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

Washington, D.C. 20549

# FORM 6-K

#### REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of May 2022.

Commission File Number: 001-40530

# **GH Research PLC**

(Exact name of registrant as specified in its charter)

28 Baggot Street Lower Dublin 2 D02 NX43 Ireland (Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

On May 18, 2022, GH Research PLC (the "Company") reported its first quarter 2022 financial results and provided business updates.

On May 18, 2022, the Company made available an updated investor presentation on its website. A copy of the investor presentation is attached hereto as Exhibit 99.4.

The fact that this presentation is being made available and furnished herewith should not be deemed an admission as to the materiality of any information contained in the materials. The information contained in the presentation is being provided as of May 18, 2022 and the Company does not undertake any obligation to update the presentation in the future or to update forward-looking statements to reflect subsequent actual results.

## SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 18, 2022

## **GH Research PLC**

By: /s/ Julie Ryan

Name: Julie Ryan Title: Vice President, Finance

## EXHIBIT INDEX

Exhibit No. 99.1 99.2 99.3 99.4

Description Unaudited Condensed Consolidated Interim Financial Statements for the three months ended March 31, 2022 Management's Discussion and Analysis of Financial Condition and Results of Operations Press release dated May 18, 2022 Corporate Presentation for May 2022

# GH Research

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS FOR THE THREE MONTHS ENDED MARCH 31, 2022



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#### **GH RESEARCH PLC**

## Condensed consolidated interim statement of comprehensive income

		Three month March 3	
	Note	2022 \$'000	2021 \$'000
Operating expenses			
Research and development		(4,714)	(692)
General and administration		(3,292)	(448)
Loss from operations		(8,006)	(1,140)
Foreign currency translation differences		2,243	(9)
Loss before tax		(5,763)	(1,149)
Tax charge/(credit)			-
Loss for the period		(5,763)	(1,149)
Other comprehensive expense			
Items that may be reclassified to profit or loss			
Currency translation adjustment		(2,261)	(202)
Total comprehensive loss for the period		(8,024)	(1,351)
Attributable to owners:			
Loss for the period		(5,763)	(1,149)
Comprehensive loss for the period		(2,261)	(202)
Loss per share			
Basic and diluted loss per share (in USD)	10	(0.111)	(0.038)

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.



# Condensed consolidated interim statement of financial position

	Note	At March 31, 2022 \$'000	At December 31, 2021 \$'000
ASSETS			
Current assets			
Cash and cash equivalents		270,750	276,776
Other current assets	4	2,713	3,066
Total current assets		273,463	279,842
Non-current assets			
Property, plant and equipment		81	82
Total non-current assets		81	82
Total assets		273,544	279,924
LIABILITIES AND EQUITY			
Current liabilities			
Trade payables	5	1,545	883
Other current liabilities	6	2,521	1,866
Total current liabilities		4,066	2,749
Total liabilities		4,066	2,749
Equity attributable to owners			
Share capital		1,301	1,301
Additional paid-in capital		291,448	291,448
Other reserves		693	366
Foreign currency translation reserve		(8,164)	(5,903)
Accumulated deficit		(15,800)	(10,037)
Total equity		269,478	277,175
Total liabilities and equity		273,544	279,924

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.

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#### GH RESEARCH PLC

# Condensed consolidated interim statement of changes in equity

	Attributable to owners					
	Share capital \$'000	Additional paid- in capital \$'000	Other reserves \$'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	-	-	-	(202)	-	(202)
Total comprehensive loss for the period	-	-	-	(202)	(1,149)	(1,351)
At March 31, 2021	871	5,430	-	(2)	(1,984)	4,315
At January 1, 2022	1,301	291,448	366	(5,903)	(10,037)	277,175
Loss for the period	-	-	-	-	(5,763)	(5,763)
Translation adjustment	-	-	-	(2,261)	-	(2,261)
Total comprehensive loss for the period	-	-	-	(2,261)	(5,763)	(8,024)
Share-based compensation expense	-	-	327	-	-	327
Total transactions with owners	-	-	327	-	-	327
At March 31, 2022	1,301	291,448	693	(8,164)	(15,800)	269,478

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.



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#### GH RESEARCH PLC

## Condensed consolidated interim statement of cash flows

	Three month March 2	
	2022 \$'000	2021 \$'000
Cash flows from operating activities		
Loss for the period	(5,763)	(1,149)
Depreciation	11	1
Share-based compensation expense	327	-
Foreign exchange translation differences	(2,243)	-
Movement in working capital	1,667	61
Cash flows used in operating activities	(6,001)	(1,087)
Finance expense paid	-	-
Net cash used in operating activities	(6,001)	(1,087)
Cash flows used in investing activities		
Purchase of property, plant and equipment	(10)	(21)
Net decrease in cash	(6,011)	(1,108)
Cash at the beginning of the period	276,776	5,895
Impact of foreign exchange on cash	(15)	(211)
Cash at the end of the period	270,750	4,576

The accompanying notes are an integral part of these unaudited condensed consolidated interim financial statements.

# GH Research

#### GH RESEARCH PLC

#### NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

#### 1. Corporate information

GH Research PLC (the "Company") was incorporated on March 29, 2021. The registered office of the Company is located at 28 Baggot Street Lower, Dublin 2, Ireland.

The Company and its subsidiary, GH Research Ireland Limited, (together the "Group" or "GH Research") are a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. Its initial focus is on developing the novel and proprietary 5-MeO-DMT therapies for the treatment of patients with Treatment Resistant Depression, or TRD. Its portfolio currently includes GH001, a proprietary inhalable 5-MeO-DMT product candidate, GH002, a proprietary injectable 5-MeO-DMT product candidate, and GH003, a proprietary intranasal 5-MeO-DMT product candidate.

These unaudited condensed consolidated interim financial statements were presented to the board of directors and approved by them for issue on May 18, 2022.

#### 2. Basis of preparation, significant judgments, and accounting policies

#### **Basis of preparation**

#### **Compliance with International Financial Reporting Standards**

The unaudited condensed consolidated interim financial statements for the three months ended March 31, 2022 have been prepared in accordance with IAS 34 "Interim Financial Reporting". The unaudited condensed consolidated interim financial statements do not include all of the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements for the year ended December 31, 2021 which were prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). These unaudited condensed consolidated interim financial statements are presented in U.S. dollar ("USD" or "\$"), which is the Company's functional currency and the Group's presentation currency.

On May 27, 2021, as part of the 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, and as a result, GH Research Ireland Limited became a wholly-owned subsidiary of GH Research PLC. The financial information presented prior to the incorporation of GH Research PLC, including the comparative financial information for the period ending March 31, 2021, relate solely to GH Research Ireland Limited.

The financial information presented in this interim report does not represent full statutory accounts as defined by the Companies Act 2014. The statutory accounts of GH Research PLC for the year ended December 31, 2021, are expected to be filed with the Companies Registration Office by November 26, 2022.

