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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, 2022.

Commission File Number: **001-40530**

**GH Research PLC**

(Exact name of registrant as specified in its charter)

**28 Baggot Street Lower  
Dublin 2  
D02 NX43  
Ireland**

(Address of principal executive office)

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

Form 20-F



Form 40-F

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

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

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On November 10, 2022, GH Research PLC (the “Company”) reported its third quarter 2022 financial results and provided business updates.

On November 10, 2022, the Company made available an updated investor presentation on its website. A copy of the investor presentation is attached hereto as Exhibit 99.4.

The fact that this presentation is being made available and furnished herewith should not be deemed an admission as to the materiality of any information contained in the materials. The information contained in the presentation is being provided as of November 10, 2022 and the Company does not undertake any obligation to update the presentation in the future or to update forward-looking statements to reflect subsequent actual results.

#### EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	Unaudited Condensed Consolidated Interim Financial Statements for the three and nine months ended September 30, 2022
<a href="#">99.2</a>	Management’s Discussion and Analysis of Financial Condition and Results of Operations
<a href="#">99.3</a>	Press release dated November 10, 2022
<a href="#">99.4</a>	Corporate Presentation for November 2022

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**SIGNATURE**

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

Date: November 10, 2022

**GH Research PLC**

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

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## Unaudited condensed consolidated interim statement of comprehensive income

	Note	Three months ended September 30,		Nine months ended September 30,	
		2022	2021	2022	2021
		\$'000	\$'000	\$'000	\$'000
<b>Operating expenses</b>					
Research and development		(4,620)	(2,556)	(13,574)	(5,202)
General and administration		(2,006)	(2,110)	(7,808)	(3,277)
<b>Loss from operations</b>		<b>(6,626)</b>	<b>(4,666)</b>	<b>(21,382)</b>	<b>(8,479)</b>
Finance expense		-	(3)	-	(9)
Foreign exchange gain		6,185	2,832	15,512	3,377
<b>Loss before tax</b>		<b>(441)</b>	<b>(1,837)</b>	<b>(5,870)</b>	<b>(5,111)</b>
Tax charge/(credit)		-	-	-	-
<b>Loss for the period</b>		<b>(441)</b>	<b>(1,837)</b>	<b>(5,870)</b>	<b>(5,111)</b>
<b>Other comprehensive expense</b>					
<i>Items that may be reclassified to profit or loss</i>					
Currency translation adjustment		(6,464)	(2,845)	(15,779)	(3,533)
<b>Total comprehensive loss for the period</b>		<b>(6,905)</b>	<b>(4,682)</b>	<b>(21,649)</b>	<b>(8,644)</b>
<b>Attributable to owners:</b>					
Loss for the period		(441)	(1,837)	(5,870)	(5,111)
Comprehensive loss for the period		(6,464)	(2,845)	(15,779)	(3,533)
<b>Loss per share</b>					
Basic and diluted loss per share (in USD)	10	(0.008)	(0.035)	(0.113)	(0.125)

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

## Unaudited condensed consolidated interim statement of financial position

	Note	At September 30, 2022 S'000	At December 31, 2021 S'000
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents		256,939	276,776
Other current assets	4	3,100	3,066
<b>Total current assets</b>		<b>260,039</b>	<b>279,842</b>
<b>Non-current assets</b>			
Property, plant and equipment		84	82
<b>Total non-current assets</b>		<b>84</b>	<b>82</b>
<b>Total assets</b>		<b>260,123</b>	<b>279,924</b>
<b>LIABILITIES AND EQUITY</b>			
<b>Current liabilities</b>			
Trade payables	5	1,750	883
Other current liabilities	6	1,635	1,866
<b>Total current liabilities</b>		<b>3,385</b>	<b>2,749</b>
<b>Total liabilities</b>		<b>3,385</b>	<b>2,749</b>
<b>Equity attributable to owners</b>			
Share capital		1,301	1,301
Additional paid-in-capital		291,448	291,448
Other reserves		1,578	366
Foreign currency translation reserve		(21,682)	(5,903)
Accumulated deficit		(15,907)	(10,037)
<b>Total equity</b>		<b>256,738</b>	<b>277,175</b>
<b>Total liabilities and equity</b>		<b>260,123</b>	<b>279,924</b>

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 \$'000
	Share capital \$'000	Additional paid in capital \$'000	Other reserves \$'000	Foreign currency translation reserve \$'000	Accumulated deficit \$'000		
<b>At January 1, 2021</b>	<b>871</b>	<b>5,430</b>	-	<b>200</b>	<b>(835)</b>	<b>5,666</b>	
Loss for the period	-	-	-	-	(5,111)	(5,111)	
Translation adjustment	-	-	-	(3,533)	-	(3,533)	
<b>Total comprehensive loss for the period</b>	-	-	-	<b>(3,533)</b>	<b>(5,111)</b>	<b>(8,644)</b>	
Share-based compensation expense	-	-	131	-	-	131	
Corporate reorganization	(112)	112	-	-	-	-	
Issue of share capital	542	285,906	-	-	-	286,448	
<b>Total transactions with owners</b>	<b>430</b>	<b>286,018</b>	<b>131</b>	-	-	<b>286,579</b>	
<b>At September 30, 2021</b>	<b>1,301</b>	<b>291,448</b>	<b>131</b>	<b>(3,333)</b>	<b>(5,946)</b>	<b>283,601</b>	
<b>At January 1, 2022</b>	<b>1,301</b>	<b>291,448</b>	<b>366</b>	<b>(5,903)</b>	<b>(10,037)</b>	<b>277,175</b>	
Loss for the period	-	-	-	-	(5,870)	(5,870)	
Translation adjustment	-	-	-	(15,779)	-	(15,779)	
<b>Total comprehensive loss for the period</b>	-	-	-	<b>(15,779)</b>	<b>(5,870)</b>	<b>(21,649)</b>	
Share-based compensation expense	-	-	1,212	-	-	1,212	
<b>Total transactions with owners</b>	-	-	<b>1,212</b>	-	-	<b>1,212</b>	
<b>At September 30, 2022</b>	<b>1,301</b>	<b>291,448</b>	<b>1,578</b>	<b>(21,682)</b>	<b>(15,907)</b>	<b>256,738</b>	

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,	
	2022 \$'000	2021 \$'000
<b>Cash flows from operating activities</b>		
Loss for the period	(5,870)	(5,111)
Depreciation	34	10
Share-based compensation expense	1,212	131
Finance expense	-	9
Foreign exchange gain	(15,512)	(3,377)
Movement in working capital	804	(3,178)
<b>Cash flows used in operating activities</b>	<b>(19,332)</b>	<b>(11,516)</b>
Finance expense paid	-	(9)
<b>Net cash used in operating activities</b>	<b>(19,332)</b>	<b>(11,525)</b>
<b>Cash flows used in investing activities</b>		
Purchase of property, plant and equipment	(49)	(85)
<b>Cash flows from financing activities</b>		
Proceeds from capital contributions	-	309,200
Transaction costs from capital contributions	-	(22,582)
<b>Net cash flows from financing activities</b>	<b>-</b>	<b>286,618</b>
<b>Net (decrease)/increase in cash</b>	<b>(19,381)</b>	<b>275,008</b>
Cash at the beginning of the period	276,776	5,895
Impact of foreign exchange on cash	(456)	(158)
<b>Cash at the end of the period</b>	<b>256,939</b>	<b>280,745</b>

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

**1. Corporate information**

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

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

These unaudited condensed consolidated interim financial statements were presented to the board of directors and approved by them on November 10, 2022.

**2. Basis of preparation, significant judgments, and accounting policies****Basis of preparation****Compliance with International Financial Reporting Standards**

The unaudited condensed consolidated interim financial statements for the three and nine months ended September 30, 2022, have been prepared in accordance with IAS 34 “Interim Financial Reporting”. The unaudited condensed consolidated interim financial statements do not include all of the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements for the year ended December 31, 2021 which were prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). These unaudited condensed consolidated interim financial statements are presented in U.S. dollar (“USD” or “\$”), which is the Company’s functional currency and the Group’s presentation currency.

On May 27, 2021, as part of the corporate reorganization, all shareholders of GH Research Ireland Limited exchanged each of the shares held by them in GH Research Ireland Limited for shares of GH Research PLC of the same share classes with the same shareholders rights as the shares held by them in GH Research Ireland Limited, and as a result, GH Research Ireland Limited became a wholly-owned subsidiary of GH Research PLC. The financial information presented prior to the incorporation of GH Research PLC relates solely to GH Research Ireland Limited.

