
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 May, 2023.

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

On May 11, 2023, GH Research PLC (the “Company”) reported its first quarter 2023 financial results and provided business highlights.

On May 11, 2023, 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 11, 2023 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.

INCORPORATION BY REFERENCE

This Report on Form 6-K (other than Exhibit 99.3 and Exhibit 99.4 hereto), including 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333-270418) of GH Research PLC and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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	Unaudited Condensed Consolidated Interim Financial Statements for the three months ended March 31, 2023
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations
99.3	Press release dated May 11, 2023
99.4	Corporate Presentation for May 2023

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 11, 2023

GH Research PLC

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



UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS FOR THE THREE MONTHS ENDED MARCH 31, 2023

Unaudited condensed consolidated interim statement of comprehensive income

	Note	Three months ended	
		March 31,	
		2023	2022
		\$'000	\$'000
Operating expenses			
Research and development	3	(7,306)	(4,714)
General and administration	3	(3,113)	(3,292)
Loss from operations		(10,419)	(8,006)
Finance income	4	1,489	-
Finance expense	4	(171)	-
Expected credit loss		(199)	-
Foreign exchange (loss)/gain		(1,637)	2,243
Total other (expense)/income		(518)	2,243
Loss before tax		(10,937)	(5,763)
Tax charge/(credit)		-	-
Loss for the period		(10,937)	(5,763)
Other comprehensive income/(expense)			
<i>Items that may be reclassified to profit or loss</i>			
Fair value movement on marketable securities		724	-
Currency translation adjustment		1,676	(2,261)
Total comprehensive loss for the period		(8,537)	(8,024)
Attributable to owners:			
Loss for the period		(10,937)	(5,763)
Comprehensive loss for the period		(8,537)	(8,024)
Loss per share			
Basic and diluted loss per share (in USD)	15	(0.210)	(0.111)

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

Unaudited condensed consolidated interim statement of financial position

	Note	At March 31,	At December 31,
		2023	2022
		\$'000	\$'000
ASSETS			
Current assets			
Cash and cash equivalents	5	105,082	165,955
Other financial assets	5	54,057	-
Marketable securities	6	3,682	-
Other current assets	7	1,896	2,586
Total current assets		164,717	168,541
Non-current assets			
Marketable securities	6	83,321	85,724
Property, plant and equipment	8	1,221	97
Total non-current assets		84,542	85,821
Total assets		249,259	254,362
LIABILITIES AND EQUITY			
Current liabilities			
Trade payables	9	2,928	1,868
Lease liability	10	334	-
Other current liabilities	11	3,376	2,678
Total current liabilities		6,638	4,546
Non-current liabilities			
Lease liability	10	791	-
Total non-current liabilities		791	-
Total liabilities		7,429	4,546
Equity attributable to owners			
Share capital		1,301	1,301
Additional paid-in capital		291,448	291,448
Other reserves		3,870	2,595
Foreign currency translation reserve		(11,359)	(13,035)
Accumulated deficit		(43,430)	(32,493)
Total equity		241,830	249,816
Total liabilities and equity		249,259	254,362

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

Unaudited condensed consolidated interim statement of changes in equity

	Attributable to owners					Total
	Share capital	Additional paid-in capital	Other reserves	Foreign currency translation reserve	Accumulated deficit	
	\$'000	\$'000	\$'000	\$'000	\$'000	
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
At January 1, 2023	1,301	291,448	2,595	(13,035)	(32,493)	249,816
Loss for the period	-	-	-	-	(10,937)	(10,937)
Other comprehensive income	-	-	724	1,676	-	2,400
Total comprehensive loss for the period	-	-	724	1,676	(10,937)	(8,537)
Share-based compensation expense	-	-	551	-	-	551
Total transactions with owners	-	-	551	-	-	551
At March 31, 2023	1,301	291,448	3,870	(11,359)	(43,430)	241,830

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

Unaudited condensed consolidated interim statement of cash flows

	Three months ended	
	March 31,	
	2023	2022
	\$'000	\$'000
Cash flows from operating activities		
Loss for the period	(10,937)	(5,763)
Depreciation	77	11
Share-based compensation expense	551	327
Finance income	(1,489)	-
Finance expense	171	-
Expected credit loss	199	-
Foreign exchange loss/(gain)	1,637	(2,243)
Movement in working capital	2,473	1,667
Cash flows used in operating activities	(7,318)	(6,001)
Finance expense paid	(246)	-
Finance income received	679	-
Net cash used in operating activities	(6,885)	(6,001)
Cash flows used in investing activities		
Purchase of other financial assets	(54,000)	-
Purchase of property, plant and equipment	(22)	(10)
Cash flows used in investing activities	(54,022)	(10)
Cash flows used in financing activities		
Payment of lease liability	(70)	-
Net decrease in cash	(60,977)	(6,011)
Cash at the beginning of the period	165,955	276,776
Impact of foreign exchange on cash	104	(15)
Cash at the end of the period	105,082	270,750

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

NOTES TO THE UNAUDITED 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 mebufotenin (5-methoxy-N,N-dimethyltryptamine, or 5-MeO-DMT) therapies for the treatment of patients with Treatment Resistant Depression, or TRD. Its portfolio currently includes GH001, a proprietary inhalable mebufotenin product candidate, GH002, a proprietary intravenous mebufotenin product candidate, and GH003, a proprietary intranasal mebufotenin product candidate.

These unaudited condensed consolidated interim financial statements were presented to the board of directors and approved by them for issue on May 11, 2023.

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, 2023 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, 2022 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.

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, 2022, are expected to be filed with the Companies Registration Office by November 26, 2023.

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, 2023, 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, except lease liabilities, as of March 31, 2023. As a result, the Group is not exposed to liquidity risk through requests for early repayment of loans.

As of March 31, 2023, the Group’s cash and cash equivalents amounted to \$105.1 million (December 31, 2022: \$166.0 million). The Group also held marketable securities of \$87.0 million and other financial assets of \$54.1 million as of March 31, 2023, (December 31, 2022: marketable securities of \$85.7 million and other financial assets of \$nil). The Group’s marketable securities are quoted in active markets and are an additional source of liquidity.

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.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)**Use of estimates and judgments**

The preparation of the unaudited condensed consolidated interim financial statements requires management to make judgments, 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 judgments 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, 2022.

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 except for the amendments and new accounting policies set out below.

Financial assets

Other financial assets represent money market funds with a weighted average maturity of more than 90 days and are carried at fair value through profit or loss as the cash flows from these funds do not represent solely payments of principal and interest.

Leases and right-of-use assets

The Group recognizes a right-of-use ("ROU") asset and a corresponding lease liability for all arrangements in which it is a lessee, except for leases with a term of 12 months or less (short-term leases) and low-value leases. Under IFRS 16 the Group recognizes a ROU asset and a lease liability at the lease commencement date at the present value of the future lease payments, discounted at the Group's incremental borrowing rate. The ROU asset is subsequently depreciated using the straight-line method over the lease term within depreciation expenses and an interest expense on lease liabilities is recognized within finance expense in the Group's unaudited condensed consolidated interim income statement. The interest expense is calculated based on the incremental borrowing rate of the Group.

For short-term or low value leases, the Group recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease.

Current and deferred income tax

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, 2023 and 2022, which is in line with the Company's estimate for the full year. No deferred tax assets have been recognized as there is no certainty that sufficient taxable profits will be generated within the required timeframe to be able to utilize these tax loss carry-forwards in full.

NOTES TO THE UNAUDITED 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 months ended	
	March 31,	
	2023	2022
	\$'000	\$'000
External research and development expenses	5,825	3,883
Employee expenses ¹	1,419	798
Depreciation	10	8
Other expenses	52	25
Total research and development expenses	7,306	4,714
External costs	2,270	2,749
Employee expenses ²	776	540
Depreciation	67	3
Total general and administrative expenses	3,113	3,292
Total operating expenses	10,419	8,006

¹Included in employee expenses is share based compensation expense of \$0.3 million and \$0.2 million for the three months ended March 31, 2023 and 2022, respectively, relating to employees in the research and development department.

² Included in employee expenses is share based compensation expense of \$0.2 million and \$0.2 million for the three months ended March 31, 2023 and 2022, respectively, relating to employees in the general and administrative department.

Foreign exchange loss/gain

Foreign exchange loss of \$1.6 million for the three months ended March 31, 2023 (foreign exchange gain of \$2.2 million for the three months ended March 31, 2022) consists primarily of losses related to the translation of the U.S. dollar cash and other financial assets balance into euro in the accounts of the Company's subsidiary, GH Research Ireland Limited, whose functional currency is euro as explained in the Group's consolidated financial statements for the year ended December 31, 2022.