#### 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, 2022, that are relevant to the Group and that have had any material impact in the interim period. New standards, amendments to standards and interpretations that are not yet effective, have been deemed by the Group as currently not relevant and are not listed here.

#### Going concern basis

GH Research is a clinical-stage biopharmaceutical company developing innovative therapeutics. The Group 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 Group's activities, generating negative cash flows from operating activities since formation.

Since its incorporation, the Group has funded its growth through capital increases. The Group has no bank loans or other debt outstanding as of March 31, 2022. As a result, the Group is not exposed to liquidity risk through requests for early repayment of loans.

As of March 31, 2022, the Group's cash amounted to \$270.8 million (December 31, 2021: \$276.8 million).



# NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

The board of directors believes that the Group 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 consolidated interim financial statements. The Group, therefore, continues to adopt the going concern basis in preparing its unaudited condensed consolidated interim financial statements.

#### Use of estimates and judgments

The preparation of the unaudited condensed consolidated 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 consolidated interim financial statements, the significant judgements made by management in applying the Group's accounting policies and the key sources of estimation uncertainty included those that applied to the consolidated financial statements for the year ended December 31, 2021.

#### Significant Accounting policies

The accounting policies, presentation and methods of computation followed in the unaudited condensed consolidated interim financial statements are consistent with those applied in the Group's most recent annual financial statements and have been applied consistently to all periods presented in the unaudited condensed consolidated interim financial statements.

#### Consolidation

The unaudited condensed consolidated interim financial statements incorporate the financial statements of the Company and its subsidiary, GH Research Ireland Limited. Subsidiaries are all entities over which the Company has control. Control is achieved when the Company has power over an entity, is exposed to or has rights to variable returns from its involvement with the entity and has the ability to affect returns through its power over the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Company. They are deconsolidated from the date that control ceases. All intercompany transactions have been eliminated.

#### Foreign currency translation

The functional currency of the Company is the U.S. dollar given it is listed on NASDAQ and its fundraising activities are in U.S. dollars. The functional currency of its subsidiary, GH Research Ireland Limited, is euro due to its expenses being mainly incurred in euro. These condensed consolidated interim financial statements are presented in U.S. dollar which is the Group's presentation currency.

Items included in the financial statement of the Company's subsidiary are measured using the currency of the primary economic environment in which the entity operates which is the euro.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are retranslated at the condensed consolidated interim statement of financial position date. The subsidiary is holding a U.S. cash balance and, as a result of the accounting treatment, when it is translated to euro in the subsidiary accounts, it results in a foreign currency translation difference in the income statement. On consolidation, the subsidiary's assets and liabilities in foreign currencies are retranslated and the resulting foreign currency difference goes through the foreign currency translation reserve.

#### Cash and cash equivalents

Cash represents cash held on bank current accounts and is carried at amortized cost. The Company's cash balance is maintained with well established, highly rated financial institutions. The majority of the cash balance is held in U.S. dollars.



# NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

#### 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
Office equipment	3 years
Medical equipment	2 years

#### Share-based compensation expense

The fair value of options granted under the share option plan is recognized as a share-based compensation expense with a corresponding increase in equity. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

#### Fair value estimation

At March 31, 2022, the carrying amount is a reasonable approximation of fair value for the following financial assets and liabilities:

- Cash and cash equivalents
- Other current assets
- Trade payables and other current liabilities

#### Current and deferred income tax

The tax expense for the financial period comprises current and deferred tax. Tax is recognized in the condensed consolidated 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 Group 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 financial period as the revenues and expenses to which they relate. Current income tax assets and liabilities for the current financial 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 chargeable.

The interim income tax expense is calculated based on the Company's estimate of the weighted average effective annual income tax rate expected for the full year. The current and deferred income tax charge was \$nil for the three months ended March 31, 2022 and 2021 which is in line with the Company's estimate for the full year.

#### Segment reporting

Management considers the Group to have only a single segment: Research and Development ("R&D"). This is consistent with the way that information is reported internally within the Group for the purpose of allocating resources and assessing performance.



# NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

#### 3. Expenses by nature

The following table provides the consolidated statement of comprehensive income classification of our expense by nature:

	Three mon Marc	
	2022 \$'000	2021 \$'000
External costs <sup>1</sup>	3,916	588
Employee expenses <sup>2</sup>	798	104
Total research and development expenses	4,714	692
External costs <sup>1</sup>	2,752	343
Employee expenses <sup>2</sup>	540	105
Total general and administrative expenses	3,292	448
Total operating expenses	8,006	1,140

<sup>1</sup>Includes depreciation expense.

<sup>2</sup>Includes share-based compensation expense.

The increase in research and development expenses in the three months ended 31 March 2022, is primarily due to increased external costs relating to our technical development and clinical trial activity and employee expenses relating to the hiring of personnel in our research and development team to support the requirements of increased clinical activities.

The increase in general and administrative expenses in the three months ended 31 March 2022, is primarily due to higher legal, professional and compliance fees as we continue to expand our business and increased employee expenses in our general and administrative functions to support our growth initiatives.

#### 4. Other current assets

Other current assets primarily represent prepayments and VAT receivable.

#### 5. Trade payables

Trade payables primarily represents amounts incurred for the provision of manufacturing, research and consulting services and legal and professional fees, which have been billed and are outstanding at the end of the period. Trade payables are due to be settled at different times within 12 months.

#### 6. Other current liabilities

Other current liabilities primarily represent amounts accrued for the provision of manufacturing, research and consulting services and legal and professional fees.

#### 7. Contingent liabilities

The Group has no material contingencies at the balance sheet date.

#### 8. Share based compensation

#### Share Options

In June 2021, the Company adopted a share option plan referred to herein as the Share Option Plan under which grants of options are made to eligible participants. The Company has reserved 1,202,734 ordinary shares for future issuance under the Share Option Plan, which include ordinary shares pursuant to share-based equity awards issued to date. As of March 31, 2022, the Company has 972,175 ordinary shares available for the future issuance of share-based equity awards.



# NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

Under the Share Option Plan, any director (including directors and directors of any other member of the Group who are not active employees of the Company or any other company that is a member of the Group) or employee of a member of the group or key consultant is eligible to be nominated by the remuneration committee to receive options.

The awards generally vest 25% on the first anniversary of the date of grant, and thereafter evenly on a monthly basis over the subsequent three years in addition to a 2 year service condition. The contractual term (expiration) of each share option award granted is eight years from the date of grant.

Under the grant, the options may be settled only in ordinary shares of the Company. Therefore, the grants of share options under the Share Option Plan have been accounted for as equity-settled under IFRS 2. As such, the Company records a charge for the vested portion of award grants and for partially earned but non-vested portions of award grants. This results in a front-loaded charge to the Company's unaudited condensed consolidated interim statement of comprehensive income and a corresponding increase to Other Reserves within equity on the unaudited condensed consolidated interim statement of financial position.

During the three months ended March 31, 2022, the Company granted the option to purchase 73,372 ordinary shares to employees which were in line with the general terms of the Share Option Plan as described above.