The financial information presented in this interim report does not represent full statutory accounts as defined by the Companies Act 2014. The statutory accounts of GH Research PLC for the year ended December 31, 2021, were filed with the Companies Registration Office on November 2, 2022.

**New and amended IFRS standards**

There are no new IFRS standards, amendments to standards or interpretations that are mandatory for the financial year beginning on January 1, 2022, that are relevant to the Group and that have had any material impact in the interim period. New standards, amendments to standards and interpretations that are not yet effective, have been deemed by the Group as currently not relevant and are not listed here.

**Going concern basis**

GH Research is a clinical-stage biopharmaceutical company developing innovative therapeutics. The Group is exposed to all risks inherent in establishing and developing its business, including the substantial uncertainty that current projects will succeed. Research and development expenses have been incurred from the start of the Group’s activities, generating negative cash flows from operating activities since formation.

Since its incorporation, the Group has funded its growth through capital increases. The Group has no bank loans or other debt outstanding as of September 30, 2022. As a result, the Group is not exposed to liquidity risk through requests for early repayment of loans.

As of September 30, 2022, the Group’s cash amounted to \$256.9 million (December 31, 2021: \$276.8 million).



**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 included those that applied to the consolidated financial statements for the year ended December 31, 2021.

**Significant accounting policies**

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

**Consolidation**

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

**Foreign currency translation**

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

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

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

**Cash and cash equivalents**

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

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

**Property, plant and equipment**

Property, plant and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, which are as follows:

	<b>Estimated Useful Life</b>
IT equipment	3 years
Office equipment	3 years
Medical equipment	2 years

**Share-based compensation expense**

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

**Transaction costs**

Incremental transaction costs are capitalized as incurred and are shown in equity as a deduction, net of tax, from the proceeds received from financing rounds and the initial public offering. If the equity instruments are not subsequently issued, the transaction costs would be expensed.

**Fair value estimation**

At September 30, 2022, the carrying amount is a reasonable approximation of fair value for the following financial assets and liabilities:

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

**Current and deferred income tax**

The tax expense for the financial period comprises current and deferred tax. Tax is recognized in the unaudited condensed consolidated income statement, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case the related tax is recognized in other comprehensive income or directly in equity, respectively.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date where the Group generates taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Taxes on income are accrued in the same financial period as the revenues and expenses to which they relate. Current income tax assets and liabilities for the current financial period are measured at the amount expected to be recovered from or paid to the taxation authorities.

Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences or the unused tax losses can be utilized. Deferred income tax assets from tax credit carry-forwards are recognized to the extent that the national tax authority confirms the eligibility of such a claim and that the realization of the related tax benefit through future taxable profits is chargeable.

The interim income tax expense is calculated based on the Company's estimate of the weighted average effective annual income tax rate expected for the full year. The current and deferred income tax charge was \$nil for the nine months ended September 30, 2022 and 2021 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)

**Research and development expenses**

Research and development expenses consist of costs incurred in performing research and development activities, including salaries, share-based compensation and benefits, travel, and external costs of outside vendors engaged to conduct clinical development activities, clinical trials, technical development activities and the cost to manufacture clinical trial materials. Research expenditure is recognized as an expense in the period in which it is incurred.

**General and administrative expenses**

General and administrative expenses relate to the administration of the Group including salaries, share-based compensation and benefits, travel and external costs including legal and professional fees.

**Loss per share**

Basic earnings and loss per share are calculated by dividing the net profit or loss attributable to shareholders by the weighted average number of shares in issue during the period. Diluted earnings per share is calculated using the treasury method which adjusts for the potential dilutive effect of outstanding share options if such share options are dilutive for the periods presented.

**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,	
	2022 \$'000	2021 \$'000	2022 \$'000	2021 \$'000
External research and development expenses	3,428	2,055	10,429	4,265
Employee expenses <sup>1</sup>	1,064	440	2,887	769
Depreciation	7	5	22	7
Other expenses	121	56	236	161
<b>Total research and development expenses</b>	<b>4,620</b>	<b>2,556</b>	<b>13,574</b>	<b>5,202</b>
External costs	1,464	1,739	6,145	2,604
Employee expenses <sup>2</sup>	537	370	1,651	670
Depreciation	5	1	12	3
<b>Total general and administrative expenses</b>	<b>2,006</b>	<b>2,110</b>	<b>7,808</b>	<b>3,277</b>
<b>Total operating expenses</b>	<b>6,626</b>	<b>4,666</b>	<b>21,382</b>	<b>8,479</b>

<sup>1</sup> Included in employee expenses is share based compensation expense of \$0.2 million and \$0.7m for the three and nine months ended September 20, 2022, relating to employees in our research and development department.

<sup>2</sup> Included in employee expenses is share based compensation expense of \$0.2 million and \$0.5m for the three and nine months ended September 20, 2022, relating to employees in our general and administrative department.

The increase in operating expenses in the three and nine months ended September 30, 2022, is primarily due to increased expenditure as the business continues to expand and grow, including the continued development of the Group’s product candidates. Employee expenses have also increased and relate to the hiring of personnel to support this increased activity.

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

**Foreign exchange gain**

Foreign exchange gain of \$6.2 million and \$15.5 million in the three and nine months ended September 30, 2022, (\$2.8 million and \$3.4 million in the three and nine months ended September 30, 2021), consist primarily of gains related to the translation of U.S. dollar cash balance into euro in the accounts of the Company's subsidiary, GH Research Ireland Limited, whose functional currency is euro as explained in Note 2, "Basis of preparation, significant judgments, and accounting policies".

At September 30, 2022, 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 30 September, 2022, would have been \$9.7 million higher/lower, mainly related to the translation of cash held in U.S. dollar in the Company's subsidiary, GH Research Ireland Limited.

**4. Other current assets**

Other current assets primarily represent prepayments and VAT receivable.

**5. Trade payables**

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

**6. Other current liabilities**

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

**7. Contingent liabilities**

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

**8. Share based compensation****Share Options**

In June 2021, the Company adopted a share option plan referred to herein as the Share Option Plan under which grants of options are made to eligible participants. The Company has reserved 1,202,734 ordinary shares for future issuance under the Share Option Plan, which include ordinary shares pursuant to share-based equity awards issued to date. As of September 30, 2022, the Company has 764,058 ordinary shares available for the future issuance of share-based equity awards.

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

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

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

During the three and the nine months ended September 30, 2022, the Company granted the option to purchase 77,936 and 281,489 ordinary shares, respectively, to employees which was in line with the general terms of the Share Option Plan as described above.

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

The following table summarizes the share option awards outstanding as of September 30, 2022:

	Average exercise price per share in USD	Number of awards	Weighted average remaining life in years
<b>At December 31, 2021</b>	<b>15.80</b>	<b>157,187</b>	<b>7.62</b>
Granted	14.31	281,489	7.62
<b>At September 30, 2022</b>	<b>15.52</b>	<b>438,676</b>	<b>7.35</b>

None of the awards outstanding as of September 30, 2022, were exercisable and they expire through 2030. As of September 30, 2022, 46,058 awards are vested and generally subject to a 2 year service condition.

The weighted average grant date fair value of awards granted during the three and nine months ended September 30, 2022, was \$10.20 and \$10.14, 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, 2022, were determined on the date of the grant using the following assumptions:

	Three months ended September 30, 2022	Nine months ended September 30, 2022
Share price, in USD	12.55-13.52	9.68-19.42
Strike price, in USD (weighted average)	13.42	14.31
Expected volatility	91%-92%	89%-92%
Award life (weighted average)	6	6
Expected dividends	-	-
Risk-free interest rate	2.89%-3.66%	1.74%-3.66%

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

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

As of September 30, 2022, the amount recorded as an increase to Other Reserves within equity on the unaudited condensed consolidated interim statement of financial position of the Share Option Plan was \$1.6 million. The amount of expense for all awards recognized for services received during the three and nine months ended September 30, 2022 was \$0.4 million and \$1.2 million, respectively, and for each of the three months and nine months ended September 30, 2021 was \$0.1 million.

## 9. Related party disclosures

There have been no transactions in the three and nine months ended September 30, 2022, with related parties that had a material effect on the financial position or performance of the Group.

