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 February, 2024.

Commission File Number: 001-40530

GH Research PLC

(Exact name of registrant as specified in its charter)

Joshua Dawson House
Dawson Street
Dublin 2
D02 RY95
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 ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

GH Research PLC (the "Company") will participate in a corporate panel and hold one-on-one investor meetings during the 44th Annual TD Cowen Health Care Conference, which is scheduled to take place from March 4-6, 2024 in Boston, Massachusetts.

On February 29, 2024, the Company reported its full year 2023 financial results, provided business updates, and made available an updated investor presentation on its website. A copy of the press release is exhibited hereto as Exhibit 99.1 and a copy of the presentation is attached hereto as Exhibit 99.2.

The fact that this press release and 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 press release and presentation is being provided as of February 29, 2024, and the Company does not undertake any obligation to update the press release or presentation in the future or to update forward-looking statements to reflect subsequent actual results.

INCORPORATION BY REFERENCE

This Report on Form 6-K (other than Exhibit 99.1 and Exhibit 99.2 hereto) shall be deemed to be incorporated by reference into the registration statement on Form S-8 (Registration No. 333-270422) and the registration statement on Form F-3 (Registration No. 333-270418) of GH Research PLC and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release dated February 29, 2024
99.2	Corporate Presentation for February 2024

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: February 29, 2024

GH Research PLC

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

GH Research Reports Full Year 2023 Financial Results and Provides Business Updates

- Phase 2b clinical trial of GH001 in patients with treatment-resistant depression on track for expected completion of double-blind phase in Q3 2024
- Phase 2a clinical trial of GH001 in postpartum depression on track for expected completion in Q3 2024
- Successfully completed Phase 1, dose-ranging clinical pharmacology trial of intravenous GH002 in healthy volunteers
- Additional patents granted in Europe
- Cash, cash equivalents, other financial assets and marketable securities of $222.7 million expected to provide cash runway into 2026

DUBLIN, Ireland, Feb 29, 2024 (GLOBE NEWSWIRE) -- 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 year ended December 31, 2023, and provided updates on its business.

Business Updates

GH001 in Patients with TRD

GH001, our proprietary inhalable mebufotenin (5-MeO-DMT) product candidate, is currently being investigated in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in approximately 80 patients with treatment-resistant depression (TRD) (GH001-TRD-201).

We have now initiated approximately 20 sites across seven European countries, and continue to see strong recruitment, supporting the expected completion of the double-blind phase of this trial in the third quarter of 2024, with top-line data expected to be available in the third or the fourth quarter of 2024. In this trial, GH001 is administered using an externally-sourced inhalation device. Consistent with previously completed trials, GH001 is administered on a single initial dosing day, without additional mandated visits for psychotherapy or psychological support before or after dosing.

GH001 in Patients with PPD and BDII

GH001 is also currently being investigated in proof-of-concept clinical trials in patients with postpartum depression (PPD) (GH001-PPD-203) and in patients with bipolar II disorder with a current depressive episode (BDII) (GH001-BD-202).

As announced in November 2023, both trials were recruiting slower than anticipated, in part due to the closure, for business reasons, of one of the two sites activated in each trial. Subsequently, we have implemented measures to strengthen recruitment of both trials, including the addition of further clinical trial sites. For the trial in patients with PPD (GH001-PPD-203), we now expect completion and availability of top-line data in the third quarter of 2024. For the trial in patients with BDII (GH001-BD-202), we need to further assess the impact of these measures on recruitment before we can provide an updated timeline.

GH002

Our Phase 1, dose-ranging clinical pharmacology trial of GH002 (GH002-HV-105), our proprietary intravenous mebufotenin (5-MeO-DMT) product candidate, in healthy volunteers has been successfully completed in the fourth quarter of 2023. Top-line results demonstrate that GH002 was well-tolerated and produced potent and ultra-rapid psychoactive effects.

This trial enrolled 64 healthy volunteers into a double-blind, placebo-controlled part where 56 subjects received single doses of GH002 or placebo in seven dose groups, and an open-label part where 8 subjects received an individualized dosing regimen (IDR) of up to three escalating doses of GH002 on a single day with a scheduled 1-hour interval between doses. The follow-up period was 7 days. GH002 was administered without additional mandated visits for psychological support before or after dosing. In this trial GH002 was found to be well-tolerated with no severe or serious adverse events. GH002 demonstrated potent pharmacodynamic (PD) effects, as assessed by psychoactive effect intensity, with an ultra-rapid onset and a short duration of the psychoactive experience. The pharmacokinetic (PK) profile of GH002 correlated with the ultra-rapid profile of the psychoactive effects.

Further trial results are described in our corporate presentation, which is available in the investor section on our website. The analyses of the PK/PD relationship and various other secondary endpoints are ongoing and will inform the further clinical development strategy for GH002.

Intellectual Property Updates

As announced in January 2024, the European Patent Office (EPO) has granted patent EP3927337 to GH Research with claims directed to mebufotenin (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in treating patients diagnosed with major depressive disorder (MDD) and treatment-resistant forms of MDD, such as TRD. This patent is now effective, with an expiry date of no earlier than 2040, and is expected to cover all mebufotenin and mebufotenin salt products marketed to treat MDD and TRD, including but not limited to products administered through pulmonary inhalation, intravenous and intranasal routes.

More recently, the European Patent Office has granted two more patents to GH Research. Newly granted patent EP4313945 is directed to crystalline hydrobromide salt of mebufotenin, and will have an effective date of March 13, 2024, and an expiry date of no earlier than 2043. Newly granted patent EP3986864 is directed to a specific method of purifying mebufotenin, and will have an effective date of March 13, 2024, and an expiry date of no earlier than 2040.

Update on IND for GH001

As previously announced, our Investigational New Drug Application (IND) for GH001 administered using our proprietary aerosol delivery device has been placed on clinical hold by the U.S. Food and Drug Administration (FDA), with the FDA requesting that we provide (i) an inhalation toxicology study in a non-rodent species and an additional inhalation toxicology study in rats, (ii) additional device design verification information and (iii) updates to our investigator brochure, to resolve the hold.