At March 31, 2023, if the U.S. dollar had weakened/strengthened by 10% against the euro with all other variables held constant, the loss before tax for the three months ended March 31, 2023, would have been \$8.2 million higher/lower, mainly related to the translation of cash and other financial assets held in U.S. dollar in the Company's subsidiary, GH Research Ireland Limited.

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

4. Finance income and expense

	Three months ended	
	2023	2022
	March 31,	March 31,
	\$'000	\$'000
Finance income		
Gain on cash equivalents and other financial assets at fair value through profit and loss	465	-
Interest income under effective interest rate method at fair value through other comprehensive income ("FVOCI")	1,024	-
Finance income	1,489	-
Finance expense		
Finance expense on investments	(153)	-
Finance expense on lease liability	(18)	-
Finance expense	(171)	-

5. Cash and cash equivalents

	March 31,	December 31,
	2023	2022
	\$'000	\$'000
Cash at bank and in hand	69,002	130,252
Cash equivalents	36,080	35,703
	105,082	165,955

During the period ended March 31, 2023, a further investment of \$54.0 million was made in a money market fund. This investment was classified as other financial assets.

6. Marketable securities

	Marketable securities
	\$'000
Fair value	
At January 1, 2023	85,724
Additions	-
Accrued interest	1,024
Interest received	(270)
Fair value gain	525
At March 31, 2023	87,003

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

The Group holds government and corporate listed bonds which comprise marketable securities measured at FVOCI. These marketable securities had a fair value of \$87.0 million at March 31, 2023, (December 31, 2022: \$85.7 million). The impairment loss allowance for expected credit losses at the reporting date was \$0.3 million (December 31, 2022: \$0.1 million). At March 31, 2023, the maturity of the Group's marketable securities ranges from 10 months to four years. This maturity has been reflected in the allocation of current and non-current assets in the unaudited condensed consolidated interim statement of financial position.

The Group is exposed to credit risk on its cash and cash equivalents, other financial assets and marketable securities in the event of default of the counterparties. The Group's cash balance is maintained with well established, highly rated financial institutions. The Group's marketable securities are mainly comprised of investment grade bonds. The Group monitors the credit risk of its investments on a regular basis.

The fair value movement on marketable securities through other comprehensive income for the three months ended March 31, 2023, is comprised of a fair value gain on marketable securities of \$0.5 million and an increase in expected credit losses associated with those marketable securities of \$0.2 million.

7. Other current assets

Other current assets primarily represent prepayments and VAT receivable.

8. Property, plant and equipment

Property, plant and equipment increased to \$1.2 million at March 31, 2023, from \$0.1 million at December 31, 2022, an increase of \$1.1 million. This was due to a lease for office space which the Group entered into during the period. The term of the lease is four years and nine months and annual cashflows associated with it are \$0.3 million.

	Right of Use Asset - Office \$'000
At January 1, 2023	-
Additions	1,179
Depreciation expense	(62)
At March 31, 2023	1,117

At the lease commencement date, a ROU asset was recognized at the present value of the future lease payments, discounted at the Group's incremental borrowing rate.

9. 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.

10. Lease liability

At March 31, 2023, the Group's lease liability amounted to \$1.1 million relating to the lease of an office as explained in Note 8, "Property, plant and equipment".

11. Other current liabilities

Other current liabilities primarily represent accruals for operating expenses and employee tax payable.

12. Contingencies

As of March 31, 2023, there were no material contingencies which required adjustment or disclosure in the unaudited condensed consolidated interim financial statements (2022: none).

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

13. 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, 2023, the Company has 718,818 ordinary shares available for the future issuance of share-based equity awards.

Under the Share Option Plan, 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.

During the three months ended March 31, 2023, the Company granted the option to purchase 22,320 ordinary shares to employees which were in line with the general terms of the Share Option Plan.

The following table summarizes the share option awards outstanding as of March 31, 2023:

	Average exercise price per share in USD	Number of awards	Weighted average remaining life in years
At December 31, 2022	15.32	461,596	7.14
Granted	9.66	22,320	7.86
At March 31, 2023	15.06	483,916	6.94

None of the awards outstanding as of March 31, 2023 were exercisable and they expire through 2031. As of March 31, 2023, 88,569 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, 2023 was \$7.22 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.

The fair values of the options granted during the three months ended March 31, 2023 and 2022 were determined on the date of the grant using the following assumptions:

	Three months ended March 31, 2023	Three months ended March 31, 2022
Share price, in USD	8.77-10.40	15.71-18.32
Strike price, in USD (weighted average)	9.66	20.26
Expected volatility	87%	89% - 90%
Award life (weighted average)	6	6
Expected dividends	-	-
Risk-free interest rate	3.63%-4.22%	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.

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

As of March 31, 2023, Other Reserves within equity includes \$2.6 million relating to the Group's Share Option Plan. The amount of expense for all awards recognized for services received during the three months ended March 31, 2023 was \$0.6 million and for the three months ended March 31, 2022 was \$0.3 million.

14. Related party disclosures

There have been no transactions in the three months ended March 31, 2023 and ended March 31, 2022 with related parties that had a material effect on the financial position or performance of the Group.

15. 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 months ended March 31,	
	2023	2022
Loss attributable to shareholders (in \$'000)	(10,937)	(5,763)
Weighted average number of shares in issue	52,020,849	52,020,849
Basic and diluted loss per share (in USD)	(0.210)	(0.111)

For the three months ended March 31, 2023 and 2022, 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.

16. Events after the reporting date

In April 2023, 174,000 share options were granted to the Group's employees. The awards 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 two year service condition. The contractual term (expiration) of each share option is seven years from the date of grant. The exercise price of these share options was set at \$0.025 per share.

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, 2023. You should also read this discussion and analysis in conjunction with our audited consolidated financial statements, including the notes thereto, and the section in our annual report on Form 20-F for the year ended December 31, 2022 titled "Item 3. Key Information—D. Risk Factors."

Our unaudited condensed consolidated interim financial statements for the three months ended March 31, 2023, 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 mebufotenin (5-methoxy-N,N-dimethyltryptamine, or 5-MeO-DMT) therapies for the treatment of patients with treatment-resistant depression, or TRD. Mebufotenin was selected as the International Nonproprietary Name (INN) for 5-MeO-DMT by the World Health Organization (WHO) Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

Our portfolio currently includes GH001, our proprietary inhalable mebufotenin product candidate which is currently delivered via a vaporization device produced by a third party, but for which we are developing a proprietary aerosol delivery device, and GH002, our proprietary intravenous mebufotenin product candidate, and GH003, our proprietary intranasal mebufotenin product candidate. With GH001, 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, or IDR, 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) psychoactive experience. Based on observed clinical activity in the Phase 2 part of the trial, we believe that administration of GH001 in an IDR 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 losses since inception, including losses of \$10.9 million for the three months ended March 31, 2023, and losses of \$22.5 million and \$9.2 million for the years ended December 31, 2022 and 2021, respectively. As of March 31, 2023, we had an accumulated deficit of \$43.4 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 mebufotenin product candidate, GH002, our intravenous mebufotenin product candidate, and GH003, our intranasal mebufotenin product candidate for our initial indications and 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, such as our proprietary aerosol delivery device for GH001;
- 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, such as our proprietary aerosol delivery device, 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;
- adapt to ongoing changes in global economic conditions, including but not limited to continuing inflation, disruptions in global supply chains and labor markets and geopolitical risks and global hostilities, including any direct or indirect economic impacts resulting from Russia's invasion of Ukraine;
- 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 also 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 Highlights

GH001

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 of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201). We expect to recruit approximately 80 patients for this trial across several European countries. The primary objective is to determine the efficacy of our single-day individualized dosing regimen (IDR) of GH001 compared with placebo in improving depressive symptoms as assessed by the mean change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) at the end of the 7-day double-blind phase. The double-blind phase is followed by a 6-month open-label extension phase where all patients can receive treatment with the GH001 IDR as-needed, based on the patient's clinical status. Further trial design details are described in our corporate presentation, which is available in the investor section on our website.

As previously announced, we expect to submit an IND for GH001 in TRD, delivered with our proprietary aerosol delivery device, in the third quarter of 2023. The IND-opening study is expected to be a Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-106), designed to support bridging to the clinical data generated with the third-party device we currently use in our clinical trials.

The Phase 2a proof-of-concept clinical trials of GH001 in bipolar II disorder and a current depressive episode (GH001-BD-202) and in postpartum depression (GH001-PPD-203) are expected to be completed in the fourth quarter of 2023.

GH002

Our randomized, double-blind, placebo-controlled, dose-ranging clinical pharmacology trial of GH002, our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach, in healthy volunteers (GH002-HV-105) is expected to be completed in the fourth quarter of 2023.

