the registrar to provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(viii) promptly make available for inspection by any seller of the Registrable Securities, any underwriter participating in any disposition pursuant to such Registration Statement and any attorney, accountant or other representative retained by any such seller or underwriter, all pertinent financial, business and other records and documents as shall be reasonably necessary to enable them to conduct appropriate due diligence, and cause the Company's officers, directors and employees to supply all information reasonably requested by any such seller, underwriter, attorney, accountant or other representative in connection with such Registration Statement;

(xi) notify the Holders' Counsel promptly in writing (A) of any comments by the SEC with respect to such Registration Statement or Prospectus, or any request by the SEC for the amending or supplementing thereof or for additional information with respect thereto, (B) of the effectiveness of such Registration Statement or any amendment thereto or of the filing of such Prospectus or any supplement thereto and the issuance by the SEC of any stop order suspending the effectiveness of such Registration Statement or any amendment thereto or the initiation of any proceedings for that purpose and (C) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Registrable Securities for sale in any jurisdiction or the initiation or threatening of any proceeding for such purposes;

(x) notify each Holder, promptly after the Company receives notice thereof, of the time when such Registration Statement has been declared effective or a supplement to any Prospectus forming a part of such Registration Statement has been filed;

(xi) after such Registration Statement becomes effective, notify each Holder of any request by the SEC that the Company amend or supplement such registration statement or Prospectus;

(xii) use its commercially reasonable efforts to prevent the issuance of any stop order or other suspension of effectiveness of a Registration Statement, or the suspension of the qualification of any of the Registrable Securities for sale in any jurisdiction and, if such an order or suspension is issued, use its commercially reasonable efforts to obtain the withdrawal of such order or suspension at the earliest possible moment and to notify the Holders of the issuance of any such order and the resolution thereof or its receipt of actual notice of the initiation or threat of any proceeding for such purpose;

(xiii) furnish without charge to each seller of the Registrable Securities such number of copies of any Prospectus, including a preliminary Prospectus, in conformity with the requirements of the Securities Act, and such other documents as such seller of the Registrable Securities may reasonably request in order to facilitate the public sale or other disposition of the Registrable Securities;

(xiv) prepare, file and/or make available to the public and/or Holders any documents that comply with all relevant applicable regulations and that do not have any material omissions or misstatements;

(xv) notify on a timely basis each seller of the Registrable Securities at any time when a Prospectus relating to the Registrable Securities is required to be delivered under the Securities Act within the appropriate period mentioned in clause (i) of Section 6(a) of the happening of any event as a result of which the Prospectus included in such Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in light of the circumstances then existing, promptly prepare and file a supplement or amendment to such Prospectus as may be necessary so that, as supplemented or amended, such Prospectus shall cease to include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading in light of the circumstances in which they were made;

(xvi) use its commercially reasonable efforts to obtain from its independent certified public accountants a "comfort" letter in customary form and covering such matters of the type customarily covered by comfort letters;

(xvii) use its commercially reasonable efforts to provide (A) a legal opinion of the Company's outside counsel dated the effective date of such registration statement addressed to the Company and to each Holder selling Registrable Securities addressing the validity of the Registrable Securities being offered thereby, (B) on the date that such Registrable Securities are delivered to the underwriters for sale, if such Registrable Securities are being sold through underwriters, or, if such Registrable Securities are not being sold through underwriters, on the closing date of the applicable sale, (1) one or more legal opinions of the Company's outside counsel, dated such date, in form and substance as customarily given to underwriters in an underwritten public offering or, in the case of a non-underwritten offering, to the broker, placement agent or other agent of the Holders assisting in the sale of the Registrable Securities, in each case, addressed to the underwriters, if any, or, if requested, in the case of a non-underwritten offering, to the broker, placement agent of the Holders assisting in the sale of the Registrable Securities, in each case, addressed to the underwriters, if any, or, if requested, in the case of a non-underwritten offering, to the broker, placement agent of the Holders assisting in the sale of the Registrable Securities, in each case, addressed to the underwriters, if any, or, if requested, in the case of a non-underwritten offering, to the broker, placement agent of the Holders assisting in the sale of the Registrable Securities, in each case, addressed to the underwriters of the Company as may be requested by any Holder or any underwriter of such Registrable Securities;

(xviii) obtain the approval of all Governmental Authorities and self-regulatory bodies as may be necessary to effect the registration of the Registrable Securities and consummate the disposition of such Registrable Securities pursuant to the Registration Statement;

(xiv) make available one or more senior executives for participation in roadshows and other marketing activities in connection with any Underwritten Offering as the Company and the underwriters for such offering may reasonably agree, but in any event subject to the limitation that such officer's or officers' participation shall not negatively interfere with the Company's normal course of business; and

(xx) otherwise use its commercially reasonable efforts to take all other steps necessary to effect the registration of the Registrable Securities contemplated hereby.

(b) Each Holder of Registrable Securities that sells Registrable Securities pursuant to a registration under this Agreement agrees that during such time as such seller may be engaged in a distribution of the Registrable Securities, such seller shall comply with Regulation M promulgated under the Exchange Act and pursuant thereto it shall, among other things: (i) distribute the Registrable Securities under the Registration Statement solely in the manner described in the Registration Statement covering such Registrable Securities; and (ii) cease distribution of the Registrable Securities pursuant to such Registration Statement upon receipt of written notice from the Company that the Prospectus covering the Registrable Securities contains any untrue statement of a material fact or omits a material fact required to be stated therein or necessary to make the statements therein not misleading.

## Section 7. EXPENSES.

All expenses incurred by the Company in complying with Section 5, including all registration and filing fees (including all expenses incident to filing with FINRA), fees and expenses of complying with securities and blue sky laws, printing expenses, fees and expenses of the Company's counsel and accountants and fees, as well as the reasonable fees and expenses of Holders' Counsel not to exceed \$25,000 (the "Holders' Counsel Reimbursement Cap") shall be paid by the Company to the fullest extent permitted by applicable law, provided, however, that that the Company shall not be required to pay for any expenses of any registration pursuant to a Demand Registration pursuant to Section 2 if the Demand Notice is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Section 3 or Section 4, as the case may be. All expenses incurred by any Holder in connection with any sale of Registrable Securities under this Agreement, including share transfer taxes and the underwriting discounts and commissions and brokerage fees and expenses incurred in connection with the sale of Registrable Securities by any Holder, such Holder's pro rata share of the fees and expenses of Holders' Counsel in excess of the Holders' Counsel Reimbursement Cap and the out-of-pocket expenses incurred by the Company for which the Holders are responsible, if any, pursuant to Sections 2(d) and 3(c), shall be paid by such Holder, except that the Company shall pay the reasonable fees and expenses of Company's counsel in each relevant jurisdiction, to the extent required by the underwriters or the rules and regulations of the SEC to deliver an opinion or other documentation in connection with an offering, in any offerings pursuant to Section 2, 3 or 4.

#### Section 8. INDEMNIFICATION.

(a) In connection with any registration of Registrable Securities under the Securities Act pursuant to this Agreement, the Company will, and hereby agrees to, and hereby does, indemnify and hold harmless, to the fullest extent permitted by applicable law the seller of such Registrable Securities, and each other Person, if any, who controls such seller and each officer, director, partner, member and registered investment advisor or subadvisor of any of the foregoing Persons (each an "Indemnified Seller"), against any losses, claims, damages or liabilities, joint or several, to which any of the foregoing Persons become subject under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement under which Registrable Securities were registered, any preliminary Prospectus or final Prospectus contained therein, any amendment or supplement thereto, any free writing prospectus or any document incident to registration or qualification of Registrable Securities, including any marketing materials, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or, with respect to any Prospectus, necessary to make the statements therein in light of the circumstances under which they were made not misleading, and the Company shall promptly reimburse, to the fullest extent permitted by applicable law, such Indemnified Seller for any reasonable legal or other expenses actually incurred by any of them in connection with investigating or defending any such loss, claim, damage, liability or action; provided, however, that the Company shall not be liable to any such Indemnified Seller to the extent that any such loss, claim, damage or liability arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in said Registration Statement, preliminary Prospectus, amendment, supplement, free writing prospectus or document incident to registration or qualification of any Registrable Securities in reliance upon and in conformity with written information furnished to the Company by such Indemnified Seller, or a Person duly acting on its behalf, specifically for use in the preparation thereof, provided, further, that indemnification pursuant to this Section 8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld.