We are working to respond to the FDA's requests and we have initiated the requested nonclinical studies and are preparing the requested device design verification information. In addition, we have recently requested a meeting with the FDA to discuss certain aspects of the FDA's feedback.

We intend to provide an update regarding the IND response submission and the planned Phase 1 healthy volunteer clinical pharmacology trial (GH001-HV-106) in the second quarter of 2024. In parallel, to mitigate a potential delay to the GH001 program, we are also progressing preparations to potentially conduct the Phase 1 healthy volunteer clinical pharmacology trial (GH001-HV-106) in Europe.

Full Year 2023 Financial Highlights

Cash position

Cash, cash equivalents, other financial assets and marketable securities were $222.7 million as of December 31, 2023, compared to cash, cash equivalents and marketable securities of $251.7 million as of December 31, 2022. Other financial assets are comprised of money market funds, and marketable securities are comprised of investment grade bonds. We believe that our existing cash, cash equivalents, other financial assets and marketable securities will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2026.

Research and development expenses

R&D expenses were $29.8 million for the year ended December 31, 2023, compared to $20.5 million for the full year 2022. The increase was primarily due to an increase in clinical trial expenses, increased expenses relating to our technical development, and increased employee expenses to support these activities. These increases have been partly offset by a decrease in nonclinical and regulatory expenses.

General and administrative expenses

G&A expenses were $11.4 million for the year ended December 31, 2023, compared to $10.1 million for the full year 2022. The increase was primarily due to higher professional fees, communications and IT costs and facility expenses, as well as increased employee expenses. These were partly offset by a decrease in insurance costs.

Net loss

Net loss was $35.6 million, or $0.68 loss per share, for the year ended December 31, 2023, compared to $22.5 million, or $0.43 loss per share, for the full year 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 mebufotenin (5-MeO-DMT) therapies for the treatment of patients with treatment-resistant depression (TRD).

About GH001

Our lead product candidate, GH001, is formulated for mebufotenin (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 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. GH001 is currently in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in patients with TRD and in two Phase 2a proof-of-concept trials in patients with bipolar II disorder and a current depressive episode and in patients with postpartum depression.

About GH002 and GH003

GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach. We have completed a Phase 1 trial of GH002 in healthy volunteers. GH003 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intranasal administration approach. GH003 is currently in preclinical development. We anticipate developing GH002 and GH003 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, business strategy, product candidates, medical devices required to deliver these product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals and their effects on our business strategy, including our plans and expectations for discussions with the FDA and the outcomes and resolution of such discussions related to the clinical hold on the GH001 IND, research and development costs, cash runway, 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 speak only as of the date hereof. 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 (Unaudited)

(in thousands, except share and per share amounts)

	Year ended December 31,	
	2023 $'000	**2022 $'000**
Operating expenses		
Research and development	(29,821)	(20,484)
General and administration	(11,401)	(10,070)
Loss from operations	**(41,222)**	**(30,554)**
Finance income	8,978	1,166
Finance expense	(723)	(123)
Movement of expected credit loss	1	(121)
Foreign exchange (loss)/gain	(2,621)	7,176
Total other income	**5,635**	**8,098**
Loss before tax	**(35,587)**	**(22,456)**
Tax charge/(credit)	—	—
Loss for the year	**(35,587)**	**(22,456)**
Other comprehensive (expense)/income		
Items that may be reclassified to profit or loss		
Fair value movement on marketable securities	(95)	558
Currency translation adjustment	2,528	(7,132)
Total comprehensive loss for the year	**(33,154)**	**(29,030)**
Attributable to owners:		
Loss for the year	(35,587)	(22,456)
Total comprehensive loss for the year	(33,154)	(29,030)
Loss per share		
Basic and diluted loss per share (in USD)	(0.68)	(0.43)

GH RESEARCH PLC

Consolidated Balance Sheet (Unaudited)

(in thousands)

	At December 31,	
	2023 $'000	**2022 $'000**
ASSETS		
Current assets		
Cash and cash equivalents	78,420	165,955
Other financial assets	55,615	—
Marketable securities	27,525	—
Other current assets	2,529	2,586
Total current assets	**164,089**	**168,541**
Non-current assets		
Marketable securities	61,142	85,724
Property, plant and equipment	1,069	97
Total non-current assets	**62,211**	**85,821**
Total assets	**226,300**	**254,362**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	3,490	1,868
Lease liability	343	—
Other current liabilities	2,868	2,678
Total current liabilities	**6,701**	**4,546**
Non-current liabilities		
Lease liability	631	—
Total non-current liabilities	**631**	**—**
Total liabilities	**7,332**	**4,546**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,463	291,448
Other reserves	4,651	2,595
Foreign currency translation reserve	(10,507)	(13,035)
Accumulated deficit	(67,940)	(32,493)
Total equity	**218,968**	**249,816**
Total liabilities and equity	**226,300**	**254,362**


GH
RESEARCH
Corporate Presentation
GH Research PLC (NASDAQ: GHRS)
February 2024
2024© GH Research PLC
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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 expectations related to the clinical hold on the GH001 IND, including plans and expectations for progressing any nonclinical programs and any other work to lift the clinical hold, the timing required to lift such clinical hold and for discussions with the FDA and the outcomes and resolution of such discussions; 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.

GH RESEARCH

Seeking Ultra-Rapid, Durable Remissions in Depression

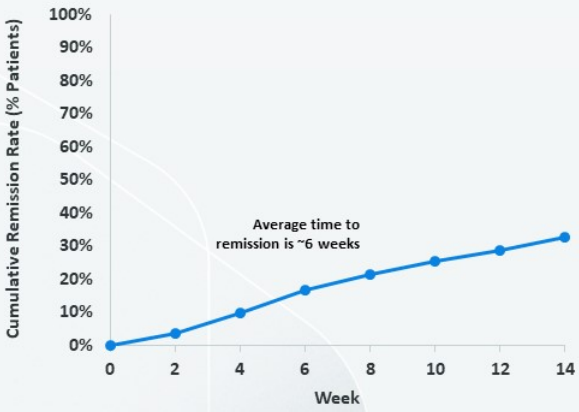
Pipeline

*Bipolar II disorder with a current major depressive episode
5-MeO-DMT, 5-Methoxy-N,N-Dimethyltryptamine; i.v., intravenous; RDBPC, Randomized, Double-Blind, Placebo-Controlled; POC, Proof-of-Concept; HV, Healthy Volunteer

