
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
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 March 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 March 28, 2022, GH Research PLC (the “Company”) issued a press release announcing its full year 2021 financial results and providing certain business updates. A copy the press release is attached hereto as Exhibit 99.1.

In connection with the release of these updates, on March 28, 2022, the Company made available on its website an updated corporate presentation. A copy of the corporate presentation is attached hereto as Exhibit 99.2. 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 March 28, 2022 and the Company does not undertake any obligation to update the presentation in the future nor 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: March 28, 2022

GH Research PLC

By: /s/ Julie Ryan
Name: Julie Ryan
Title: Vice President, Finance

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated March 28, 2022
99.2	Corporate Presentation dated March 28, 2022

GH Research Reports Full Year 2021 Financial Results and Provides Business Updates

Dublin, Ireland, March 28, 2022 – GH Research PLC (Nasdaq: GHR), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported financial results for the full year ended December 31, 2021 and gave updates on its business.

Fourth Quarter 2021 Business Highlights

In December 2021, we reported the successful outcome of the Phase 2 part of our Phase 1/2 clinical trial of GH001, our proprietary inhalable 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) product candidate, in patients with treatment-resistant depression (TRD) (GH001-TRD-102). The primary endpoint of the Phase 2 part of the trial was met with 7 of 8 patients (87.5%) in remission (Montgomery-Åsberg Depression Rating Scale (MADRS) ≤ 10) at day 7 after dosing ($p < 0.0001$). Patients followed a proprietary individualized dosing regimen (IDR) 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.

Furthermore, we reported positive preliminary safety results from a Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-103), which supported the safety profile of GH001 single doses (6 mg, 12 mg and 18 mg) and the proprietary GH001 IDR with up to three increasing GH001 doses (6 mg, 12 mg and 18 mg) on a single day, given in two dose intervals (1 hour, 2 hours).

Full Year 2021 Financial Highlights*Cash position*

Cash was \$276.8 million as of December 31, 2021, compared to \$5.9 million as of December 31, 2020.

Research and development expenses

R&D expenses were \$8.6 million for the year ended December 31, 2021, compared to \$338 thousand for the full year 2020. The increase was primarily due to increased activities relating to our technical developments and clinical trials and increases in employee expenses to support these activities.

General and administrative expenses

G&A expenses were \$6.5 million for the year ended December 31, 2021, compared to \$108 thousand for the full year 2020. The increase was primarily due to higher professional and compliance fees associated with being a public company, as well as increased employee expenses.

Net loss

Net loss was \$9.2 million, or \$0.211 loss per share, for the year ended December 31, 2021, compared to \$446 thousand, or \$0.016 loss per share, for the full year 2020.

Business Updates

GH001 for the treatment of TRD

We plan to submit clinical trial applications in several European countries for a multi-center, randomized, controlled Phase 2b trial of GH001 in TRD (GH001-TRD-201) in the third quarter of 2022.

GH001 for the treatment of additional disorders

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

GH001 in healthy volunteers

We now have the final safety results of our Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-103) and the data continue to support the safety profile of GH001 single doses and the proprietary GH001 IDR. Results from pharmacokinetic analyses were aligned with the ultra-rapid onset and short duration of observed psychoactive effects. Results of cognitive function tests as well as psychoactive effect assessments were aligned with results of previous trials. The full results of the trial support that an interval down to 1 hour between individual doses of the IDR is feasible for use in future clinical trials.

Other GH001 regulatory interactions

We have recently submitted a request for a pre-IND meeting with the FDA to discuss our planned filing of a U.S. IND for GH001 in TRD. The meeting has been granted by the FDA for the second quarter of 2022. The proposed 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). There are no current plans for additional regulatory meetings with other agencies.

Intellectual property

We have recently filed a number of new patent applications, which have not yet been published, that relate to further aspects of 5-MeO-DMT use in a therapeutic context, including novel manufacturing methods of 5-MeO-DMT, novel salt forms of 5-MeO-DMT and novel uses of 5-MeO-DMT.

Financial

Cash was approximately \$273.8 million as of February 28, 2022, and we believe that our existing cash will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2025.

Filing of Annual Report on Form 20-F

In connection with the announcement of our full year 2021 financial highlights, we have filed our annual report on Form 20-F with the U.S. Securities and Exchange Commission. The annual report is available on our website at www.ghres.com and shareholders may receive a hard copy free of charge upon request.

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).

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 be 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 document speak only as of the date of this press release. We expressly disclaim any obligation or undertaking to update these 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

GH RESEARCH PLC

Consolidated Statement of Comprehensive Income

(in thousands, except share and per share amounts)

	Year ended December 31,		
	2021	2020	2019
	\$ '000	\$ '000	\$ '000
Operating expenses			
Research and development	(8,553)	(338)	(296)
General and administration	(6,547)	(108)	(14)
Loss from operations	(15,100)	(446)	(310)
Finance expense	(9)	—	—
Foreign currency translation differences	5,907	—	—
Loss before tax	(9,202)	(446)	(310)
Tax charge/(credit)	—	—	—
Loss for the year	(9,202)	(446)	(310)
Other comprehensive income/(expense)			
<i>Items that may be reclassified to profit or loss</i> Currency translation adjustment	(6,103)	212	(12)
Total comprehensive loss for the year	(15,305)	(234)	(322)
Attributable to owners:			
Loss for the year	(9,202)	(446)	(310)
Comprehensive loss for the year	(15,305)	(234)	(322)
Loss per share			
Basic and diluted loss per share (in USD)	(0.211)	(0.016)	(0.011)

GH RESEARCH PLC
Consolidated Balance Sheet
(in thousands)