(b) In connection with any registration of Registrable Securities under the Securities Act pursuant to this Agreement, each seller of Registrable Securities shall, severally and not jointly, indemnify and hold harmless the Company, to the fullest extent permitted by applicable law, each other seller of Registrable Securities under such registration, each Person who controls any of the foregoing Persons within the meaning of the Securities Act and each officer, director, partner, and member of any of the foregoing Persons, against any losses, claims, damages or liabilities to which any of the foregoing Persons may become subject under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement under which Registrable Securities were registered, any preliminary Prospectus or final Prospectus contained therein, any amendment or supplement thereto, any free writing prospectus or any document incident to registration or qualification of any Registrable Securities, if such statement or omission was made in reliance upon and in conformity with written information furnished to the Company by such seller specifically for use in connection with the preparation of such Registration Statement, preliminary Prospectus, final Prospectus, amendment or supplement; provided, however, that the maximum amount of liability in respect of such indemnification shall be limited, in the case of each seller of Registrable Securities, to an amount equal, when combined with the amount of any contribution under Section 8(d) below, to the net proceeds (after the payment of underwriting discounts and commissions) actually received by such seller from the sale of Registrable Securities effected pursuant to such registration, provided, further, that indemnification pursuant to this Section 8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the sellers of Registrable Securities, which consent shall not be unreasonably withheld.

(c) Promptly after receipt by an indemnified party of notice of the commencement of any action involving a claim referred to in the preceding paragraphs of this Section 8, such indemnified party will, if a claim in respect thereof is made against an indemnifying party, give written notice to the latter of the commencement of such action; provided, however, that an indemnified party's failure to give such notice in a timely manner shall only relieve the indemnification obligations of an indemnifying party to the extent such indemnifying party is prejudiced or harmed by such failure. In case any such action is brought against an indemnified party, the indemnifying party will be entitled to participate in and to assume the defense thereof, jointly with any other indemnifying party similarly notified to the extent that it may wish, with counsel reasonably satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party shall not be responsible for any legal or other expenses subsequently incurred by the indemnified party in connection with the defense thereof; provided, however, that if any indemnified party shall have reasonably concluded that there may be one or more legal or equitable defenses available to such indemnified party that conflict with those available to the indemnifying party, the indemnifying party shall not have the right to assume the defense of such action on behalf of such indemnified party and such indemnifying party shall reimburse such indemnified party and any Person controlling such indemnified party for that portion of the reasonably incurred and documented fees and expenses of any one lead counsel retained by the indemnified party in connection with the matters covered by the indemnity agreement provided in this Section 8. If the defense is assumed by the indemnifying party, the indemnifying party shall not be liable for any settlement of any action, claim or proceeding effected by the indemnified party without its prior written consent; provided, however, that the indemnifying party shall not unreasonably withhold, delay or condition its consent. No indemnifying party shall, without the prior written consent of the indemnified party, consent to entry of any judgment or enter into any settlement or other compromise which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified party of a release from all liability in respect to such action, claim or proceeding.

(d) If, other than for the reason set forth in the proviso to the first sentence in Section 8(c), the indemnification provided for in this Section 8 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any loss, claim, damage or liability referred to herein, then the indemnifying party, in lieu of indemnifying such indemnified party hereunder, shall, to the fullest extent permitted by applicable law contribute to the amounts paid or payable by such indemnified party as a result of such loss, claim, damage or liability in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other hand in connection with the statements or omissions which resulted in such loss, claim, damage or liability as well as any other relevant equitable considerations; provided, however, that the maximum amount of liability in respect of such contribution shall be limited, in the case of each seller of Registrable Securities, when combined with the amount of any indemnification pursuant to Section 8(b) above, to an amount equal to the net proceeds (after the payment of underwriting discounts and commissions) actually received by such seller from the sale of Registrable Securities effected pursuant to such registration, except in the case of willful misconduct or fraud by such Holder. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 8(d) were determined by pro rata allocation or by any other method of allocation that does not take account of the equitable considerations referred to in this Section 8(d). Further, no Person guilty of fraudulent misrepresentation (within the meaning of Section 10(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

(e) The indemnification and contribution provided for under this Agreement will be in addition to any other rights to indemnification or contribution that any indemnified party may have pursuant to law or contract (and the Company and its subsidiaries shall be considered the indemnitors of first resort in all such circumstances to which this Section 8 applies) and will remain in full force and effect regardless of any investigation made by or on behalf of the indemnified party or any officer, director or controlling Person of such indemnified party.

## Section 9. UNDERWRITING AGREEMENT.

(a) Notwithstanding the provisions of Sections 7 and 8, to the extent that the Holders selling Registrable Securities in a proposed registration shall, to the fullest extent permitted by applicable law, enter into an underwriting or similar agreement, which agreement contains provisions covering one or more issues addressed in such Sections of this Agreement (it is understood and agreed that, for purposes of this clause (a), any indemnification provisions in any such underwriting or similar agreement that does not provide for the indemnification by the Company of a seller of Registrable Securities and other Persons or the indemnification by the seller of Registrable Securities of the Company and other Persons shall not supersede Section 8(a) or 8(b) above), the provisions contained in such Sections of this Agreement addressing such issue or issues shall be of no force or effect with respect to such registration, but this provision shall not apply to the Company if the Company is not a party to the underwriting or similar agreement.

(b) If any registration pursuant to Sections 2 or 3 is requested to be an Underwritten Offering, the Company shall negotiate in good faith to enter into a reasonable and customary underwriting agreement with the underwriters thereof. The Company shall, to the fullest extent permitted by applicable law, be entitled to receive indemnities from lead institutions, underwriters, dealer managers and similar securities industry professionals participating in the distribution, to the same extent as provided above with respect to information so furnished in writing by such Persons specifically for inclusion in any Prospectus or Registration Statement and to the extent customary given their role in such distribution.

(c) No Holder may participate in any registration hereunder that is underwritten unless such Holder agrees to (i) sell Registrable Securities proposed to be included therein on the basis provided in any underwriting arrangements acceptable to the Company and a Holder Majority and (ii) as expeditiously as possible, notify the Company of the occurrence of any event concerning such Holder as a result of which the Prospectus relating to such registration contains an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. Notwithstanding the foregoing, no Holder shall be required to make any representations or warranties to the Company or the underwriters (other than representations and warranties regarding (i) such Holder's ownership of Registrable Securities to be transferred free and clear of all liens, claims and encumbrances created by such Holder, (ii) such Holder's power and authority to effect such transfer, (iii) such matters pertaining to such Holder's compliance with securities laws as reasonably may be requested and (iv) such Holder's intended method of distribution) or to undertake any indemnification obligations to the Company with respect thereto, except as otherwise provided in Section 8 hereof.