The Problem for Patients with Depression

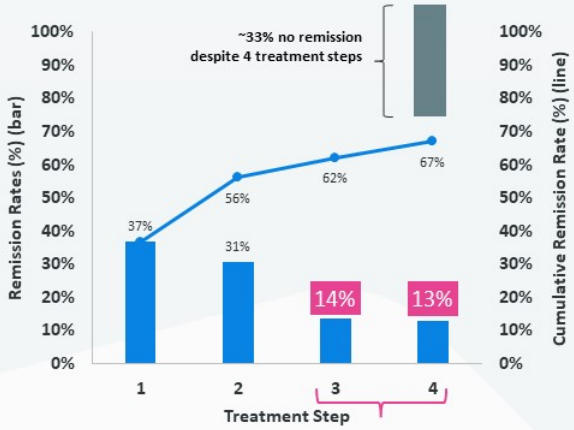
Established Therapies are Slow-Acting

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



... Remission Rates in TRD < 15%

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



Adapted from Trivedi et al., Am J Psychiatry 2006 and Rush et al., Am J Psychiatry 2006
TRD, Treatment-Resistant Depression

Large and Open Depression Market in the EU and US

First Line MDD
- Diagnosed: ~**48M**
- Treated (pharmacotherapy ± psychotherapy): ~**24M**

Second Line MDD
- Non-response to first line: ~**13M**

Treatment-Resistant Depression (TRD)
- Non-response to two prior lines: **~9M**

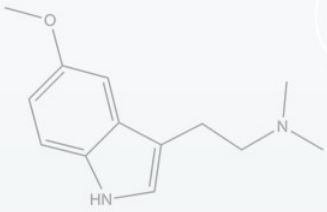
Patients cycle through ineffective therapies for TRD

*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

Mebufotenin (5-MeO-DMT) and GH001

Mebufotenin (5-Methoxy-N,N-Dimethyltryptamine, 5-MeO-DMT)

- Naturally-occurring psychoactive substance from tryptamine class
- **Highly potent** agonist on 5-HT1A and 5-HT2A receptors



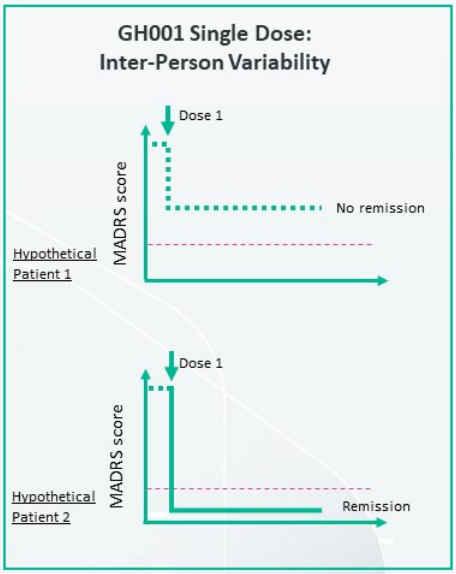
Mebufotenin (5-MeO-DMT)

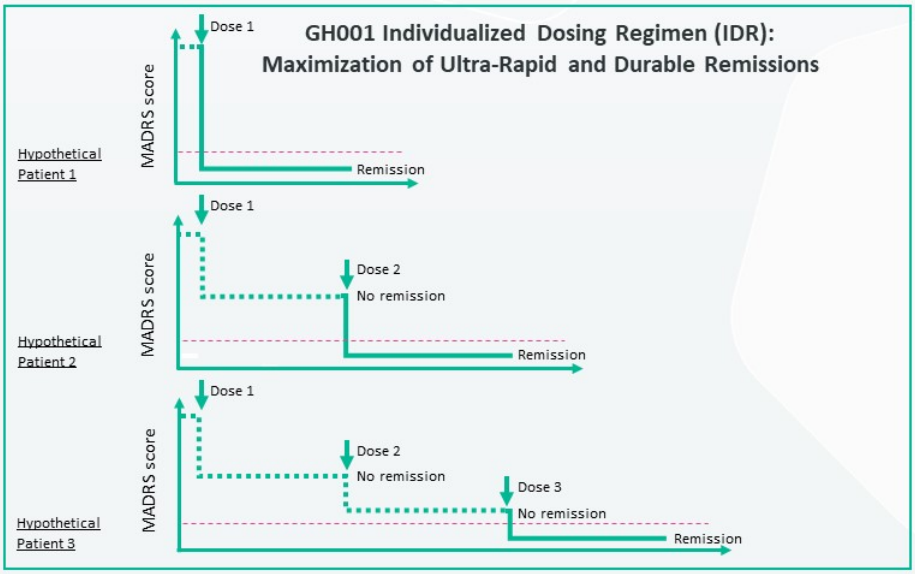
GH001 (Mebufotenin administration via a proprietary pulmonary inhalation approach)

- **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**
- **Intraday individualized dosing regimen (IDR)** for **maximization of ultra-rapid and durable remissions**
- **Single visit initial treatment,** without additional mandated visits for psychotherapy or psychological support before or after dosing
- Potential for **convenient and infrequent retreatment**

Foundational IP

GH001 – Individualized Dosing Regimen (IDR) for Maximization of Ultra-Rapid and Durable Remissions