	At December 31,			
	2021		2020	
	\$	'000	\$	'000
ASSETS				
Current assets				
Cash and cash equivalents		276,776		5,895
Other current assets		3,066		17
Total current assets		279,842		5,912
Non-current assets				
Property, plant and equipment		82		—
Total non-current assets		82		—
Total assets		279,924		5,912
LIABILITIES AND EQUITY				
Current liabilities				
Trade payables		883		1
Other current liabilities		1,866		245
Total current liabilities		2,749		246
Total liabilities		2,749		246
Equity attributable to owners				
Share capital		1,301		871
Additional paid-in capital		291,448		5,430
Other reserves		366		—
Foreign currency translation reserve		(5,903)		200
Accumulated deficit		(10,037)		(835)
Total equity		277,175		5,666
Total liabilities and equity		279,924		5,912



Corporate Presentation

GH Research PLC (NASDAQ: GHR)

March 2022

Disclaimer Regarding Forward-Looking Statements

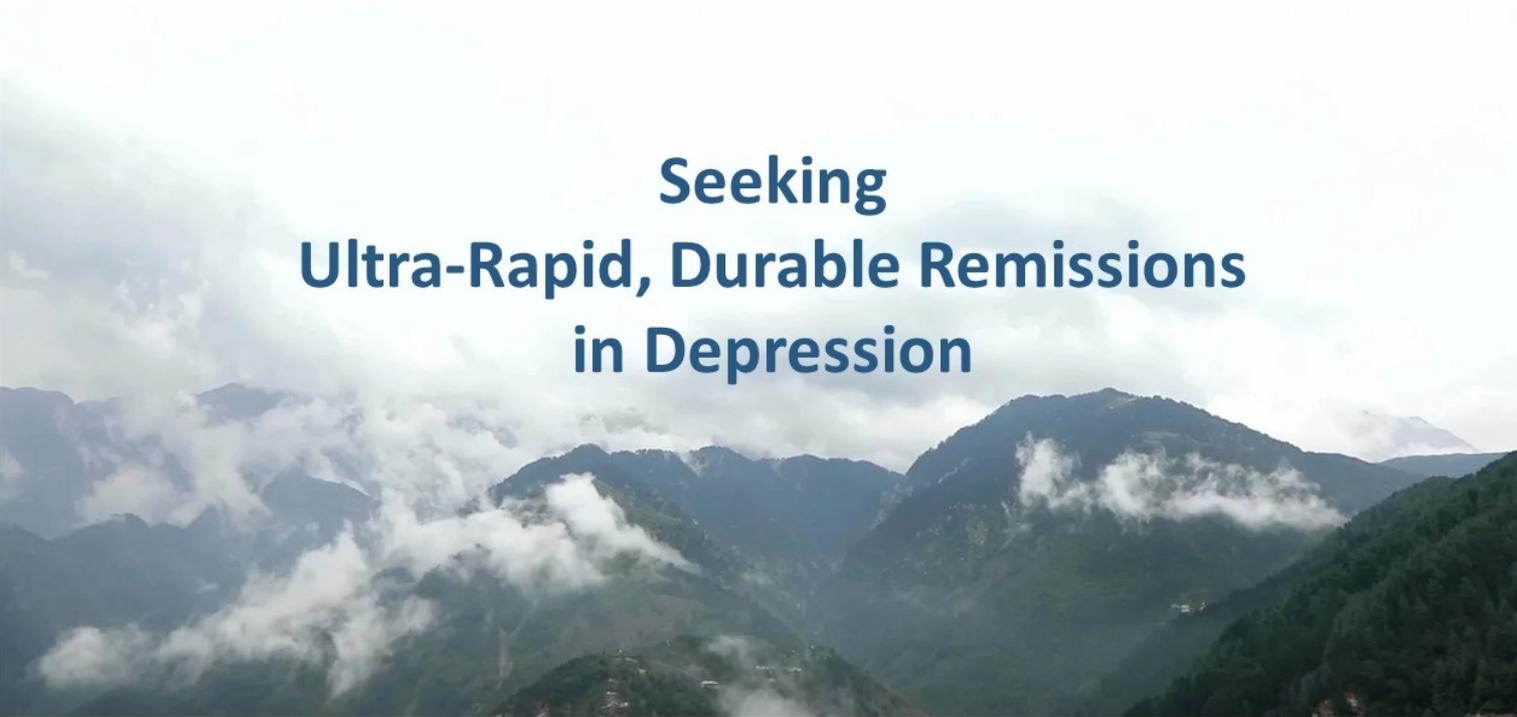
This presentation has been prepared by GH Research PLC ("GH Research") for informational purposes only and not for any other purpose. Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the presenter or GH Research or any director, employee, 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.

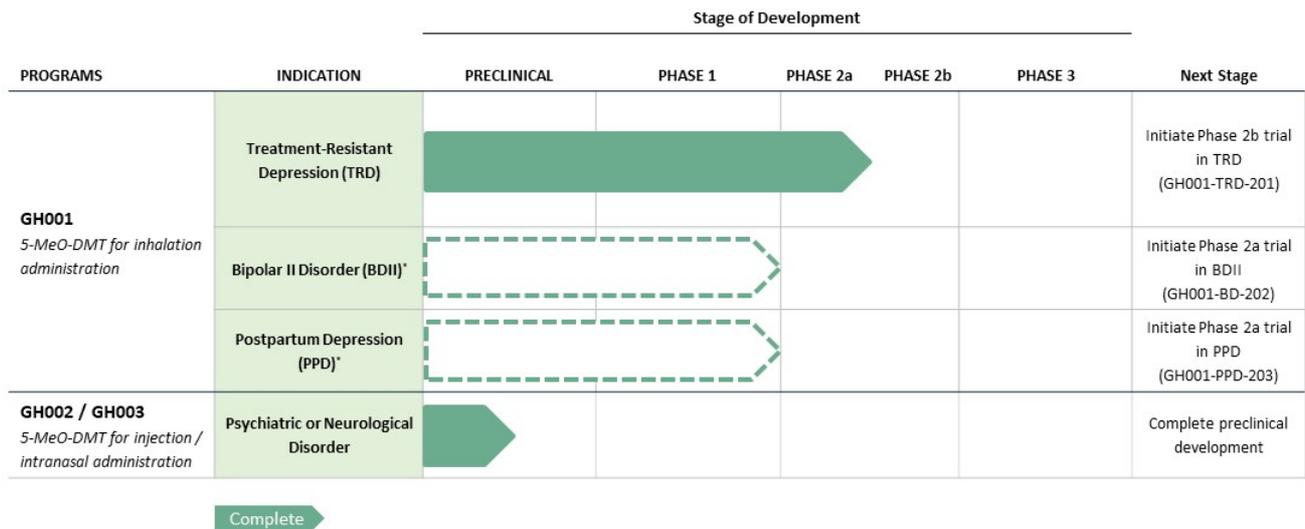
Any statements contained herein that do not describe historical facts are forward-looking statements that are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcomes, timing and performance to differ materially from those 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.