# Section 10. SUSPENSION.

Anything contained in this Agreement to the contrary notwithstanding, the Company may by notice in writing to each Holder of Registrable Securities to which a Prospectus relates, delay, for up to 90 calendar days (the "**Delay/Suspension Period**"), the filing or the effectiveness of any Registration Statement filed (or to be filed) under Section 2, 3 or 4 or require such Holder to suspend, for up to the Delay/Suspension Period the use of any Prospectus included in a Registration Statement filed under Sections 2, 3 or 4 if at the time of such delay or suspension, the Company furnishes to the requesting Holders a certificate signed by the Company's chief executive officer stating that in the good faith judgment of the Board, the Board considers that it would be materially detrimental for the Registration Statement to become or remain effective because such action would: (a) interfere with a Material Transaction, (b) require premature disclosure of material information that the Company has a <u>bona fide</u> business purpose for preserving as confidential or (c) render the Company unable to comply with requirements under the Securities Act or the Exchange Act; and <u>provided</u>, that the Company may not invoke this right more than once in any 12 month period. The period during which such registration must remain effective shall be extended by a period equal to the Delay/Suspension Period. The Company may (but shall not be obligated to) withdraw the effectiveness of any Registration Statement subject to this provision.

# Section 11. INFORMATION BY HOLDER.

Each Holder of Registrable Securities to be included in any registration shall promptly furnish to the Company and the managing underwriter such customary written information regarding such Holder and the distribution proposed by such Holder as the Company or the managing underwriter may reasonably request in writing at least four Business Days prior to the first anticipated filing date of any Registration Statement or amendment thereto, or Prospectus, as applicable, and as shall be reasonably required in connection with any registration, qualification or compliance referred to in this Agreement. It is understood and agreed that the obligations of the Company under Sections 2, 3 and 4 with respect to any particular Holder are conditioned on the timely provisions of the foregoing information by each such Holder and, without limitation of the foregoing, will be conditioned on compliance by each such Holder with the following:

(a) each such Holder will, and will cause its Affiliates to, cooperate with the Company as reasonably requested by the Company in connection with the preparation of the applicable registration statement, and for so long as the Company is obligated to keep such registration statement effective, such Holder will and will cause its Affiliates to, provide to the Company, in writing and in a timely manner, for use in such registration statement (and expressly identified in writing as such), all customary information reasonably requested by the Company regarding itself and its Affiliates and such other customary information as may reasonably be requested by the Company or required by applicable law to enable the Company to prepare such registration statement and the related prospectus covering the Registrable Securities owned by such Holder and to maintain the currency and effectiveness thereof;

(b) each such Holder shall, and it shall cause its Affiliates to, supply to the Company, its representatives and agents in a timely manner any customary information regarding itself and its Affiliates as the Company, its representatives or agents may be reasonably requested to provide in connection with the offering or other distribution of Registrable Securities by such Holder; and

(c) on receipt of written notice from the Company upon the occurrence of any of the events specified in Section 10, or that requires the suspension by such Holder and its Affiliates of the distribution of any Registrable Securities owned by such Holder pursuant to applicable law, then such Holder shall, and it shall cause its Affiliates to, cease offering or distributing such Registrable Securities owned by such Holder until the offering and distribution of Registrable Securities owned by such Holder may recommence in accordance with the terms hereof and applicable law.

# Section 12. TERMINATION.

This Agreement shall terminate and be of no further force or effect upon the earliest to occur of: (i) when there shall not be any Registrable Securities, (ii) upon the occurrence of an Asset sale or a Deemed Liquidation Event in which the consideration received by the Investors in such Asset Sale or Deemed Liquidation Event is in the form of cash and/or publicly traded securities, or if the Investors receive registration rights from the acquiring company or other successor to the Company reasonably comparable to those set forth, (iii) all Registrable Securities are eligible to be sold pursuant to Rule 144 without limitation thereunder as to volume or manner of sale, or (iv) the date that is three years from the closing of the IPO; provided, however, that Sections 8 and 9 shall survive the termination of this Agreement. In addition, the Company shall have no obligation pursuant to this Agreement if all such securities proposed to be sold by such Holder are eligible to be sold pursuant to Rule 144 without limitation thereunder as to volume or manner of sale.

# Section 13. LIMITATION ON OTHER REGISTRATION RIGHTS.

The Company agrees that it shall not enter into any agreement with any holder or prospective holder of any securities of the Company that is not a party to this Agreement so long as any Registrable Securities are outstanding without the prior written consent of a Holder Majority (i) that would allow such holder or prospective holder to include such securities in any Demand Registration, Shelf Registration or Piggyback Registration unless, under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only on a pro rata basis or on a subordinate basis to the extent that their inclusion would not reduce the amount of the Registrable Securities of the Holders included therein or (ii) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder.

# Section 14. MISCELLANEOUS.

14.1 <u>NOTICES</u>. All notices or other communications required or permitted hereunder shall be given in writing and given by certified or registered mail, return receipt requested, nationally recognized overnight delivery service, such as Federal Express, facsimile or e-mail with confirmation of transmission by the transmitting equipment or personal delivery against receipt to the party to whom it is given, in each case, at such party's address, facsimile number or e-mail address set forth below or such other address, facsimile number or e-mail address as such party may hereafter specify by notice to the other parties hereto given in accordance herewith. Any such notice or other communication shall be deemed to have been given as of the date so personally delivered or transmitted by facsimile, e-mail or like transmission (or, if delivered or transmitted after normal business hours, on the next Business Day):

if to the Company, to:

GH Research PLC 28 Baggot Street Lower Dublin 2 D02 NX43 Ireland Telephone: +353 1 437 8443 e-mail: [•] Attention: [•]

with a copy to:

Davis Polk & Wardwell LLP 450 Lexington Avenue New York, NY 10017 Telephone: +1 (212) 450 4389 e-mail: yasin.keshvargar@davispolk.com Attention: Yasin Keshvargar

if to a Holder, to its address on a signature page hereto or, if none, in the books of the Company.

14.2 <u>ASSIGNMENT</u>. Except as otherwise expressly provided herein, this Agreement and all of the provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective heirs (in the case of any individual), successors and permitted assigns; <u>provided</u>, <u>however</u>, that neither this Agreement nor any of the rights, interests or obligations hereunder may be assigned by any Holder without the prior written consent of the Company; <u>provided</u>, <u>further</u>, <u>however</u>, that, notwithstanding the provisions of the foregoing proviso, to the extent that any Holder transfers any Registrable Securities to any Permitted Transferee in a transaction that does not violate the Constitution and is otherwise permissible under applicable law, such Holder may transfer and assign, without the prior written consent of the Company, its rights, interests or obligations hereunder with respect to such Registrable Securities hereunder to such Permitted Transferee.

Notwithstanding the foregoing, in each case, if such transfer is subject to covenants, agreements or other undertakings restricting transferability thereof, the registration rights provided for hereunder shall not be transferred in connection with such transfer unless such transferee complies with all such covenants, agreements and other undertakings.

Any purported assignment or delegation in violation of this Agreement shall be null and void <u>ab initio</u>.

14.3 <u>ENTIRE AGREEMENT</u>. This Agreement embodies the entire agreement and understanding of the parties and their respective Affiliates with respect to the transactions contemplated hereby and supersedes and cancels all prior written or oral commitments, arrangements or understandings with respect thereto. There are no restrictions, agreements, promises, warranties, covenants or undertakings with respect to the transactions contemplated hereby other than those expressly set forth in this Agreement.