The following table summarizes the share option awards outstanding as of March 31, 2022:

			Weighted
	Average exercise		average
	price per share		remaining
	in	Number of	life
	USD	awards	in years
At December 31, 2021	15.80	157,187	7.62
Granted	20.26	73,372	7.80
At March 31, 2022	18.50	230,559	7.51

None of the awards outstanding as of March 31, 2022 were exercisable and they expire through 2030. As of March 31, 2022, 7,296 awards are vested and generally subject to a 2 year service condition.

The weighted average grant date fair value of awards granted during the three months ended March 31, 2022 was \$13.13 per award.

The fair values of the options granted were determined on the date of the grant using the Black-Scholes option-pricing model. The Company used an independent valuation firm to assist in calculating the fair value of the award grants per participant.

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# NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)

The fair values of the options granted during the three months ended March 31, 2022 were determined on the date of the grant using the following assumptions:

	Three months ended
	March 31, 2022
Share price, in USD	15.71-18.32
Strike price, in USD (weighted average)	20.26
Expected volatility	89% - 90%
Award life (weighted average)	6
Risk-free interest rate	1.74% - 1.87%

The expected volatility was based on selected volatility determined by median values observed among other comparable public companies.

The award life is based on the time interval between the date of grant and the date during the eight-year life after which, when making the grant, the Company expected on average that participants would exercise their options.

As of March 31, 2022, the amount recorded as an increase to Other Reserves within equity on the unaudited condensed consolidated interim statement of financial position of the Share Option Plan was \$693 thousand. The amount of expense for all awards recognized for services received during the three months ended March 31, 2022 was \$327 thousand (2021: \$nil).

#### 9. Related party disclosures

There have been no transactions in the three months ended March 31, 2022 and ended March 31, 2021 with related parties that had a material effect on the financial position or performance of the Group.

#### 10. Loss per share

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:

	Three mont March	
	2022	2021
Loss attributable to shareholders (in \$'000)	(5,763)	(1,149)
Weighted average number of shares in issue <sup>(1)</sup>	52,020,849	30,369,232
Basic and diluted loss per share (in USD) <sup>(2)</sup>	(0.111)	(0.038)

<sup>(1)</sup> Share data for the period ended March 31, 2021 has been revised to give effect to the share conversion and share consolidation. This is explained further in the most recently filed annual report on Form 20-F for the year-ended December 31, 2021.

<sup>(2)</sup> Ordinary and preferred shares as of March 31, 2021 have been treated as a single class for the purpose of calculating loss per share as they contractually shared equally in the profits and losses of the entity.

For the three months ended March 31, 2022 and 2021, basic and diluted loss per share are calculated on the weighted average number of shares issued and outstanding and exclude shares to be issued under the Share Option Plan, as the effect of including those shares would be anti-dilutive.

#### 11. Events after the reporting date

There were no events after the reporting date requiring disclosure in these condensed consolidated interim financial statements.

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

This management's discussion and analysis is designed to provide you with a narrative explanation of our financial condition and results of operations. You should read this discussion and analysis in conjunction with our unaudited condensed consolidated interim financial statements, including the notes thereto, as of and for the three months ended March 31, 2022. You should also read this discussion and analysis in conjunction with our audited financial statements, including the notes thereto, and the section in our annual report on Form 20-F for the year ended December 31, 2021 titled "Item 3. Key Information – D. Risk Factors".

Our unaudited condensed consolidated interim financial statements were prepared in accordance with International Accounting Standard 34, Interim Financial Reporting. The terms "dollar," "USD" or "\$" refer to U.S. dollars. We have made rounding adjustments to some of the figures included in this discussion. Accordingly, any numerical discrepancies in any table between totals and sums of the amounts listed are due to rounding.

Unless otherwise indicated or the context otherwise requires, all references in this discussion and analysis to "GH Research" or "GH," the "Company," "we," "our," "ours," "us" or similar terms refer to GH Research PLC and its consolidated subsidiary.

#### 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, and GH003, our proprietary intranasal 5-MeO-DMT product candidate. We have completed two Phase 1 healthy volunteer clinical trials (GH001-HV-101 and GH001-HV-103), 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. We have also completed a Phase 1/2 clinical trial in patients with TRD (GH001-TRD-102). Based on observed clinical activity in the Phase 1 part of the clinical trial, 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 ultra-rapid onset of psychoactive effects (commonly within seconds) and an intense and short-lived (commonly five to 30 minutes) initial psychoactive experience. Based on observed clinical activity in the Phase 2 part of the trial, we believe that administration of 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 dose of GH001.

We have incurred recurring operating losses since inception, including net losses of \$5.8 million, \$9.2 million and \$0.4 million for the three months ended March 31, 2022 and the years ended December 31, 2021 and 2020, respectively. As of March 31, 2022, we had an accumulated deficit of \$15.8 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, our expenditures on other research and development activities and based on foreign currency translation differences. 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, GH002, our injectable 5-MeO-DMT product candidate, and GH003, our intranasal 5-MeO-DMT product candidate for our initial indications and any additional indications;
- continue both the technical development and expansion of our external manufacturing capabilities for our current product candidates GH001, GH002 and GH003 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, GH002 and GH003 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.

#### **Business Updates**

#### GH001 for the treatment of TRD

We recently announced our plan to submit clinical trial applications in several European countries for a multi-center, randomized, controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201) in the third quarter of 2022. Preparation of those submissions is ongoing.

On May 11, 2022, we held a pre-IND meeting with the U.S. Food and Drug Administration (FDA), the planning of which had been previously announced. In preparation for this meeting, we had provided the FDA with a detailed description of the development status and plans for GH001 including clinical, nonclinical, and chemistry, manufacturing and controls activities. The outcome of the meeting was positive and positions us for an anticipated IND submission not later than the first quarter of 2023. The planned IND-opening study is a Phase 1 imaging study in patients with TRD designed to further elucidate the mechanism of action of GH001 (GH001-TRD-104).

The data from our previously reported Phase 1/2 clinical trial of GH001 in patients with TRD (GH001-TRD-102) has been recently accepted for oral presentation at the American Society of Clinical Psychopharmacology 2022 Annual Meeting in Scottsdale, AZ, and will be presented during the Pharmaceutical Pipelines session on May 31, 2022. The primary endpoint of the Phase 2 part of the trial was met with 7 of 8 patients (87.5%) in remission (Montgomery–Asberg Depression Rating Scale (MADRS)  $\leq$ 10) at day 7 after dosing (p<0.0001). Patients followed a proprietary individualized dosing regimen with up to three increasing GH001 doses (6 mg, 12 mg and 18 mg) on a single day. No serious and no severe adverse events, no clinically significant changes in any of the safety laboratory analyses, vital signs, psychiatric safety assessments or measures of cognitive function and no signal for suicidal ideation or behavior were observed.