Seeking Ultra-Rapid, Durable Remissions in Depression

Pipeline

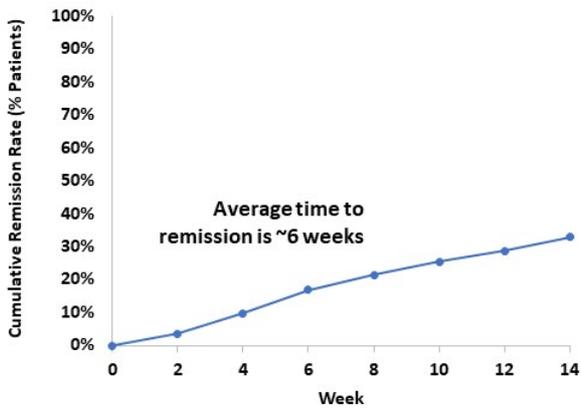


**In light of our completed Phase 1 clinical trials of GH001 in healthy volunteers and our completed Phase 1/2 trial in TRD, we recently submitted clinical trial applications to begin two Phase 2a trials in patients with BDII and a current major depressive episode and in patients with PPD, respectively.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

The Problem for Patients with Depression

Established Therapies are **Slow-Acting**

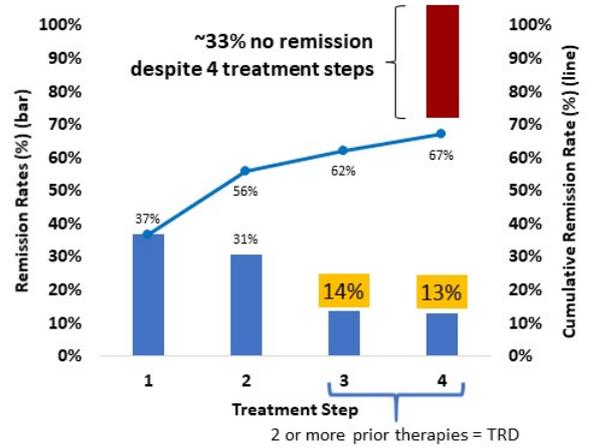
(STAR*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



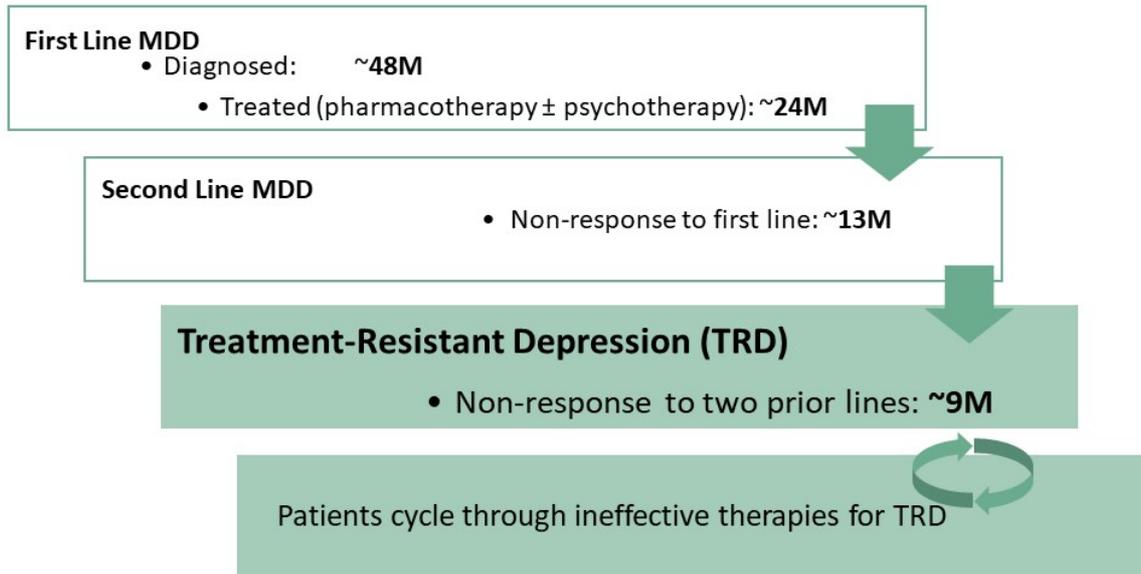
Adapted from Trivedi et al., Am J Psychiatry 2006 and Rush et al., Am J Psychiatry 2006

... Remission Rates in TRD < 15%

(STAR*D study, Remission Rates Treatment Steps 1 to 4)



Large and Open Depression Market in the EU and US

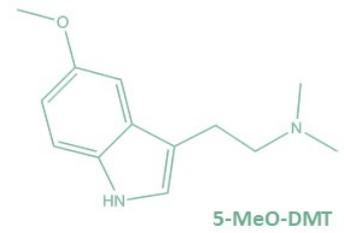


Company estimates based on: <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>; Wittchen et al., *The size and burden of mental disorders and other disorders of the brain in Europe 2010*, *European Neuropsychopharmacology* (2011); Rush et al., *Acute and Longer-Term Outcomes in Depressed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

