
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 November, 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 November 9, 2023, GH Research PLC (the "Company") reported its third quarter 2023 financial results and provided business updates.

On November 9, 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 November 9, 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333-270418) of GH Research PLC and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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 and nine months ended September 30, 2023
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations
99.3	Press release dated November 9, 2023
99.4	Corporate Presentation for November 2023
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

GH Research PLC

Date: November 9, 2023

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

Unaudited condensed consolidated interim statement of comprehensive income

	Note	Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		\$'000	\$'000	\$'000	\$'000
Operating expenses					
Research and development	3	(7,088)	(4,620)	(21,570)	(13,574)
General and administration	3	(2,631)	(2,006)	(8,493)	(7,808)
Loss from operations		(9,719)	(6,626)	(30,063)	(21,382)
Other income					
Finance income	4	2,438	-	6,049	-
Finance expense	4	(184)	-	(534)	-
Movement of expected credit loss		(17)	-	1	-
Foreign exchange gain	3	1,833	6,185	232	15,512
Total other income		4,070	6,185	5,748	15,512
Loss before tax		(5,649)	(441)	(24,315)	(5,870)
Tax charge/(credit)		-	-	-	-
Loss for the period		(5,649)	(441)	(24,315)	(5,870)
Other comprehensive expense					
<i>Items that may be reclassified to profit or loss</i>					
Fair value movement on marketable securities		(428)	-	(1,216)	-
Currency translation adjustment		(1,780)	(6,464)	(161)	(15,779)
Total comprehensive loss for the period		(7,857)	(6,905)	(25,692)	(21,649)
Attributable to owners:					
Loss for the period		(5,649)	(441)	(24,315)	(5,870)
Total comprehensive loss for the period		(7,857)	(6,905)	(25,692)	(21,649)
Loss per share					
Basic and diluted loss per share (in USD)	15	(0.11)	(0.01)	(0.47)	(0.11)

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

	Note	<u>At September 30,</u> 2023 \$'000	<u>At December 31,</u> 2022 \$'000
ASSETS			
Current assets			
Cash and cash equivalents	5	86,439	165,955
Other financial assets	5	55,494	-
Marketable securities	6	19,343	-
Other current assets	7	2,765	2,586
Total current assets		164,041	168,541
Non-current assets			
Marketable securities	6	67,449	85,724
Property, plant and equipment	8	1,078	97
Total non-current assets		68,527	85,821
Total assets		232,568	254,362
LIABILITIES AND EQUITY			
Current liabilities			
Trade payables	9	2,707	1,868
Lease liability	10	260	-
Other current liabilities	11	3,167	2,678
Total current liabilities		6,134	4,546
Non-current liabilities			
Lease liability	10	661	-
Total non-current liabilities		661	-
Total liabilities		6,795	4,546
Equity attributable to owners			
Share capital		1,301	1,301
Additional paid-in capital		291,448	291,448
Other reserves		2,888	2,595
Foreign currency translation reserve		(13,196)	(13,035)
Accumulated deficit		(56,668)	(32,493)
Total equity		225,773	249,816
Total liabilities and equity		232,568	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	-	-	-	-	(5,870)	(5,870)
Translation adjustment	-	-	-	(15,779)	-	(15,779)
Total comprehensive loss for the period	-	-	-	(15,779)	(5,870)	(21,649)
Share-based compensation expense	-	-	1,212	-	-	1,212
Total transactions with owners	-	-	1,212	-	-	1,212
At September 30, 2022	1,301	291,448	1,578	(21,682)	(15,907)	256,738
At January 1, 2023	1,301	291,448	2,595	(13,035)	(32,493)	249,816
Loss for the period	-	-	-	-	(24,315)	(24,315)
Other comprehensive expense	-	-	(1,216)	(161)	-	(1,377)
Total comprehensive loss	-	-	(1,216)	(161)	(24,315)	(25,692)
Share-based compensation expense	-	-	1,649	-	-	1,649
Share option exercises	-	-	(140)	-	140	-
Total transactions with owners	-	-	1,509	-	140	1,649
At September 30, 2023	1,301	291,448	2,888	(13,196)	(56,668)	225,773

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

Unaudited condensed consolidated interim statement of cash flows

	Nine Months Ended September 30,	
	2023 \$'000	2022 \$'000
Cash flows from operating activities		
Loss for the period	(24,315)	(5,870)
Depreciation	237	34
Share-based compensation expense	1,649	1,212
Finance expense	534	-
Finance income	(6,049)	-
Movement of expected credit loss	(1)	-
Foreign exchange gain	(232)	(15,512)
Movement in working capital	1,119	804
Cash flows used in operating activities	(27,058)	(19,332)
Finance expense paid	(466)	-
Finance income received	2,273	-
Net cash used in operating activities	(25,251)	(19,332)
Cash flows used in investing activities		
Purchase of other financial assets	(54,000)	-
Purchase of property, plant and equipment	(76)	(49)
Cash flows used in investing activities	(54,076)	(49)
Cash flows used in financing activities		
Payment of lease liability	(163)	-
Net decrease in cash and cash equivalents	(79,490)	(19,381)
Cash and cash equivalents at the beginning of the period	165,955	276,776
Impact of foreign exchange on cash and cash equivalents	(26)	(456)
Cash and cash equivalents at the end of the period	86,439	256,939

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 Joshua Dawson House, Dawson Street, 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 November 9, 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 and nine months ended September 30, 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 September 30, 2023. As a result, the Group is not exposed to liquidity risk through requests for early repayment of loans.

As of September 30, 2023, the Group’s cash and cash equivalents amounted to \$86.4 million (December 31, 2022: \$166.0 million). The Group also held marketable securities of \$86.8 million and other financial assets of \$55.5 million as of September 30, 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.

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

The board of directors believes that the Group has sufficient financial resources available to cover its planned cash outflows for at least the next twelve months from the date of issuance of these unaudited condensed consolidated interim financial statements. The Group, therefore, continues to adopt the going concern basis in preparing its unaudited condensed consolidated interim financial statements.

Use of estimates and judgments

The preparation of the unaudited condensed consolidated interim financial statements requires management to make 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 are consistent with those that applied in the preparation of the consolidated financial statements for the year ended December 31, 2022.

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.

Other 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 and nine months ended September 30, 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)

Segment reporting

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

3. Expenses by nature

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

	Three months ended September 30,		Nine months ended September 30,	
	2023 \$'000	2022 \$'000	2023 \$'000	2022 \$'000
External research and development expenses	5,207	3,428	16,521	10,429
Employee expenses ¹	1,812	1,064	4,857	2,887
Depreciation	8	7	28	22
Other expenses	61	121	164	236
Total research and development expenses	7,088	4,620	21,570	13,574
External costs	1,725	1,464	5,834	6,145
Employee expenses ²	834	537	2,450	1,651
Depreciation	72	5	209	12
Total general and administrative expenses	2,631	2,006	8,493	7,808
Total operating expenses	9,719	6,626	30,063	21,382

¹ Included in employee expenses is share based compensation expense of \$0.4 million and \$1.0 million for the three and nine months ended September 30, 2023, respectively, relating to employees in our research and development department (three and nine months ended September 30, 2022, \$0.2 million and \$0.7 million, respectively).

² Included in employee expenses is share based compensation expense of \$0.2 million and \$0.7 million for the three and nine months ended September 30, 2023, respectively, relating to employees in the general and administrative department (three and nine months ended September 30, 2022, \$0.2 million and \$0.5 million, respectively).

Foreign exchange gain

Foreign exchange gain of \$1.8 million and \$0.2 million in the three and nine months ended September 30, 2023 (gain of \$6.2 million and \$15.5 million in the three and nine months ended September 30, 2022), consist primarily of gains related to the translation of 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 September 30, 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 nine months ended September 30, 2023, would have been \$7.3 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		Nine months ended	
	September 30,		September 30,	
	2023	2022	2023	2022
	\$'000	\$'000	\$'000	\$'000
Finance income				
Finance income on cash	141	-	141	-
Gain on cash equivalents and other financial assets at fair value through profit and loss	1,257	-	2,811	-
Interest income under effective interest rate method at fair value through other comprehensive income ("FVOCI")	1,040	-	3,097	-
Finance income	2,438	-	6,049	-
Finance expense				
Finance expense on investments	(168)	-	(484)	-
Finance expense on lease liability	(16)	-	(50)	-
Finance expense	(184)	-	(534)	-

5. Cash and cash equivalents

	September 30,	December 31,
	2023	2022
	\$'000	\$'000
Cash at bank and in hand	49,496	130,252
Cash equivalents	36,943	35,703
	86,439	165,955

During the nine months ended September 30, 2023, an investment of \$54.0 million was made in a money market fund. This investment has been classified as other financial assets and has a fair value of \$55.5 million at September 30, 2023.