14.4 <u>MODIFICATIONS, AMENDMENTS AND WAIVERS</u>. This Agreement may not be modified or amended except by an instrument or instruments in writing that expressly states that it is modifying or amending this Agreement and that is signed by the Company and a Holder Majority. Any party hereto (or a Holder Majority) may, only by an instrument in writing that expressly states that it is waiving compliance with this Agreement, waive compliance by any other party or parties hereto with any term or provision hereof on the part of such other party or parties hereto to be performed or complied with. Notwithstanding the foregoing, the terms and conditions of this Agreement as they apply to any Holder of the Company's securities or related parties may not be modified or amended in any manner that results in a non-<u>pro rata</u> material adverse effect on the rights of such Holder without the prior written consent of such Holder. No failure or delay of any party in exercising any right or remedy hereunder shall operate as a waiver thereof, nor will any single or partial exercise of any right or power, or any abandonment or discontinuance of steps to enforce such right or power, preclude any other or further exercise thereof or the exercise of any other right or power. The waiver by any party hereto of a breach of any term or provision hereof shall not be construed as a waiver of any subsequent breach. The rights and remedies of the parties hereunder are cumulative and are not exclusive of any rights or remedies that they would otherwise have hereunder.

14.5 <u>COUNTERPARTS</u>. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same agreement and each of which shall be deemed an original, and will become effective when one or more counterparts have been signed by a party and delivered to the other parties. Copies of executed counterparts transmitted by telecopy, telefax or other electronic transmission service shall be considered original executed counterparts for purposes of this Section 14.5, <u>provided</u> that receipt of copies of such counterparts is confirmed.

14.6 <u>GOVERNING LAW</u>. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK THAT APPLY TO CONTRACTS MADE AND PERFORMED ENTIRELY IN SUCH STATE.

14.7 <u>SUBMISSION TO JURISDICTION; WAIVER OF JURY TRIAL</u>. Each party to this Agreement, for itself and its Affiliates, hereby irrevocably and unconditionally:

(a) (i) agrees that any suit, action or proceeding instituted against it by any other party with respect to this Agreement may be instituted, and that any suit, action or proceeding by it against any other party with respect to this Agreement shall be instituted, only in the courts of the State of New York, located in New York County or the U.S. District Court for the Southern District of New York (and appellate courts from any of the foregoing) as the party instituting such suit, action or proceeding may in its sole discretion elect, (ii) consents and submits, for itself and its property, to the jurisdiction of such courts for the purpose of any such suit, action or proceeding instituted against it by any other party and (iii) agrees that a final judgment in any such suit, action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law;

(b) agrees that service of all writs, process and summonses in any suit, action or proceeding pursuant to Section 14.7(a) may be effected by the mailing of copies thereof by registered or certified mail, postage prepaid, to the Company or the applicable Holder, as the case may be, at the addresses for notices pursuant to Section 14.1 (with copies to such other Persons as specified therein); provided, however, that: (i) the Company agrees that the documents which start any proceedings and any other documents required to be served in relation to those proceedings may be served on it by being delivered to Cogency Global, Inc. at 122 East 42nd Street, 18th Floor New York, NY 10168 or, if different, its registered office for the time being, and if such Person is not or ceases to be effectively appointed to accept service of process on behalf of the Company, the Company shall, appoint a further person in New York to accept service of process on its behalf and, failing such appointment within 30 days, the Holders jointly shall be entitled to appoint such a person by written notice addressed to the Company and delivered to the Company; <u>provided</u>, <u>however</u>, that a copy of any such documents shall in each instance be delivered to Davis Polk & Wardwell LLP at the address provided in Section 14.1, above; and (ii) nothing contained in this Section 14.7 shall affect the right of the Company or any Holder to serve process in any other manner permitted by law;

(c) (i) waives any objection that it may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Agreement brought in any court specified in Section 14.7(a), (ii) waives any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum and (iii) agrees not to plead or claim either of the foregoing;

# (d) WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY OF ANY DISPUTE ARISING OUT OF OR RELATING TO THIS AGREEMENT AND AGREES THAT ANY SUCH DISPUTE SHALL BE TRIED BEFORE A JUDGE SITTING WITHOUT A JURY; and

(e) to the extent it has or hereafter may acquire any immunity from jurisdiction of any court or from any legal process (whether through service or notice, attachment prior to judgment, attachment in aid of execution, execution or otherwise) with respect to itself, or its property, hereby irrevocably waives such immunity in respect of its obligations with respect to this Agreement.

14.8 <u>SEVERABILITY</u>. To the fullest extent permissible under applicable law, the parties hereto hereby waive any provision of law which renders any provision of this Agreement invalid, illegal or unenforceable in any respect. Such parties further agree that any provision of this Agreement which, notwithstanding the preceding sentence, is rendered or held invalid, illegal or unenforceable in any respect in any jurisdiction shall be ineffective, but such ineffectiveness shall be limited as follows: (a) if such provision is rendered or held invalid, illegal or unenforceable in such jurisdiction only as to a particular Person or Persons or under any particular circumstance or circumstances, such provision shall be ineffective, but only in such jurisdiction and only with respect to such particular Person or Persons or under such particular circumstances, as the case may be; (b) without limitation of clause (a), such provision shall in any event be ineffective only as to such jurisdiction and only to the extent of such invalidity, illegality or unenforceability, and such invalidity, illegality or unenforceability in such jurisdiction shall not render invalid, illegal or unenforceable this Agreement or any of the remaining provisions hereof.

14.9 <u>NO THIRD PARTY BENEFICIARY</u>. Except for the Persons indemnified pursuant to Section 8(a) or 8(b), this Agreement is for the sole benefit of the parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement, except that any nominee holding Registrable Securities beneficially for an Investor may enforce this Agreement as if it were a Holder, <u>provided</u>, <u>however</u>, that (i) the name of any such nominee shall be previously disclosed to the Company in writing, and (ii) such nominee will have no investment discretion with respect to the Registrable Securities, and such Investor will remain the beneficial owner of the Registrable Securities for all purposes.

14.10 <u>NON-RECOURSE</u>. No past, present or future director, officer, employee, incorporator, member, manager, partner, shareholder, Affiliate, agent, attorney, consultant, representative or principal of the Company or any Affiliate of the Company shall have any liability for any liabilities of the Company under this Agreement or for any claim based on, in respect of, or by reason of, the transactions contemplated hereby.



14.11 <u>SPECIFIC PERFORMANCE</u>. Each of the parties hereto acknowledges that the others would not have an adequate remedy at law for money damages in the event that any of the covenants or agreements set forth in this Agreement were not performed in accordance with its terms and therefore, each of the parties agrees that the others shall be entitled to specific performance, injunctive and other equitable relief in addition to any other remedy to which it may be entitled at law or in equity (without the necessity of proving the inadequacy as a remedy of money damages or the posting of a bond).

14.12 <u>BUSINESS DAYS</u>. If any date provided for in this Agreement shall fall on a day that is not a Business Day, the date provided for shall be deemed to refer to the next Business Day.

14.13 <u>ELECTRONIC EXECUTION</u>. Delivery of an executed counterpart of a signature page of this Agreement and any other Transaction Document by telecopy or electronic format (including pdf) shall be effective as delivery of a manually executed counterpart of this Agreement or other Transaction Document.

14.14 <u>CAPTIONS</u>. Article and Section headings and the Table of Contents used herein are for convenience of reference only, are not part of this Agreement, and shall not affect the construction of, or be taken into consideration in interpreting, this Agreement.

[Signature Pages Follow]

The parties have executed and delivered this Registration Rights Agreement as of the date first written above.