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**



Foundational IP

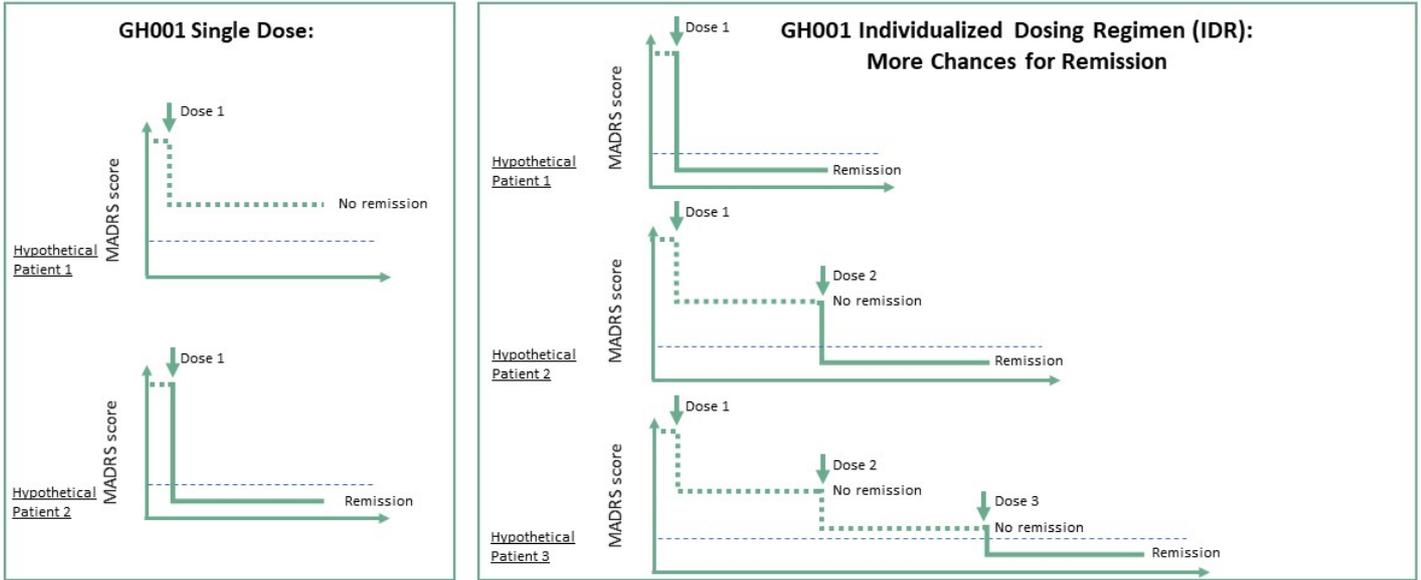
(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)
 (19) World Intellectual Property Organization
 International Bureau
 (43) International Publication Date: 27 August 2020 (27.08.2020) WIPO | PCT (51) International Publication Number: WO 2020/169850 A1

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 (43) International Publication Date: 02 September 2021 (02.09.2021) WIPO | PCT (51) International Publication Number: WO 2021/170614 A1

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 (19) World Intellectual Property Organization
 International Bureau
 (43) International Publication Date: 24 December 2020 (24.12.2020) WIPO | PCT (51) International Publication Number: WO 2020/254584 A1

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

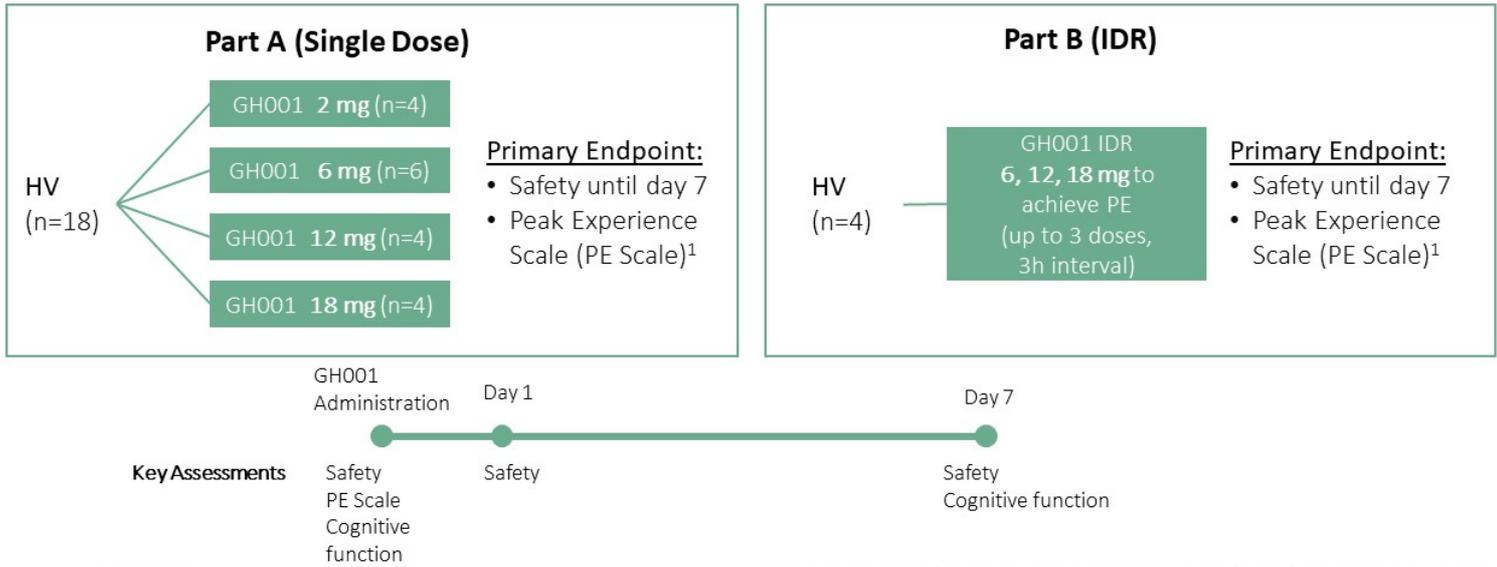


Phase 1 Trial in Healthy Volunteers GH001-HV-101

(Completed)

[Clinicaltrials.gov ID NCT04640831](https://clinicaltrials.gov/ct2/show/study/NCT04640831)

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



PE, Peak Experience
IDR, Individualized Dosing Regimen

¹The PE Scale averages answers scored by the subject by marking a visual analogue scale between 0 and 100 for the following three questions:
1. How intense was the experience; 2. To what extent did you lose control; 3. How profound (i.e., deep and significant) was the experience?