6. Marketable securities

	Marketable securities
	\$'000
Fair value	
At January 1, 2023	85,724
Additions	-
Accrued interest	3,097
Interest received	(814)
Fair value movement	(1,215)
At September 30, 2023	86,792

GH RESEARCH PLC
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 \$86.8 million at September 30, 2023 (December 31, 2022: \$85.7 million). The impairment loss allowance for expected credit losses at the reporting date was \$0.1 million (December 31, 2022: \$0.1 million). At September 30, 2023, the maturity of the Group's marketable securities ranges from four 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.

A reconciliation of the movement through OCI relating to marketable securities for the three and nine months ended September 30, 2023, is as follows:

	Three months ended September 30, 2023 \$'000
At July 1, 2023	230
Revaluation adjustments	445
Movement of expected credit losses on assets measured at FVOCI	(17)
At September 30, 2023	658
	Nine months ended September 30, 2023 \$'000
At January 1, 2023	(558)
Revaluation adjustments	1,215
Movement of expected credit losses on assets measured at FVOCI	1
At September 30, 2023	658

7. Other current assets

Other current assets primarily represent prepayments and VAT receivable.

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

8. Property, plant and equipment

Property, plant and equipment increased to \$1.1 million at September 30, 2023, from \$0.1 million at December 31, 2022, an increase of \$1.0 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	(185)
Translation adjustment	(27)
At September 30, 2023	967

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 September 30, 2023, the Group's lease liability amounted to \$0.9 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 September 30, 2023, there were no material contingencies which required adjustment or disclosure in the unaudited condensed consolidated interim financial statements (2022: none).

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 had 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 September 30, 2023, the Company has 466,918 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 and nine months ended September 30, 2023, the Company granted the option to purchase 81,000 and 351,820 ordinary shares, respectively, to employees which were in line with the general terms of the Share Option Plan. During the three and nine months ended September 30, 2023, 19,000 and 97,499 share options were forfeited.

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

Of the 351,820 share options granted to employees during the nine months ended September 30, 2023, 175,000 share options were granted with a contractual term (expiration) of seven years from the grant date with an exercise price of \$0.025 per share, with 1,000 of those share options granted in the three months ended September 30, 2023. A further 20,000 share options of those granted during the nine months ended September 30, 2023, vested immediately and had no service condition attached to them. Aside from the 175,000 share options identified above, all other share options granted to employees during the three and nine month period ending September 30, 2023, have a contractual term (expiration) of eight years from the grant date with the exercise price at the closing market price on the day prior to the grant.

During the three and nine months ended September 30, 2023, the Company granted the option to purchase 19,899 ordinary shares to members of the board of directors which vested on the date of grant and are subject to a two year service condition. These share options have a contractual term (expiration) of seven years from the grant date with an exercise price of \$0.025 per share. During the three and nine months ended September 30, 2023, members of the board of directors exercised a total of 7,296 options at an exercise price of \$2.05 per option. The shares relating to the exercise of these options were issued in October 2023.

The following table summarizes the share option awards outstanding as of September 30, 2023:

	Weighted 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	5.04	371,719	7.14
Forfeited	12.16	(97,499)	7.00
Exercised	2.05	(7,296)	5.99
At September 30, 2023¹	10.63	728,520	6.70

¹ 93,033 of the awards outstanding as of September 30, 2023, were exercisable.

The weighted average grant date fair value of awards granted during the three and nine months ended September 30, 2023, was \$8.63 and \$8.18, respectively, 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 and nine months ended September 30, 2023, were determined on the date of the grant using the following assumptions:

	Three months ended September 30, 2023	Nine months ended September 30, 2023
Share price, in USD	10.84	9.53
Strike price, in USD - employees (weighted average)	10.97	5.32
Strike price, in USD – non-executive directors	0.025	0.025
Expected volatility	83%-87%	83%-88%
Award life (weighted average)	5.7	5.6
Expected dividends	-	-
Risk-free interest rate	4.11%-4.62%	3.50%-4.62%

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 life of the share option after which, when making the grant, the Company expected on average that participants would exercise their options.

As of September 30, 2023, Other Reserves within equity includes \$3.5 million (December 31, 2022: \$2.0 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 September 30, 2023 was \$0.6 million (three months ended September 30, 2022: \$0.4 million) and for the nine months ended September 30, 2023 was \$1.6 million (nine months ended September 30, 2022: \$1.2 million).

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS (continued)
14. Related party disclosures

Other than those transactions reported in Note 13, “Share based compensation”, there have been no other transactions in the three and nine months ended September 30, 2023, with related parties that had a material effect on the financial position or performance of the Group.

15. Loss per share

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Loss attributable to shareholders (in \$'000)	(5,649)	(441)	(24,315)	(5,870)
Weighted average number of shares in issue	52,020,849	52,020,849	52,020,849	52,020,849
Basic and diluted earnings/(loss) per share (in USD)	(0.11)	(0.01)	(0.47)	(0.11)

For the three and nine month period ended September 30, 2023 and September 30, 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 August 2023, the Group submitted an Investigational New Drug Application (“IND”) for GH001 with the U.S. Food and Drug Administration (“FDA”) with the purpose to initiate a Phase 1 healthy volunteer clinical pharmacology trial where GH001 would be administered using the Group’s own proprietary aerosol delivery device. In September 2023, the IND was placed on clinical hold by the FDA due to “21 CFR 312.42(b)(1)(iv): Insufficient information to assess risks to human subjects”. Post quarter end, the Group received a formal clinical hold letter from the FDA. Following the receipt of the formal clinical hold letter, the Group is currently assessing future costs associated with the steps to be undertaken to address the matters identified by the FDA to be in a position to provide the IND response submission and is also assessing the potential broader business impacts.

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 and nine months ended September 30, 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/A 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 and nine months ended September 30, 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 \$24.3 million for the nine months ended September 30, 2023, and losses of \$22.5 million and \$9.2 million for the years ended December 31, 2022 and 2021, respectively. As of September 30, 2023, we had an accumulated deficit of \$56.7 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, or the ongoing military conflict between Israel and Hamas and any resulting conflicts in the region;
- 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 Updates

GH001 in 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 patients with treatment-resistant depression (TRD) (GH001-TRD-201). The trial has been approved in seven European countries and is expected to recruit approximately 80 patients across approximately 20 sites. Patient enrollment is on schedule and we continue to expect completion of the double-blind phase of this trial in the third quarter of 2024, with availability of top-line data in the third or the fourth quarter of 2024. In this trial, GH001 is administered using an externally-sourced inhalation device.

Update on IND for GH001

In August 2023, we submitted an Investigational New Drug Application (IND) for GH001 with the U.S. Food and Drug Administration (FDA), with the purpose to initiate a Phase 1 healthy volunteer clinical pharmacology trial, where GH001 is administered using our proprietary aerosol delivery device (GH001-HV-106). The trial is designed to support bridging to the clinical data generated with the third-party device we currently use in our clinical trials. As previously announced in September, the FDA advised that it had placed our IND on clinical hold.

We have now received a formal clinical hold letter from the FDA. To remove the hold, they have requested that we provide (i) an inhalation toxicology study in a non-rodent species and an additional inhalation toxicology study in rats, related to respiratory tract histology findings from a previously completed inhalation toxicology study in rats, (ii) additional device design verification information and (iii) updates to our investigator brochure. We are working to respond to the FDA's requests, including by initiating the requested nonclinical studies. We intend to request a meeting with the FDA, expected to take place in the first quarter of 2024, if granted, to discuss the feedback, provide clarifications, and discuss our plan to address their comments. 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 due course after taking into account the conclusions of that meeting.

GH001 in BD and PPD

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

Recently, the clinical research organization that manages one of our clinical trial sites informed us that the site will be closed for business reasons. As this is one of two sites activated in each trial, and because both trials have been recruiting slower than previously projected, we expect a delay in the completion of the trials. We are in the process of putting measures in place to support recruitment of both trials, including the addition of further clinical trial sites, and we plan to provide an updated timeline for expected trial completion in the first quarter of 2024.

GH002

As previously announced, 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.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30		
	2023	2022	Change
	(in USD thousands)		
Operating Expenses:			
Research and development	(7,088)	(4,620)	(2,468)
General and administrative	(2,631)	(2,006)	(625)
Loss from operations	(9,719)	(6,626)	(3,093)
Net finance income ¹	2,237	—	2,237
Foreign exchange gain	1,833	6,185	(4,352)
Loss for the period	(5,649)	(441)	(5,208)

¹ Net finance income for the three months ended September 30, 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 September 30, 2023 and 2022:

	Three Months Ended September 30		
	2023	2022	Change
	(in USD thousands)		
External research and development expenses	(5,207)	(3,428)	(1,779)
Employee expenses ¹	(1,812)	(1,064)	(748)
Depreciation	(8)	(7)	(1)
Other expenses	(61)	(121)	60
Research and development	(7,088)	(4,620)	(2,468)

¹ Includes share-based compensation expense of \$0.4 million and \$0.2 million for the three months ended September 30, 2023 and 2022, respectively.