Intellectual Property

We have recently filed 19 new international patent applications, which claim priority to earlier filings, further expanding our patent portfolio, which relates to various aspects of mebufotenin (5-MeO-DMT) use in a therapeutic context, including but not limited to the use of mebufotenin (5-MeO-DMT) for treatment of various disorders when administered by inhalation, or by nasal, buccal, sublingual, intravenous, intramuscular or subcutaneous routes.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31		
	2023	2022	Change
		(in USD thousands)	
Operating Expenses:			
Research and development	(7,306)	(4,714)	(2,592)
General and administrative	(3,113)	(3,292)	179
Loss from operations	(10,419)	(8,006)	(2,413)
Net finance income ¹	1,119	—	1,119
Foreign exchange (loss)/gain	(1,637)	2,243	(3,880)
Loss for the period	(10,937)	(5,763)	(5,174)

¹Net finance income for the three months ended March 31, 2023, comprises finance income, finance expense and expected credit losses.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31		
	2023	2022	Change
	(in USD thousands)		
External research and development expenses	(5,825)	(3,883)	(1,942)
Employee expenses ¹	(1,419)	(798)	(621)
Depreciation	(10)	(8)	(2)
Other expenses	(52)	(25)	(27)
Research and development	(7,306)	(4,714)	(2,592)

¹ Includes share based compensation expense of \$0.3 million and \$0.2 million for the three months ended March 31, 2023 and 2022, respectively.

The following table summarizes our research and development expenses for our product candidates for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31		
	2023	2022	Change
	(in USD thousands)		
GH001	(4,663)	(2,637)	(2,026)
GH002	(535)	(332)	(203)
GH003	(8)	-	(8)
Related to multiple product candidates (GH001, GH002 and GH003) ¹	(2,100)	(1,745)	(355)
Research and development	(7,306)	(4,714)	(2,592)

¹ Includes expenses that relate to any combination of GH001, GH002 and/or GH003.

Research and development expenses increased by \$2.6 million to \$7.3 million for the three months ended March 31, 2023, from \$4.7 million for the three months ended March 31, 2022. The increase was primarily due to increased expenses relating to our technical development including device development, active pharmaceutical ingredient and drug product development and manufacturing as well as an increase in clinical trial expenses. These increases have been partly offset by a decrease in expenses relating to nonclinical activities. Employee expenses increased by \$0.6 million primarily due to the hiring of personnel to support our research and development activities.

Research and development expenses for our product candidates will fluctuate from period to period primarily due to the nature and timing associated with the various lifecycle stages of each candidate.

Research and development expenses relating to GH001 increased by \$2.0 million in the three months ended March 31, 2023, primarily due to increased technical development including device development, active pharmaceutical ingredient and drug product development and manufacturing, and clinical trial expenses, partly offset by a decrease in expenses relating to nonclinical activities.

Research and development expenses relating to GH002 increased by \$0.2 million in the three months ended March 31, 2023, primarily due to clinical trial expenses, partly offset by a decrease in expenses relating to our technical development including active pharmaceutical ingredient and drug product development and manufacturing.

Research and development expenses which relate to multiple product candidates increased by \$0.4 million in the three months ended March 31, 2023, primarily due to the hiring of personnel to support our research and development activities and increased expenses relating to our technical development including drug product development and manufacturing. These increases have been partly offset by a decrease in expenses relating to nonclinical activities.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2023 and 2022:

	Three Months Ended		
	2023	2022	Change
	(in USD thousands)		
External costs	(2,270)	(2,749)	479
Employee expenses ¹	(776)	(540)	(236)
Depreciation	(67)	(3)	(64)
General and administrative	(3,113)	(3,292)	179

¹ Includes share based compensation expense of \$0.2 million and \$0.2 million for the three months ended March 31, 2023 and 2022, respectively.

General and administrative expenses decreased by \$0.2 million to \$3.1 million for the three months ended March 31, 2023, from \$3.3 million for the three months ended March 31, 2022. The decrease was primarily due to a reduction in insurance costs offset by increases in professional costs, employee expenses in our general and administrative functions to support our growth initiatives and depreciation relating to the lease on a new office space entered into in January 2023.

Net Finance Income

Our net finance income increased to \$1.1 million for the three months ended March 31, 2023, from \$nil for the three months ended March 31, 2022. The increase is primarily due to interest income of \$1.0 million relating to our marketable securities, as well as a gain of \$0.5 million relating to our cash equivalents and other financial assets. These increases have been partially offset by finance expenses relating to our investments and the expected credit loss on our marketable securities.

Foreign Exchange (Loss)/Gain

Foreign exchange loss was \$1.6 million for the three months ended March 31, 2023, a movement of \$3.9 million from a gain of \$2.2 million for the three months ended March 31, 2022. This movement was primarily as a result of the translation of the U.S. dollar cash and other financial assets balance in the accounts of our subsidiary into its functional currency, which is the euro. During the three months ended March 31, 2023, the U.S. dollar weakened compared to the euro which resulted in the foreign exchange loss.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred 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, 2023, we had cash, cash equivalents, other financial assets and marketable securities of \$246.1 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, 2023 and 2022:

	Three months Ended March 31		
	2023	2022 (in USD thousands)	Change
Net cash flows used in operating activities	(6,885)	(6,001)	(884)
Net cash flows used in investing activities	(54,022)	(10)	(54,012)
Net cash flows used in financing activities	(70)	—	(70)
Net decrease in cash	(60,977)	(6,011)	(54,966)

Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities increased by \$0.9 million to \$6.9 million for the three months ended March 31, 2023 from \$6.0 million for the three months ended March 31, 2022. The increase was primarily due to a \$2.4 million increase in loss from operations which has been partially offset by an increase in share-based compensation expense, an increase related to changes in the components of working capital and an increase in net interest received.

Net Cash Flows Used in Investing Activities

Net cash flows used in investing activities increased to \$54.0 million for the three months ended March 31, 2023 from \$10 thousand for the three months ended March 31, 2022. The increase was due to the investment in a money market fund of \$54.0 million in the period.

Net Cash Flows Used in Financing Activities

Net cash flows used in financing activities increased to \$0.1 million for the three months ended March 31, 2023, from \$nil for the three months ended March 31, 2022. The increase was due to the payment of the lease liability for the lease on a new office space entered into in January 2023.

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, such as our proprietary aerosol delivery device for GH001. 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 public or private 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, 2022 and this discussion and analysis. We believe that we have sufficient financial resources available to cover our planned cash outflows for at least the next twelve months.

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, 2022 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 2012 (“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 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 \$1.24 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 be deemed to be, forward-looking. 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, medical devices required to deliver these product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals, 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. 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, 2022 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, such as our proprietary aerosol delivery device for GH001;
 - 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 trial 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 trial 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, such as our proprietary aerosol delivery device for GH001;
-

- our commercialization and marketing capabilities and strategy;
- the effects of undesirable clinical trial outcomes and potential adverse public perception regarding the use of mebufotenin (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, or CSA, 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;
- changes in economic, capital market and political conditions, including fluctuations in commodity prices, continuing inflation, interest rates and foreign currency exchange rates, disruptions in global supply chains and labor markets, volatility and stress within the banking sector and the measures governments and financial services companies have taken in response, and geopolitical risks and global hostilities, including any direct or indirect economic impacts resulting from Russia's invasion of Ukraine or related sanctions;
- 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, 2022 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 forward-looking 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 forward-looking 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 2023 Financial Results and Provides Business Highlights

DUBLIN, Ireland, May 11, 2023 (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 first quarter ended March 31, 2023 and provided business highlights.

First Quarter 2023 Financial Highlights*Cash position*

Cash, cash equivalents, other financial assets and marketable securities were \$246.1 million as of March 31, 2023, compared to cash, cash equivalents and marketable securities of \$251.7 million as of December 31, 2022. Cash equivalents and other financial assets comprise money market funds. Marketable securities comprise 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 \$7.3 million for the quarter ended March 31, 2023, compared to \$4.7 million for the same quarter in 2022. 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 \$3.1 million for the quarter ended March 31, 2023, compared to \$3.3 million for the same quarter in 2022. The decrease was primarily due to lower insurance costs offset by an increase in professional costs, as well as increased employee expenses.

Net loss

Net loss was \$10.9 million, or \$0.210 loss per share, for the quarter ended March 31, 2023, compared to \$5.8 million, or \$0.111 loss per share, for the same quarter in 2022.

Business Highlights*GH001*

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 of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201). We expect to recruit approximately 80 patients for this trial across several European countries. The primary objective is to determine the efficacy of our single-day individualized dosing regimen (IDR) of GH001 compared with placebo in improving depressive symptoms as assessed by the mean change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) at the end of the 7-day double-blind phase. The double-blind phase is followed by a 6-month open-label extension phase where all patients can receive treatment with the GH001 IDR as-needed, based on the patient's clinical status. Further trial design details are described in our corporate presentation, which is available in the investor section on our website.

As previously announced, we expect to submit an IND for GH001 in TRD, delivered with our proprietary aerosol delivery device, in the third quarter of 2023. The IND-opening study is expected to be a Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-106), designed to support bridging to the clinical data generated with the third-party device we currently use in our clinical trials.