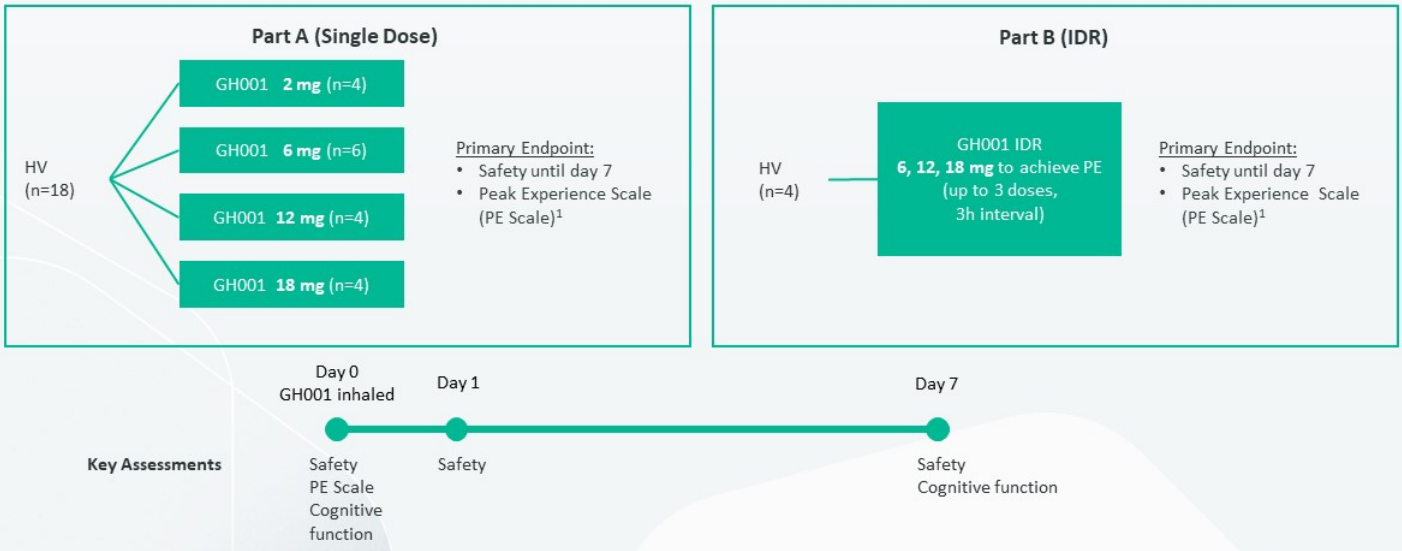
MADRS, Montgomery-Åsberg Depression Rating Scale

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

(Completed)

Clinicaltrials.gov ID: NCT04640831

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



HV, Healthy Volunteer; PE, Peak Experience; IDR, Individualized Dosing Regimen

[1]The 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

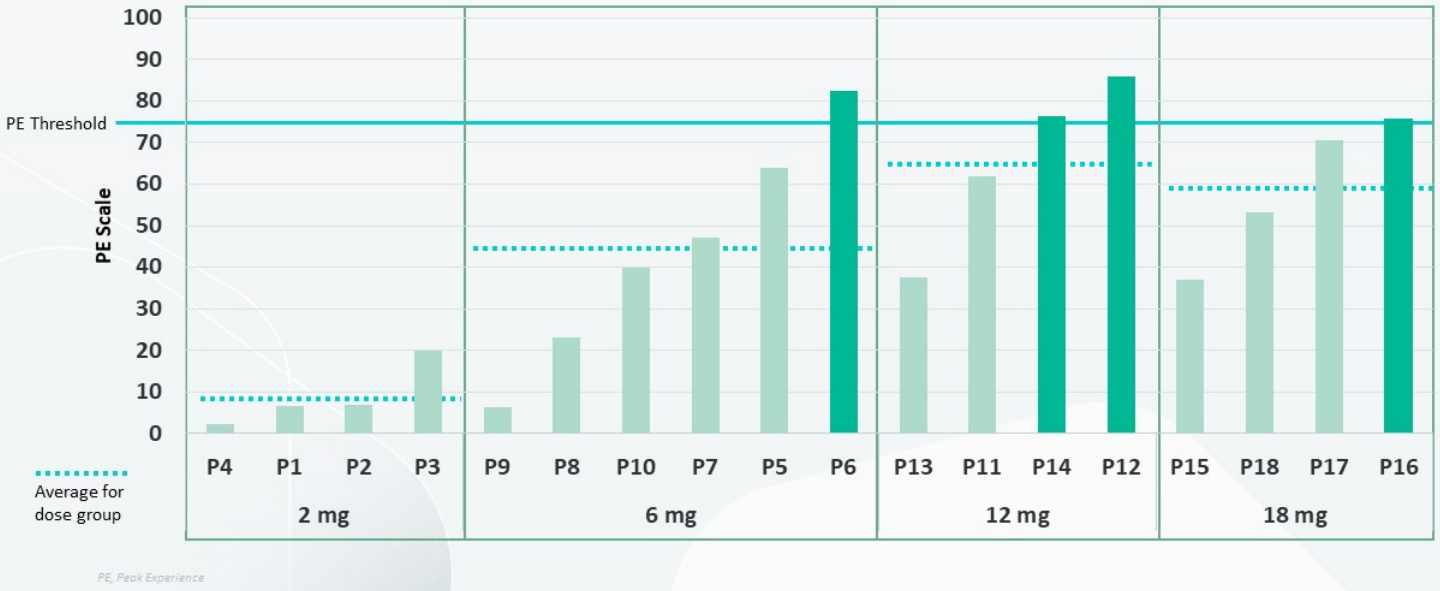
- **No SAEs**
- **All ADRs mild, except two moderate** (*)
- **All ADRs resolved spontaneously**
- **Inhalation well-tolerated**
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
-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

SAE, Serious Adverse Event; ADR, Adverse Drug Reaction, 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