The following table summarizes our research and development expenses for our product candidates for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30		
	2023	2022	Change
	(in USD thousands)		
GH001	(4,298)	(2,748)	(1,550)
GH002	(400)	(475)	75
GH003	(19)	-	(19)
Related to multiple product candidates (GH001, GH002 and GH003) ¹	(2,371)	(1,397)	(974)
Research and development	(7,088)	(4,620)	(2,468)

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

Research and development expenses increased by \$2.5 million from \$4.6 million for the three months ended September 30, 2022, to \$7.1 million for the three months ended September 30, 2023. The increase is primarily due to increased expenses relating to our clinical trials. Employee expenses increased by \$0.7 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 \$1.6 million in the three months ended September 30, 2023, primarily due to increased clinical trial expenses, technical development including device development, active pharmaceutical ingredient and drug product development and manufacturing.

Research and development expenses which relate to multiple product candidates increased by \$1.0 million in the three months ended September 30, 2023, primarily due to the hiring of personnel to support our research and development activities.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30		Change
	2023	2022	
	(in USD thousands)		
External costs	(1,725)	(1,464)	(261)
Employee expenses ¹	(834)	(537)	(297)
Depreciation	(72)	(5)	(67)
General and administrative	(2,631)	(2,006)	(625)

¹ Includes share-based compensation expense of \$0.2 million and \$0.2 million for the three months ended September 30, 2023 and 2022, respectively.

General and administrative expenses increased by \$0.6 million from \$2.0 million for the three months ended September 30, 2022, to \$2.6 million for the three months ended September 30, 2023. The increase is primarily due to an increase in professional fees and an increase in employee expenses in our general and administrative functions to support our growth initiatives, partly offset by a decrease in insurance costs.

Net Finance Income

Our net finance income increased to \$2.2 million for the three months ended September 30, 2023, from \$nil for the three months ended September 30, 2022. The increase is primarily due to interest income of \$1.0 million relating to our marketable securities, as well as a fair value gain of \$1.3 million relating to our cash equivalents and other financial assets. These increases have been partly offset by finance expenses relating to our investments.

Foreign Exchange Gain

Foreign exchange gain is \$1.8 million for the three months ended September 30, 2023, a decrease of \$4.4 million from a gain of \$6.2 million for the three months ended September 30, 2022. This movement is primarily as a result of the translation of the U.S. dollar cash and other financial assets balances in the accounts of our subsidiary into its functional currency, which is the euro. During the three months ended September 2023, the U.S. dollar strengthened compared to the euro which resulted in the foreign exchange gain.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30		
	2023	2022	Change
	(in USD thousands)		
Operating Expenses:			
Research and development	(21,570)	(13,574)	(7,996)
General and administrative	(8,493)	(7,808)	(685)
Loss from operations	(30,063)	(21,382)	(8,681)
Net finance income ¹	5,516	—	5,516
Foreign exchange gain	232	15,512	(15,280)
Loss for the period	(24,315)	(5,870)	(18,445)

¹ Net finance income for the nine months ended September 30, 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 nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30		
	2023	2022	Change
	(in USD thousands)		
External research and development expenses	(16,521)	(10,429)	(6,092)
Employee expenses ¹	(4,857)	(2,887)	(1,970)
Depreciation	(28)	(22)	(6)
Other expenses	(164)	(236)	72
Research and development	(21,570)	(13,574)	(7,996)

¹ Includes share-based compensation expense of \$1.0 million and \$0.7 million for the nine months ended September 30, 2023 and 2022, respectively.

The following table summarizes our research and development expenses for our product candidates for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30		
	2023	2022	Change
	(in USD thousands)		
GH001	(12,913)	(7,751)	(5,162)
GH002	(1,528)	(987)	(541)
GH003	(161)	-	(161)
Related to multiple product candidates (GH001, GH002 and GH003) ¹	(6,968)	(4,836)	(2,132)
Research and development	(21,570)	(13,574)	(7,996)

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

Research and development expenses increased by \$8.0 million from \$13.6 million for the nine months ended September 30, 2022, to \$21.6 million for the nine months ended September 30, 2023. The increase is 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 and regulatory compliance activities. Employee expenses increased by \$2.0 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 \$5.2 million in the nine months ended September 30, 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 and regulatory compliance activities.

Research and development expenses relating to GH002 increased by \$0.5 million in the nine months ended September 30, 2023, primarily due to clinical trial expenses and 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 relating to GH003 increased by \$0.2 million in the nine months ended September 30, 2023, primarily due to an increase in nonclinical expenses.

Research and development expenses which relate to multiple product candidates increased by \$2.1 million in the nine months ended September 30, 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 nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30		Change
	2023	2022	
	(in USD thousands)		
External costs	(5,834)	(6,145)	311
Employee expenses ¹	(2,450)	(1,651)	(799)
Depreciation	(209)	(12)	(197)
General and administrative	(8,493)	(7,808)	(685)

¹ Includes share-based compensation expense of \$0.7 million and \$0.5 million for the nine months ended September 30, 2023 and 2022, respectively.

General and administrative expenses increased by \$0.7 million from \$7.8 million for the nine months ended September 30, 2022, to \$8.5 million for the nine months ended September 30, 2023. The increase is primarily due to an increase in professional fees and an increase in employee expenses in our general and administrative functions to support our growth initiatives, partly offset by a decrease in insurance costs.

Net Finance Income

Our net finance income increased to \$5.5 million for the nine months ended September 30, 2023, from \$nil for the nine months ended September 30, 2022. The increase is primarily due to interest income of \$3.1 million relating to our marketable securities, as well as a gain of \$2.8 million relating to our cash equivalents and other financial assets, and a movement of expected credit loss in the period. These increases have been partly offset by finance expenses relating to our investments.

Foreign Exchange Gain

Foreign exchange gain is \$0.2 million for the nine months ended September 30, 2023, a movement of \$15.3 million from a gain of \$15.5 million for the nine months ended September 30, 2022. This movement is primarily due to the translation of the U.S. dollar cash and other financial assets balances in the accounts of our subsidiary into its functional currency, which is the euro. During the nine months ended September 30, 2023, the U.S. dollar strengthened compared to the euro, which resulted in the foreign exchange gain.

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 September 30, 2023, we had cash, cash equivalents, other financial assets and marketable securities of \$228.7 million, 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, while marketable securities comprise investment grade bonds.

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 nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30		
	2023	2022	Change
	(in USD thousands)		
Net cash flows used in operating activities	(25,251)	(19,332)	(5,919)
Net cash flows used in investing activities	(54,076)	(49)	(54,027)
Net cash flows used in financing activities	(163)	—	(163)
Net decrease in cash and cash equivalents	(79,490)	(19,381)	(60,109)

Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities increased by \$5.9 million to \$25.3 million for the nine months ended September 30, 2023, from \$19.3 million for the nine months ended September 30, 2022. The increase is primarily due to a \$8.7 million increase in loss from operations, which has been partly offset by an increase in finance income received.

Net Cash Flows Used in Investing Activities

Net cash flows used in investing activities increased to \$54.1 million for the nine months ended September 30, 2023, from \$49 thousand for the nine months ended September 30, 2022. The increase is due to the investment in a money market fund of \$54.0 million in the period.

Net Cash Flows from Financing Activities

Net cash flows from financing activities increased to \$0.2 million for the nine months ended September 30, 2023, from \$nil for the nine months ended September 30, 2022. The increase is 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/A 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/A 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, we rely on 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 \$1.235 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.

Risk Factors

There have been no material changes in our risk factors from those disclosed in our annual report on Form 20-F/A for the year ended December 31, 2022, other than as follows:

It may take considerable time and expense to resolve the clinical hold that has been placed on the study we proposed in our IND for GH001 by the FDA, and no assurance can be given that the FDA will remove the clinical hold, in which case our business and financial prospects may be materially adversely affected.

On September 29, 2023, we announced that we were notified by the FDA that the study we proposed in our IND for GH001 has been placed on clinical hold. We recently received the formal clinical hold letter from the FDA, requesting to provide an additional inhalation toxicology studies in rats and an inhalation toxicology study in a non-rodent species, additional device design verification information, as well as updates to our investigator brochure. We are working to respond to the FDA's requests, including by initiating certain nonclinical studies. However, those studies and any other work we may initiate may take a considerable period of time and there are no assurances that the FDA will accept the results of such nonclinical studies or other responses we may provide, and the FDA may require us to conduct additional nonclinical studies or other work or have additional questions. If the FDA does not accept the results of our nonclinical studies or other responses we may provide, or requires us to conduct additional trials or studies, it may take a further considerable period of time, the length of which is not certain at this time, and expense for us to fully address the FDA's concerns. Further, comparable foreign regulatory authorities may also have questions or requests or may initiate the equivalent of a clinical hold, in each case prompted by the clinical hold by the FDA or by the nonclinical studies or any other work we may initiate, which may similarly take considerable time and expense for us to address. Even if we are able to fully respond to the FDA's current concerns, the FDA may subsequently make additional requests that we would need to fulfill prior to the lifting of the clinical hold. It is possible that we will be unable to fully address the FDA's concerns and, as a result, the clinical hold may never be lifted and we may never be able to initiate clinical trials for GH001 in the United States. These matters could have a material adverse effect on our business and financial prospects.