Our Phase 2a proof-of-concept clinical trials of GH001 in bipolar II disorder and a current depressive episode (GH001-BD-202) and in postpartum depression (GH001-PPD-203) are expected to be completed in the fourth quarter of 2023.

GH002

Our randomized, double-blind, placebo-controlled, dose-ranging clinical pharmacology trial of GH002, our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach, in healthy volunteers (GH002-HV-105) is expected to be completed in the fourth quarter of 2023.

Intellectual Property

We have recently filed 19 new international patent applications, which claim priority to earlier filings, further expanding our patent portfolio, which relates to various aspects of mebufotenin (5-MeO-DMT) use in a therapeutic context, including but not limited to the use of mebufotenin (5-MeO-DMT) for treatment of various disorders when administered by inhalation, or by nasal, buccal, sublingual, intravenous, intramuscular or subcutaneous routes.

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).

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, 2022 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 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 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. GH001 is currently in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of GH001 in TRD.

About GH002 and GH003

GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach. GH002 is currently in Phase 1 clinical development. 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 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, 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, 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

Condensed Consolidated Interim Statement of Comprehensive Income (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2023 \$'000	2022 \$'000
Operating expenses		
Research and development	(7,306)	(4,714)
General and administration	(3,113)	(3,292)
Loss from operations	(10,419)	(8,006)
Finance income	1,489	—
Finance expense	(171)	—
Expected credit loss	(199)	—
Foreign exchange (loss)/gain	(1,637)	2,243
Total other (expense)/income	(518)	2,243
Loss before tax	(10,937)	(5,763)
Tax charge/(credit)	—	—
Loss for the period	(10,937)	(5,763)
Other comprehensive income/(expense)		
<i>Items that may be reclassified to profit or loss</i>		
Fair value movement on marketable securities	724	—
Currency translation adjustment	1,676	(2,261)
Total comprehensive loss for the period	(8,537)	(8,024)
Attributable to owners:		
Loss for the period	(10,937)	(5,763)
Comprehensive loss for the period	(8,537)	(8,024)
Loss per share		
Basic and diluted loss per share (in USD)	(0.210)	(0.111)

GH RESEARCH PLC

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At March 31, 2023 \$'000	At December 31, 2022 \$'000
ASSETS		
Current assets		
Cash and cash equivalents	105,082	165,955
Other financial assets	54,057	—
Marketable securities	3,682	—
Other current assets	1,896	2,586
Total current assets	164,717	168,541
Non-current assets		
Marketable securities	83,321	85,724
Property, plant and equipment	1,221	97
Total non-current assets	84,542	85,821
Total assets	249,259	254,362
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	2,928	1,868
Lease liability	334	—
Other current liabilities	3,376	2,678
Total current liabilities	6,638	4,546
Non-current liabilities		
Lease liability	791	—
Total non-current liabilities	791	—
Total liabilities	7,429	4,546
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,448	291,448
Other reserves	3,870	2,595
Foreign currency translation reserve	(11,359)	(13,035)
Accumulated deficit	(43,430)	(32,493)
Total equity	241,830	249,816
Total liabilities and equity	249,259	254,362



Corporate Presentation

GH Research PLC (NASDAQ: GHR)

May 2023

Disclaimer Regarding Forward-Looking Statements

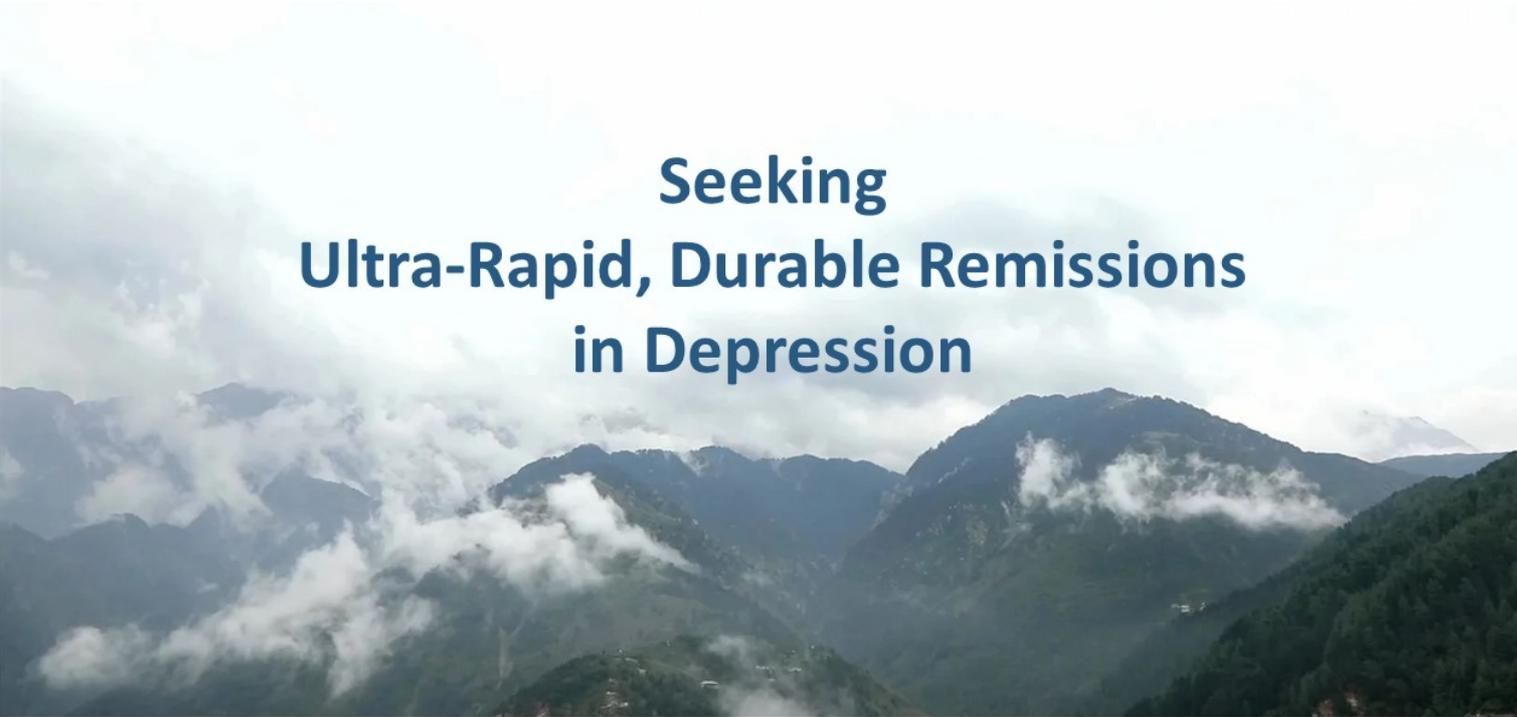
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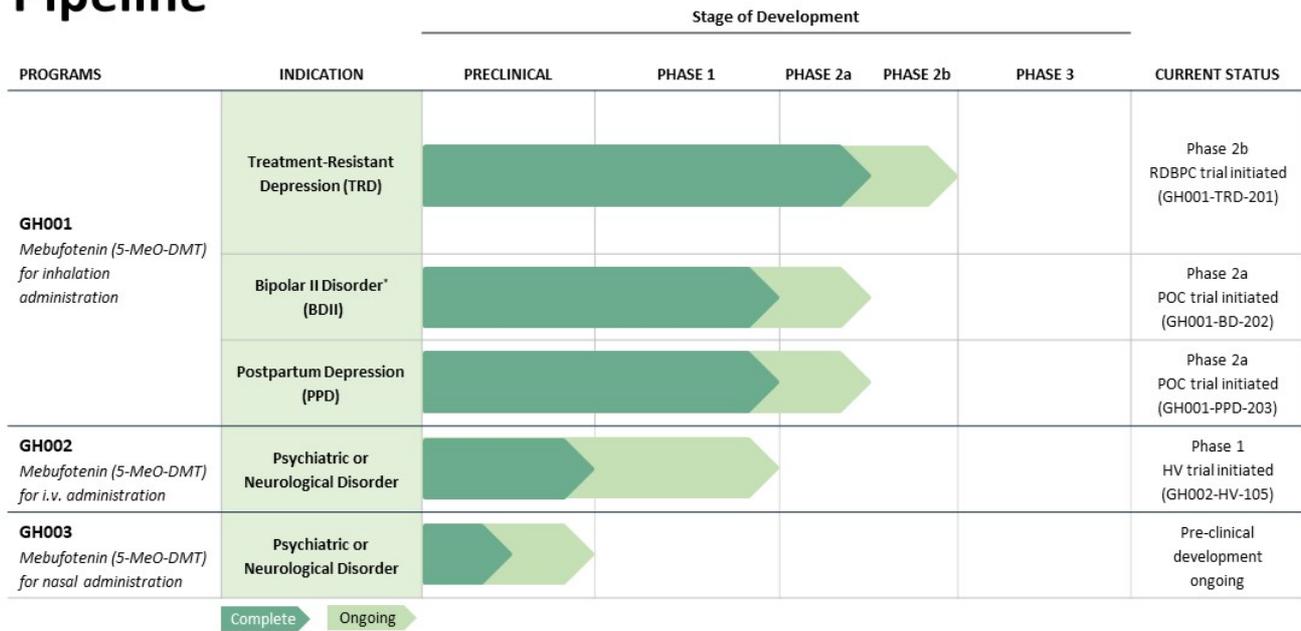
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Seeking Ultra-Rapid, Durable Remissions in Depression