**10. Loss per share**

The basic loss per share is calculated by dividing the net loss attributable to shareholders by the weighted average number of shares in issue during the period as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Loss attributable to shareholders (in \$'000)	(441)	(1,837)	(5,870)	(5,111)
Weighted average number of shares in issue <sup>(1)</sup>	52,020,849	52,020,849	52,020,849	40,912,190
Basic and diluted earnings/(loss) per share (in USD) <sup>(2)</sup>	(0.008)	(0.035)	(0.113)	(0.125)

<sup>(1)</sup> Share data for the nine month period ended September 30, 2021, has been revised to give effect to the share conversion and share consolidation. This is explained further in the most recently filed annual report on Form 20-F for the year-ended December 31, 2021.

<sup>(2)</sup> Ordinary and preferred shares as of September 30, 2021, have been treated as a single class for the purpose of calculating loss per share as they contractually shared equally in the profits and losses of the entity.

For the three and nine month period ended September 30, 2022 and September 30, 2021, basic and diluted loss per share are calculated on the weighted average number of shares issued and outstanding and exclude shares to be issued under the Share Option Plan, as the effect of including those shares would be anti-dilutive.

**11. Events after the reporting date**

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

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

This management's discussion and analysis is designed to provide you with a narrative explanation of our financial condition and results of operations. You should read this discussion and analysis in conjunction with our unaudited condensed consolidated interim financial statements, including the notes thereto, as of and for the three and nine months ended September 30, 2022. You should also read this discussion and analysis in conjunction with our audited consolidated financial statements, including the notes thereto, and the section in our annual report on Form 20-F for the year ended December 31, 2021 titled "Item 3. Key Information – D. Risk Factors".

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

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

**Overview**

We are a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. Our initial focus is on developing our novel and proprietary 5-Methoxy-N,N-Dimethyltryptamine, or 5-MeO-DMT, therapies for the treatment of patients with Treatment-Resistant Depression, or TRD. Our portfolio currently includes GH001, our proprietary inhalable 5-MeO-DMT product candidate which is delivered via a vaporization device produced by a third party, and GH002, our proprietary injectable 5-MeO-DMT product candidate, and GH003, our proprietary intranasal 5-MeO-DMT product candidate. We have completed two Phase 1 healthy volunteer clinical trials (GH001-HV-101 and GH001-HV-103), in which administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in an individualized dosing regimen with intra-subject dose escalation within a single day. We have also completed a Phase 1/2 clinical trial in patients with TRD (GH001-TRD-102). Based on observed clinical activity in the Phase 1 part of the clinical trial, we believe that administration of a single dose of GH001 has the potential to induce ultra-rapid remissions as measured by the Montgomery-Åsberg Depression Rating Scale, or MADRS, in certain patients, driven by the ultra-rapid onset of psychoactive effects (commonly within seconds) and an intense and short-lived (commonly five to 30 minutes) initial psychoactive experience. Based on observed clinical activity in the Phase 2 part of the trial, we believe that administration of an individualized dosing regimen with intra-subject dose escalation within a single day can further increase the MADRS remission rate as compared to a single dose of GH001.

We have incurred recurring operating losses since inception, including net losses of \$5.9 million, \$9.2 million and \$0.4 million for the nine months ended September 30, 2022, and the years ended December 31, 2021 and 2020, respectively. As of September 30, 2022, we had an accumulated deficit of \$15.9 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 exchange movements. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue to develop and conduct clinical trials, including in expanded geographies such as the United States, for GH001, our inhalable 5-MeO-DMT product candidate, GH002, our injectable 5-MeO-DMT product candidate, and GH003, our intranasal 5-MeO-DMT product candidate for our initial indications and any additional indications;
  - continue both the technical development and expansion of our external manufacturing capabilities for our current product candidates GH001, GH002 and GH003 and of the medical devices required to deliver these product candidates;
  - initiate and continue research and development, including nonclinical, clinical, and discovery efforts for any future product candidates;
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- seek to identify additional product candidates;
- seek regulatory approvals for our product candidates GH001, GH002 and GH003 including the medical devices required to deliver these product candidates, or any other product candidates that successfully complete clinical development;
- add operational, financial and management information systems and personnel, including personnel to support our product candidate and device development and help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, quality control, scientific, commercial, sales, marketing and administrative personnel;
- continue to prepare, file, prosecute, maintain, protect and enforce our intellectual property rights and claims;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval;
- comply with ongoing regulatory requirements for products approved for commercial sale, if ever;
- 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 recent invasion of Ukraine;
- acquire or in-license other product candidates, medical devices to deliver our product candidates, and other technologies; and
- incur increased costs as a result of operating as a public company.

In addition, as we progress toward marketing approval for any of our product candidates, we 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; 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 recent invasion of Ukraine; and the need to obtain adequate additional financing to fund the development of our product candidates.

## **Business Updates**

### ***GH001 for the treatment of TRD***

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

We have recently submitted clinical trial applications in several European countries for a multi-center, randomized, controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201). Pending regulatory approval, we expect to initiate this trial in the first quarter of 2023. We expect to recruit approximately 80 patients for this trial. The primary objective will be to determine the efficacy of a single-day individualized dosing regimen (IDR) of GH001 compared with placebo in improving depressive symptoms as assessed by the mean change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) at the end of the 7-day double-blind phase. The double-blind phase will be followed by a 6-month open-label extension phase where all patients can receive treatment with the GH001 IDR as-needed, based on the patient's clinical response.

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In May 2022, we also announced the positive outcome of our pre-IND meeting with the U.S. Food and Drug Administration (FDA), and we expect to submit our IND for GH001 in TRD in the first quarter of 2023. The planned IND-opening study is a Phase I imaging study in patients with TRD designed to further elucidate the mechanism of action of GH001 (GH001-TRD-104).

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

We have recently initiated Phase 2a proof-of-concept clinical trials of GH001 for the treatment of patients with bipolar II disorder and a current depressive episode (BDII) (GH001-BD-202) and for the treatment of patients with postpartum depression (PPD) (GH001-PPD-203). We expect to complete these studies by the end of 2023.

#### ***GH002 and GH003***

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. GH002 has completed pre-clinical development to support early clinical trials and we have recently submitted a clinical trial application for a double-blind, placebo-controlled, randomized, dose-ranging clinical pharmacology trial in healthy volunteers (GH002-HV-105). Pending regulatory approval, we expect to initiate this trial in the fourth quarter of 2022.

GH003 is our 5-MeO-DMT product candidate formulated for administration via a proprietary intranasal administration approach. GH003 is currently in preclinical development.

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

As the COVID-19 pandemic continues to evolve, we have followed, and continue to follow, guidance issued by national and local governments to address and mitigate the impact of the COVID-19 pandemic on our employees and our business, including our nonclinical studies and clinical trials. We are focused on the health and safety of our employees, and have, among other things, implemented a work-from-home policy and eliminated non-essential business travel. While we are experiencing limited financial impacts at this time, the extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains highly uncertain. The overall disruption of global healthcare systems and the other risks and uncertainties associated with the pandemic as well as any economic slowdown as a result of the COVID-19 pandemic, could materially and adversely affect our planned clinical trials, business, financial condition and results of operations. We continue to closely monitor the COVID-19 pandemic as we evolve our business continuity plans, clinical development plans and response strategy.

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## Results of Operations

### Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021 (in thousands):

	2022	Three Months Ended September 30 2021 (in USD thousands)	Change
Operating Expenses:			
Research and development	(4,620)	(2,556)	(2,064)
General and administrative	(2,006)	(2,110)	104
<b>Loss from operations</b>	<b>(6,626)</b>	<b>(4,666)</b>	<b>(1,960)</b>
Finance expense	—	(3)	3
Foreign exchange gain	6,185	2,832	3,353
<b>Loss for the period</b>	<b>(441)</b>	<b>(1,837)</b>	<b>1,396</b>

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30		
	2022	2021	Change
	(in USD thousands)		
External research and development expenses	(3,428)	(2,055)	(1,373)
Employee expenses <sup>1</sup>	(1,064)	(440)	(624)
Depreciation	(7)	(5)	(2)
Other expenses	(121)	(56)	(65)
<b>Research and development</b>	<b>(4,620)</b>	<b>(2,556)</b>	<b>(2,064)</b>

<sup>1</sup> Included in employee expenses is share based compensation expense of \$0.2 million for the three months ended September 30, 2022.