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

Study Safety Group review

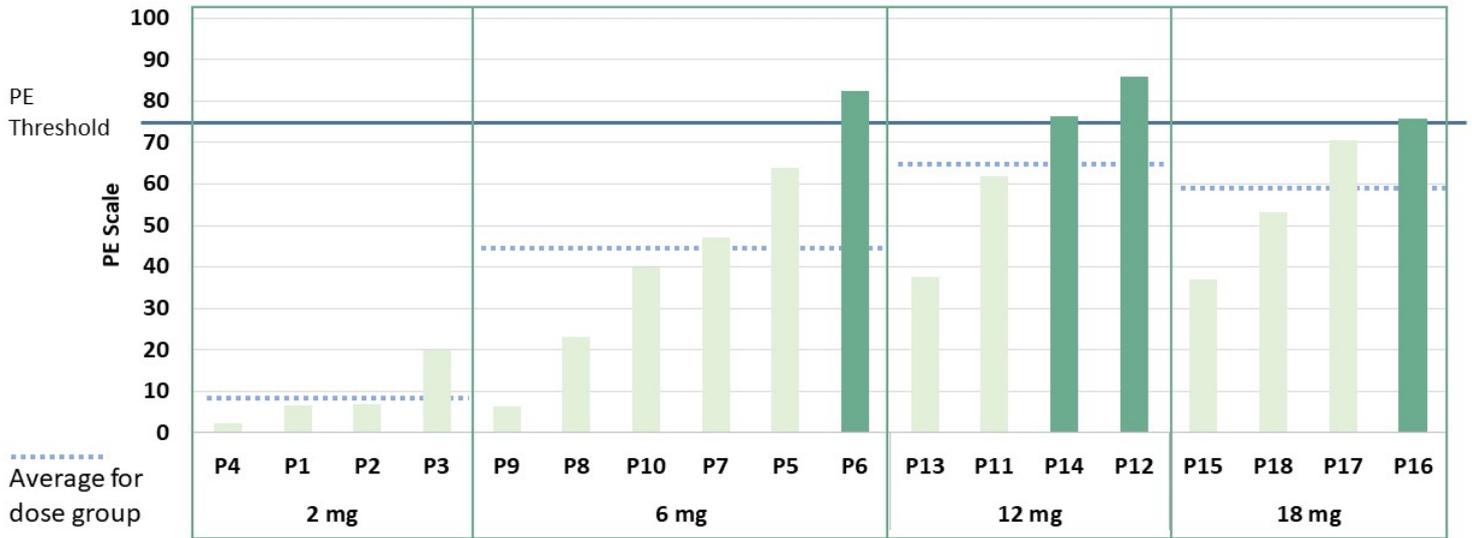
- No SAEs
- All ADRs mild, except two moderate (*)
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant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

ADRs	Part A (Single Dose)				Part B (IDR)
	2 mg (N=4)	6 mg (N=6)	12 mg (N=4)	18 mg (N=4)	IDR ¹ (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

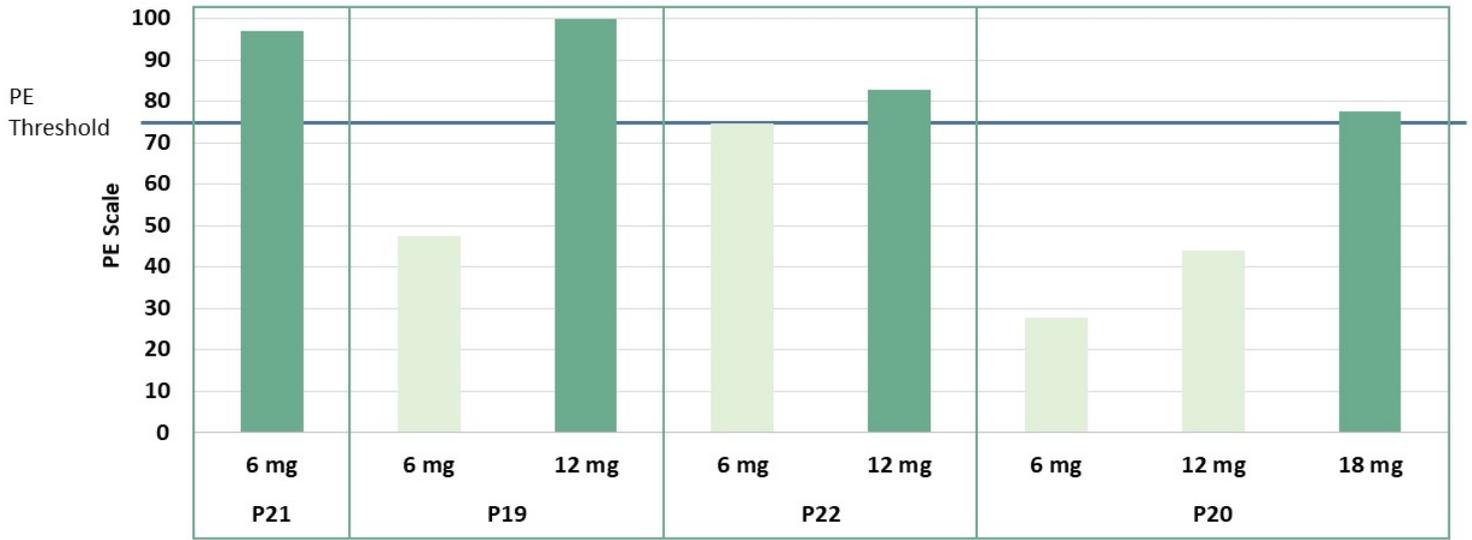
* 6 mg (N=1); 6-12 mg (N=2); 6-12-18 mg (N=1)