Pipeline

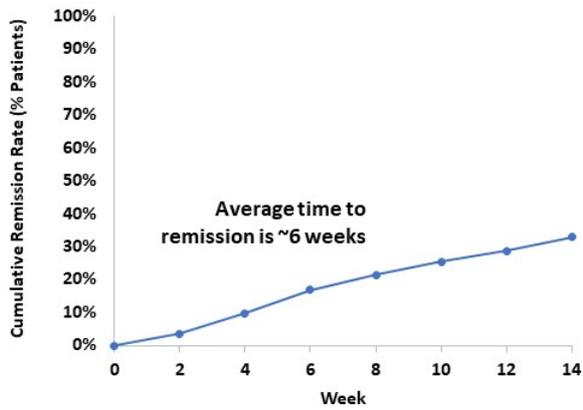


*Bipolar II disorder with a current major depressive episode
5-MeO-DMT, 5-Methoxy-N,N-Dimethyltryptamine; i.v., intravenous; RDBPC, Randomized, Double-Blind, Placebo-Controlled; POC, Proof-of-Concept; HV, Healthy Volunteer

The Problem for Patients with Depression

Established Therapies are **Slow-Acting**

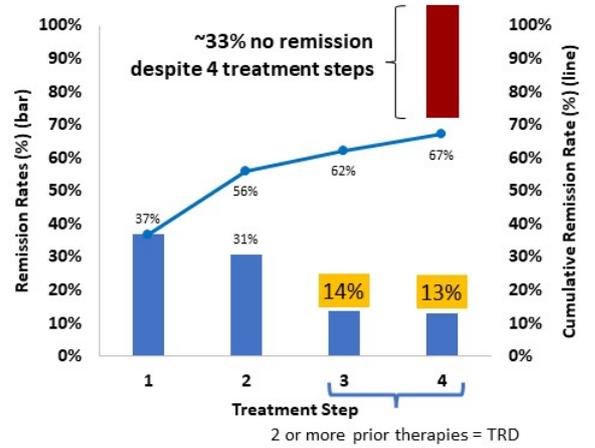
(STAR*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



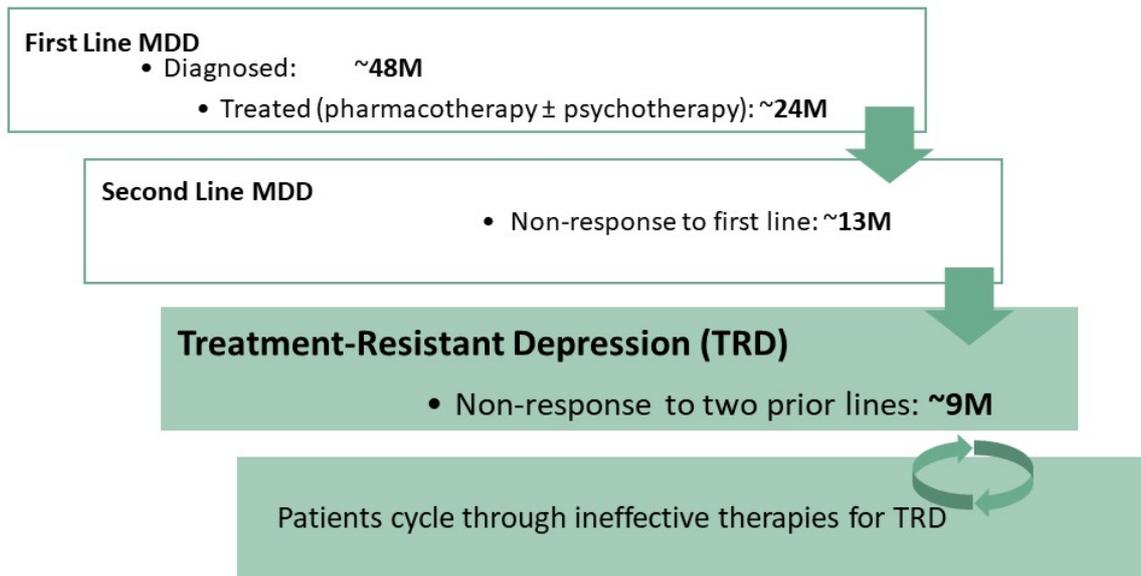
Adapted from Trivedi et al., Am J Psychiatry 2006 and Rush et al., Am J Psychiatry 2006
TRD, Treatment-Resistant Depression

... Remission Rates in TRD < 15%

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



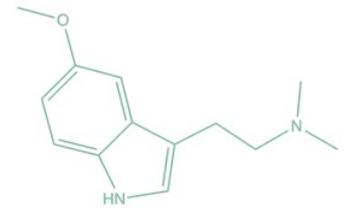
Large and Open Depression Market in the EU and US



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

Mebufotenin (5-MeO-DMT) and GH001

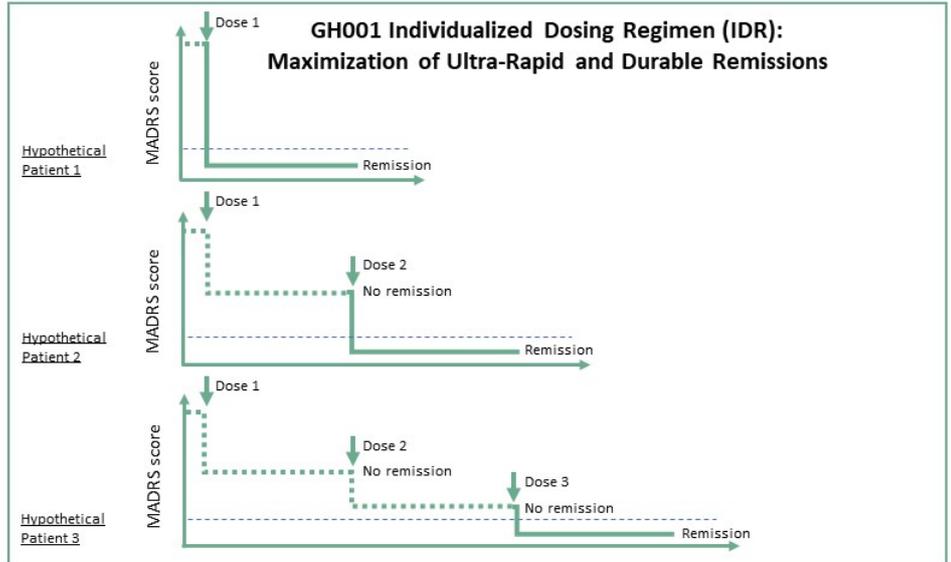
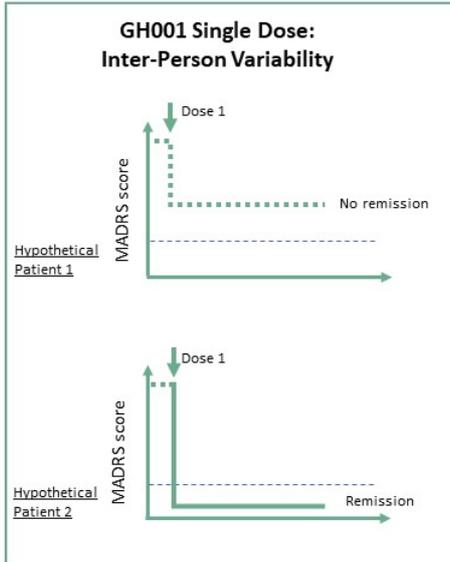
- Mebufotenin (5-Methoxy-N,N-Dimethyltryptamine, 5-MeO-DMT)
 - Naturally-occurring psychoactive substance from tryptamine class
 - **Highly potent** agonist on 5-HT1A and 5-HT2A receptors
- GH001 (Mebufotenin administration via a proprietary pulmonary inhalation approach)
 - **Psychoactive effects with 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**, with no structured psychotherapy
 - Potential for **convenient and infrequent retreatment**



Mebufotenin (5-MeO-DMT)