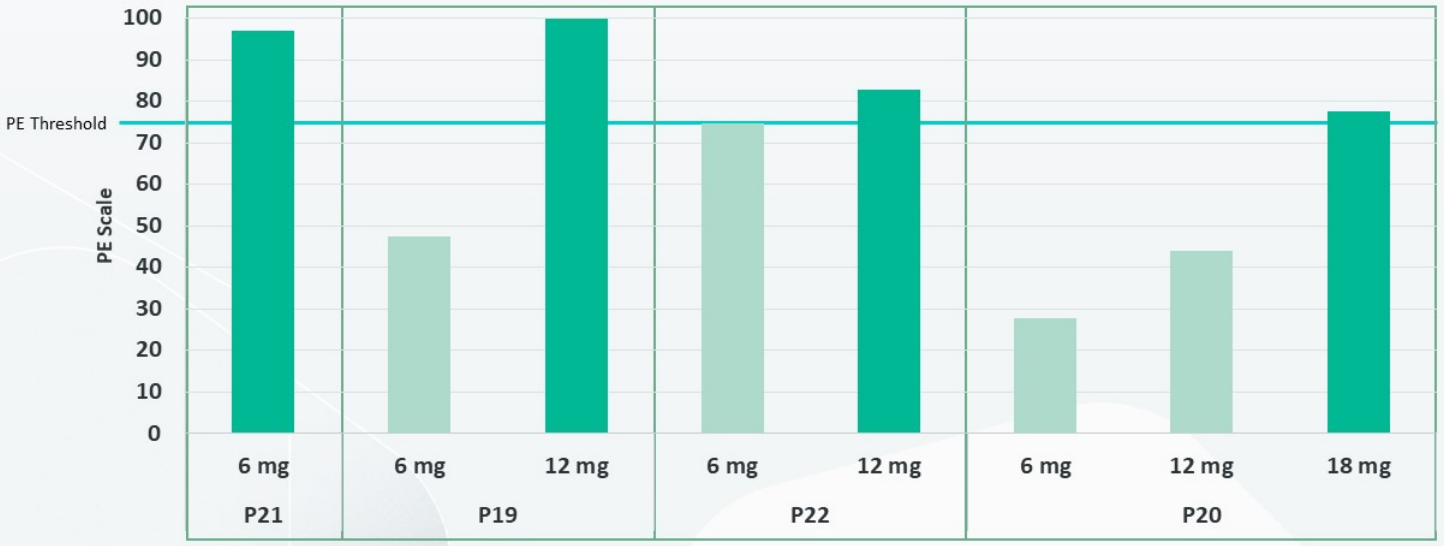
[1] 6 mg (n=1); 6-12 mg (n=2); 6-12-18 mg (n=1)

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 (IDR)



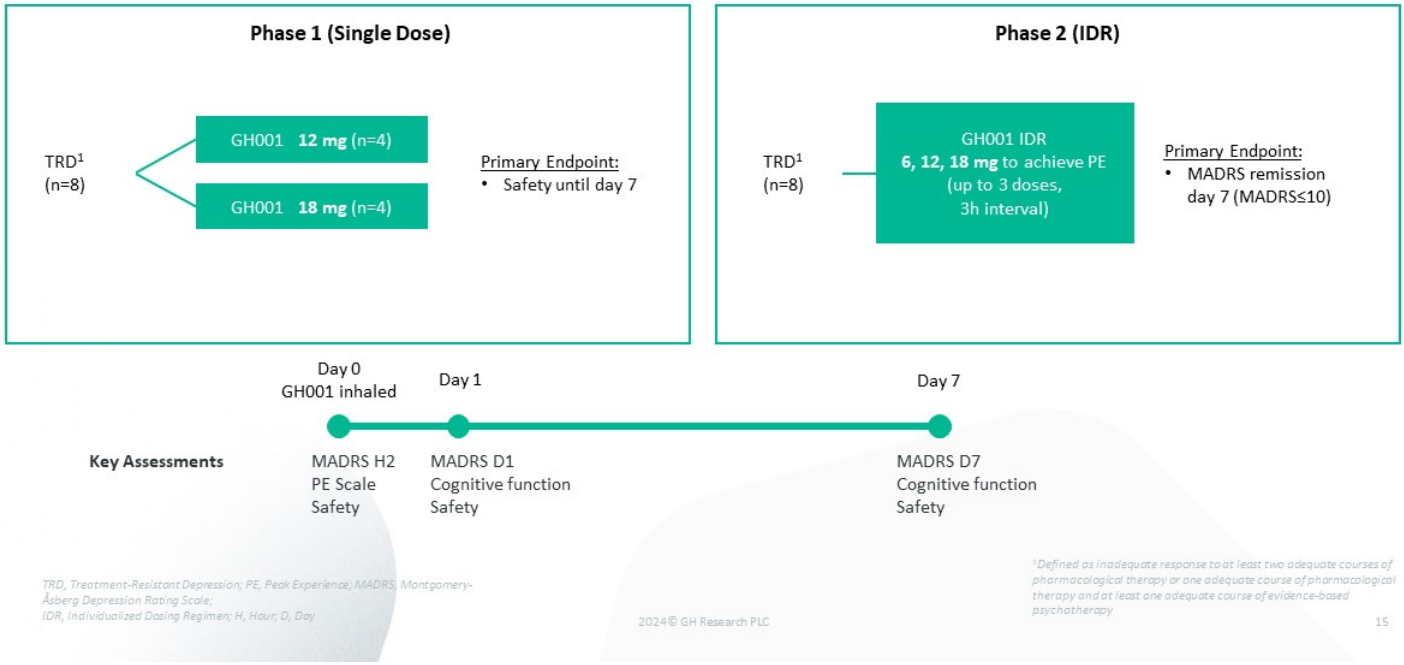
PE, Peak Experience

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

(Completed)

Clinicaltrials.gov ID: NCT04698603

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



TRD, Treatment-Resistant Depression; PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen; H, Hour; D, Day

[1]Defined 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

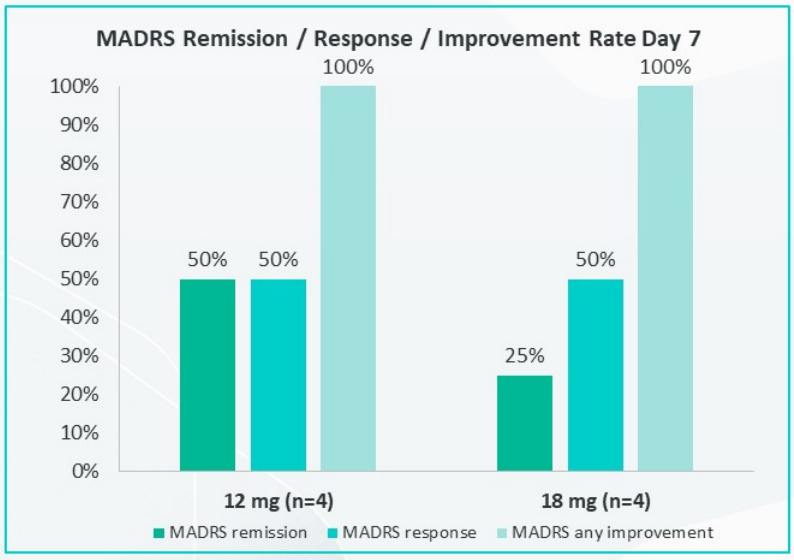
- **No SAEs**
- **All ADRs mild, except three moderate** (*)
- **All ADRs resolved spontaneously**
- **Inhalation well-tolerated**
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically relevant 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	Number of Events		
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