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



PE, Peak Experience

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

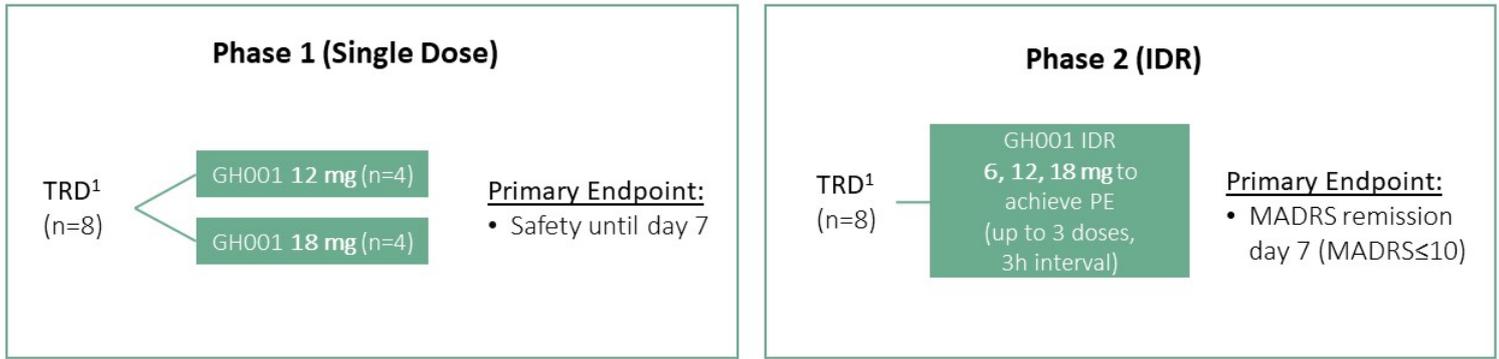


PE, Peak Experience

Phase 1/2 Trial in Treatment-Resistant Depression GH001-TRD-102 (Completed)

[Clinicaltrials.gov ID NCT04698608](https://clinicaltrials.gov/ct2/show/study/NCT04698608)

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



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

¹Defined as inadequate response to 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

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

Study Safety Group review

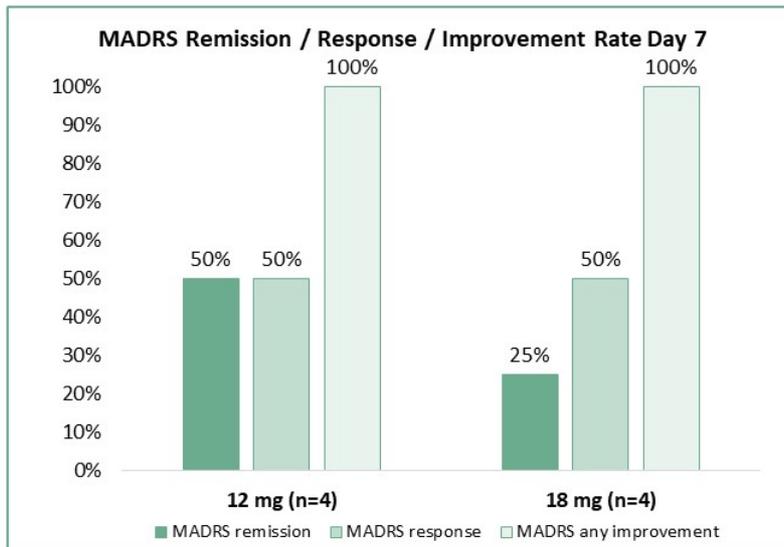
- No SAEs
- All ADRs mild, except three moderate*
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant 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 (Single Dose)		Phase 2 (IDR)
	12 mg (N=4)	18 mg (N=4)	IDR ¹ (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

*6-12 mg (N=6); 6-12-18 mg (N=2)

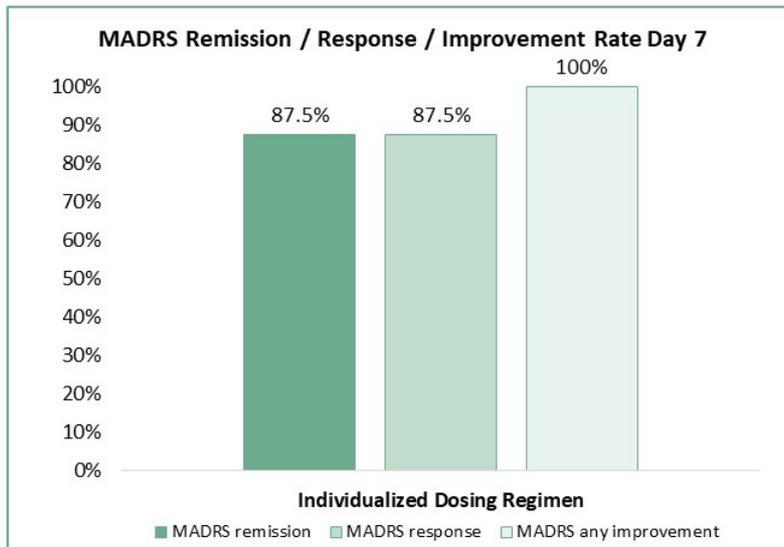
Phase 1 (Single Dose) – Efficacy (MADRS)



- 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 ≤ 10 ; MADRS response = Reduction of $\geq 50\%$ from baseline in MADRS.