# GH RESEARCH PLC

By:

Name: Title:

[Company Signature Page to Registration Rights Agreement]

# FLORIAN SCHÖNHARTING

By:

Name: Title:

[Shareholder Signature Page to Registration Rights Agreement]

# DUNE CAPITAL

By:

Name: Title:

[Shareholder Signature Page to Registration Rights Agreement]

# INWOOD SETTLEMENT

By:

Name: Title:

# BIOTECHNOLOGY VALUE FUND L.P.

By:

Name: Title:

# **BIOTECHNOLOGY VALUE FUND II, L.P.**

By:

Name: Title:

# BIOTECHNOLOGY VALUE TRADING FUND OS, L.P.

By:

Name: Title:

# RA CAPITAL HEALTHCARE FUND, L.P

By:

Name: Title:

# RA CAPITAL NEXUS FUND II, L.P

By:

Name: Title:

# RTW MASTER FUND, LTD.

By:

Name: Title:

# RTW INNOVATION MASTER FUND, LTD.

By:

Name: Title:

# **RTW VENTURE FUND LIMITED**

By:

Name: Title:

# THE BIOTECH GROWTH TRUST PLC

By:

Name: Title:

# CORMORANT PRIVATE HEALTHCARE FUND III, LP

By:

Name: Title:

# CORMORANT GLOBAL HEALTHCARE MASTER FUND, LP

By:

Name: Title:

# CRMA SPV, L.P.

By:

Name: Title:

# VENROCK HEALTHCARE CAPITAL PARTNERS EG, L.P.

By:

Name: Title:

# VENROCK HEALTHCARE CAPITAL PARTNERS III, L.P.

By:

Name: Title:

# VHCP CO-INVESTMENT HOLDINGS III, LLC

By:

Name: Title:

# BOXER CAPITAL, LLC

By:

Name: Title:

# MVA INVESTORS, LLC

By:

Name: Title:

# CITADEL MULTI- STRATEGY EQUITIES (IRELAND) DESIGNATED ACTIVITY COMPANY

By:

Name: Title:

# DEERFIELD PARTNERS, L.P.

By:

Name: Title:

# ACUTA CAPITAL FUND, LP

By:

Name: Title:

# ACUTA OPPORTUNITY FUND, LP

By:

Name: Title:

# VERITION MULTI- STRATEGY MASTER FUND LTD.

By:

Name: Title:

# GH CO-INVESTMENT LLC

By:

Name: Title:

# THEIS TERWEY

By:

Name: Title:

# MARKUS BREUER

By:

Name: Title:

# CLAUS BO SVENDSEN

By:

Name: Title:

# MAGNUS CLEMENSEN HALLE

By:

Name: Title:

# DUNE CAPITAL

By:

Name: Title:

# MICHAEL FORER

By:

Name: Title:

### Schedule A

Florian Schönharting Dune Capital Inwood Settlement Biotechnology Value Fund L.P. Biotechnology Value Fund II, L.P. Biotechnology Value Trading Fund OS, L.P. RA CAPITAL HEALTHCARE FUND, L.P RA Capital NEXUS Fund II, L.P RTW MASTER FUND, LTD. RTW INNOVATION MASTER FUND, LTD. **RTW VENTURE FUND LIMITED** The Biotech Growth Trust Plc Cormorant Private Healthcare Fund III, LP Cormorant Global Healthcare Master Fund, LP CRMA SPV, L.P. Venrock Healthcare Capital Partners EG, L.P. Venrock Healthcare Capital Partners III, L.P. VHCP Co-Investment Holdings III, LLC Boxer Capital, LLC MVA Investors, LLC Citadel Multi- Strategy Equities (Ireland) Designated Activity Company Deerfield Partners, L.P. Acuta Capital Fund, LP Acuta Opportunity Fund, LP Verition Multi- Strategy Master Fund Ltd. **GH** Co-Investment LLC Theis Terwey Markus Breuer Claus Bo Svendsen Magnus Clemensen Halle Dune Capital Michael Forer

Rules

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# **GH Research PLC Share Option Plan**

Board Approval on \*\* 2021

- The Company to confirm that no award recipients are US tax payers.
- Shares issued under the plan will need to be registered by the issuer on a Form S-8 with the SEC (which will need to be filed prior to the exercise of any options under the plan).
- To the extent there are US taxpayers being granted options, the Market Value of a Share needs to be determined in a manner consistent with Section 409A of the U.S. tax Code.

# **GH Research PLC**

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### **Share Option Plan**

### 1 Establishment and Purpose

The Plan was adopted by a resolution of the Board of Directors of the Company passed on **\*\*** 2021. The purpose of the Plan is to attract, retain, and motivate employees and directors of GH Research plc, its subsidiaries and affiliates, to provide for competitive compensation opportunities, to encourage long term service, to recognize individual contributions and reward achievement of performance goals, and to promote the creation of long term value for shareholders by aligning the interests of such persons with those of shareholders.

### 2 Definitions

2.1 In the Plan, the following expressions bear the following meanings and all references to statutes are to Irish statutes:

the Act means the Taxes Consolidation Act 1997;

Acquiring Company means a company that obtains Control of the Company in accordance with Rule 14;

Adoption Date means the date on which the Board adopts this Plan;

**Board** means the board of directors for the time being of the Company or the directors present at a duly convened meeting of the board of directors of the Company at which a quorum is present or a duly constituted committee of such board;

**Control** means control as defined in Section 11 of the Act;

**Committee** means the compensation committee;

**Company** means GH Research plc registered in Ireland under registration number 691405;

**Date of Grant** means the date on which the Grantor grants an Option to an Eligible Person, which date will be borne on the Option Agreement communicating the grant of an Option hereunder as provided in Rule 6.6;

**Director** means a director of the Company or any other member of the Group who is not an active employee of the Company or any other company that is a member of the Group;

**Eligible Person** means any person who is a Director or employee of a member of the Group;

**Exercise Price** means the price payable by the Participant to acquire Shares subject to an Option, subject to any adjustment under Rule 16;

**Grantor** means the Company;

**Group** means the Company and its Subsidiaries (and references to Group Company or member of the Group will be construed accordingly);

**Health Reasons** means reasons of ill health which as certified by a medical practitioner (approved by the Committee) compel a Participant to discontinue or alter the nature of his employment, office or occupation;

Market Value means the market price of a Share, determined in accordance with Rule 5.3;

**Option** means an award of a right under Rule 6 entitling the holder to purchase or subscribe for Shares;

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**Option Agreement** means any written agreement, contract, or other instrument or document setting out details of an Option in the form prescribed by Rule 6.6;

**Participant** means any Eligible Person who is for the time being the holder of part or all of an Option granted under the Plan;

**Performance Conditions** means the conditions attached to an Option as prescribed in an Option Agreement;

**Performance Period** means the period in respect of which any Performance Condition is to be satisfied as set out in an Option Agreement;

**Plan** means the Company's Share Option Plan consisting of these plan rules together with any sub-plans, as amended from time to time in accordance with the provisions in that regard herein contained;

**Share** means an ordinary share of US\$0.025 each in the capital for the time being of the Company;

**Stock Exchange** means any recognised stock exchange on which Shares are traded (including NASDAQ or any successor body) and, if more than one, such stock exchange as the Committee determines;

**Subsidiary** means any company which is, for the time being, a subsidiary of the Company within the meaning of Section 7 of the Companies Act, 2014;

**Termination of Service** means, unless otherwise defined in an applicable Option Agreement, that a Participant is no longer employed by, nor a director of, the Company or any other member of the Group, as the case may be. A Participant employed by a Subsidiary of the Company will also be deemed to incur a Termination of Service if the Subsidiary of the Company ceases to be such a Subsidiary, and the Participant does not immediately thereafter become an employee of the Company or another Subsidiary of the Company. Temporary absences from employment or service because of illness, vacation or leave of absence and transfers among the Company and its Subsidiaries will not be considered a Termination of Service.

- 2.2 Where the context permits the singular will include the plural and vice versa and the masculine will include the feminine. Headings are to be ignored in construing the terms of the Plan.
- 2.3 References to any statute will include any statutory modification, amendment or re-enactment thereof.