#### GH001 for the treatment of BDII and PPD

We recently submitted additional clinical trial applications in further European countries for the planned Phase 2a proof-of-concept clinical trial of GH001 for the treatment of patients with bipolar II disorder and a current depressive episode (BDII) (GH001-BD-202) and for the planned Phase 2a proof-of-concept clinical trial of GH001 for the treatment of patients with postpartum depression (PPD) (GH001-PPD-203). Pending regulatory clearance, we expect to initiate these trials in the third quarter of 2022.

#### **COVID-19 Business Update**

With the global spread of the COVID-19 pandemic ongoing, 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 non-essential 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.

# **Results of Operations**

# Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31				Change
	 2022		2021		
Operating Expenses:					
Research and development	\$ (4,714)	\$	(692)	\$	(4,022)
General and administrative	(3,292)		(448)		(2,844)
Loss from operations	(8,006)		(1,140)		(6,866)
Foreign currency translation differences	2,243		(9)		2,252
Loss for the period	\$ (5,763)	\$	(1,149)	\$	(4,614)

#### Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31				Change	
	2022		2021			
External costs <sup>1</sup>	\$ (3,916)	\$	(588)	\$	(3,328)	
Employee expenses <sup>2</sup>	(798)		(104)		(694)	
Research and development	\$ (4,714)	\$	(692)	\$	(4,022)	

<sup>1</sup> Includes depreciation expense.

#### <sup>2</sup> Includes share-based compensation expense.

Research and development expenses increased by \$4.0 million from \$0.7 million for the three months ended March 31, 2021, to \$4.7 million for the three months ended March 31, 2022. The increase was primarily due to increased external costs relating to our technical development 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. The research and development expenses in the three months ended March 31, 2022 and March 31, 2021 have been substantially incurred pursuant to the development of GH001.

#### General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2022 and 2021 (in thousands):

	 Three Months Ended March 31				Change	
	 2022		2021			
External costs <sup>1</sup>	\$ (2,752)	\$	(343)	\$	(2,409)	
Employee expenses <sup>2</sup>	(540)		(105)		(435)	
General and administrative	\$ (3,292)	\$	(448)	\$	(2,844)	

1 Includes depreciation expense.

<sup>2</sup> Includes share-based compensation expense.

General and administrative expenses increased by \$2.8 million from \$0.4 million for the three months ended March 31, 2021, to \$3.3 million for the three months ended March 31, 2022. The increase was primarily due to higher legal, professional and compliance fees as we continue to expand our business and increased employee expenses in our general and administrative functions to support our growth initiatives.

#### Foreign currency translation differences

Foreign currency translation gains increased to \$2.2 million for the three months ended March 31, 2022, from a loss of \$9 thousand for the three months ended March 31, 2021. This increase was primarily due to the translation of the U.S. dollar cash balance into euro in the accounts of our subsidiary, GH Research Ireland Limited, which uses the euro as its functional currency. This resulted in a foreign currency translation gain.

#### 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 through equity financings, including our initial public offering. As of March 31, 2022, we had cash of \$270.8 million.

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, 2022 and 2021 (in thousands):

	Three Months Ended March 31			Change	
	 2022		2021		
Net cash flows used in operating activities	\$ (6,001)	\$	(1,087)	\$	(4,914)
Net cash flows used in investing activities	(10)		(21)		11
Net decrease in cash	\$ (6,011)	\$	(1,108)	\$	(4,903)

#### Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities increased by \$4.9 million to \$6.0 million for the three months ended March 31, 2022 from \$1.1 million for the three months ended March 31, 2021. The increase was primarily due to a \$6.9 million increase in loss from operations which has been partially offset by an increase in share-based compensation expense of \$0.3 million and an increase of \$1.6 million related to changes in the components in working capital, including a \$1.3 million increase in the movement in other current assets.

#### Net Cash Flows Used in Investing Activities

Net cash flows used in investing activities decreased to \$10 thousand for the three months ended March 31, 2022 from \$21 thousand for the three months ended March 31, 2021. The decrease was due to fewer purchases of property, plant and equipment.

#### 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, we expect to continue to incur additional costs associated with 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. 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. Our future capital requirements will depend on many factors, which are outlined in our annual report on Form 20-F for the year ended December 31, 2021 and this discussion and analysis.

#### **Critical Accounting Estimates**

There have been no material changes to the significant accounting policies and significant judgments and estimates from those referred to in the section in our annual report on Form 20-F for the year ended December 31, 2021 titled "Item 5. Operating and Financial Review and Prospects—E. Critical Accounting Estimates".

#### **Emerging Growth Company Status**

On April 5, 2012, the Jumpstart our Business Act of 2021 ("JOBS Act") was enacted. As an emerging growth company, or EGC, under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. This provision allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. 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.

As an EGC, we also rely on other exemptions and reduced reporting requirements under the JOBS Act including exemptions from (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 completion of our initial public 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 unaudited condensed consolidated interim financial statements, there are no standards issued but not yet adopted which are expected to have a material impact on our unaudited condensed consolidated interim financial statements.

#### **Cautionary Statement Regarding Forward-Looking Statements**

This discussion contains statements that are, or may deemed to be, forward-looking statements. All statements other than statements of historical fact included in this discussion, 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 discussion 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 discussion 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 in our annual report on Form 20-F for the year ended December 31, 2021 titled "Item 3. Key Information – D. Risk Factors". These risks and uncertainties include, among others, factors relating to:

- · the commencement, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- the timing, progress and results of developing and conducting clinical trials for our GH001, GH002 and GH003 product candidates and the medical devices required to deliver these
  product candidates for our initial and any 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, GH002 and GH003 product candidates as well as the
  medical devices required to deliver these product candidates;
- our reliance on the success of our GH001, GH002 and GH003 product candidates;
- the timing, scope or likelihood of regulatory filings and approvals by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other comparable foreign regulatory authorities, for our GH001, GH002 and GH003 product candidates and our initial and any additional indications;
- our expectations regarding the size of the eligible patient populations for our GH001, GH002 and GH003 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, GH002 and GH003 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, GH002 and GH003 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, GH002 and GH003 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, GH002 and GH003 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, GH002 and GH003 product candidates and our approach generally;
- our expectations around regulatory development paths and with respect to Controlled Substances Act classification;
- 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, GH002 and GH003 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;
- the amount of time that our existing cash 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 EGC under the JOBS Act and as a foreign private issuer; and
- the future trading price of the ordinary shares and impact of securities analysts' reports on these prices.

These forward-looking statements speak only as of the date of this discussion and are subject to a number of risks, uncertainties and assumptions described under the section in our annual report on Form 20-F for the year ended December 31, 2021 titled "Item 3. Key Information – D. Risk Factors" and elsewhere in this discussion. 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 forwardlooking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forwardlooking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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 discussion, 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.





#### GH Research Reports First Quarter 2022 Financial Results and Provides Business Updates

**Dublin, Ireland, May 18, 2022** – GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported financial results for the first quarter ended March 31, 2022 and gave updates on its business.