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/A 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 related to the clinical hold on the study we proposed in our IND for GH001, including our 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;
 - 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 the ongoing military conflict between Israel and Hamas and any resulting conflicts in the region;
-

- 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/A 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 Third Quarter Financial Results and Provides Business Updates

DUBLIN, Ireland, November 9, 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 third quarter ended September 30, 2023, and provided business updates.

Third Quarter 2023 Financial Highlights*Cash position*

Cash, cash equivalents, other financial assets and marketable securities were \$228.7 million as of September 30, 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 \$7.1 million for the quarter ended September 30, 2023, compared to \$4.6 million for the same quarter in 2022. The increase was primarily due to increased activities relating to our clinical trials and increases in employee expenses to support these activities.

General and administrative expenses

G&A expenses were \$2.6 million for the quarter ended September 30, 2023, compared to \$2.0 million for the same quarter in 2022. The increase was primarily due to an increase in professional fees and employee expenses offset by lower insurance costs.

Net loss

Net loss was \$5.6 million, or \$0.11 loss per share, for the quarter ended September 30, 2023, compared to a net loss of \$0.4 million, or \$0.01 loss per share, for the same quarter in 2022.

Business Updates*GH001 in 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 patients with treatment-resistant depression (TRD) (GH001-TRD-201). The trial has been approved in seven European countries and is expected to recruit approximately 80 patients across approximately 20 sites. Patient enrollment is on schedule and we continue to expect completion of the double-blind phase of this trial in the third quarter of 2024, with availability of top-line data in the third or the fourth quarter of 2024. In this trial, GH001 is administered using an externally-sourced inhalation device.

Update on IND for GH001

In August 2023, we submitted an Investigational New Drug Application (IND) for GH001 with the U.S. Food and Drug Administration (FDA), with the purpose to initiate a Phase 1 healthy volunteer clinical pharmacology trial, where GH001 is administered using our proprietary aerosol delivery device (GH001-HV-106). The trial is designed to support bridging to the clinical data generated with the third-party device we currently use in our clinical trials. As previously announced in September, the FDA advised that it had placed our IND on clinical hold.

We have now received a formal clinical hold letter from the FDA. To remove the hold, they have requested that we provide (i) an inhalation toxicology study in a non-rodent species and an additional inhalation toxicology study in rats, related to respiratory tract histology findings from a previously completed inhalation toxicology study in rats, (ii) additional device design verification information and (iii) updates to our investigator brochure. We are working to respond to the FDA's requests, including by initiating the requested nonclinical studies. We intend to request a meeting with the FDA, expected to take place in the first quarter of 2024, if granted, to discuss the feedback, provide clarifications, and discuss our plan to address their comments. 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 due course after taking into account the conclusions of that meeting.

GH001 in BD and PPD

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

Recently, the clinical research organization that manages one of our clinical trial sites informed us that the site will be closed for business reasons. As this is one of two sites activated in each trial, and because both trials have been recruiting slower than previously projected, we expect a delay in the completion of the trials. We are in the process of putting measures in place to support recruitment of both trials, including the addition of further clinical trial sites, and we plan to provide an updated timeline for expected trial completion in the first quarter of 2024.

GH002

As previously announced, 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.

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/A 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 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. 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, 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
Condensed Consolidated Interim Statement of Comprehensive Income (Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
	\$'000	\$'000	\$'000	\$'000
Operating expenses				
Research and development	(7,088)	(4,620)	(21,570)	(13,574)
General and administration	(2,631)	(2,006)	(8,493)	(7,808)
Loss from operations	(9,719)	(6,626)	(30,063)	(21,382)
Other income				
Finance income	2,438	-	6,049	-
Finance expense	(184)	-	(534)	-
Movement of expected credit loss	(17)	-	1	-
Foreign exchange gain	1,833	6,185	232	15,512
Total other income	4,070	6,185	5,748	15,512
Loss before tax	(5,649)	(441)	(24,315)	(5,870)
Tax charge/(credit)	-	-	-	-
Loss for the period	(5,649)	(441)	(24,315)	(5,870)
Other comprehensive expense				
<i>Items that may be reclassified to profit or loss</i>				
Fair value movement on marketable securities	(428)	-	(1,216)	-
Currency translation adjustment	(1,780)	(6,464)	(161)	(15,779)
Total comprehensive loss for the period	(7,857)	(6,905)	(25,692)	(21,649)
Attributable to owners:				
Loss for the period	(5,649)	(441)	(24,315)	(5,870)
Total comprehensive loss for the period	(7,857)	(6,905)	(25,692)	(21,649)
Loss per share				
Basic and diluted loss per share (in USD)	(0.11)	(0.01)	(0.47)	(0.11)

GH RESEARCH PLC

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	<u>At September 30,</u>	<u>At December 31,</u>
	<u>2023</u>	<u>2022</u>
	<u>\$'000</u>	<u>\$'000</u>
ASSETS		
Current assets		
Cash and cash equivalents	86,439	165,955
Other financial assets	55,494	-
Marketable securities	19,343	-
Other current assets	2,765	2,586
Total current assets	<u>164,041</u>	<u>168,541</u>
Non-current assets		
Marketable securities	67,449	85,724
Property, plant, and equipment	1,078	97
Total non-current assets	<u>68,527</u>	<u>85,821</u>
Total assets	<u>232,568</u>	<u>254,362</u>
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	2,707	1,868
Lease liability	260	-
Other current liabilities	3,167	2,678
Total current liabilities	<u>6,134</u>	<u>4,546</u>
Non-current liabilities		
Lease liability	661	-
Total non-current liabilities	<u>661</u>	<u>-</u>
Total liabilities	<u>6,795</u>	<u>4,546</u>
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,448	291,448
Other reserves	2,888	2,595
Foreign currency translation reserve	(13,196)	(13,035)
Accumulated deficit	(56,668)	(32,493)
Total equity	<u>225,773</u>	<u>249,816</u>
Total liabilities and equity	<u>232,568</u>	<u>254,362</u>



GH Research

Corporate Presentation

GH Research PLC (NASDAQ: GHR)

November 2023

Disclaimer Regarding Forward-Looking Statements

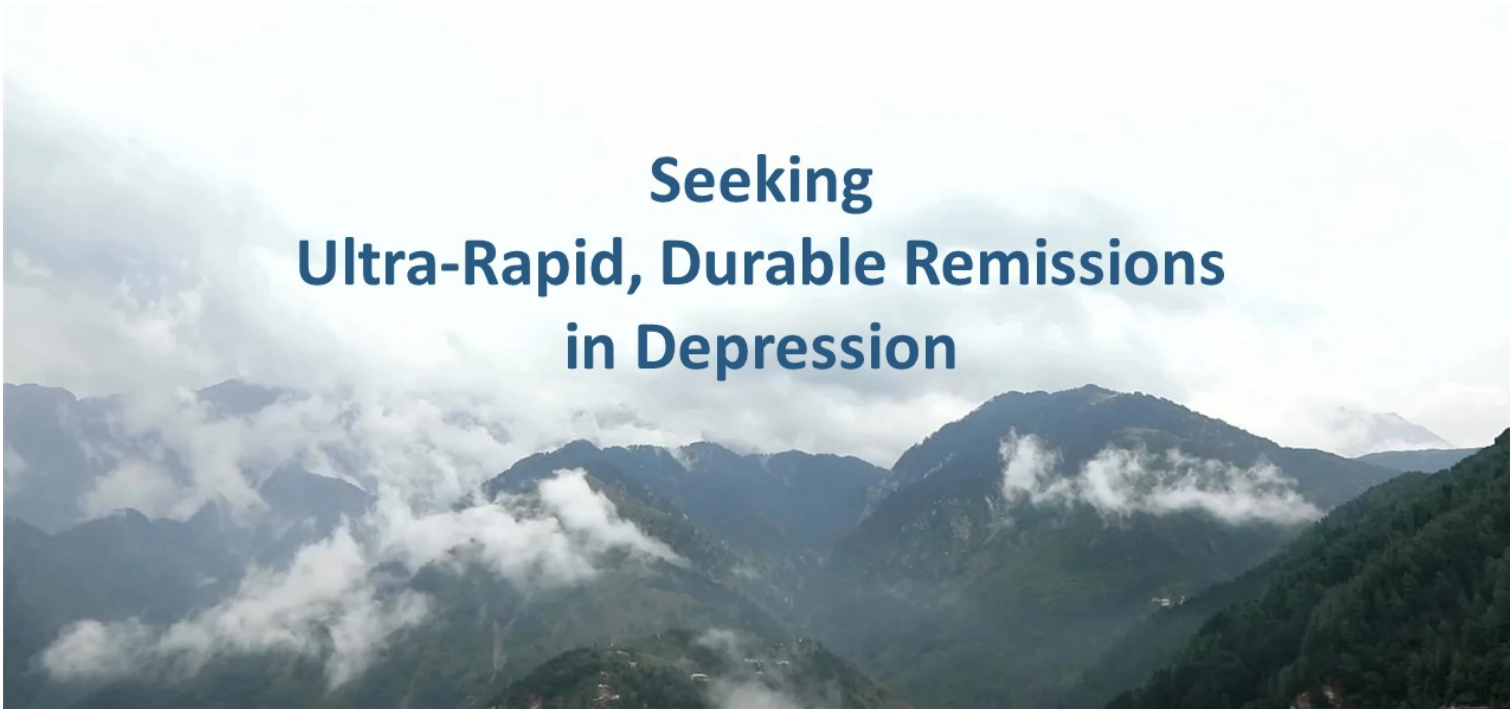
This presentation has been prepared by GH Research PLC ("GH Research") for informational purposes only and not for any other purpose. Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the presenter or GH Research or any director, employee,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