The following table summarizes our research and development expenses for our product candidates for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30		
	2022	2021	Change
	(in USD thousands)		
GH001	(2,748)	(1,549)	(1,199)
GH002	(475)	—	(475)
Related to multiple product candidates (GH001, GH002 and GH003) <sup>1</sup>	(1,397)	(1,007)	(390)
<b>Research and development</b>	<b>(4,620)</b>	<b>(2,556)</b>	<b>(2,064)</b>

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

Research and development expenses increased by \$2.1 million from \$2.6 million for the three months ended September 30, 2021, to \$4.6 million for the three months ended September 30, 2022. The increase was primarily due to increased expenses relating to our technical development including device development, active pharmaceutical ingredient and drug product development and manufacturing, partly offset by a decrease in clinical trial expenses. Employee expenses increased by \$0.6 million primarily due to the hiring of personnel to support our research and development activities.

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

Research and development expenses relating to GH001 increased by \$1.2 million in the three months ended September 30, 2022, primarily due to increased technical development including device development, active pharmaceutical ingredient and drug product development and manufacturing, partly offset by a decrease in clinical trial expenses.

Research and development expenses relating to GH002 increased by \$0.5 million in the three months ended September 30, 2022, primarily due to active pharmaceutical ingredient and drug product development and manufacturing.

Research and development expenses which relate to multiple product candidates increased by \$0.4 million in the three months ended September 30, 2022, 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, 2022 and 2021 (in thousands):

	Three Months Ended September 30		
	2022	2021	Change
		(in USD thousands)	
External costs	(1,464)	(1,739)	275
Employee expenses <sup>1</sup>	(537)	(370)	(167)
Depreciation	(5)	(1)	(4)
<b>General and administrative</b>	<b>(2,006)</b>	<b>(2,110)</b>	<b>104</b>

<sup>1</sup> Included in employee expenses is share based compensation expense of \$0.2 million for the three months ended September 30, 2022.

General and administrative expenses decreased by \$0.1 million from \$2.1 million for the three months ended September 30, 2021, to \$2.0 million for the three months ended September 30, 2022. The decrease was primarily due to a decrease of \$0.8 million in insurance costs offset by an increase of \$0.5 million in professional costs and \$0.2 million of employee expenses in our general and administrative functions to support our growth initiatives.

#### *Finance expense*

Our finance expense decreased from \$3 thousand for the three months ended September 30, 2021 to \$nil for the three months ended September 30, 2022.

#### *Foreign exchange gain*

Foreign exchange gain increased to \$6.2 million for the three months ended September 30, 2022, from \$2.8 million for the three months ended September 30, 2021. This increase was primarily due to the strengthening of the U.S. dollar versus the euro in the period which resulted in a foreign exchange gain on the translation of the U.S. dollar cash balance into euro in the accounts of our subsidiary, GH Research Ireland Limited, which uses the euro as its functional currency.

*Comparison of the Nine months Ended September 30, 2022 and 2021*

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine months Ended September 30		
	2022	2021	Change
		(in USD thousands)	
Operating Expenses:			
Research and development	(13,574)	(5,202)	(8,372)
General and administrative	(7,808)	(3,277)	(4,531)
<b>Loss from operations</b>	<b>(21,382)</b>	<b>(8,479)</b>	<b>(12,903)</b>
Finance expense	—	(9)	9
Foreign exchange gain	15,512	3,377	12,135
<b>Loss for the period</b>	<b>(5,870)</b>	<b>(5,111)</b>	<b>(759)</b>

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30		
	2022	2021	Change
	(in USD thousands)		
External research and development costs	(10,429)	(4,265)	(6,164)
Employee expenses <sup>1</sup>	(2,887)	(769)	(2,118)
Depreciation	(22)	(7)	(15)
Other expenses	(236)	(161)	(75)
<b>Research and development</b>	<b>(13,574)</b>	<b>(5,202)</b>	<b>(8,372)</b>

<sup>1</sup> Included in employee expenses is share based compensation expense of \$0.7 million for the nine months ended September 30, 2022.

The following table summarizes our research and development expenses for our product candidates for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30		
	2022	2021	Change
	(in USD thousands)		
GH001	(7,751)	(3,392)	(4,359)
GH002	(987)	—	(987)
Related to multiple product candidates (GH001, GH002 and GH003) <sup>1</sup>	(4,836)	(1,810)	(3,026)
<b>Research and development</b>	<b>(13,574)</b>	<b>(5,202)</b>	<b>(8,372)</b>

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

Research and development expenses increased by \$8.4 million from \$5.2 million for the nine months ended September 30, 2021, to \$13.6 million for the nine months ended September 30, 2022. The increase was primarily due to increased expenses relating to our technical development including device development, active pharmaceutical ingredient and drug product development and manufacturing, as well as an increase in nonclinical and clinical trial expenses. Employee expenses increased by \$2.1 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 \$4.4 million in the nine months ended September 30, 2022, primarily due to increased technical development including device development, active pharmaceutical ingredient and drug product development and manufacturing, as well as an increase in nonclinical and clinical trial expenses.

Research and development expenses relating to GH002 increased by \$1.0 million in the nine months ended September 30, 2022, primarily due to active pharmaceutical ingredient and drug product development and manufacturing.

Research and development expenses which relate to multiple product candidates increased by \$3.0 million in the nine months ended September 30, 2022, primarily due to the hiring of personnel to support our research and development activities, as well as an increase in nonclinical expenses.

#### *General and Administrative Expenses*

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine Months Ended September 30		
	2022	2021	Change
		(in USD thousands)	
External costs	(6,145)	(2,604)	(3,541)
Employee expenses <sup>1</sup>	(1,651)	(670)	(981)
Depreciation	(12)	(3)	(9)
<b>General and administrative</b>	<b>(7,808)</b>	<b>(3,277)</b>	<b>(4,531)</b>

<sup>1</sup> Included in employee expenses is share based compensation expense of \$0.5 million for the nine months ended September 30, 2022.

General and administrative expenses increased by \$4.5 million from \$3.3 million for the nine months ended September 30, 2021, to \$7.8 million for the nine months ended September 30, 2022. The increase was primarily due to an increase of \$2.1 million in insurance costs, an increase of \$1.4 million in professional fees and an increase of \$1.0 million in employee expenses in our general and administrative functions to support our growth initiatives.

#### *Finance expense*

Our finance expense decreased from \$9 thousand for the nine months ended September 30, 2021 to \$nil for the nine months ended September 30, 2022.

### Foreign exchange gain

Foreign exchange gain increased to \$15.5 million for the nine months ended September 30, 2022, from \$3.4 million for the nine months ended September 30, 2021. This increase was primarily due to the strengthening of the U.S. dollar versus the euro in the period which resulted in a foreign exchange gain on the translation of the U.S. dollar cash balance into euro in the accounts of our subsidiary, GH Research Ireland Limited, which uses the euro as its functional currency.

### Liquidity and Capital Resources

#### Sources of Liquidity

We have incurred operating losses since inception, and we have not generated any revenue from any product sales or any other sources. We have not yet commercialized any of our product candidates, which are in various phases of technical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We have funded our operations to date primarily through equity financings, including our initial public offering. As of September 30, 2022, we had cash of \$256.9 million.

We plan to continue to fund our operating and capital funding needs through sales of additional equity or other forms of financing. We may also consider pursuing strategic partnerships for clinical development and commercialization of our product candidates. The sale of additional equity would result in additional dilution to our shareholders.

#### Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	Nine months Ended September 30		
	2022	2021 (in USD thousands)	Change
Net cash flows used in operating activities	(19,332)	(11,525)	(7,807)
Net cash flows used in investing activities	(49)	(85)	36
Net cash flows from financing activities	—	286,618	(286,618)
<b>Net (decrease)/increase in cash</b>	<b>(19,381)</b>	<b>275,008</b>	<b>(294,389)</b>

#### Net Cash Flows Used in Operating Activities

Net cash flows used in operating activities increased by \$7.8 million to \$19.3 million for the nine months ended September 30, 2022 from \$11.5 million for the nine months ended September 30, 2021. The increase was primarily due to a \$12.9 million increase in loss from operations which has been partially offset by an increase in share-based compensation expense of \$1.1 million and an increase of \$4.0 million related to changes in the components in working capital.



#### *Net Cash Flows Used in Investing Activities*

Net cash flows used in investing activities decreased to \$49 thousand for the nine months ended September 30, 2022 from \$85 thousand for the nine months ended September 30, 2021. The decrease was due to the timing of the purchase of property, plant and equipment.