#### First Quarter 2022 Financial Highlights

#### Cash position

Cash was \$270.8 million as of March 31, 2022, compared to \$276.8 million as of December 31, 2021. We believe that our existing cash will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2025.

#### Research and development expenses

R&D expenses were \$4.7 million for the quarter ended March 31, 2022, compared to \$692 thousand for the same quarter in 2021. The increase was primarily due to increased activities relating to our technical development and clinical trials and increases in employee expenses to support these activities.

#### General and administrative expenses

G&A expenses were \$3.3 million for the quarter ended March 31, 2022, compared to \$448 thousand for the same quarter in 2021. The increase was primarily due to higher legal, professional and compliance fees, as well as increased employee expenses.

#### Net loss

Net loss was \$5.8 million, or \$0.111 loss per share, for the quarter ended March 31, 2022, compared to \$1.1 million, or \$0.038 loss per share, for the same quarter in 2021.

#### **Business Updates**

#### GH001 for the treatment of TRD

GH001 is our proprietary inhalable 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) product candidate.

We recently announced our plan to submit clinical trial applications in several European countries for a multi-center, randomized, controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201) in the third quarter of 2022. Preparation of those submissions is ongoing.

On May 11, 2022, we held a pre-IND meeting with the U.S. Food and Drug Administration (FDA), the planning of which had been previously announced. In preparation for this meeting, we had provided the FDA with a detailed description of the development status and plans for GH001 including clinical, nonclinical, and chemistry, manufacturing and controls activities. The outcome of the meeting was positive and positions us for an anticipated IND submission not later than the first quarter of 2023. The planned IND-opening study is a Phase 1 imaging study in patients with TRD designed to further elucidate the mechanism of action of GH001 (GH001-TRD-104).



The data from our previously reported Phase 1/2 clinical trial of GH001 in patients with TRD (GH001-TRD-102) has been recently accepted for oral presentation at the American Society of Clinical Psychopharmacology 2022 Annual Meeting in Scottsdale, AZ, and will be presented during the Pharmaceutical Pipelines session on May 31, 2022. The primary endpoint of the Phase 2 part of the trial was met with 7 of 8 patients (87.5%) in remission (Montgomery–Asberg Depression Rating Scale (MADRS)  $\leq$ 10) at day 7 after dosing (p<0.0001). Patients followed a proprietary individualized dosing regimen with up to three increasing GH001 doses (6 mg, 12 mg and 18 mg) on a single day. No serious and no severe adverse events, no clinically significant changes in any of the safety laboratory analyses, vital signs, psychiatric safety assessments or measures of cognitive function and no signal for suicidal ideation or behavior were observed.

#### GH001 for the treatment of BDII and PPD

We recently submitted additional clinical trial applications in further European countries for the planned Phase 2a proof-of-concept clinical trial of GH001 for the treatment of patients with bipolar II disorder and a current depressive episode (BDII) (GH001-BD-202) and for the planned Phase 2a proof-of-concept clinical trial of GH001 for the treatment of patients with postpartum depression (PPD) (GH001-PPD-203). Pending regulatory clearance, we expect to initiate these trials in the third quarter of 2022.

#### About GH Research PLC

GH Research PLC is a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. GH Research PLC's initial focus is on developing its novel and proprietary 5-MeO-DMT therapies for the treatment of patients with treatment-resistant depression (TRD).

GH Research PLC's annual report on Form 20-F filed with the U.S. Securities and Exchange Commission for the year ended December 31, 2021 is available at www.ghres.com and shareholders may receive a hard copy free of charge upon request.

#### About GH001

Our lead product candidate, GH001, is formulated for 5-MeO-DMT administration via a proprietary inhalation approach. With GH001, we have completed two Phase 1 healthy volunteer clinical trials and a Phase 1/2 clinical trial in patients with treatment-resistant depression (TRD). Based on the observed clinical activity, where 87.5% of patients with TRD were brought into an ultra-rapid remission with our GH001 individualized single-day dosing regimen in the Phase 2 part of the trial, we believe that GH001 has potential to change the way TRD is treated today. Across the GH001 program, no serious adverse events have been reported and GH001 was well tolerated at the investigated single dose levels and in the individualized dosing regimen.



#### About GH002 and GH003

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. GH003 is our 5-MeO-DMT product candidate formulated for administration via a proprietary intranasal administration approach. GH002 and GH003 are currently in preclinical development, and we anticipate developing them in subpopulations and confined use scenarios within our focus area of psychiatric and neurological disorders.

#### **Forward-Looking Statements**

This press release contains statements that are, or may deemed to be, forward-looking statements. All statements other than statements of historical fact included in this press release, including statements regarding our future results of operations and financial position, our cash runway, 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. Forward-looking statements appear in a number of places in this press release 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 described in our filings with the U.S. Securities and Exchange Commission. No assurance can be given that such future results will be achieved. Such forward-looking statements contained in this press release to reflect any change in our expectations or any change in events, conditions, or circumstances on which such statements are based unless required to do so by applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Investor Relations: Julie Ryan GH Research PLC investors@ghres.com



# Condensed Consolidated Interim Statement of Comprehensive Income (Unaudited)

## (in thousands, except share and per share amounts)

		Three months ended March 31,	
	2022 \$'000	2021 \$'000	
Operating expenses			
Research and development	(4,714)	(692)	
General and administration	(3,292)	(448)	
Loss from operations	(8,006)	(1,140)	
Foreign currency translation differences	2,243	(9)	
Loss before tax	(5,763)	(1,149)	
Tax charge/(credit)	-	-	
Loss for the period	(5,763)	(1,149)	
Other comprehensive expense			
Items that may be reclassified to profit or loss			
Currency translation adjustment	(2,261)	(202)	
Total comprehensive loss for the period	(8,024)	(1,351)	
Attributable to owners:			
Loss for the period	(5,763)	(1,149)	
Comprehensive loss for the period	(2,261)	(202)	
Loss per share			
Basic and diluted loss per share (in USD)	(0.111)	(0.038)	



# Condensed Consolidated Interim Balance Sheet (Unaudited)

## (in thousands)

	At March 31, 2022 \$'000	At December 31, 2021 \$'000
ASSETS		
Current assets		
Cash and cash equivalents	270,750	276,776
Other current assets	2,713	3,066
Total current assets	273,463	279,842
Non-current assets		
Property, plant and equipment	81	82
Total non-current assets	81	82
Total assets	273,544	279,924
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	1,545	883
Other current liabilities	2,521	1,866
Total current liabilities	4,066	2,749
Total liabilities	4,066	2,749
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,448	291,448
Other reserves	693	366
Foreign currency translation reserve	(8,164)	(5,903)
Accumulated deficit	(15,800)	(10,037)
Total equity	269,478	277,175
Total liabilities and equity	273,544	279,924



# **Corporate Presentation**

GH Research PLC (NASDAQ: GHRS)

May 2022

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# **Disclaimer Regarding Forward-Looking Statements**

This presentation has been prepared by GH Research PLC ("GH Research") for informational purposes only and not for any other purpose. Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the presenter or GH Research or any director, employee, agent, or adviser of GH Research. This presentation does not purport to be all-inclusive or to contain all of the information you may desire.