### 3 Administration

The Plan will be administered by the Committee, and the Committee will have full and final authority to exercise discretion and make any determinations under the Plan, subject to and consistent with the provisions of the Plan. Any action of the Committee with respect to the Plan will be final, conclusive, and binding on all persons, including the Company, Subsidiaries, Eligible Persons, any person claiming any rights under the Plan from or through any Eligible Person, and shareholders. By accepting an Option under the Plan, each Eligible Person accepts the authority and discretion of the Committee as set forth in, and exercised in accordance with, this Plan. The express grant of any specific power to the Committee, and the taking of any action by the Committee, will not be construed as limiting any power or authority of the Committee. The Committee may delegate to other members of the Board or officers or managers of the Company or any Subsidiary the authority, subject to such terms as the Committee will determine, to perform administrative functions and to perform such other functions as the Committee may determine, to the extent permitted by applicable law.

#### 4 Eligibility for participation

- 4.1 The Plan is available for Eligible Persons who will be nominated for that purpose by the Committee.
- 4.2 The Committee will at its absolute discretion determine whether or not a person is an Eligible Person and will nominate such persons for participation in the Plan.
- 4.3 No person will be entitled as of right to participate in the Plan and the decision as to who will have the opportunity of participating and the time and extent of his participation will, subject to the terms of the Plan, be made by the Committee in its absolute discretion.

#### 5 Limitation as to Participation

- 5.1 No Option will be capable of being granted under the Plan more than ten years after the Adoption Date.
- 5.2 If at the relevant time:
- 5.2.1 the Company's shares are listed on a Stock Exchange, the Market Value of a Share will be determined by the Committee by reference to the closing price of a Share on the dealing day immediately preceding the Date of Grant or, if the Committee so determines, by reference to an averaging of closing prices over a period of up to 5 dealing days immediately preceding the Date of Grant.
- 5.2.2 If the Company's shares are not listed on a Stock Exchange, the Market Value of a Share will be determined by the Company in accordance with section 548 of the Act.
- 5.2.3 For the avoidance of doubt an Option which has lapsed due to failure to meet applicable Performance Conditions set out in the relevant Option Agreement within the Performance Period (or similar criteria under any other share incentive plan adopted by the Company or its Subsidiaries) or otherwise will not be taken into account for the purpose of this Rule 5.

### 6 Grant of Options

- 6.1 The Grantor may at any time within ten years from the Adoption Date grant Options to one or more Participants.
- 6.2 Any Options granted under the Plan must be approved in advance by the Committee, which will have absolute discretion in respect of the approval of Options.
- 6.3 No consideration will be payable by a Participant in respect of the grant of an Option.
- 6.4 Each Option granted will be evidenced by an Option Agreement given to the Participant. Option Agreements may be in writing or in such other form as the Grantor determines and the Committee approves.
- 6.5 Each Option Agreement will specify:
- 6.5.1 the Date of Grant of the Option;
- 6.5.2 the number of Shares subject to the Option;
- 6.5.3 the Exercise Price;
- 6.5.4 the Performance Conditions and Performance Period, if any, to be satisfied as a condition of the vesting of the Option in accordance with the Option Agreement; and

- 6.5.5 such additional terms and conditions of the Option as the Committee may from time to time prescribe, including, but not limited to, conditions relating to transferability or forfeiture, exercisability and waiver or accelerations thereof, and waivers of performance conditions relating to an Option, based in each case on such considerations as the Committee will determine.
- 6.6 When issuing Option Agreements the Grantor will:
- 6.6.1 refer the Participant to all the provisions of the Plan; and
- 6.6.2 notify the Participant of his right to renounce the Option under Rule 6.8.
- 6.7 A Participant to whom an Option has been granted may by notice in writing given to the Grantor within 30 days from the Date of Grant renounce his rights thereunder and in such case the Option will be deemed never to have been granted.
- 6.8 An Option which has been granted to a Participant will be treated as having been accepted unless a renunciation in writing in respect thereof has been received by the Grantor from such person under Rule 6.8.
- 6.9 In the event that a Participant loses or misplaces his Option Agreement the Grantor may issue a replacement in writing or in such other form as the Grantor determines, upon application in writing by the Participant.

### 7 Limitations on Grant of Options

- 7.1 Until otherwise resolved by the Company in general meeting the number of Shares for which Options may be granted under the Plan on any day will not, when added to the number of Shares which immediately prior to that day will have been or remain to be issued or purchased on the market pursuant to Options granted during the period of ten years immediately preceding that day under the Plan or any other share incentive plan adopted by the Company or its Subsidiaries, exceed options over 1,202,734 of the number of Shares for the time being in issue.
- 7.2 Calculating limits

### For the avoidance of doubt:

- 7.2.1 Shares which will have been the subject of Options or rights which have lapsed will not be taken into account for the purposes of this Rule 7.
- 7.2.2 Shares acquired by a trustee of any employee's trust established by the Company in conjunction with this Plan, or acquired by any third party in conjunction with this Plan, which have been counted as issued or purchased on the market for the purposes of this Rule 7 will not also be counted when they are delivered to Participants to satisfy any Option.

### 8 Specific Terms of Options

- 8.1 Options may be granted on the terms and conditions set forth in this Rule 8. In addition, the Committee may impose on any Option or the vesting or exercise thereof, at the Date of Grant or thereafter (subject to Rule 6) such additional terms and conditions, not inconsistent with the provisions of the Plan, as the Committee will determine, including terms regarding forfeiture of Options or continued exercisability of Options in the event of Termination of Service of the Participant.
- 8.2 The Committee is authorised to grant Options to Eligible Persons on the following terms and conditions:

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- 8.2.1 **Exercise Price**: Unless the Committee determines otherwise at the Date of Grant, the Exercise Price per Share in relation to an Option will be not less than the Market Value of a Share on the day preceding the Date of Grant, PROVIDED THAT in all cases it will not be less than the nominal value of a Share.
- 8.2.2 **Option Term**: The term of each Option will be determined by the Committee; provided, however, that such term will not be longer than eight years from the Date of Grant of the Option.
- 8.2.3 **Time and Method of Exercise**: The Committee will determine at the Date of Grant or thereafter the time or times at which an Option may be exercised in whole or in part (including, without limitation, upon achievement of performance criteria if deemed appropriate by the Committee), the methods by which such Exercise Price may be paid or deemed to be paid (including, without limitation, broker-assisted exercise arrangements), the form of such payment (cash or Shares), and the methods by which Shares will be delivered or deemed to be delivered to Eligible Persons.

### 9 Non-transfer of Option

Subject to Rule 10.2, the Options will be personal to a Participant and the Participant will not assign, transfer, sell, mortgage, charge, pledge or encumber in any way whatsoever the Option or any of the Shares subject to the Option or any interest therein. An Option will lapse forthwith if the Participant purports to assign, transfer it etc. as aforesaid.

### 10 Termination of Service

10.1 General Rule

Except where the provisions of Rule 10.2 or Rule 10.3 or a Participant's Option Agreement apply to provide otherwise in relation to the whole or a specified part of the Option, on a Termination of Service:

- 10.1.1 any part of the Option that has not vested as at the date of cessation will lapse immediately on that date; and
- 10.1.2 any part of the Option that has vested as at the date of cessation will lapse in full 30 days after the date of cessation to the extent not exercised by such date.
- 10.2 Death of Participant

Except as otherwise provided in a Participant's Option Agreement, if a Participant dies the Committee may determine that either the whole or a specified percentage of any Option held by such Participant at the date of his death will be capable of vesting in, being exercised by or otherwise transferred to his legal personal representative on such terms and conditions as they may determine. Unless the Committee determines that an Option will be transferred to the legal personal representative of a Participant, the Option will lapse automatically on the death of the Participant.