#### *Net Cash Flows from Financing Activities*

Net cash flows from financing activities decreased to \$nil for the nine months ended September 30, 2022, from \$286.6 million for the nine months ended September 30, 2021. The decrease was due to the proceeds received from the issuance of Series B preferred shares and our initial public offering, each of which took place during the nine months ended September 30, 2021.

#### **Funding Requirements**

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance the technical development work, nonclinical studies and clinical trials of our product candidates and the medical devices required to deliver such product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, convertible debt financings, strategic collaborations and licensing arrangements. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our future capital requirements will depend on many factors, which are outlined in our annual report on Form 20-F for the year ended December 31, 2021 and this discussion and analysis. We believe that the Group has sufficient financial resources available to cover its planned cash outflows for at least the next twelve months.

#### **Critical Accounting Estimates**

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

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

On April 5, 2012, the Jumpstart our Business Act of 2012 ("JOBS Act") was enacted. As an emerging growth company, or EGC, under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. This provision allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. This transition period is only applicable under U.S. GAAP. As a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required or permitted by the International Accounting Standards Board.

As an EGC, we also rely on other exemptions and reduced reporting requirements under the JOBS Act including exemptions from (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

We will remain classified as an EGC until the earlier of (1) the last day of the fiscal year (i) in which we have total annual gross revenue of \$1.07 billion; (ii) following the fifth anniversary of the completion of our initial public offering; or (iii) in which we are deemed to be a "large accelerated filer," which requires the market value of our ordinary shares that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three-year period.

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## Recently Issued Accounting Pronouncements

As disclosed in note 2 to our unaudited condensed consolidated interim financial statements, there are no standards issued but not yet adopted which are expected to have a material impact on our unaudited condensed consolidated interim financial statements.

## Cautionary Statement Regarding Forward-Looking Statements

This discussion contains statements that are, or may be deemed to be, forward-looking statements. All statements other than statements of historical fact included in this discussion, including statements regarding our future results of operations and financial position, business strategy, product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations are forward-looking statements. Many of the forward-looking statements contained in this discussion can be identified by the use of forward-looking words such as “may,” “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate,” “will,” “potential” and “ongoing,” among others.

Forward-looking statements appear in a number of places in this discussion and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section in our annual report on Form 20-F for the year ended December 31, 2021 titled “Item 3. Key Information – D. Risk Factors”. These risks and uncertainties include, among others, factors relating to:

- the commencement, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
  - the timing, progress and results of developing and conducting clinical trials for our GH001, GH002 and GH003 product candidates and the medical devices required to deliver these product candidates for our initial and any additional indications;
  - our efforts to expand into other jurisdictions such as the United States and in the European Union;
  - our expectations related to the technical development and expansion of our external manufacturing capabilities for our GH001, GH002 and GH003 product candidates as well as the medical devices required to deliver these product candidates;
  - our reliance on the success of our GH001, GH002 and GH003 product candidates;
  - the timing, scope or likelihood of regulatory filings and approvals by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other comparable foreign regulatory authorities, for our GH001, GH002 and GH003 product candidates and our initial and any additional indications;
  - our expectations regarding the size of the eligible patient populations for our GH001, GH002 and GH003 product candidates, if approved for commercial use;
  - our ability to identify third-party clinical sites to conduct trials and our ability to identify and train appropriately qualified therapists to administer our investigational therapy;
  - the effect of the COVID-19 pandemic on aspects of our business or operations, including delays in the regulatory approval process, contracting with clinical sites and engaging in clinical trials;
  - our ability to implement our business model and our strategic plans for our business and GH001, GH002 and GH003 product candidates;
  - our ability to identify, develop or acquire and obtain approval by the FDA, EMA or other comparable foreign regulatory authorities of medical devices required to deliver our GH001, GH002 and GH003 product candidates;
  - our commercialization and marketing capabilities and strategy;
  - the effects of undesirable clinical trial outcomes and potential adverse public perception regarding the use of 5-MeO-DMT and psychedelics generally on the regulatory approval process and future development of our product;
  - the pricing, coverage and reimbursement of our GH001, GH002 and GH003 product candidates, if approved;
  - the scalability and commercial viability of our manufacturing methods and processes;
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- the rate and degree of market acceptance and clinical utility of our GH001, GH002 and GH003 product candidates;
- our reliance on third-party suppliers for our nonclinical study and clinical trial drug substance and product candidate supplies, as well as key raw materials used in our manufacturing processes;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our expectations regarding potential benefits of our GH001, GH002 and GH003 product candidates and our approach generally;
- our expectations around regulatory development paths and with respect to Controlled Substances Act classification;
- the scope of protection we and any current or future licensors or collaboration partners are able to establish and maintain for intellectual property rights covering our GH001, GH002 and GH003 product candidates;
- our ability to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to protect our intellectual property rights, including enforcing and defending intellectual property-related claims;
- regulatory developments in the United States, under the laws and regulations of the European Union and other jurisdictions;
- 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 and geopolitical risks and global hostilities, including any direct or indirect economic impacts resulting from Russia's invasion of Ukraine or related sanctions;
- developments and projections relating to our competitors and our industry;
- our ability to remediate our material weaknesses in our internal control over financial reporting;
- the amount of time that our existing cash will be sufficient to fund our operations and capital expenditures;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- whether we are classified as a passive foreign investment company for current and future periods;
- our expectations regarding the time during which we will be an EGC under the JOBS Act and as a foreign private issuer; and
- the future trading price of the ordinary shares and impact of securities analysts' reports on these prices.

These forward-looking statements speak only as of the date of this discussion and are subject to a number of risks, uncertainties and assumptions described under the section in our annual report on Form 20-F for the year ended December 31, 2021 titled "Item 3. Key Information – D. Risk Factors" and elsewhere in this discussion. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the 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.

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

**Dublin, Ireland, November 10, 2022** – GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported financial results for the third quarter ended September 30, 2022 and gave updates on its business.

### Third Quarter 2022 Financial Highlights

#### *Cash position*

Cash was \$256.9 million as of September 30, 2022, compared to \$276.8 million as of December 31, 2021. We believe that our existing cash will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2025.

#### *Research and development expenses*

R&D expenses were \$4.6 million for the quarter ended September 30, 2022, compared to \$2.6 million for the same quarter in 2021. The increase was primarily due to increased activities relating to our technical development and increases in employee expenses to support these activities.

#### *General and administrative expenses*

G&A expenses were \$2.0 million for the quarter ended September 30, 2022, compared to \$2.1 million for the same quarter in 2021. The decrease was primarily due to a decrease in insurance costs which has been partially offset by an increase in professional costs and employee expenses.

#### *Net profit/loss*

Net loss was \$0.4 million, or \$0.008 loss per share, for the quarter ended September 30, 2022, compared to a net loss of \$1.8 million, or \$0.035 loss per share, for the same quarter in 2021. The decrease was due to the foreign exchange gain in the quarter.

### Business Updates

#### *GH001 for the treatment of TRD*

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

We have recently submitted clinical trial applications in several European countries for a multi-center, randomized, controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201). Pending regulatory approval, we expect to initiate this trial in the first quarter of 2023. We expect to recruit approximately 80 patients for this trial. The primary objective will be to determine the efficacy of a single-day individualized dosing regimen (IDR) of GH001 compared with placebo in improving depressive symptoms as assessed by the mean change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) at the end of the 7-day double-blind phase. The double-blind phase will be followed by a 6-month open-label extension phase where all patients can receive treatment with the GH001 IDR as-needed, based on the patient's clinical response.

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In May 2022, we also announced the positive outcome of our pre-IND meeting with the U.S. Food and Drug Administration (FDA), and we expect to submit our IND for GH001 in TRD in the first quarter of 2023. The planned IND-opening study is a Phase 1 imaging study in patients with TRD designed to further elucidate the mechanism of action of GH001 (GH001-TRD-104).

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

We have recently initiated Phase 2a proof-of-concept clinical trials of GH001 for the treatment of patients with bipolar II disorder and a current depressive episode (BDII) (GH001-BD-202) and for the treatment of patients with postpartum depression (PPD) (GH001-PPD-203). We expect to complete these studies by the end of 2023.

#### *GH002 and GH003*

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. GH002 has completed pre-clinical development to support early clinical trials and we have recently submitted a clinical trial application for a double-blind, placebo-controlled, randomized, dose-ranging clinical pharmacology trial in healthy volunteers (GH002-HV-105). Pending regulatory approval, we expect to initiate this trial in the fourth quarter of 2022.