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

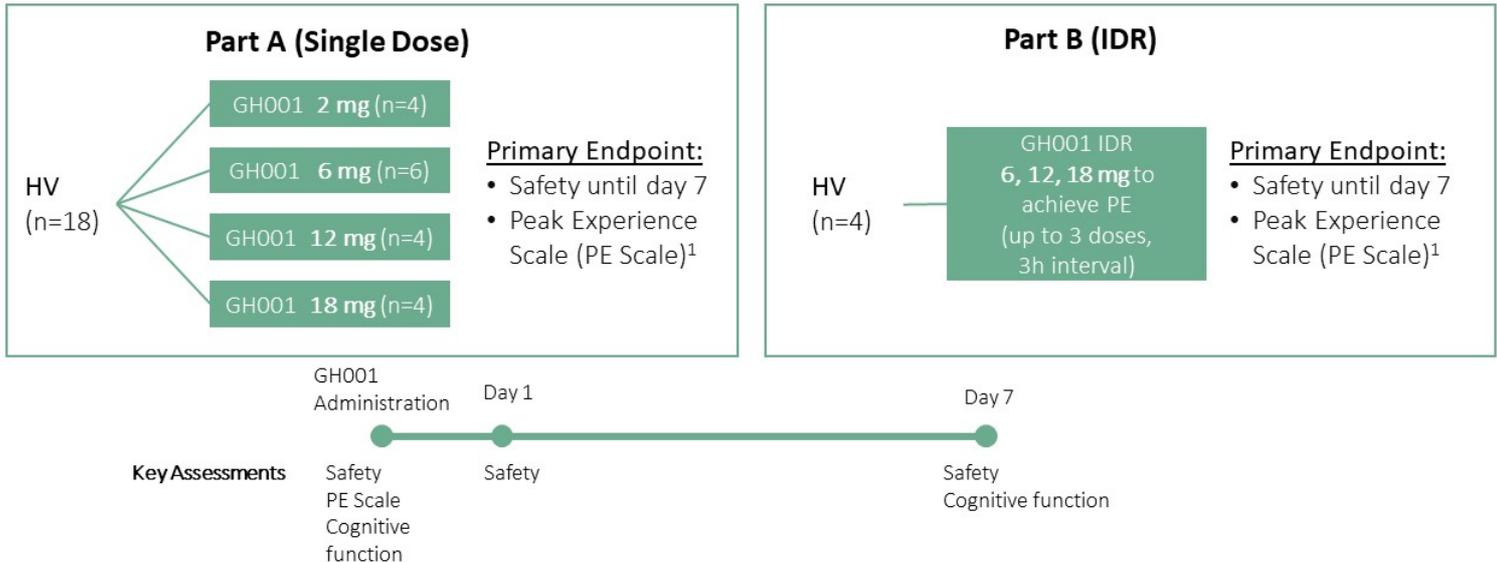


MADRS, Montgomery-Asberg Depression Rating Scale

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

Clinicaltrials.gov ID: NCT04640831

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



HV, Healthy Volunteer; 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

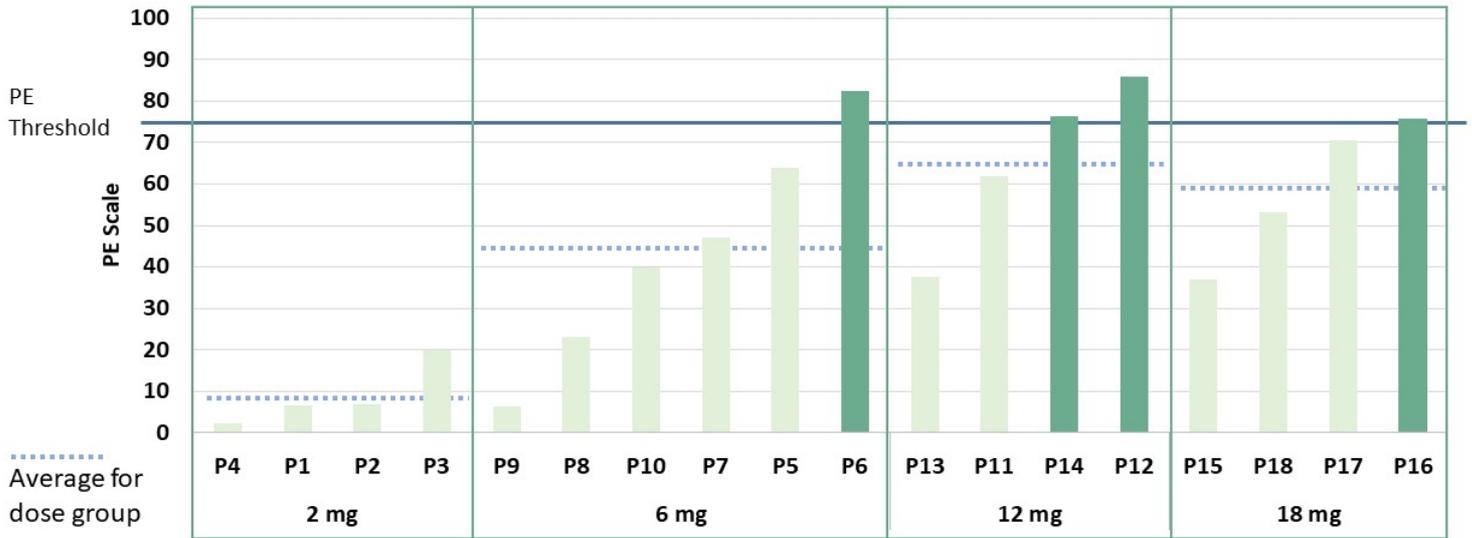
- No SAEs
- All ADRs mild, except two moderate (*)
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant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

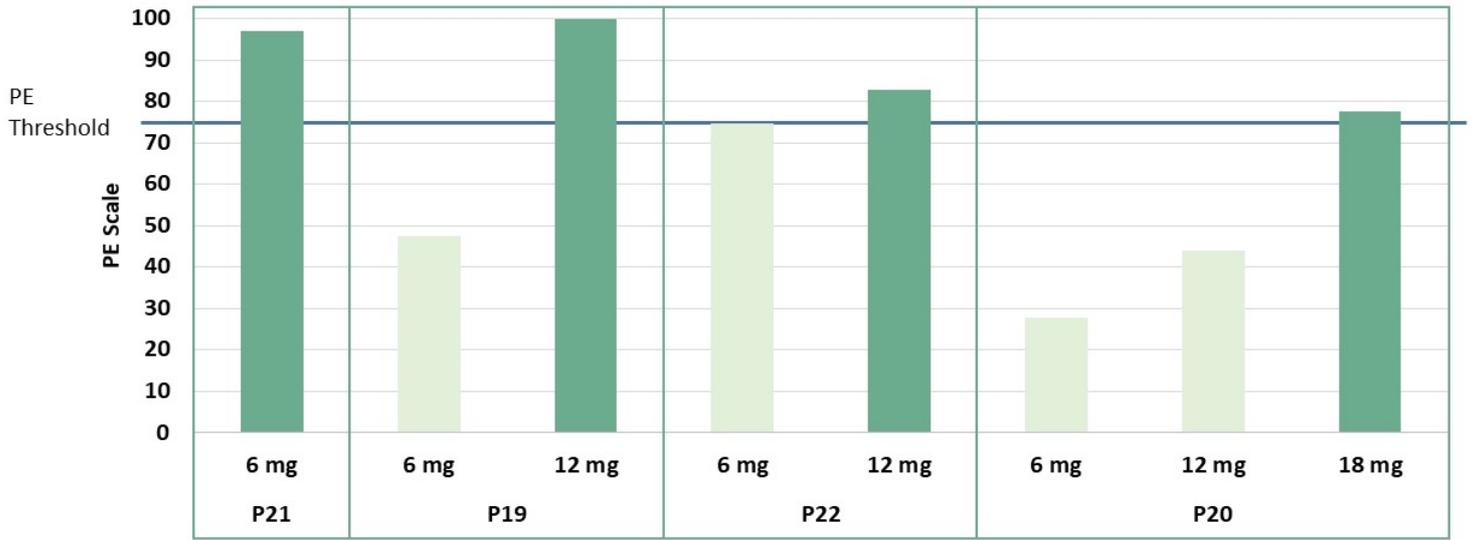
¹6 mg (n=1); 6-12 mg (n=2); 6-12-18 mg (n=1)

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)