- 10.3 Good Leaver
- 10.4 In the event of a Termination of Service on account of:
- 10.4.1 Health Reasons;
- 10.4.2 with respect to Participants who are employees only, redundancy (within the meaning of the Redundancy Payments Acts 1967 to 2014);
- 10.4.3 any form of voluntary severance by agreement with the Company;
- 10.4.4 the transfer of the undertaking or part-undertaking in which the Participant is employed to a person other than a member of the Group;



- 10.4.5 the company by which the Participant is employed ceasing to be under the Control of the Group; or
- 10.4.6 any other reasons in the absolute discretion of the Committee where exceptional circumstances have arisen,

the Committee may in its absolute discretion determine the extent to which the Performance Conditions attaching to the Option, if any, have been satisfied, having due regard to that part of the Performance Period to which the Performance Conditions set out in the relevant Option Agreement apply which has then expired, and the Committee will specify what proportionate part, if any, of the Shares under the Option will vest. If no determination is made by the Committee under this Rule 10.4 the Option will lapse.

### 11 Clawback

If at any time in the 12 month period after the Date of Grant of an Option,

- 11.1 the Company is required to restate its accounts to a material extent; or
- 11.2 the Committee becomes aware of any material wrongdoing on the part of the Participant that would have entitled the Company to terminate the Participant's employment in accordance with the Participant's contract of employment

then (notwithstanding that such Participant's employment may not have been, or may not be, cancelled as a result of the wrongdoing in question) the Committee will be entitled to recalculate (in good faith) the number of Shares subject to the Option to reflect the number of Shares that it would have granted to the Participant under the Option had these facts been known at the time the Option was granted.

### 12 Procedure on Exercise of Options

- 12.1 Unless otherwise provided in the Option Agreement, an Option will be exercised by a Participant as follows:
- 12.1.1 The Participant will give notice in writing to the Company (in such form as the Committee may require from time to time) setting out the number of Shares over which the Participant wishes to exercise the Option and delivering such further details as the Committee may require to the Company. No exercise will be permitted without (i) the prior consent of the Committee and (ii) unless the Committee is satisfied at the relevant time that the Option is exercisable and (if then applicable) that such exercise would not breach any applicable laws or regulations, including but not limited to any code regarding the regulation of dealings in shares in the Company by employees or directors.
- 12.1.2 The Participant will make payment to the Company of the Exercise Price and any taxation in accordance with clause 15 as is applicable, at the same time as notification of exercise, by way of:
- (a) delivery to the Company of cash in lawful currency or a bankers' draft in favour of the Company for the appropriate amount;
- (b) delivery to the Company (on a form prescribed by the Committee) of an irrevocable direction approved by the Committee to sell the Shares and to deliver all or part of the sales proceeds to the Company in payment of all or such portion of the Exercise Price and, if directed any Taxation as is applicable; or
- (c) payment by such other means as is consistent with applicable laws and regulations and agreed between the Company and the Participant.

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- 12.2 Subject to the Company receiving any regulatory or other consent which is necessary to enable it to allot the Shares pursuant to the exercise of the Option and subject to the terms of any such consent, as soon as practicable after the notice exercising the Option has been received by the Company, the Committee on behalf of the Company will allot to the Participant the Shares in respect of which the notice has taken effect.
- 12.3 Shares allotted and issued in satisfaction of the exercise of the Option will rank pari passu in all respects with the other shares of the same class in issue at the date of the allotment, except for any restriction or any rights determined by reference to a date before the date of allotment and will be subject to all relevant provisions of the constitution of the Company and the provisions of the Companies Act 2014.
- 12.4 Shares transferred in satisfaction of the exercise of the Option will be transferred free of any lien, charge or other security interest, and with all rights attaching to them, other than any restriction or rights determined by reference to a date before the date of transfer.
- 12.5 If the Shares are listed or traded on a Stock Exchange, the Company will apply to the appropriate body for any newly issued Shares allotted on exercise of the Option to be listed or admitted to trading on that exchange. For the avoidance of doubt, all certificates for Shares and/or other securities delivered under the Plan pursuant to the exercise of Options shall be subject to such stop transfer orders and other restrictions as the Committee may deem advisable under the Plan or the rules, regulations and other requirements of the Securities and Exchange Commission, any Stock Exchange upon which such Shares or other securities are then listed or traded, and any applicable securities laws, and the Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions.

### 13 Lapse of Options

- 13.1 An Option will lapse and be forfeited on the occurrence of the earliest of the following:
- 13.1.1 the eighth anniversary of the Date of Grant; or
- 13.1.2 the expiry of the Performance Period without the Performance Conditions having been satisfied or the date on which it becomes apparent that any such condition has become incapable of being satisfied; or
- 13.1.3 subject to Rule 10, the date on which a Termination of Service occurs; or
- 13.1.4 the date on which a resolution is passed for the winding up of the Company, or an order is made by any court for the compulsory winding-up of the Company; or
- 13.1.5 the date on which the Participant becomes bankrupt or does or attempts or omits to do anything as a result of which he is deprived of the beneficial ownership of the Shares.
- 13.2 Where a Participant is temporarily absent from his normal occupation with a member of the Group due to illness, vacation or other unpaid leave of absence, provided he returns to his normal occupation with a member of the Group within the agreed period an Option held by such Participant may be adjusted on a pro-rata basis in such proportion as the Committee may determine.

#### 14 Change in Control of the Company, Reconstruction & Winding Up

14.1 Change in Control

Subject to Rule 14.2 and except as otherwise provided in a Participant's Option Agreement, in the event that the Company is a party to a merger, sells all or substantially all of its assets, is subject to a takeover or other reorganisation including but not limited to a court-sanctioned compromise or arrangement, or the Committee considers this is about to occur, the Committee will be entitled (without the Participant's consent unless the Committee otherwise requires) at its discretion and notwithstanding anything herein contained (except the proviso below):

- 14.1.1 to accelerate vesting of Options in relation to the whole or a specified portion of the Shares to which such Options relate and within such time or times and subject to any other conditions or limitations as the Committee may at its discretion determine;
- 14.1.2 to agree that outstanding Options will be assumed or substituted by the surviving company or its parent (or the Acquiring Company or its parent where a takeover occurs) for Options which are equivalent to the Options originally granted under the Plan but which relate to shares in the surviving company or its parent (or the Acquiring Company or its parent where a takeover occurs);
- 14.1.3 to arrange for the continuation by the Company of outstanding Options (if the Company is a surviving company or an acquiring company in a takeover);
- 14.1.4 to make payment of a cash settlement to Participants equal, per Share, to the amount to be paid for one Share under the agreement of merger or takeover terms; or
- 14.1.5 to otherwise vary the outstanding Options on such conditions as the Committee may decide,

and the Committee may determine that any one or any combination of the above will occur. In the event that no such determination is made, or is not made in respect of a portion of an Option, the Option (or said portion of an Option) will lapse.