GH003 is our 5-MeO-DMT product candidate formulated for administration via a proprietary intranasal administration approach. GH003 is currently in preclinical development.

#### **About GH Research PLC**

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

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

#### **About GH001**

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

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**About GH002 and GH003**

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. GH002 has completed preclinical development to support early clinical trials. GH003 is our 5-MeO-DMT product candidate formulated for administration via a proprietary intranasal administration approach. GH003 is currently in preclinical development.

**Forward-Looking Statements**

This press release contains statements that are, or may be deemed to be, forward-looking statements. All statements other than statements of historical fact included in this press release, including statements regarding our future results of operations and financial position, our cash runway, business strategy, product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. Forward-looking statements appear in a number of places in this press release and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those described in our filings with the U.S. Securities and Exchange Commission. No assurance can be given that such future results will be achieved. Such forward-looking statements contained in this document speak only as of the date of this press release. We expressly disclaim any obligation or undertaking to update these forward-looking statements contained in this press release to reflect any change in our expectations or any change in events, conditions, or circumstances on which such statements are based unless required to do so by applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

**Investor Relations:**

Julie Ryan  
GH Research PLC  
[investors@ghres.com](mailto:investors@ghres.com)

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## GH RESEARCH PLC

## Condensed Consolidated Interim Statement of Comprehensive Income (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2022 \$'000	2021 \$'000	2022 \$'000	2021 \$'000
Operating expenses				
Research and development	(4,620)	(2,556)	(13,574)	(5,202)
General and administration	(2,006)	(2,110)	(7,808)	(3,277)
Loss from operations	<u>(6,626)</u>	<u>(4,666)</u>	<u>(21,382)</u>	<u>(8,479)</u>
Finance expense	-	(3)	-	(9)
Foreign exchange gain	6,185	2,832	15,512	3,377
Loss before tax	(441)	(1,837)	(5,870)	(5,111)
Tax charge/(credit)	-	-	-	-
Loss for the period	<u>(441)</u>	<u>(1,837)</u>	<u>(5,870)</u>	<u>(5,111)</u>
Other comprehensive expense				
<i>Items that may be reclassified to profit or loss</i>				
Currency translation adjustment	(6,464)	(2,845)	(15,779)	(3,533)
Total comprehensive loss for the period	<u>(6,905)</u>	<u>(4,682)</u>	<u>(21,649)</u>	<u>(8,644)</u>
Attributable to owners:				
Loss for the period	(441)	(1,837)	(5,870)	(5,111)
Comprehensive loss for the period	<u>(6,464)</u>	<u>(2,845)</u>	<u>(15,779)</u>	<u>(3,533)</u>
Loss per share				
Basic and diluted loss per share (in USD)	(0.008)	(0.035)	(0.113)	(0.125)

## GH RESEARCH PLC

## Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At September 30, 2022 \$'000	At December 31, 2021 \$'000
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	256,939	276,776
Other current assets	3,100	3,066
<b>Total current assets</b>	<b>260,039</b>	<b>279,842</b>
<b>Non-current assets</b>		
Property, plant and equipment	84	82
<b>Total non-current assets</b>	<b>84</b>	<b>82</b>
<b>Total assets</b>	<b>260,123</b>	<b>279,924</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities</b>		
Trade payables	1,750	883
Other current liabilities	1,635	1,866
<b>Total current liabilities</b>	<b>3,385</b>	<b>2,749</b>
<b>Total liabilities</b>	<b>3,385</b>	<b>2,749</b>
<b>Equity attributable to owners</b>		
Share capital	1,301	1,301
Additional paid-in-capital	291,448	291,448
Other reserves	1,578	366
Foreign currency translation reserve	(21,682)	(5,903)
Accumulated deficit	(15,907)	(10,037)
<b>Total equity</b>	<b>256,738</b>	<b>277,175</b>
<b>Total liabilities and equity</b>	<b>260,123</b>	<b>279,924</b>





GH Research

# Corporate Presentation

GH Research PLC (NASDAQ: GHR)

November 2022

# Disclaimer Regarding Forward-Looking Statements

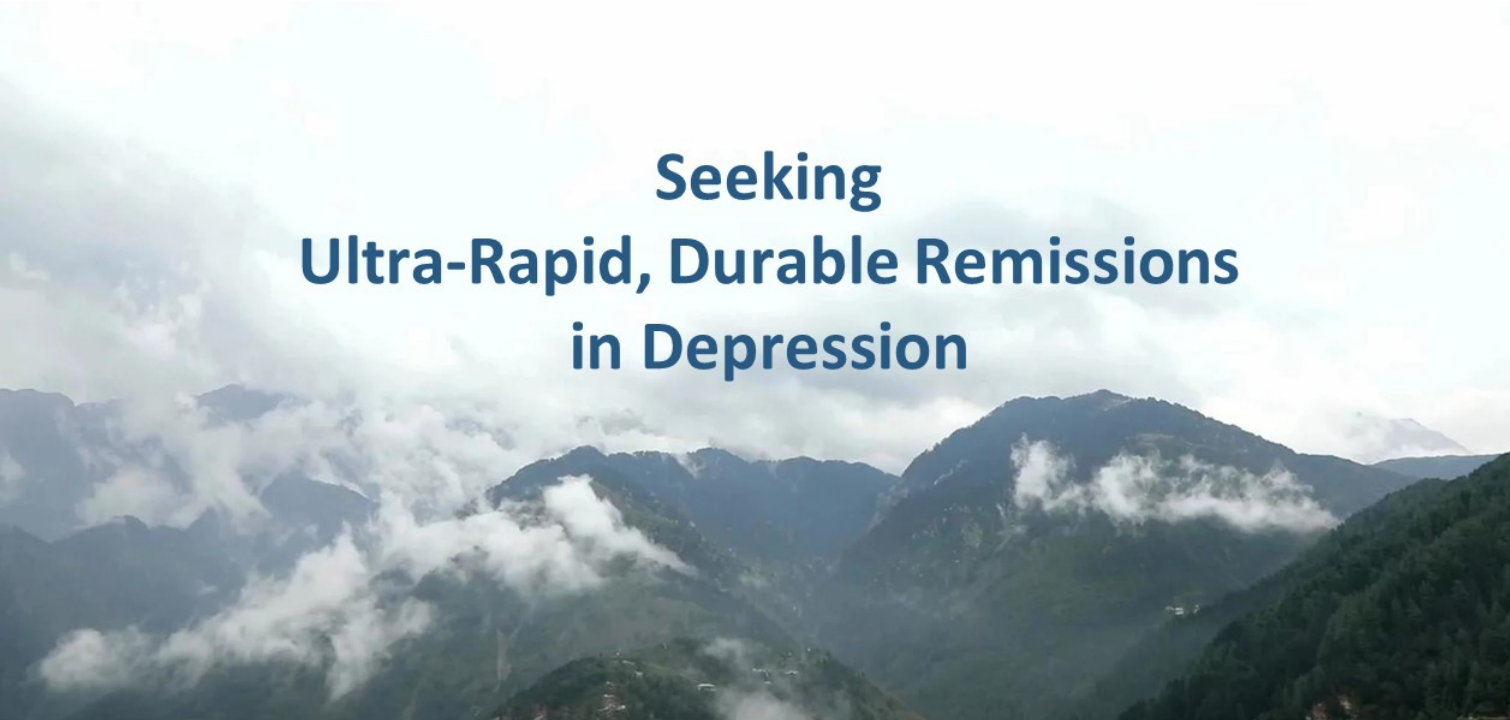
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This presentation contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Many of the forward-looking statements contained herein can be identified by the use of forward-looking words such as "may", "anticipate", "believe", "could", "expect", "should", "plan", "intend", "estimate", "will", "potential" and "ongoing", among others, although not all forward-looking statements contain these identifying words.