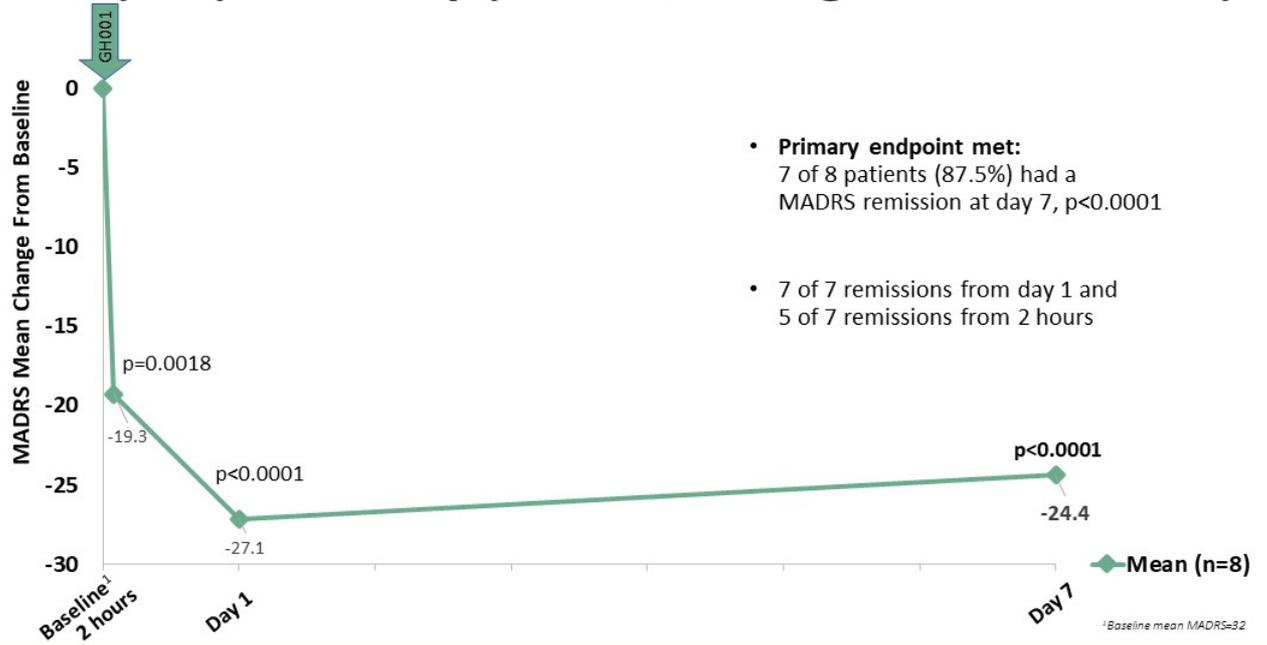
Phase 2 (IDR) – Efficacy (MADRS)



- **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

PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale
MADRS remission = MADRS of ≤ 10 ; MADRS response = Reduction of $\geq 50\%$ from baseline in MADRS.

Phase 2 (IDR) – Efficacy (MADRS Change from Baseline)



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

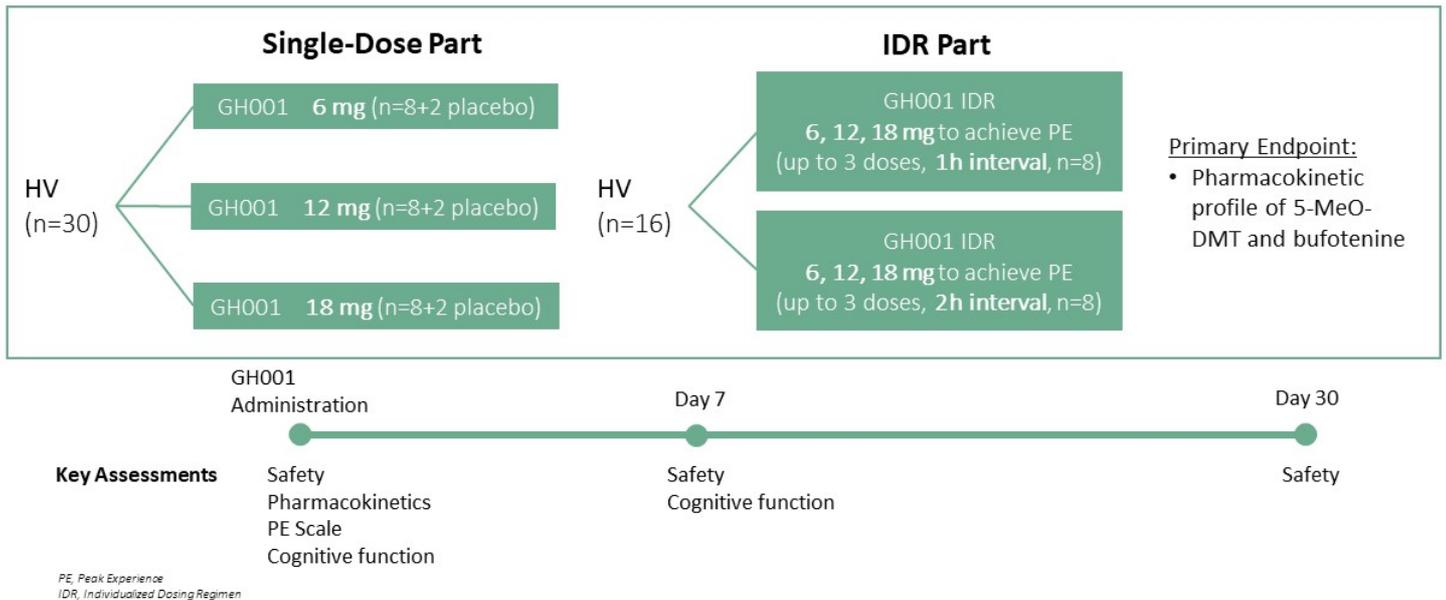
	Phase 2 (IDR)	Phase 1 (Single Dose) 12 mg	Phase 1 (Single Dose) 18 mg
MADRS Remission Rate Day 7	87.5% (7 of 8)	50% (2 of 4)	25% (1 of 4)
Mean MADRS Change Day 7	-24.4 (-76%)	-21.0 (-65%)	-12.8 (-41%)
Rate of PE	87.5% (7 of 8)	50% (2 of 4)	0% (0 of 4)
Mean PE Score	90.4 (at final dose)	58.2	59.1