This presentation does not constitute an offer to sell or the solicitation of an offer to buy securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. This presentation contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Many of the forward-looking statements contained herein 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, although not all forward-looking statements contain these identifying words.

Any statements contained herein that do not describe historical facts are forward-looking statements that are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcomes, timing and performance to differ materially from those expressed or implied by such statements. These factors, risks and uncertainties include, but are not limited to: the costs and uncertainties associated with GH Research's research and development efforts; the inherent uncertainties associated with the conduct, timing and results of nonclinical and clinical studies of GH Research's product candidates; GH Research's ability to obtain, maintain, enforce and defend issued patents; the adequacy of GH Research's capital resources, the availability of additional funding and GH Research's cash runway; and other factors, risks and uncertainties described in GH Research's filings with the U.S. Securities and Exchange Commission.

Except as otherwise noted, these forward-looking statements speak only as of the date of this presentation, and GH Research undertakes no obligation to update or revise any of such statements to reflect events or circumstances occurring after this presentation. 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 GH Research's control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in any such forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. GH Research cautions you not to place undue reliance on the forward-looking statements contained in this presentation.

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# Seeking Ultra-Rapid, Durable Remissions in Depression

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# Pipeline

		Stage of Development					_
PROGRAMS	INDICATION	PRECLINICAL	PHASE 1	PHASE 2a	PHASE 2b	PHASE 3	Next Stage
GH001	Treatment-Resistant Depression (TRD)						Initiate Phase 2b trial in TRD (GH001-TRD-201)
5-MeO-DMT for inhalation administration	Bipolar II Disorder (BDII)*	[		>			Initiate Phase 2a trial in BDII (GH001-BD-202)
	Postpartum Depression (PPD)*			>			Initiate Phase 2a trial in PPD (GH001-PPD-203)
GH002 / GH003 5-MeO-DMT for injection / intranasal administration	Psychiatric or Neurological Disorder						Complete preclinical development

<sup>1</sup>/n light of our completed Phase 1 clinical trials of GH001 in healthy volunteers and our completed Phase 1/2 trial in TRD, we recently submitted clinical trial applications to begin two Phase 2a trials in patients with BDII and a current major depressive episode and in patents with PPD, respectively. We believe that we can proceed to Phase 2a trials for these two indications based on existing precinical and clinical data for GH001.

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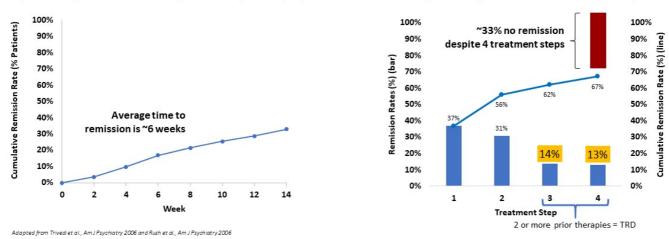


# The Problem for Patients with Depression

# **Established Therapies are Slow-Acting**

(STAR\*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



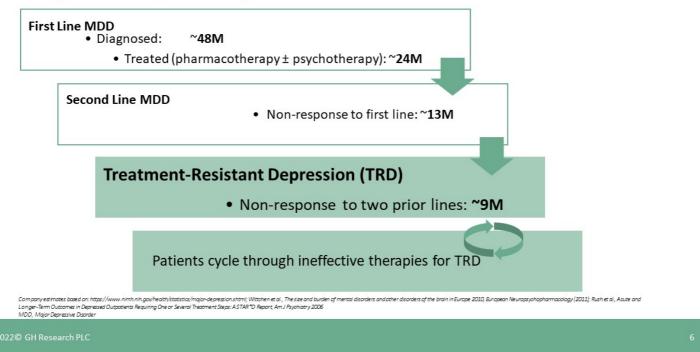


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# Large and Open Depression Market in the EU and US

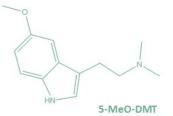


# GH Research

# 5-MeO-DMT and GH001

## • 5-MeO-DMT (5-Methoxy-N,N-Dimethyltryptamine)

- Naturally-occurring psychoactive substance from tryptamine class
- Highly potent agonist on 5-HT1A and 5-HT2A receptors
- Psychoactive effects with ultra-rapid onset (within seconds) and short duration (5 to 30 min)
- High propensity to induce peak experiences (PE), which may be a surrogate marker for therapeutic effects
- GH001 (5-MeO-DMT administration via a proprietary inhalation approach)
  - Intraday individualized dosing regimen for maximization of ultra-rapid remissions
  - Single visit initial treatment, with no structured psychotherapy
  - Potential for convenient and infrequent retreatment

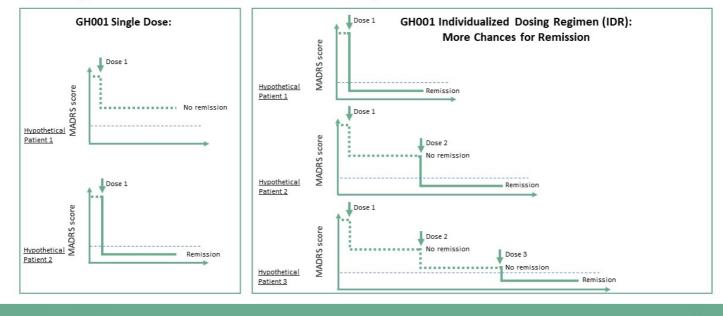


n)	<ul> <li>(12) INTERNATIONAL APPLICATION (19) World Intellectual Property Organization International Publication Date (33) International Publication Date 27 August 2020 (27.08.2020)</li> </ul>	WIPOIPCT	(1) International Publication Number WO 2020/169850 A1
r) s Foundational IP	<ul> <li>(E) INTERVATIONAL APPLICATIO</li> <li>(35) World Intellectual Property Departments</li> <li>(37) International Dustas</li> <li>(32) International Publication Date</li> <li>27 August 2020 (27.08.2020)</li> </ul>	WIPOIPCT	019 International Publication Number WO 2020/169851 A1
	<ul> <li>(2) INTERNATIONAL APPLICATION (2) World Intellicitual Property Organization International Downs</li> <li>(40) International Publication Bate 02 September 2021 (02.09.2021)</li> </ul>	WIPOIPCT	(1) International Publication Number WO 2021/170614 A1
	<ul> <li>(23) INTERNATIONAL APPLICATION (19) World Issufficiental Property Organization International Paymen</li> <li>(24) International Publication Date 24 December 2020 (24:12.2020)</li> </ul>	WIPOIPCT	THE PATENT COOPERATION THEATY (PCT)

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### GH Research

## GH001 – Individualized Dosing Regimen (IDR) Designed to Achieve Ultra-Rapid and Durable Remissions



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# Phase 1 Trial in Healthy Volunteers GH001-HV-101