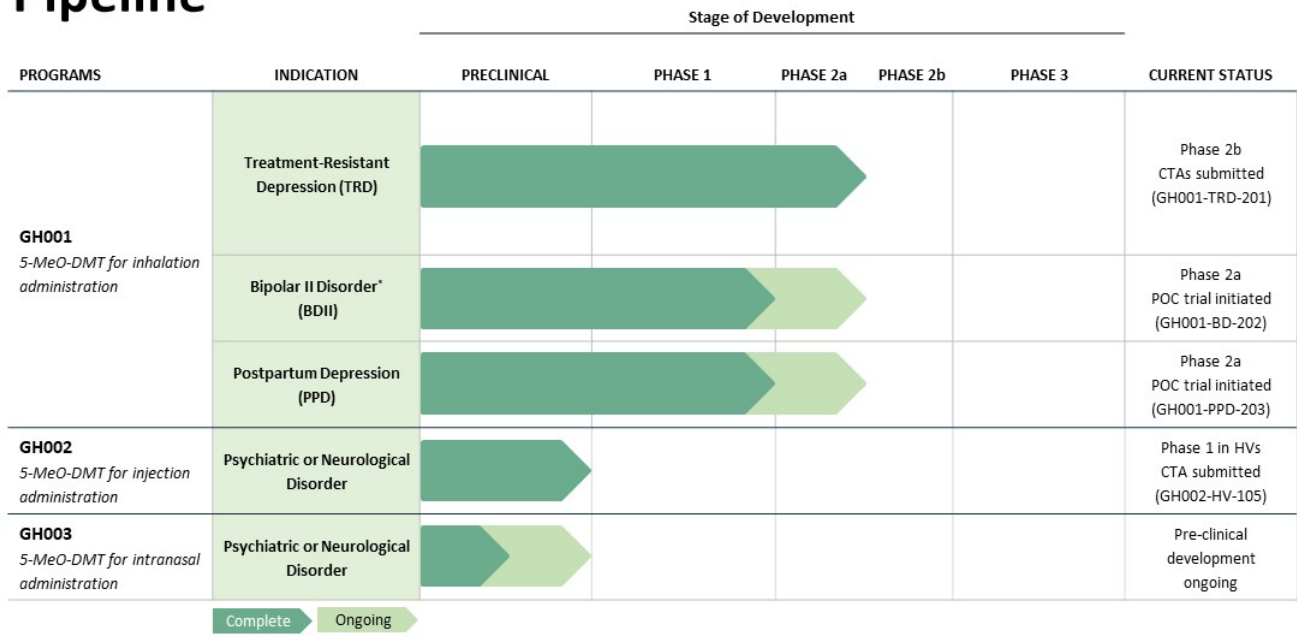
Any statements contained herein that do not describe historical facts are forward-looking statements that are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcomes, timing and performance to differ materially from those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

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



# Seeking Ultra-Rapid, Durable Remissions in Depression

# Pipeline

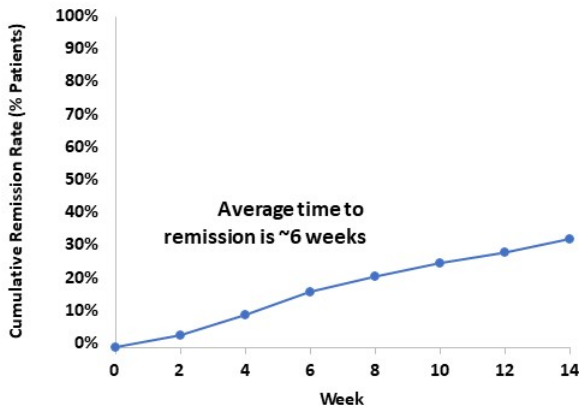


\*Bipolar II disorder with a current major depressive episode; 5-MeO-DMT, 5-Methoxy-N,N-Dimethyltryptamine; CTA, Clinical Trial Application; POC, Proof-of-Concept; HV, Healthy Volunteer

# The Problem for Patients with Depression

## Established Therapies are **Slow-Acting**

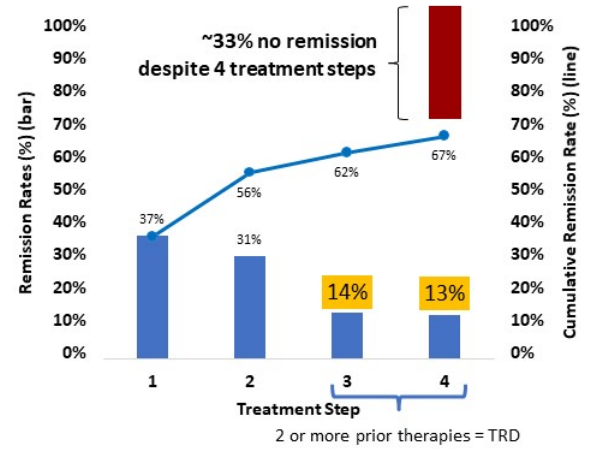
(STAR\*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



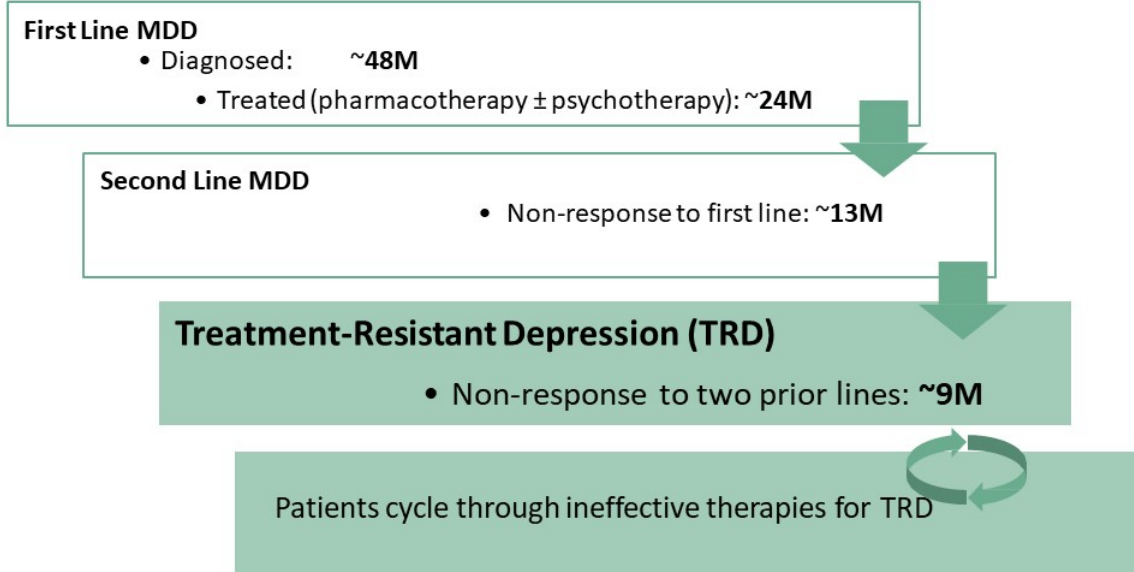
*Adapted from Trivedi et al., Am J Psychiatry 2006 and Rush et al., Am J Psychiatry 2006*

## ... Remission Rates in TRD < 15%

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



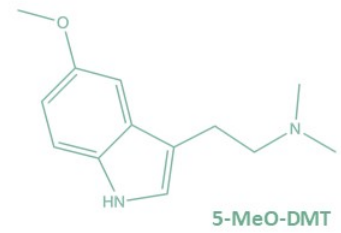
# Large and Open Depression Market in the EU and US



Company estimates based on: <https://www.nlm.nih.gov/health/statistics/major-depression.html>; 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 Long-Term Outcomes in Depressed Outpatients Requiring One or Several Treatment Steps: A STAR\*D Report, *Am J Psychiatry* 2006  
MDD, Major Depressive Disorder