SAE, Serious Adverse Event; ADR, Adverse Drug Reaction, 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; MADRS, Montgomery-Åsberg Depression Rating Scale

[1] 6-12 mg (n=6); 6-12-18 mg (n=2)

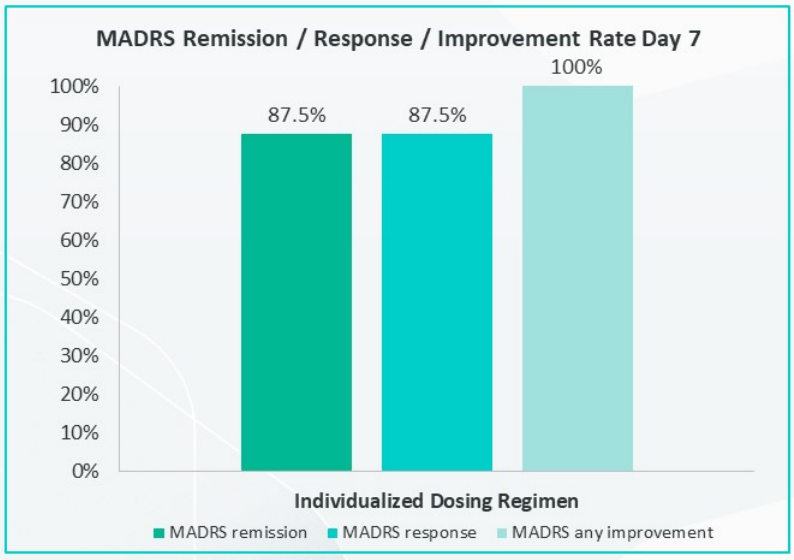
Phase 1 (Single Dose) – Efficacy (MADRS)



- 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 ≥50% from baseline in MADRS; MADRS any improvement = any reduction from baseline in MADRS

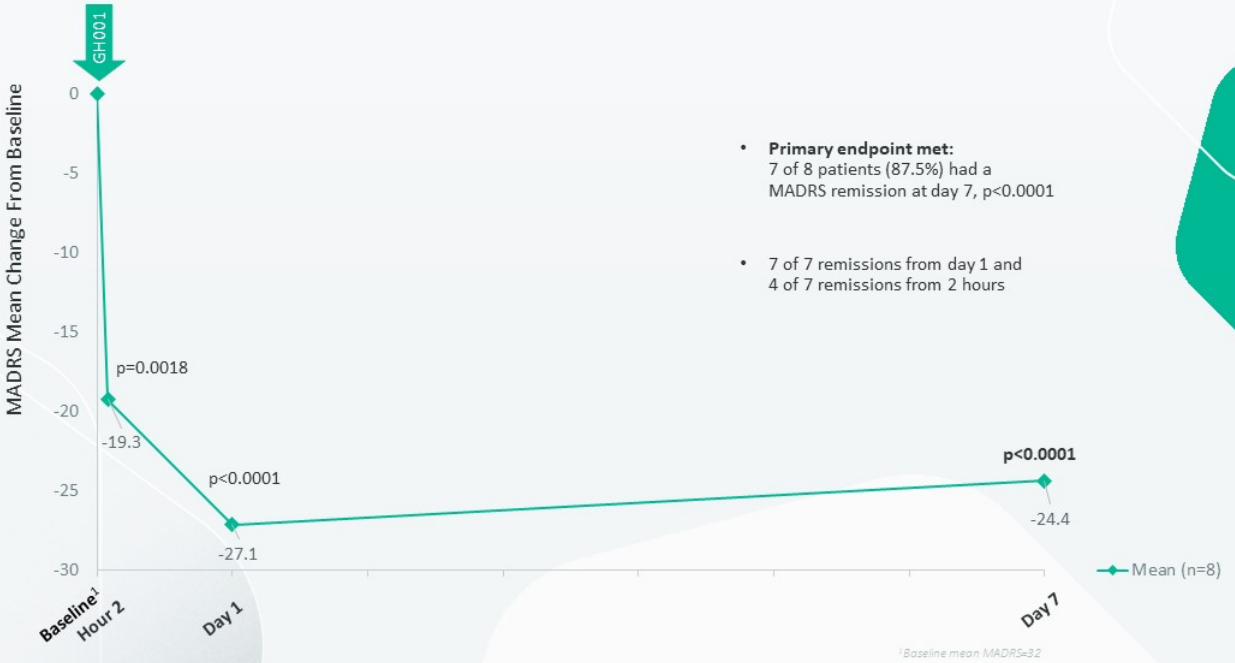
Phase 2 (IDR) – Efficacy (MADRS)



- **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 ≥50% from baseline in MADRS; MADRS any improvement = any reduction from baseline in MADRS

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



- **Primary endpoint met:**
  7 of 8 patients (87.5%) had a MADRS remission at day 7, p<0.0001
- 7 of 7 remissions from day 1 and 4 of 7 remissions from 2 hours

[1]Baseline mean MADRS=32

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%)	-12.5 (-40%)
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