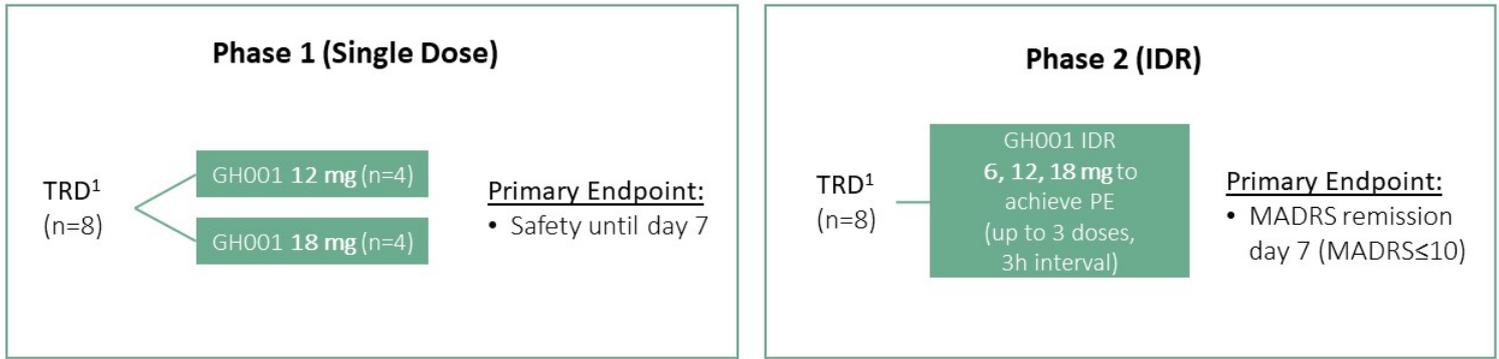


PE, Peak Experience

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

Clinicaltrials.gov ID: NCT04658603

Design of Phase 1/2 Trial 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

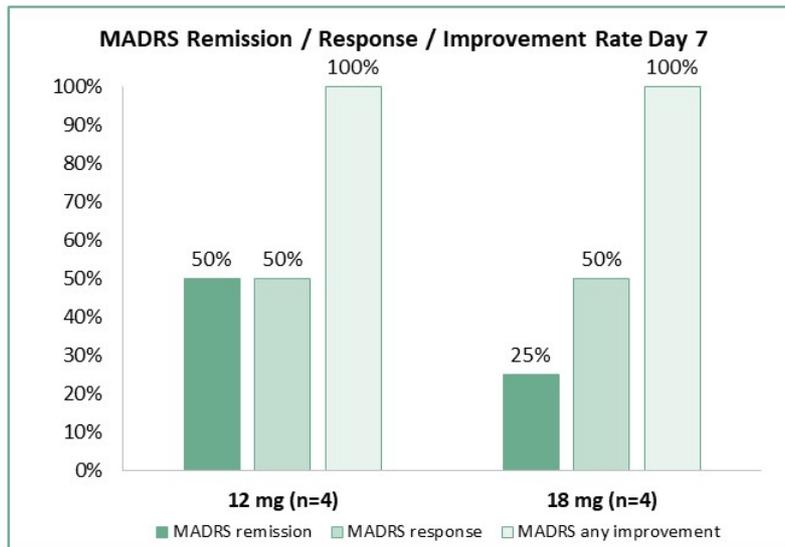
- No SAEs
- All ADRs mild, except three moderate*
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant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

¹6-12 mg (n=6); 6-12-18 mg (n=2)

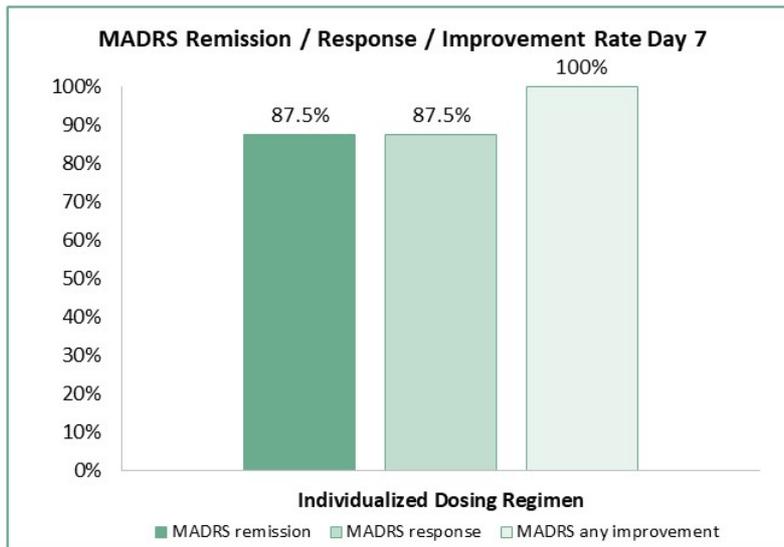
Phase 1 (Single Dose) – Efficacy (MADRS)



- 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; MADRS any improvement = any reduction from baseline in MADRS.

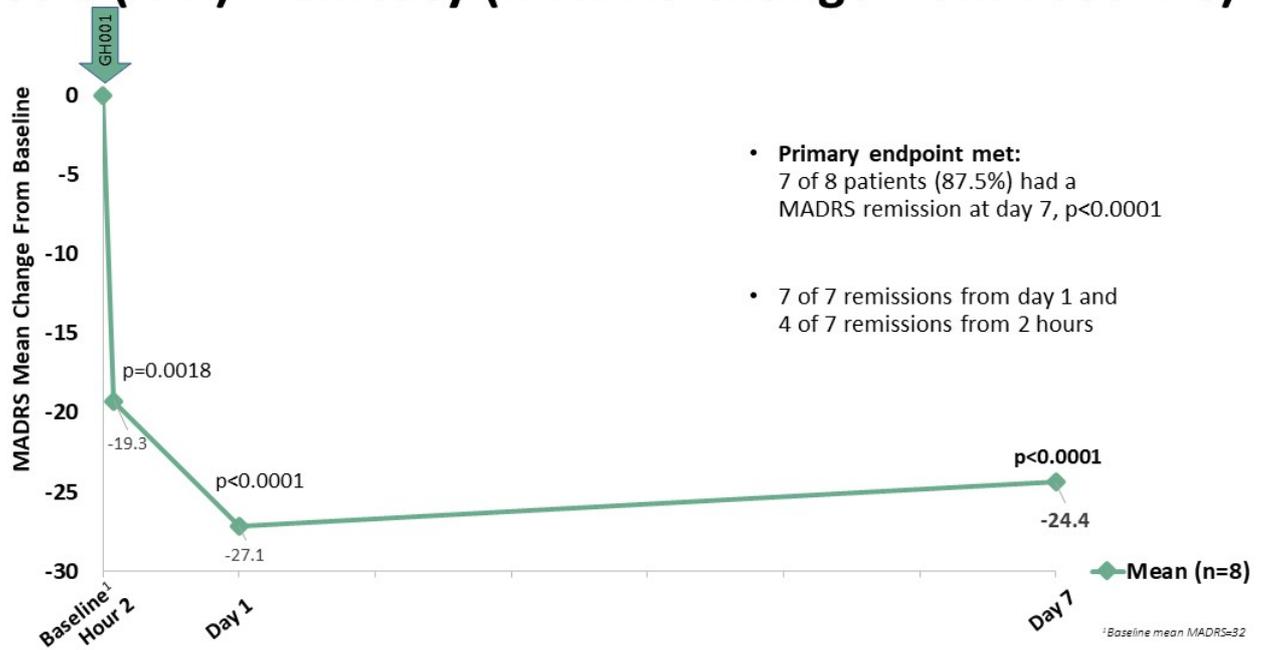
Phase 2 (IDR) – Efficacy (MADRS)



- **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 $\geq 50\%$ from baseline in MADRS; MADRS any improvement = any reduction 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)