Seeking Ultra-Rapid, Durable Remissions in Depression

Pipeline

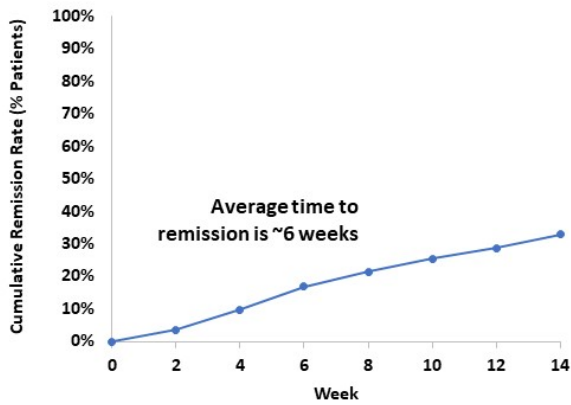


*Bipolar II disorder with a current major depressive episode
 5-MeO-DMT, 3-Methoxy-N,N-Dimethyltryptamine; i.v., intravenous; RDBPC, Randomized, Double-Blind, Placebo-Controlled; POC, Proof-of-Concept; HV, Healthy Volunteer

The Problem for Patients with Depression

Established Therapies are **Slow-Acting**

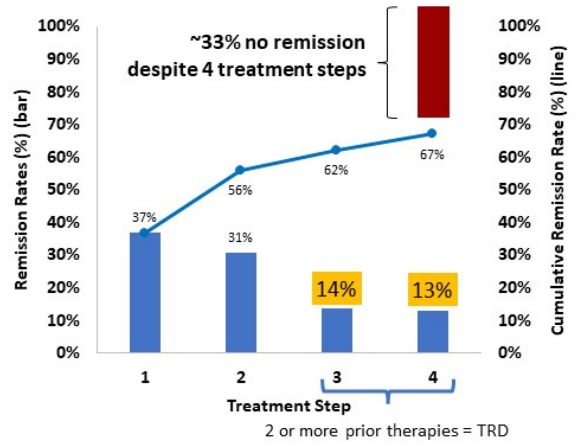
(STAR*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



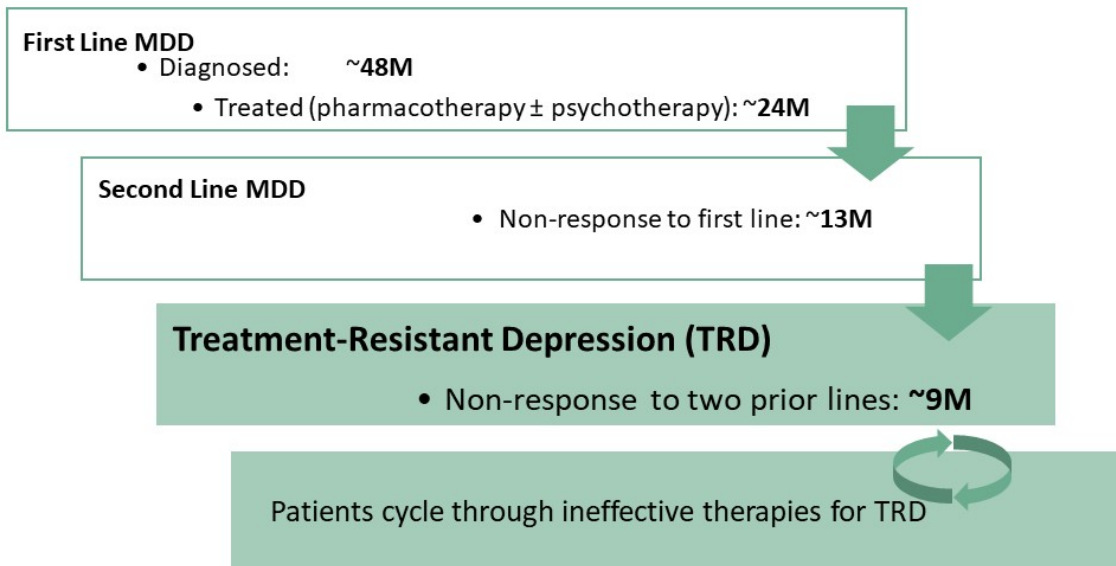
Adapted from Trivedi et al., Am J Psychiatry 2006 and Rush et al., Am J Psychiatry 2006
TRD, Treatment-Resistant Depression

... Remission Rates in TRD < 15%

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



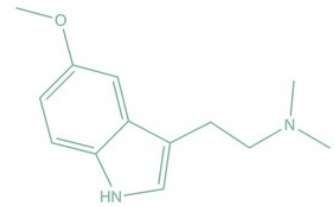
Large and Open Depression Market in the EU and US



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**

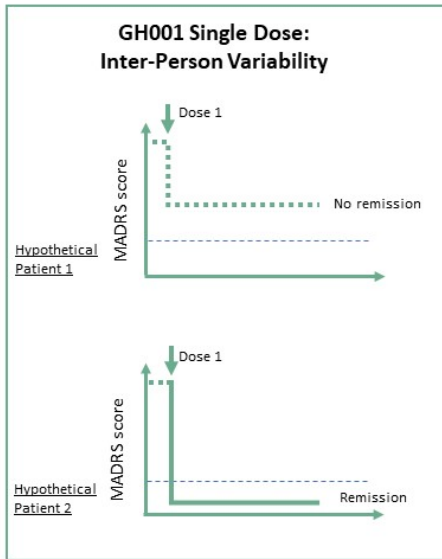


Mebufotenin (5-MeO-DMT)