14.2 Re-organisation

Where the Company becomes a wholly-owned subsidiary of a holding company which will be owned in substantially the same proportions by the persons who held the Company's issued shares immediately before such transaction, the Committee may resolve with the agreement of the board of the holding company that Options granted hereunder will be treated as if they were in all respects options over shares in the holding company, but so that:

- 14.2.1 the new award will vest in the same manner as the Option;
- 14.2.2 the total market value of the new shares subject to the new award will, immediately after such reorganisation, be equal to the total market value of the Shares comprised in the Option immediately prior to such reorganisation;
- 14.2.3 the new award will be subject to performance conditions that will be at least equivalent (as determined by the Committee) to the Performance Conditions, if any, attaching to the Option;
- 14.2.4 the new shares will, at the date of any resolution by the Committee under this Rule 14.2, have the same rights attaching thereto as the Shares in the Company; and
- 14.2.5 the new award will be deemed to have been granted as at the Date of Grant of the Option.
- 14.3 Reconstruction and Winding-Up

In the event of:

14.3.1 any proposal for the reorganisation of the capital of the Company or for the reconstruction or amalgamation of the Company involving a material change in the nature of the Shares comprised in any Option (and for the purposes of this sub-rule the determination by the Committee of a material change in the nature of Shares in any particular case will be final and conclusive and will be communicated to each Participant in writing); or



14.3.2 the Company passing a resolution for its winding-up or an order being made for the compulsory winding-up of the Company (the passing of which resolution or the making of which order will be communicated by the Committee to each Participant in writing);

any Option held by a Participant may, at the discretion of the Committee, on the date that such proposal, reconstruction or amalgamation becomes unconditional or such winding-up takes effect or within such period before or after such date as the Committee may determine, vest on a pro-rata basis in such proportion as the Committee will determine and upon and subject to any conditions or limitations as the Committee may at its discretion determine. In the event that no such determination is made, or is not made in respect of a portion of an Option, the Option (or said portion of an Option) will lapse.

### 15 Tax Indemnity

- 15.1 The Participant will indemnify the Company (and, where relevant, any member of the Group) against any tax and social security contributions (or their equivalent in any jurisdiction) arising in respect of the Option which is a liability of the Participant but for which the Company or relevant member of the Group is required to account to a tax authority under the laws of any relevant territory. The Company may, to the extent permitted by law, recover the tax and social security from the Participant in such manner as the Committee think fit including (but without prejudice to the generality of the foregoing):
- 15.1.1 withholding Shares when the Option is exercised and selling same;
- 15.1.2 deducting the necessary amount from the Participant's remuneration; or
- 15.1.3 requiring the Participant to account directly to the Company or relevant tax authority for such tax and social security.
- 15.2 The Company will not be required to transfer any Shares to the Participant under the Plan until such obligations are satisfied.

### 16 Adjustments in the Event of Capitalisation and Rights Issues etc.

- 16.1 In the event of any alteration or re-organisation whatsoever taking place in the capital structure of the Company whether by way of capitalisation of profits or reserves, capital distribution, rights issue, consolidation or sub-division of Shares, the conversion of one class of share to another or reduction of capital or otherwise, the Committee may adjust any one or more of the following in such manner as is in the opinion of the Committee fair and reasonable:
- 16.1.1 the number of Shares subject to the Plan;
- 16.1.2 the definition of Share;
- 16.1.3 where the Option has been granted but no Shares have been delivered pursuant thereto, the number of Shares which may be delivered;
- 16.1.4 the Exercise Price per Share PROVIDED THAT this amount will not be reduced to less than the par value of a Share.
- 16.2 In the event of any alteration to the subject matter of an Option pursuant to the provisions of this Rule 16 the original Option Agreement will remain valid except to the extent modified by the alteration. The Grantor may issue revised Option Agreements or take whichever action it deems appropriate.

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### 17 Alterations

- 17.1 Except to the extent prohibited by applicable law and unless otherwise expressly provided in a Option Agreement, the Committee may at any time and from time to time by resolution and without further formality alter, amend or revoke any provisions of the Plan in such manner as the Committee may consider necessary or desirable (including any retrospective, prospective or coincident alteration, amendment or revocation) PROVIDED THAT that no alteration, amendment or revocation shall be made without (i) shareholder approval, if such approval is required by applicable law or the rules of the Stock Exchange, if any, on which the Shares are principally listed or traded or (ii) the consent of the affected Participant, if such action would materially adversely affect the rights of such Participant under any outstanding Option, except to the extent any such alteration, amendment or revocation is made to cause the Plan to comply with applicable law, Stock Exchange rules and regulations or accounting or tax rules and regulations, or to impose any clawback provisions on any Options in accordance with Rule 11.
- 17.2 The Committee may establish sub-plans in order to comply with, take advantage of or otherwise in connection with any taxation, legal, regulatory or other rule, law, guidelines, regulations or other provision of or prevailing in any jurisdiction in which the Plan is or is intended to be operated.

### 18 Share Capital

The Company will maintain sufficient authorised and unissued Shares to enable it to satisfy the Options in full.

### 19 Termination

- 19.1.1 The Plan may be terminated at any time by ordinary resolution of the Company or by resolution of the Board and will in any event terminate on the tenth anniversary of the Adoption Date.
- 19.1.2 As from the date of any termination of the Plan under Rule 19.1 the Company will not grant any further Options but no such termination will affect or modify any subsisting rights or obligations of the Participants in respect of any Options already granted and notwithstanding such termination the Company will continue to act, administer and manage the Plan in accordance with its terms.

### 20 Notices

20.1 Notices to a Participant

Any notification or other communication to be given to a Participant in connection with the Plan will be deemed to have been duly given if sent either by electronic mail to the Participant's electronic mail address at his place of work, or by post in a pre-paid cover to the Participant's postal address last known to the Company or if sent to him at his place of work, and will be deemed to have been duly given on the date of dispatch or posting. The Group will have no liability whatsoever to a Participant in respect of any notification, document, payment or other communication so given, sent or made, nor will the Group be concerned to see that any Participant actually receives the same.

20.2 Notices from a Participant

Any notification or other communication to be given to the Company or any of its Subsidiaries in connection with the Plan will be delivered by hand or sent by electronic mail, fax or post to the registered office of the Company or the relevant Subsidiary or such other electronic mail or postal address as may from time to time be notified to Participants, but will not in any event be duly given unless it is actually received.

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### 21 General

- 21.1 In the event of any dispute or disagreement as to the interpretation of the Plan, or as to any question or right arising from or related to the Plan, the decision of the Committee will be final and binding upon all persons.
- 21.2 Subject thereto the Committee's decision on any matter relating to the interpretation of the Plan and any other matter concerning the Plan will be final and binding.
- 21.3 The Company will bear the costs of setting up and administering the Plan.
- 21.4 Neither the Plan nor any action taken thereunder will be construed as giving any Eligible Person a right to be retained in the employment or service of the Group. No Eligible Person or Participant will be entitled to any compensation or damages whatsoever or howsoever described, by reason of any termination, withdrawal or alteration of rights or expectations under the Plan whether such compensation is claimed by way of damages for wrongful dismissal or other breach of contract or by way of compensation for loss of office or otherwise howsoever.
- 21.5 Any stamp duty chargeable on any instrument of the transfer entered into pursuant to each Option will be borne by the Company, or where relevant, any member of the Group in respect of Participants employed by it.
- 21.6 The Company will maintain all necessary books of account and records relating to the Plan.
- 21.7 The Committee will be entitled to authorise any person to execute on behalf of a Participant, at the request of the Participant, any document relating to the Plan, insofar as such document is required to be executed pursuant thereto.
- 21.8 The Participant will be responsible for obtaining any governmental or other official consent that may be required by any country or jurisdiction in order to permit the grant, vesting or exercise (as the case may be) of Options to or by him. The Company will not be responsible for any failure by the Participant to obtain any such consent or for any tax or other liability to which the Participant may become subject as a result of Options made hereunder.
- 21.9 The Plan will be governed by and construed and interpreted in accordance with Irish law and the Company and Participants agree to submit to the non-exclusive jurisdiction of the Courts of Ireland in relation to any claim, dispute or difference which may arise hereunder.

### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Registration Statement on Form F-1 of GH Research PLC of our report dated April 20, 2021 relating to the financial statements of GH Research Ireland Limited, which appears in this Registration Statement. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers SA Lausanne, Switzerland June 21, 2021