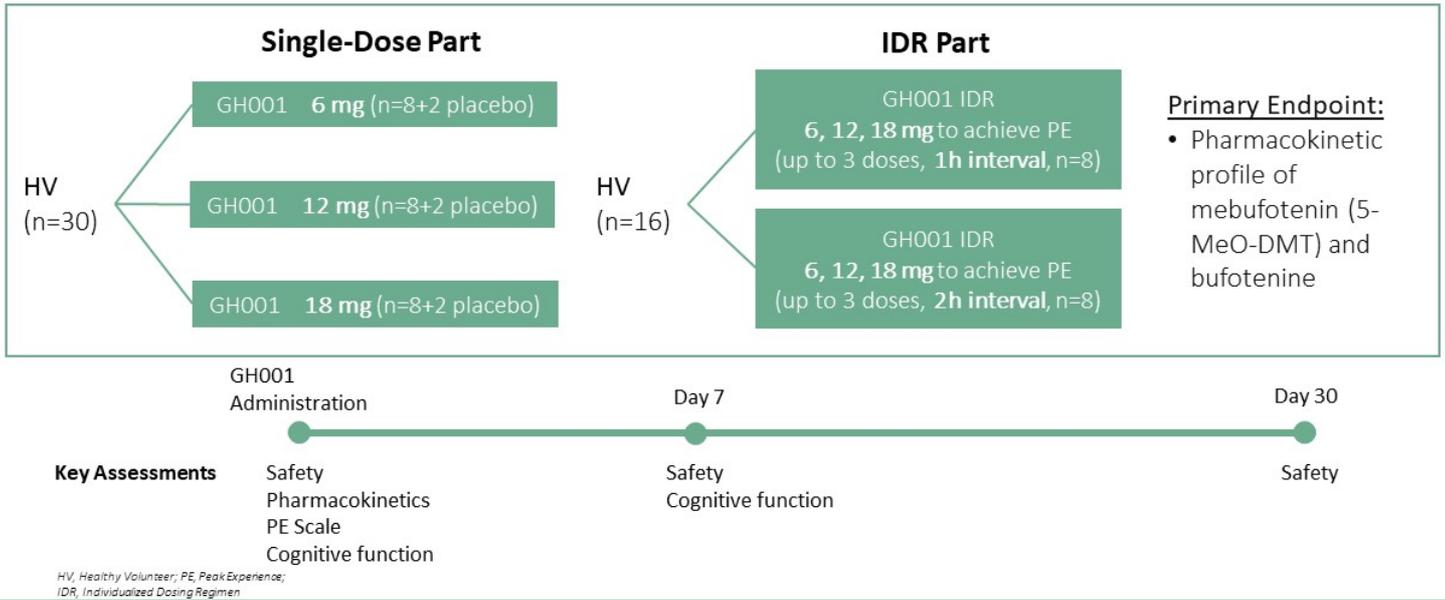
	Phase 2 (IDR)	Phase 1 (Single Dose) 12 mg	Phase 1 (Single Dose) 18 mg
MADRS Remission Rate Day 7	87.5% (7 of 8)	50% (2 of 4)	25% (1 of 4)
Mean MADRS Change Day 7	-24.4 (-76%)	-21.0 (-65%)	-12.5 (-40%)
Rate of PE	87.5% (7 of 8)	50% (2 of 4)	0% (0 of 4)
Mean PE Score	90.4 (at final dose)	58.2	59.1

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

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

Clinicaltrials.gov ID: NCT05163691

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) 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			

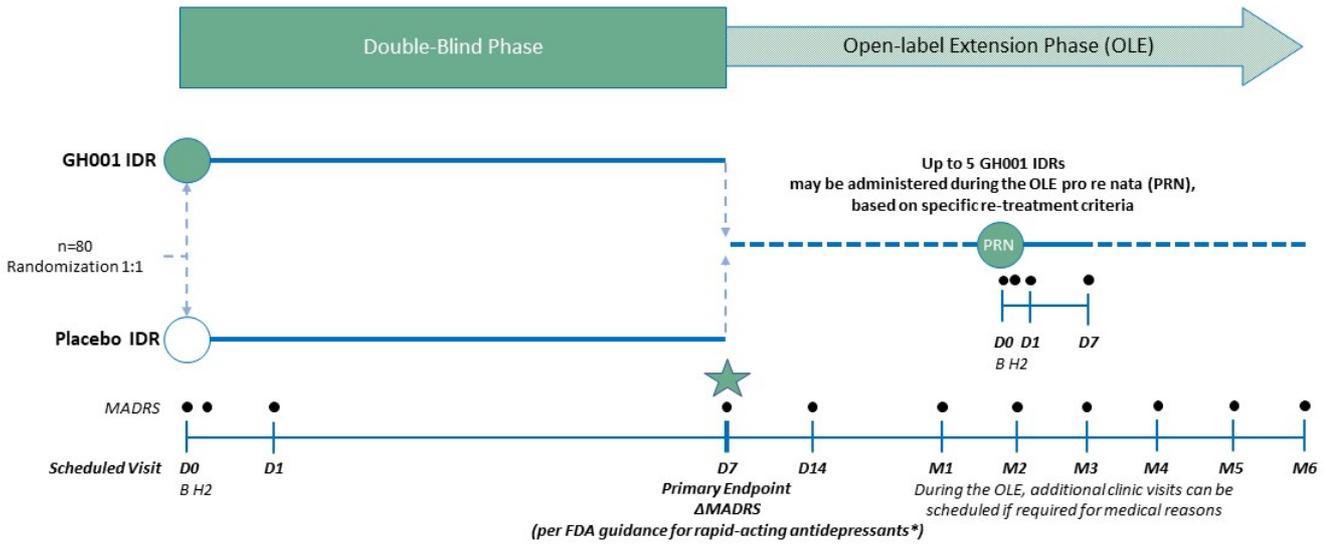
SAE, Serious Adverse Event; ADR, Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing; IDR, Individualized Dosing Regimen; C-SSRS, Columbia-Suicide Severity Rating Scale; PE, Peak Experience

¹6 mg (n=1), 6-12 mg (n=3), 6-12-18 mg (n=4)
²6-12 mg (n=3), 6-12-18 mg (n=3)

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

Patent families filed 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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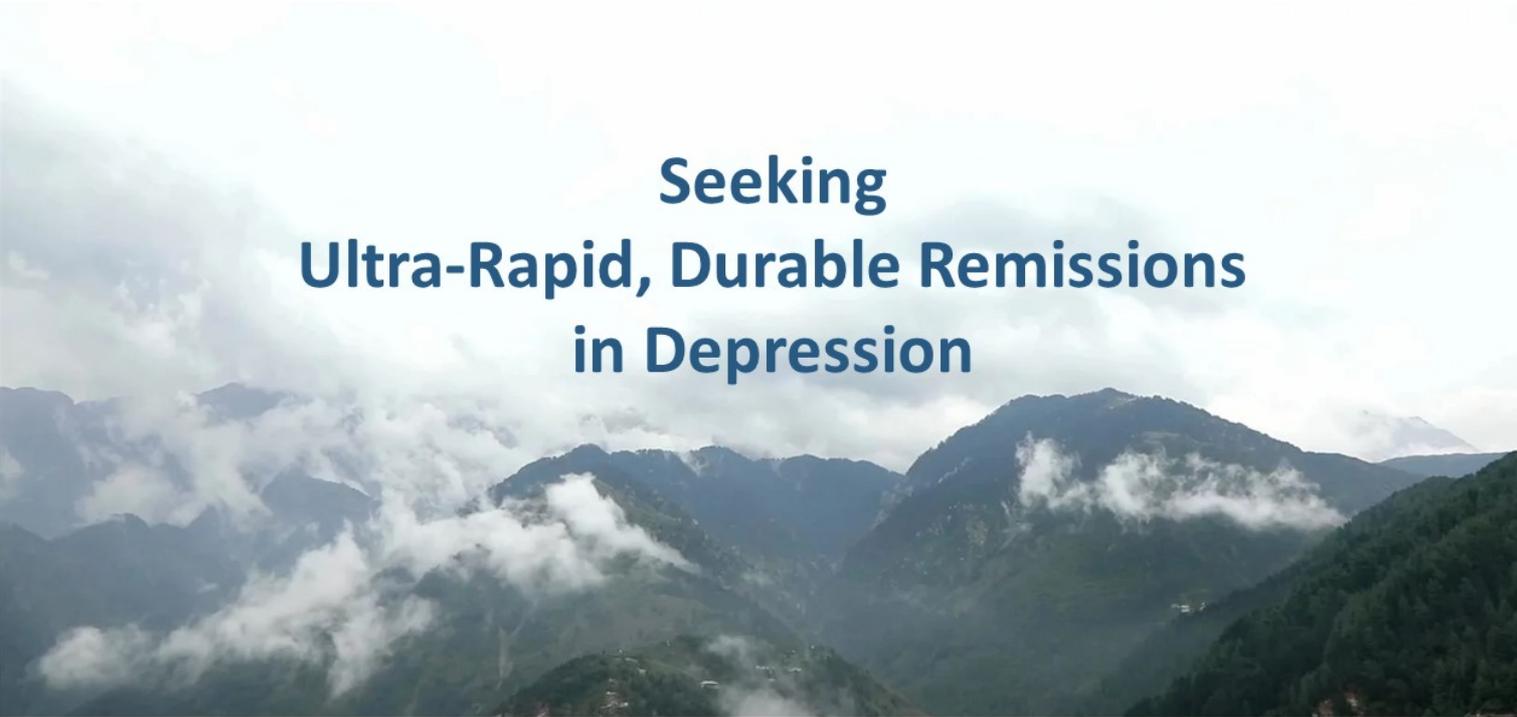
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Anticipated Milestones and Financial Overview

- **GH001**
 - Complete multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in TRD
 - Submit U.S. IND for GH001 with proprietary aerosol delivery device in Q3 2023
 - Complete proof-of-concept Phase 2a trials in BDII and in PPD in Q4 2023
- **GH002**
 - Complete Phase 1 clinical pharmacology trial in healthy volunteers in Q4 2023
- **GH003**
 - Complete preclinical development
- **Financial Overview**
 - Cash, cash equivalents, other financial assets and marketable securities were \$246.1 million as of March 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



Seeking Ultra-Rapid, Durable Remissions in Depression