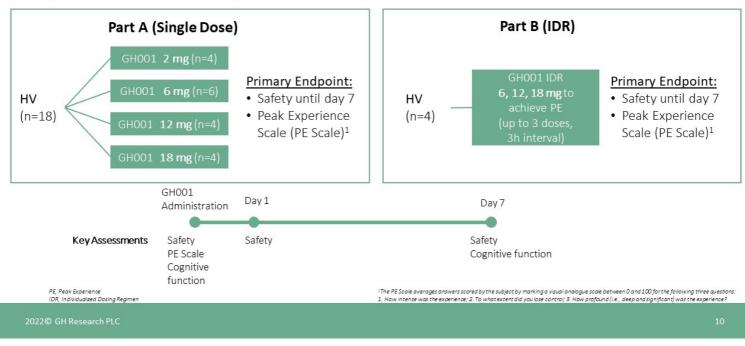
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Clinicaltrials.gov ID NCT04640831

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# Design of Phase 1 Trial in Healthy Volunteers (GH001-HV-101)





# Part A (Single Dose) and Part B (IDR) – Safety

Study Safety Group review

- No SAEs
- All ADRs mild, except two moderate (\*)
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant changes in safety laboratory analyses, psychiatric safety assessments or measures of cognitive function

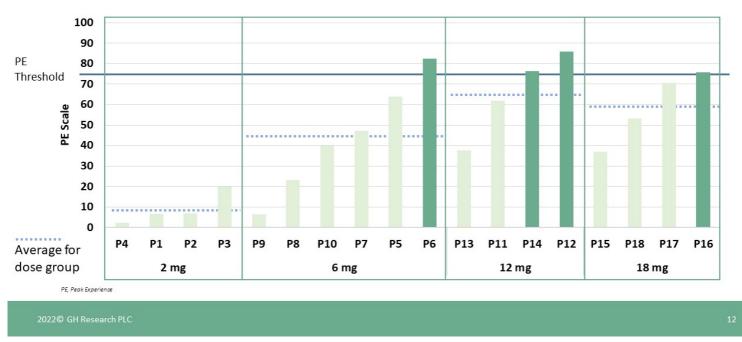
400-		Part B (IDR)			
ADRs	2 mg (N=4)	6 mg (N=6)	12 mg (N=4)	18 mg (N=4)	IDR <sup>1</sup> (N=4)
MedDRA Preferred Term	n	n	n	n	n
Abnormal dreams				1	
Anxiety		1	1		
Clumsiness		1			
Confusional state		1			
Euphoric mood		1			
Fatigue				1	1*
Feeling hot		1			
Flashback				1	
Hallucination				1	
Head discomfort					1
Headache		2		1	1
Heart rate increased			1*		
Hyperacusis				1	
Insomnia				1	
Mental fatigue				1	
Nausea	2	1		1	2
Vision blurred	1				

Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing IDR, Individualized Dosing Regimen 16 mg (N=1); 6-12 mg (N=2); 6-12-18 mg (N=1)

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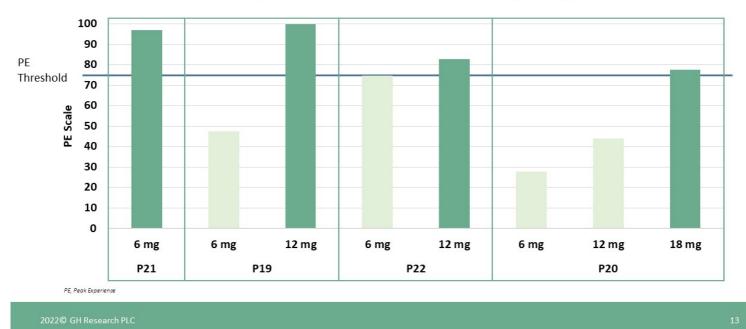


# Part A – Peak Experience (PE) Dose-Effects and Inter-Person Variability





# Part B – Peak Experience (PE) Effect of Intraday Individualized Dosing Regimen





# Phase 1/2 Trial in Treatment-Resistant Depression GH001-TRD-102

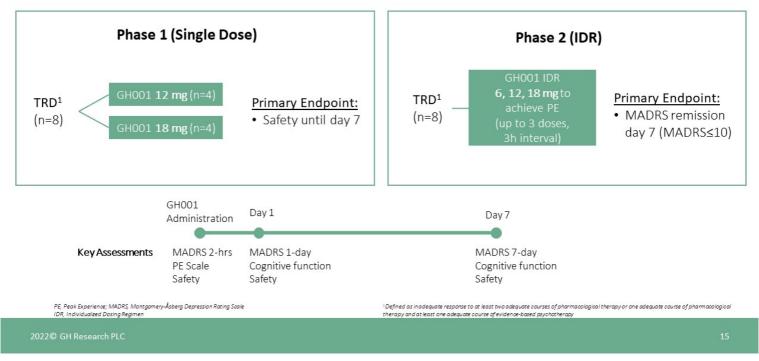
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Clinicaltrials.govID NCT04698603

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# Design of Phase 1/2 Trial in TRD (GH001-TRD-102)





## Phase 1 (Single Dose) and Phase 2 (IDR) – Safety

### Study Safety Group review

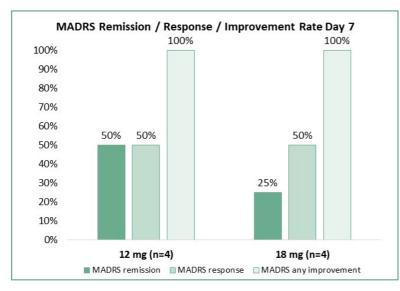
- No SAEs
- All ADRs mild, except three moderate\*
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant changes in safety laboratory analyses, psychiatric safety assessments or measures of cognitive function
- No safety signal relating to suicidal ideation or suicidal behavior, based on C-SSRS and MADRS subscore item "suicidal thoughts"

ADRs	Phase 1 (Si	ingle Dose)	Phase 2 (IDR)
ADRS	12 mg (N=4)	18 mg (N=4)	IDR1 (N=8)
MedDRA Preferred Term	n	n	n
Abdominal discomfort			1
Anxiety			2
Depressive symptom			1*
Dizziness	1		
Feeling abnormal	1	1	
Flashback	1	1	2
Headache	2	1	3
Muscle discomfort			1
Muscle spasms		1	
Nausea			2*
Paresthesia			1
Sensory disturbance			3

Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing IDR, Individualized Dosing Regimen; C-SSRS, Columbia-Suicide Severity Rating Scale <sup>1</sup>6-12 mg (N=6); 6-12-18 mg (N=2)