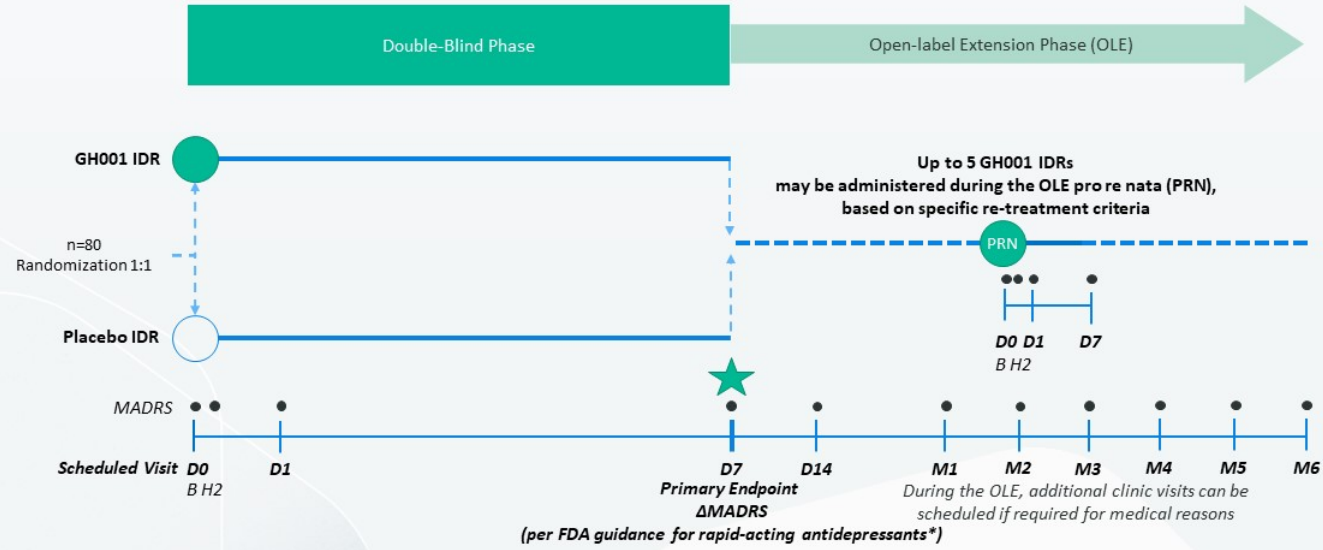
PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen

Phase 2b Trial in Treatment-Resistant Depression GH001-TRD-201

(Initiated)

EudraCT Number: 2022-000574-26

Design of Phase 2b Trial in TRD (GH001-TRD-201)



*The bold solid lines indicate the fixed duration of 7 days (± 1 day) after an IDR with visits on D0, D1 and D7. The bold dotted line indicates the variable duration until a potential GH001 IDR in the OLE. The GH001 IDR consists of up to 3 increasing doses (6, 12, 18 mg) and the Placebo IDR consists of up to three placebo doses, to achieve a peak experience, given at a 1H interval. As in previously completed trials, the GH001-TRD-201 trial will be conducted under the supervision of a healthcare provider, but without any planned psychotherapeutic interventions before, during, or after dosing. IDR, Individualized Dosing Regimen; PRN, pro re nata (as needed); B, Baseline; H, Hour; D, Day; M, Month. *FDA draft guidance for industry "Major Depressive Disorder: Developing Drugs for Treatment"*

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

Granted patents and patent applications relating to mebufotenin (5-MeO-DMT), including:

- Novel uses in various disorders (including inhaled, nasal, buccal, sublingual, i.v., i.m., s.c. routes)
- Novel aerosol compositions of matter
- Novel manufacturing methods and novel salt forms
- Novel device-related aspects

LAYER 3: TECHNICAL

Complex bioequivalence for systemically-acting inhalation/intranasal products with high intra- and inter-subject variability

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Anticipated Milestones and Financial Overview

GH001

- Complete double-blind phase of European multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in TRD in Q3 2024, and provide top-line data in Q3 or Q4 2024
- Complete Phase 2a trial in PPD and provide top-line data in Q3 2024
- Provide update on U.S. IND clinical hold and planned Phase 1 clinical pharmacology trial with proprietary aerosol delivery device in Q2 2024

GH002

- Complete analysis of Phase 1 clinical pharmacology trial in healthy volunteers

GH003

- Complete preclinical development

Financial Overview

- Cash, cash equivalents, other financial assets and marketable securities were $222.7 million as of December 31, 2023
- We believe existing cash, cash equivalents, other financial assets and marketable securities will be sufficient to fund operating expenses and capital expenditure requirements into 2026