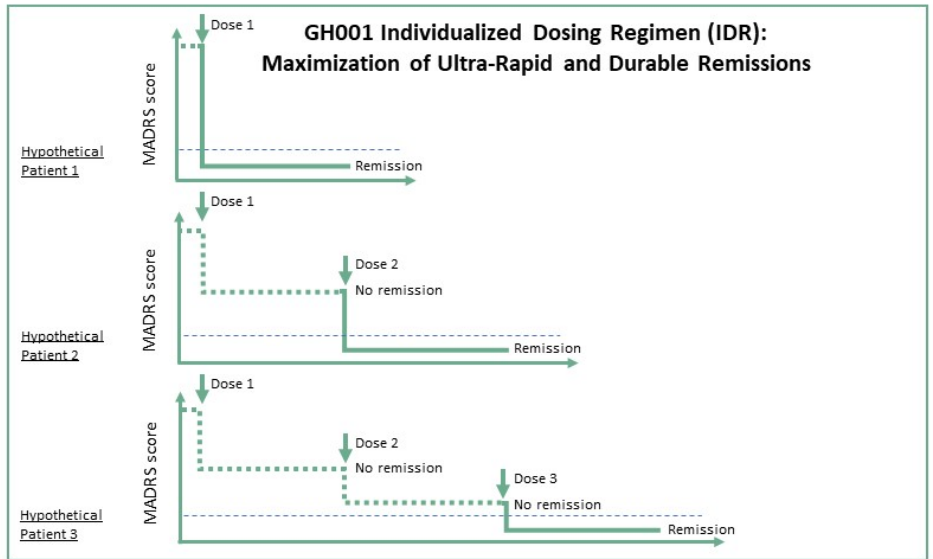
Foundational IP



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



MADRS, Montgomery-Asberg Depression Rating Scale

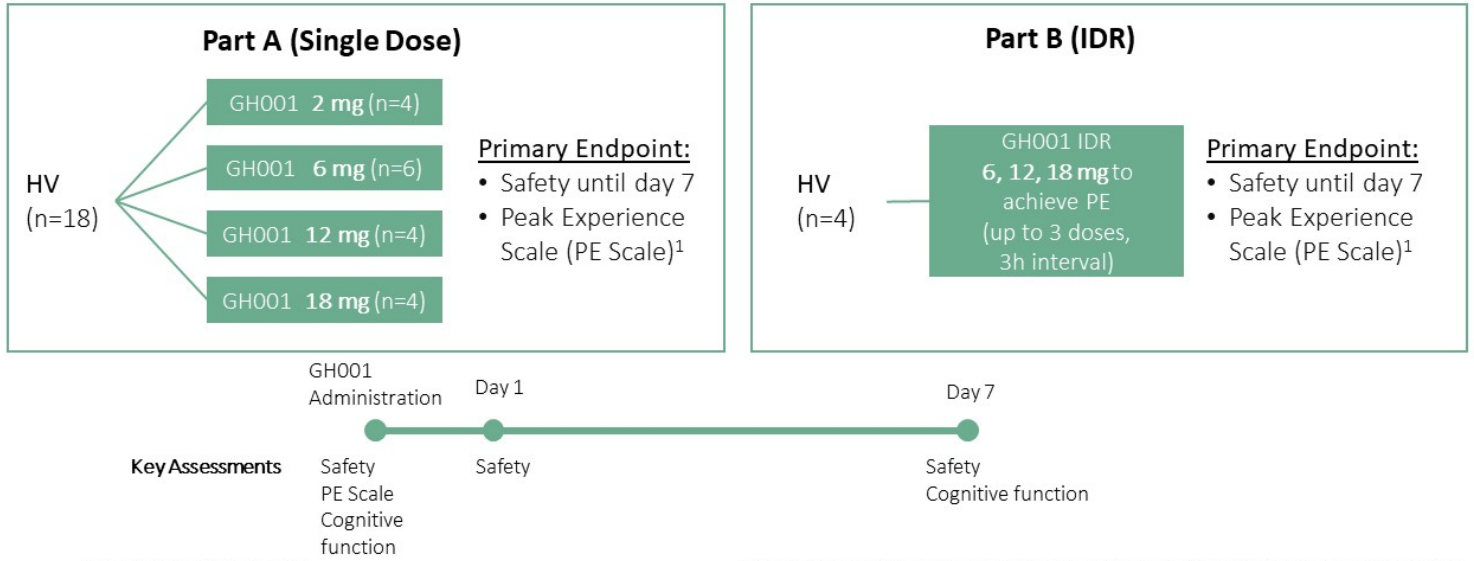


Phase 1 Trial in Healthy Volunteers GH001-HV-101

(Completed)

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

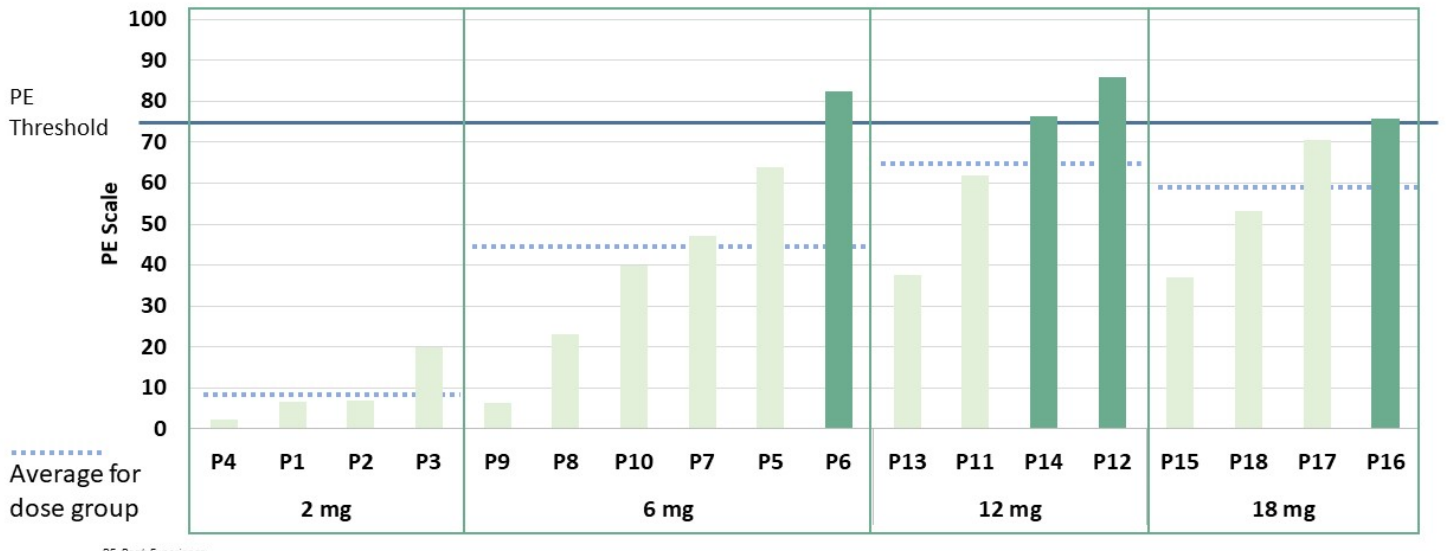
- No SAEs
- All ADRs mild, except two moderate (*)
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant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

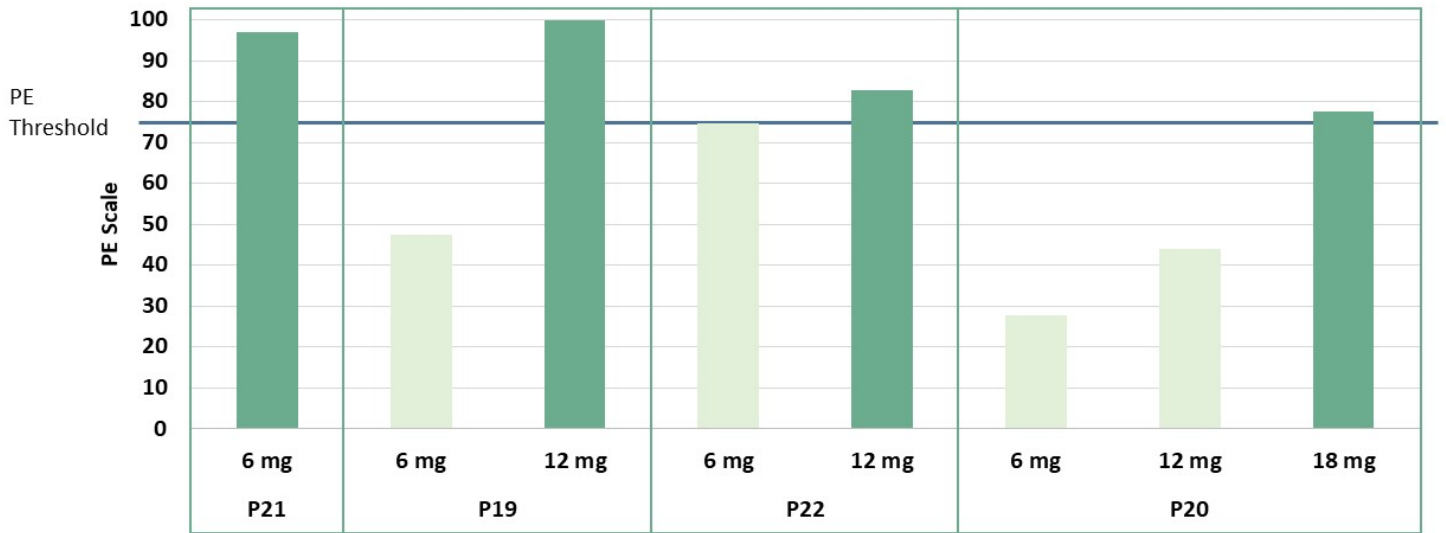
*6 mg (n=1); 6-12 mg (n=2); 6-12-18 mg (n=1)

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)