# Phase 1 (Single Dose) – Efficacy (MADRS)



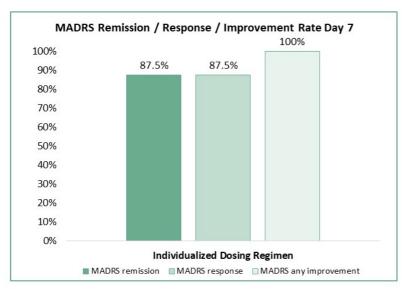
- 2 of 4 (50%) in the 12 mg group and 1 of 4 (25%) in the 18 mg group had a MADRS remission at day 7
- 2 of 8 patients had a PE and both had a MADRS remission at day 7

PE, Peak Experience; MADRS, Montgomery–Åsberg Depression Rating Scale MADRS remission = MADRS of S10; MADRS response = Reduction of 250% from baseline in MADRS

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# Phase 2 (IDR) – Efficacy (MADRS)

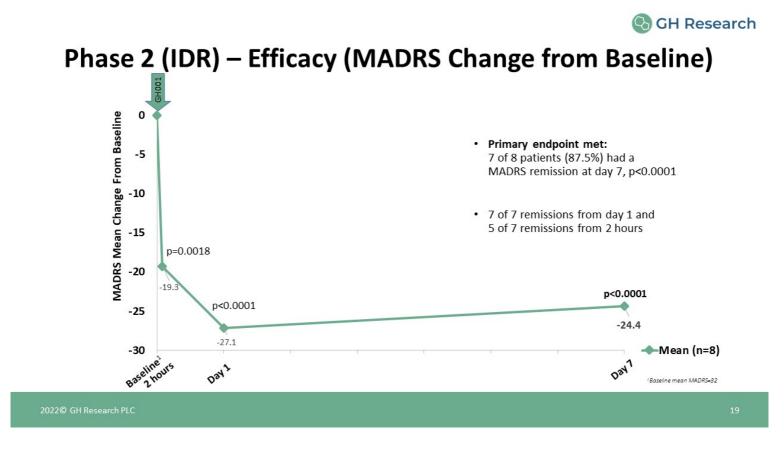


PE, Peak Experience; MADRS, Montgomeny–Åsberg Depression Rating Scale MADRS remission = MADRS of 510; MADRS response = Reduction of 250% from baseline in MADRS

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• Primary endpoint met: 7 of 8 patients (87.5%) had a MADRS remission at day 7, p<0.0001

• 7 of 8 patients had a PE and 6 of those had a MADRS remission at day 7





# MADRS and PE – Observed Improved Outcome in Phase 2 (IDR) vs Phase 1 (Single Dose)

	Phase 2 (IDR)	Phase 1 (Single Dose) 12 mg	Phase 1 (Single Dose) 18 mg
MADRS Remission Rate Day 7	87.5% (7 of 8)	50% (2 of 4)	25% (1 of 4)
Mean MADRS Change Day 7	-24.4 (-76%)	-21.0 (-65%)	-12.8 (-41%)
Rate of PE	87.5% (7 of 8)	50% (2 of 4)	0% (0 of 4)
Mean PE Score	90.4 (at final dose)	58.2	59.1

PE, Peak Experience; MADRS, Montgameny-Åsberg Depression Rating Scale IDR, Individualized Dosing Regimen

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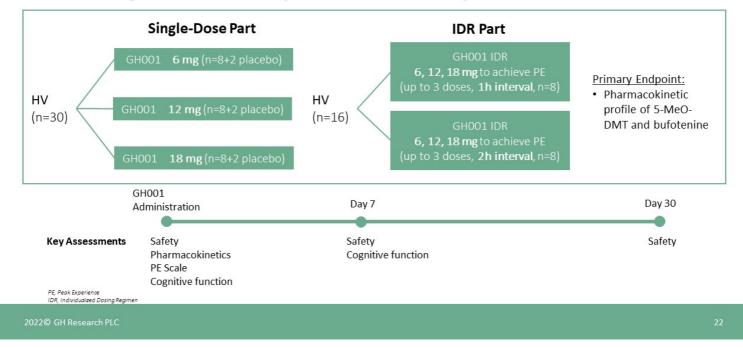
# Phase 1 Clinical Pharmacology Trial in Healthy Volunteers GH001-HV-103

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# Design of Phase 1 Clinical Pharmacology Trial in Healthy Volunteers (GH001-HV-103)





### Single Dose and IDR – Safety and Further Results

#### Safety Review

- No SAEs
- All ADRs mild
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically relevant changes in ECG, safety laboratory analyses, peak flow, cognitive function, psychiatric safety assessments, including the C-SSRS

#### **Further Results**

 Pharmacokinetic analyses and psychoactive effect assessments (PE Scale) support that an interval down to 1 hour between individual doses of the IDR is feasible for future clinical trials

	Single-dose				IDR	
ADRs	6 mg (N=8)	12 mg (N=8)	18 mg (N=8)	Placebo (N=6)	1h interval (N=8) <sup>2</sup>	2h interval (N=8) <sup>3</sup>
MedDRA Preferred Term	n	n	n	n	n	n
Abnormal dreams						1
Chest discomfort		1				
Crying			2		2	
Dizziness			1			
Dry mouth	1					
Dyskinesia			1			
Fatigue		1			2	1
Headache	3		1		1	1
Hypoesthesia oral		1				
Paresthesia oral						1
Retching			1			
Somnolence		1				
Tachycardia			2			
Tension						1
Tremor			1			

Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing IDR, Individualized Dosing Regimen; C-SSRS, Columbia-Suicide Severity Rating Scale; PE, Peak Experience

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<sup>3</sup>6 mg (N=1), 6-12 mg (N=3); 6-12-18 mg (N=4) <sup>3</sup>6-12 mg (N=3); 6-12-18 mg (N=5)



# **Three-Layer Protection Strategy**

LAYER 1 FDA: EMA:	5 years	ORY EXCLUSIVITY (+2.5 years paragraph IV stay) (+1 year for new indication)
	<ul> <li>Novel a</li> <li>Novel r</li> <li>Novel t</li> </ul>	PATENTS tent applications filed: aerosol compositions of matter of 5-MeO-DMT manufacturing methods and novel salt forms of 5-MeO-DMT uses of 5-MeO-DMT in various disorders ing inhaled, intranasal, i.v., i.m., s.c., and other routes)
		LAYER 3: TECHNICAL Complex bioequivalence for systemically-acting inhalation/intranasal products with high intra- and inter-subject variability

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### **Board of Directors & Management**



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### **Scientific Advisors**





and Neuroscience of Maastricht University

Maastricht University



## **Anticipated Milestones and Financial Overview**

#### • GH001

- Submit clinical trial applications for multi-center, randomized, controlled Phase 2b trial in TRD in 3Q 2022
- Initiate Phase 2a trials in BDII and in PPD in 3Q 2022
- Submit U.S. IND for GH001 in TRD not later than 1Q 2023

#### • GH002 and GH003

· Complete preclinical development and initiate Phase 1 trial in healthy volunteers

### · Financial Overview

- Cash was \$270.8 million as of March 31, 2022
- We believe existing cash will be sufficient to fund operating expenses and capital expenditure requirements into 2025

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# Seeking Ultra-Rapid, Durable Remissions in Depression

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