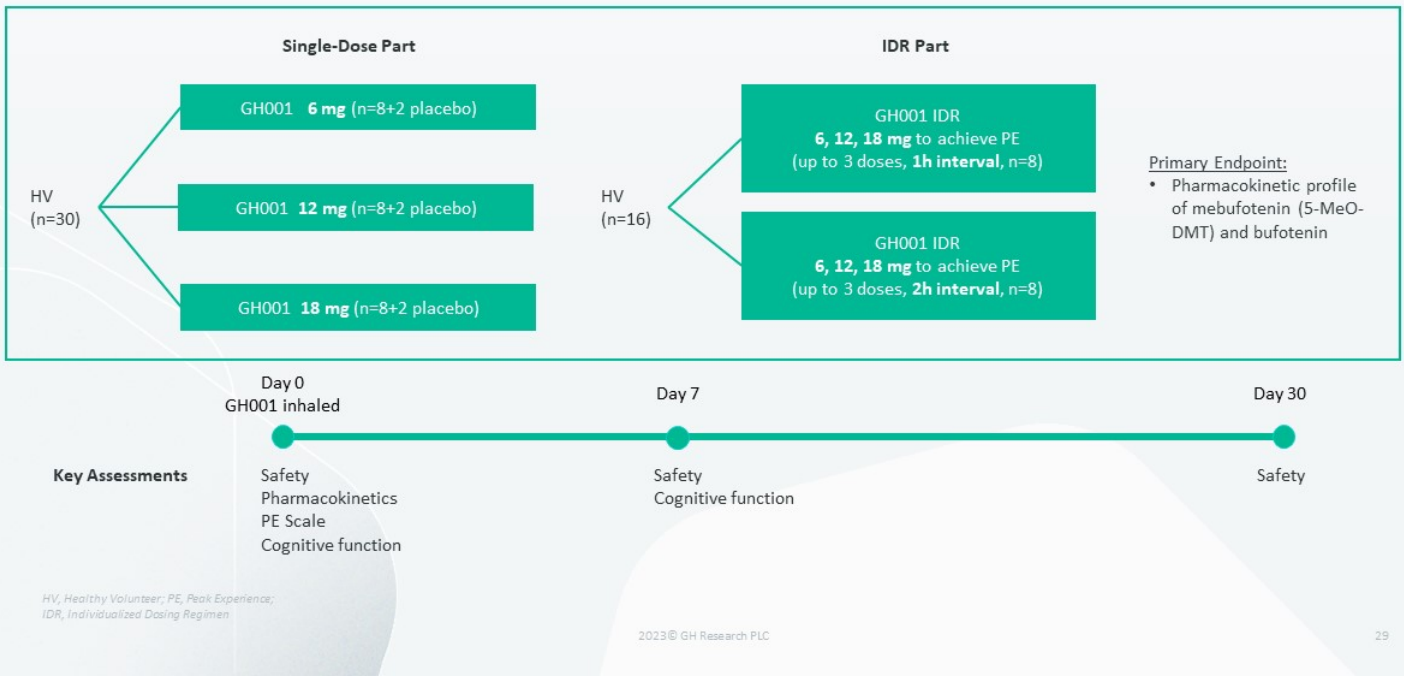
Appendix
Additional Completed Trials

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

(Completed)

Clinicaltrials.gov ID: NCT05163691

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



HV, Healthy Volunteer; PE, Peak Experience; IDR, Individualized Dosing Regimen

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 or psychiatric symptom scales, 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)[1]	2h interval (n=8)[2]
MedDRA Preferred Term	**Number of Events**					
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			

[1] 6 mg (n=1), 6-12 mg (n=3); 6-12-18 mg (n=4)
[2] 6-12 mg (n=3); 6-12-18 mg (n=5)

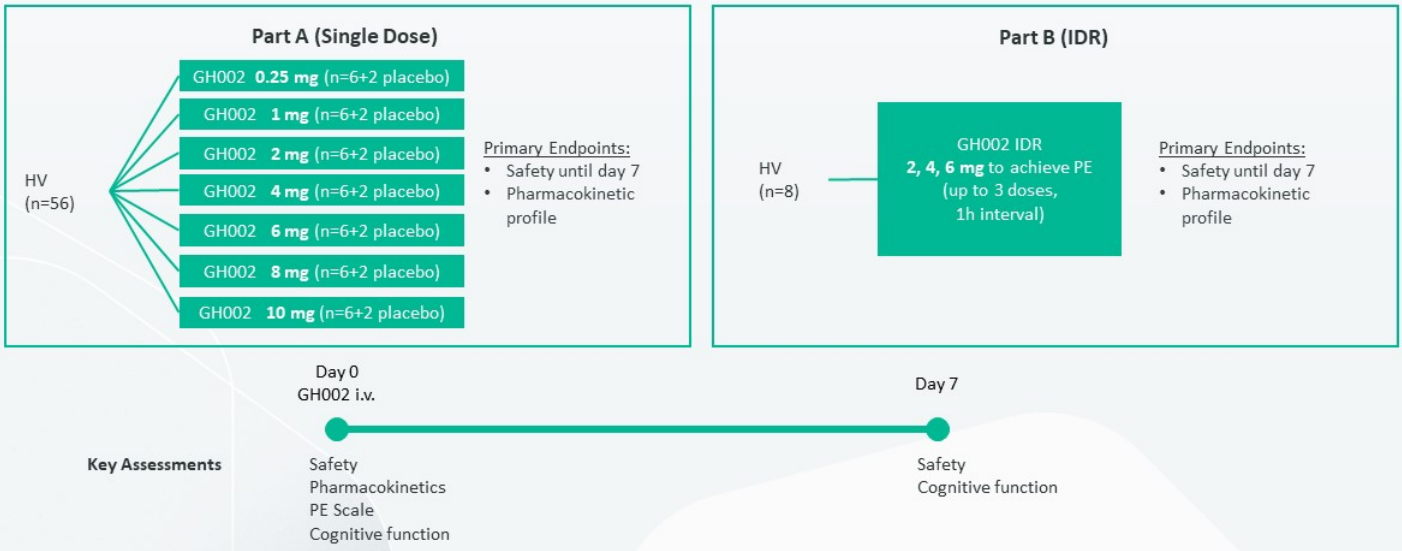
SAE, Serious Adverse Event; Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing; IDR, Individualized Dosing Regimen; C-SSRS, Columbia-Suicide Severity Rating Scale; PE, Peak Experience

Phase 1 Clinical Pharmacology Trial of GH002 in Healthy Volunteers GH002-HV-105

(Completed)

Clinicaltrials.gov ID: NCT05753956

Design of Phase 2 Trial of GH002 in Healthy Volunteers (GH002-HV-105)



HV, Healthy Volunteer; PE, Peak Experience; IDR, Individualized Dosing Regimen

Single Dose and IDR – Safety and Further Results

Safety review

- **No SAEs**
- **All ADRs mild, except one moderate (*)**
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH002
- No clinically relevant changes in ECG and safety laboratory analyses
- No clinically relevant changes in psychiatric symptoms scales, except for changes associated with the ADRs of emotional distress and poor quality sleep

Further Results

- Potent psychoactive effects (PsE) with ultra-rapid onset and short duration were observed. The pharmacokinetic profile correlated with the ultra-rapid profile of the PsE.

ADRs	Single Dose							IDR
	0.25 mg (n=6)	1 mg (n=6)	2 mg (n=6)	4 mg (n=6)	6 mg (n=6)	8 mg (n=6)	10 mg (n=6)	Placebo (n=14) [1]	1h interval (n=8) [2]
MedDRA Preferred Term	Number of Events								
Abnormal dreams							1		
Body temperature increased			1						
Chest discomfort				1					
Cold sweat				1					
Dizziness			2	1		1			
Dyspnoea									1
Emotional distress			1			1*			
Fatigue			2		1	1	1		
Grunting							2		
Headache					1			1	2
Head discomfort				1		1			1
Muscle spasms							2		
Muscle twitching							1		
Nausea	1	1		2		1			2
Neck pain							1		
Pain in extremity							2		
Poor quality sleep							1		
Sleep disorder							1		
Vomiting		1				1	1		1

[1] n=2 subjects received placebo in each dose group
[2] 2 mg (n=4); 2-4 mg (n=2); 2-4-6 mg (n=2)

SAE, Serious Adverse Event; 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

GH RESEARCH

Seeking Ultra-Rapid, Durable Remissions in Depression