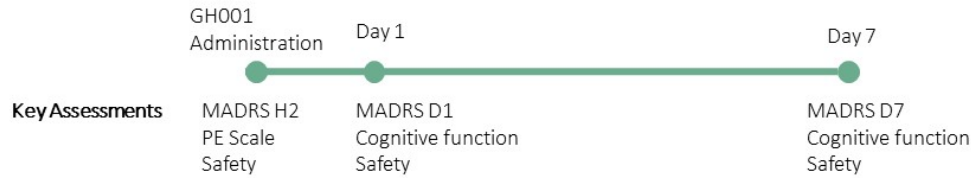
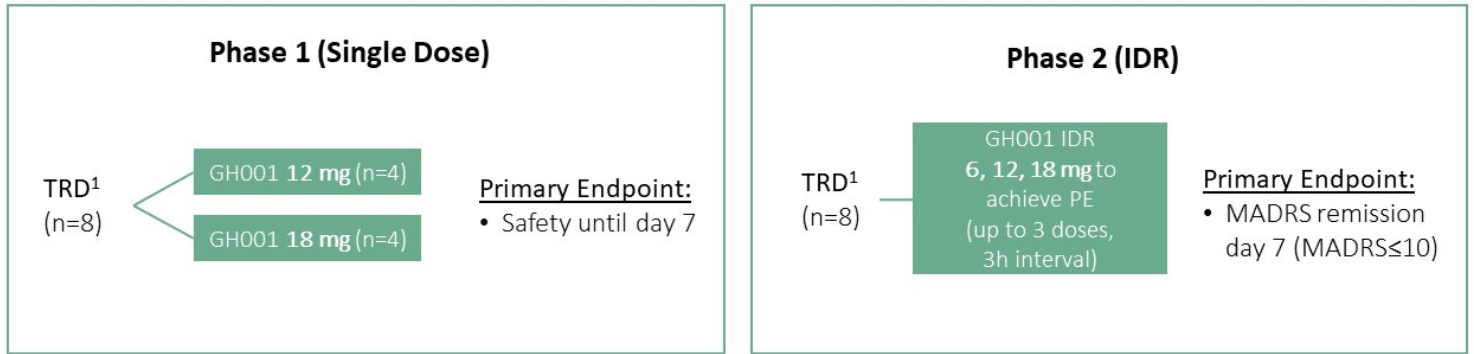
PE, Peak Experience

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

(Completed)

Clinicaltrials.gov ID: NCT04698603

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



¹TRD, Treatment-Resistant Depression; PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen; H, Hour; D, Day

²Defined 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

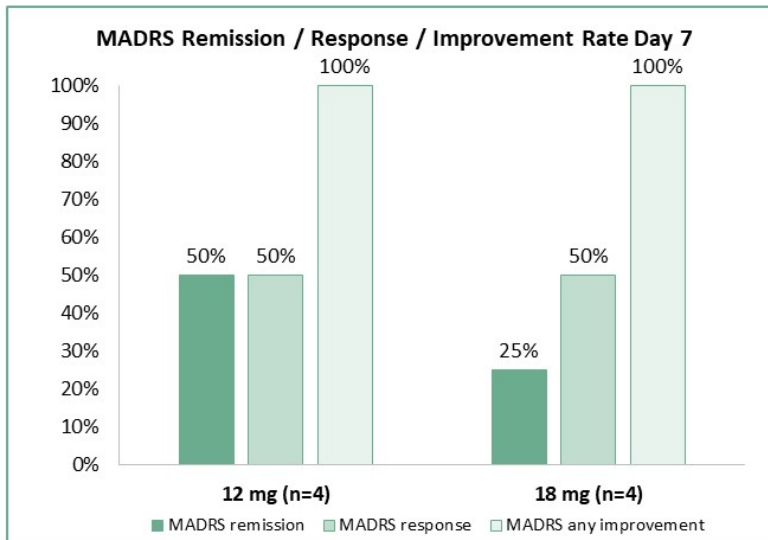
- No SAEs
- All ADRs mild, except three moderate*
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant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

¹ 6-12 mg (n=6); 6-12-18 mg (n=2)

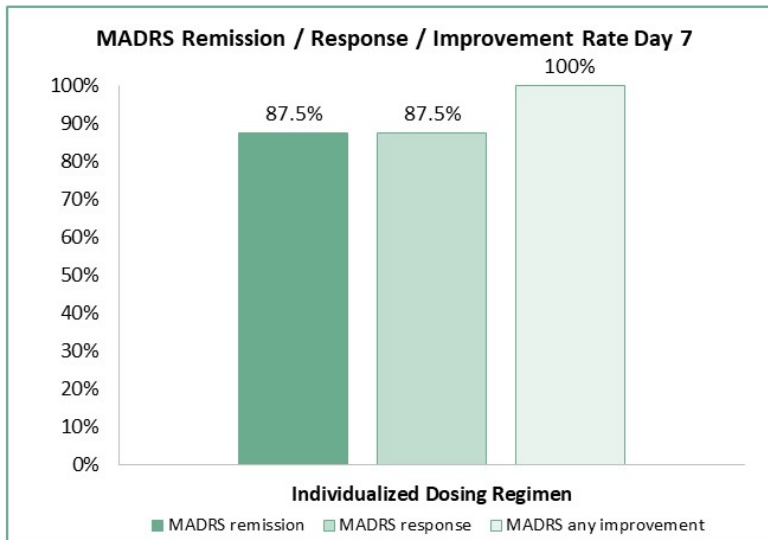
Phase 1 (Single Dose) – Efficacy (MADRS)



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

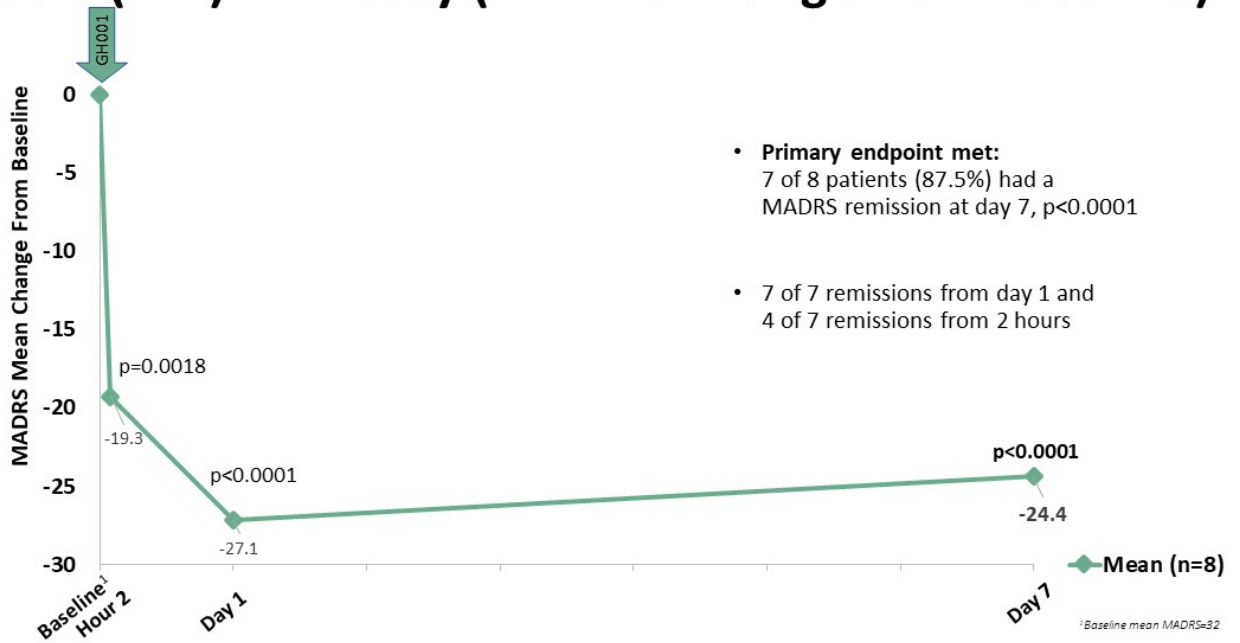
Phase 2 (IDR) – Efficacy (MADRS)



- **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

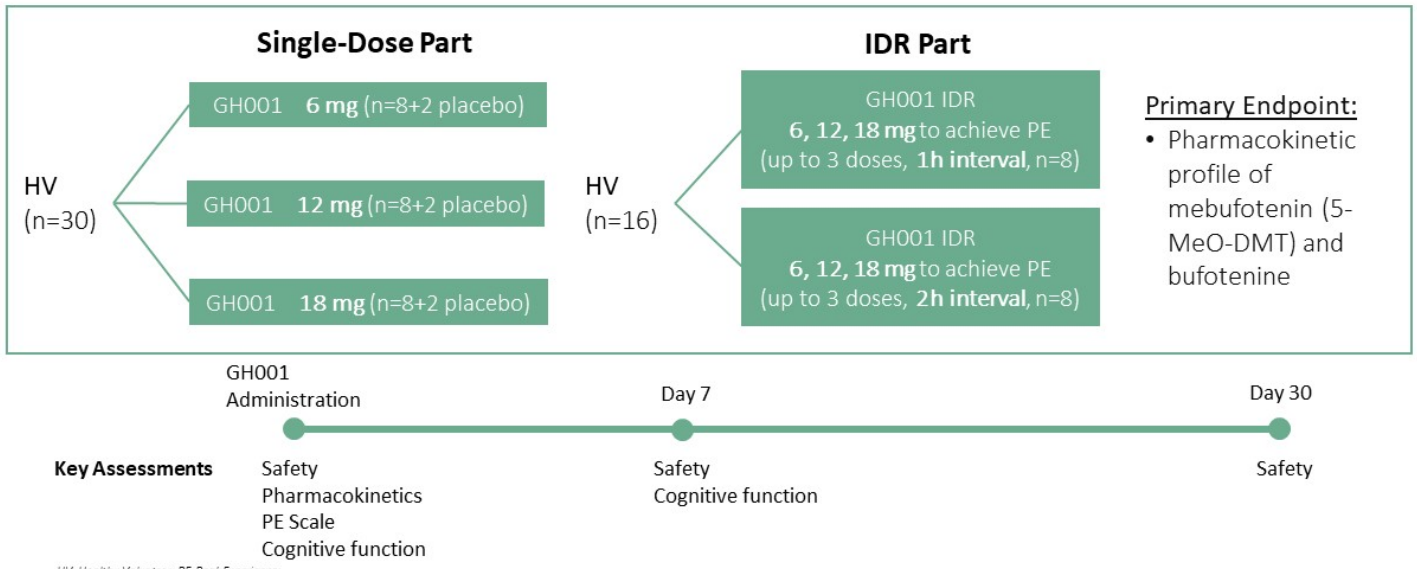
PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen

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

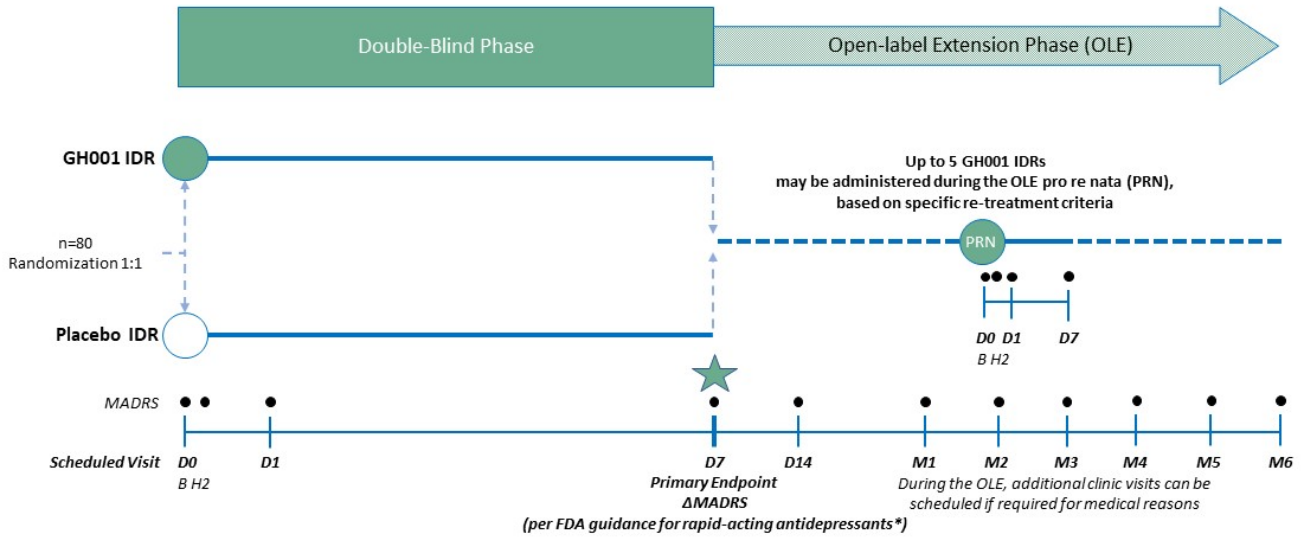
¹6 mg (n=1), 6-12 mg (n=3); 6-12-18 mg (n=4)
²6-12 mg (n=3); 6-12-18 mg (n=5)

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

Board of Directors & Executive Management



Florian Schönharting
MSc
Chairman of the Board, Co-founder



Michael Forer
BA, LLB
Vice-Chairman of the Board



Dermot Hanley
BSC, MBA
Board Member



Duncan Moore
MPhil, PhD
Board Member



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



Velichka (Villy) Valcheva
MD, MSc
VP, Clinical Research and Medical Affairs



Julie Ryan
ACA, MAcc, BComm
VP, Finance



Aaron Cameron
MSc, MBA
VP, Technical Development and Operational Planning



Magnus Halle
BSc
Managing Director, Ireland, Co-founder



Scientific Advisors



Madhukar Trivedi
M.D.
Professor of Psychiatry,
UT Southwestern Medical Center



Michael Thase
M.D.
Professor of Psychiatry, Perelman School of Medicine
University of Pennsylvania



Mark Zimmerman
M.D.
Professor of Psychiatry and Human Behavior,
Brown University



Eduard Vieta
Prof. Dr.
Head, Psychiatry Unit,
Hospital Clinic de Barcelona



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



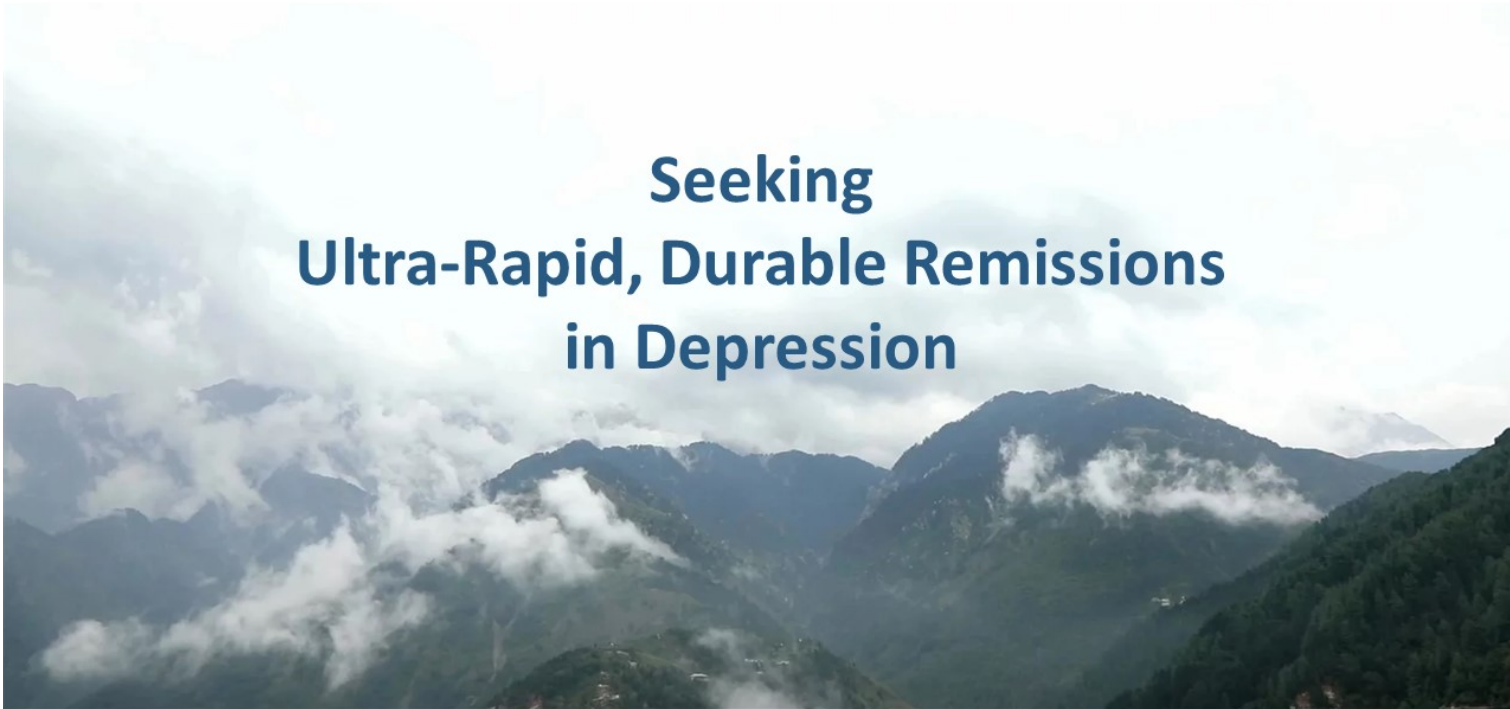
Malek Bajbouj
Prof. Dr. med.
Head, Center for Affective Neuroscience,
Charité, Berlin



Johannes Ramaekers
Prof. Dr.
Professor, Faculty of Psychology
and Neuroscience of Maastricht University

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, with top-line data expected in Q3 or Q4 2024
 - Provide update on U.S. IND clinical hold and planned Phase 1 clinical pharmacology trial with proprietary aerosol delivery device after expected meeting with FDA in Q1 2024
 - Provide update on timeline for completion of Phase 2a trials in PPD in BDII in Q1 2024
- **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 \$228.7 million as of September 30, 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