PE, Peak Experiences; MADRS, Montgomery-Åsberg Depression Rating Scale
IDR, Individualized Dosing Regimen

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

(Completed)

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

ADRs	Single-dose				IDR	
	6 mg (N=8)	12 mg (N=8)	18 mg (N=8)	Placebo (N=6)	1h interval (N=8) ²	2h interval (N=8) ³
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

²6 mg (N=1), 6-12 mg (N=3), 6-12-18 mg (N=4)
³6-12 mg (N=3), 6-12-18 mg (N=5)

Three-Layer Protection Strategy

LAYER 1: REGULATORY EXCLUSIVITY

FDA: 5 years (+2.5 years paragraph IV stay)
EMA: 10 years (+1 year for new indication)

LAYER 2: PATENTS

Several patent applications filed:

- Novel aerosol compositions of matter of 5-MeO-DMT
- Novel manufacturing methods and novel salt forms of 5-MeO-DMT
- Novel uses of 5-MeO-DMT in various disorders (including 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

Board of Directors & Management



Florian Schönharting
MSc
Chairman of the Board, Co-founder



Michael Forer
BA, LLB
Board Member



Dermot Hanley
BSC, MBA
Board Member



Duncan Moore
MPhil, PhD
Board Member



Theis Terwey
PD Dr. med.
CEO, Co-founder



Julie Ryan
ACA, MAcc, BComm
VP, Finance



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Managing Director, Ireland, Co-founder



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Michael Bauer
Prof. Dr. rer. nat. Dr. med.
Chair, Department of Psychiatry and Psychotherapy,
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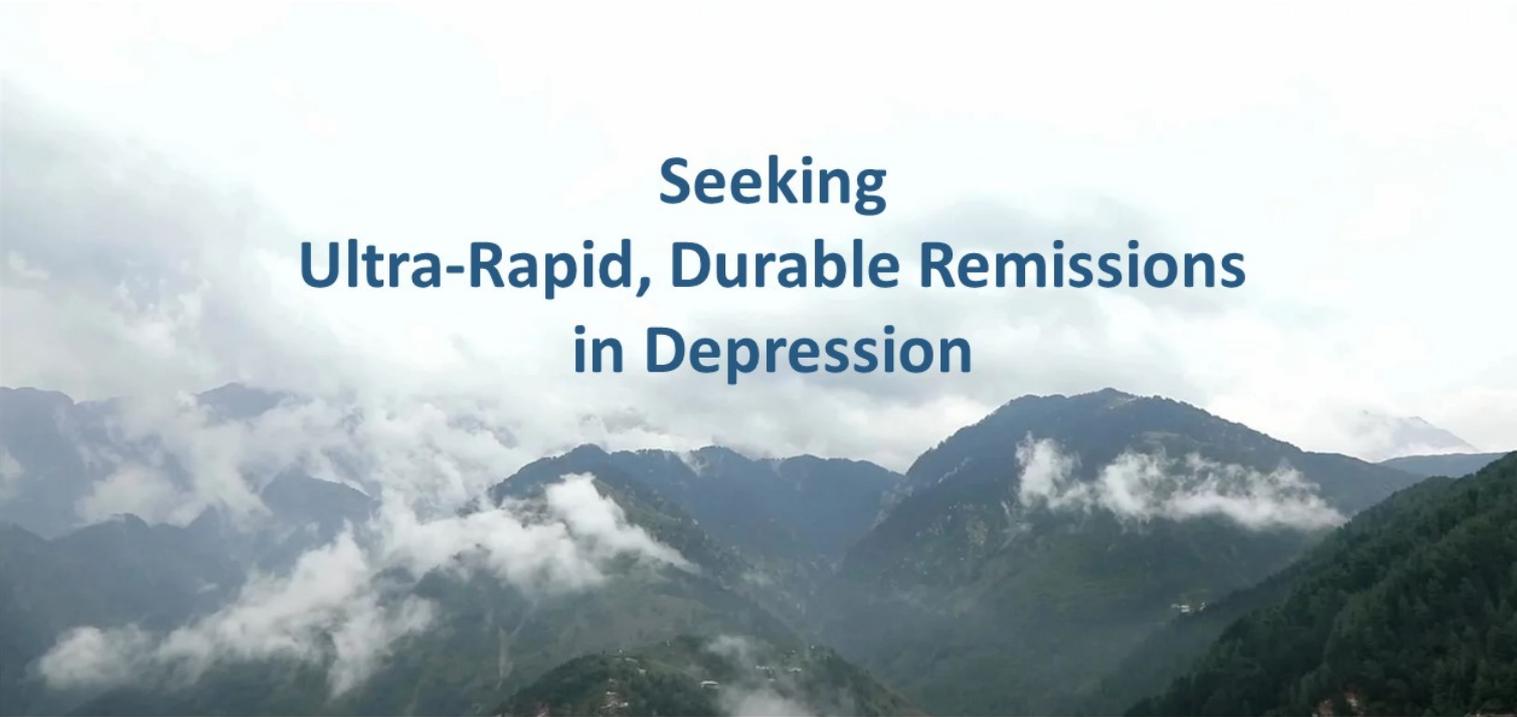

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Johannes Ramaekers
Prof. Dr.
Professor, Faculty of Psychology
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Anticipated Milestones and Financial Overview

- **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
 - Hold pre-IND meeting with the FDA for GH001 in TRD in 2Q 2022
- **GH002 and GH003**
 - Complete preclinical development and initiate Phase 1 trial in healthy volunteers
- **Financial Overview**
 - Cash was \$276.8 million as of December 31, 2021
 - We believe existing cash will be sufficient to fund operating expenses and capital expenditure requirements into 2025



Seeking Ultra-Rapid, Durable Remissions in Depression