# 5-MeO-DMT and GH001

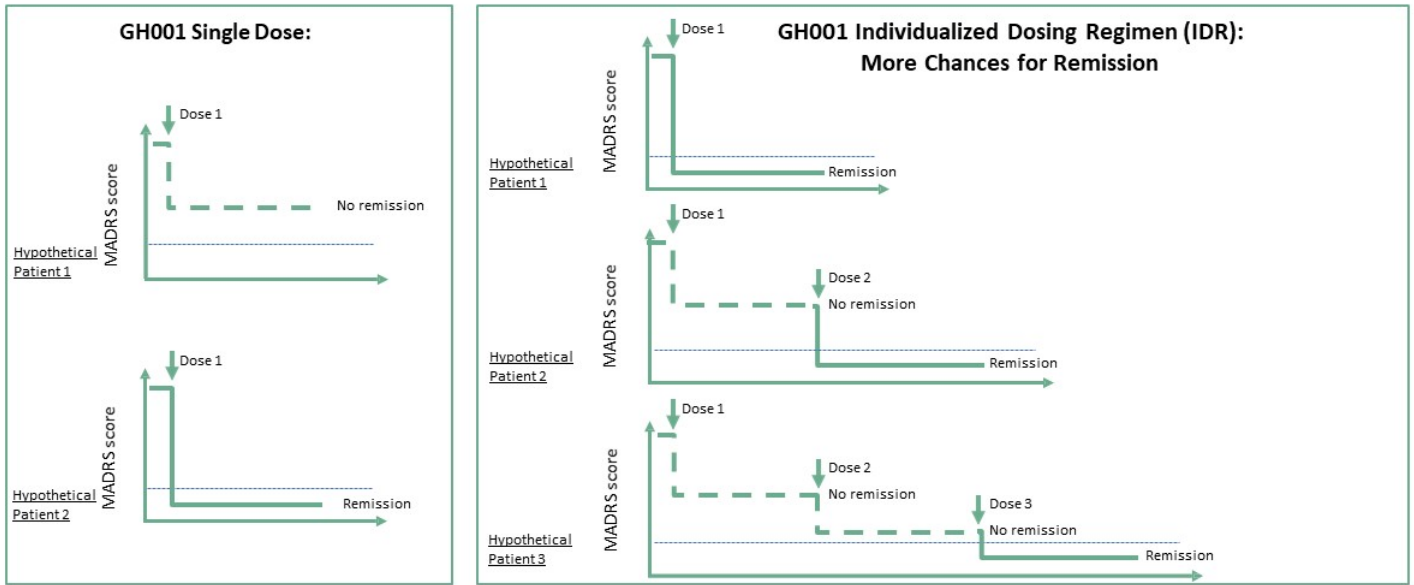
- 5-MeO-DMT (5-Methoxy-N,N-Dimethyltryptamine)
  - Naturally-occurring psychoactive substance from tryptamine class
  - **Highly potent** agonist on 5-HT1A and 5-HT2A receptors
  - **Psychoactive effects with ultra-rapid onset** (within seconds) **and short duration** (5 to 30 min)
  - **High propensity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



Foundational IP



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



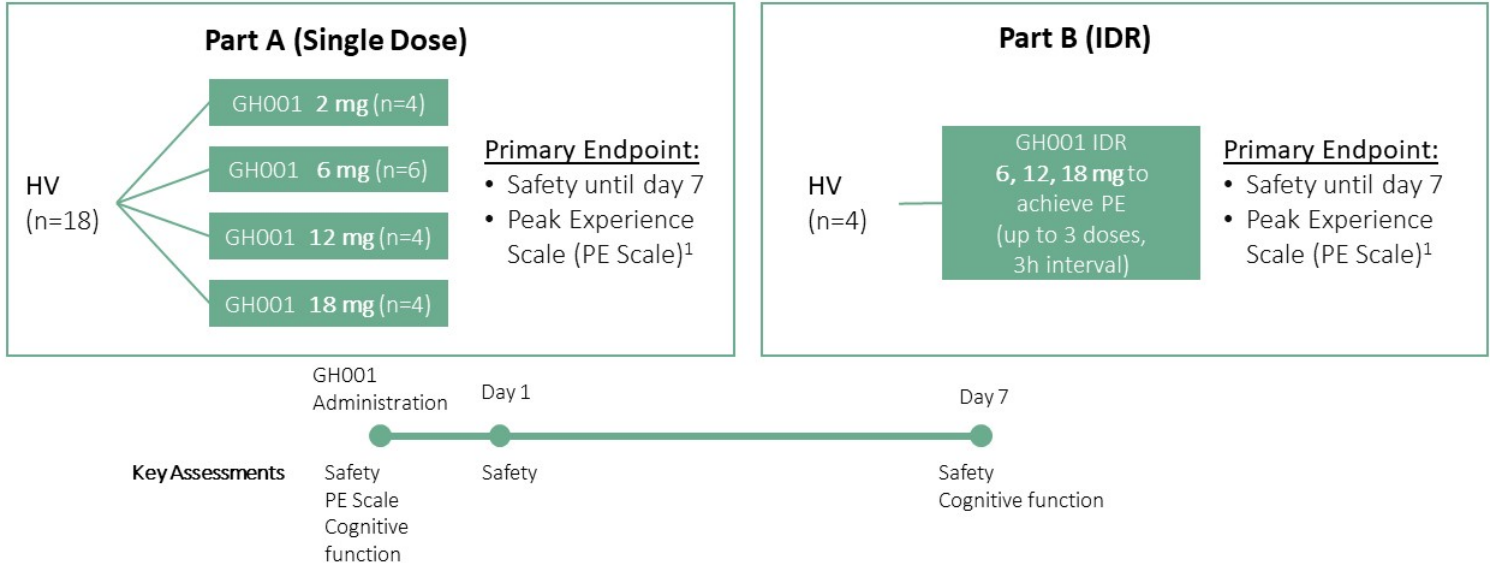


# Phase 1 Trial in Healthy Volunteers GH001-HV-101

**(Completed)**

Clinicaltrials.gov ID NCT04640831

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



<sup>1</sup>PE, Peak Experience  
IDR, Individualized Dosing Regimen

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

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

## Study Safety Group review

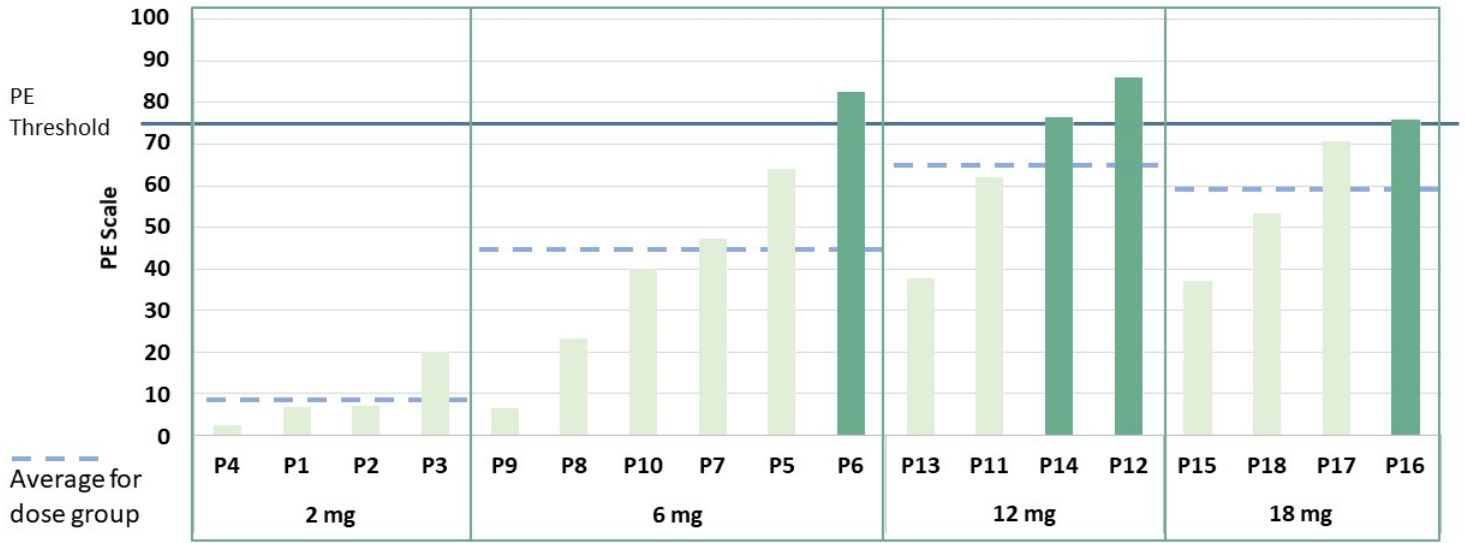
- No SAEs
- All ADRs mild, except two moderate (\*)
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically 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 <sup>1</sup> (N=4)
MedDRA Preferred Term	n	n	n	n	n
Abnormal dreams				1	
Anxiety		1	1		
Clumsiness		1			
Confusional state		1			
Euphoric mood		1			
Fatigue				1	1*
Feeling hot		1			
Flashback				1	
Hallucination				1	
Head discomfort					1
Headache		2		1	1
Heart rate increased			1*		
Hyperacusis				1	
Insomnia				1	
Mental fatigue				1	
Nausea	2	1		1	2
Vision blurred	1				

Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing  
IDR, Individualized Dosing Regimen

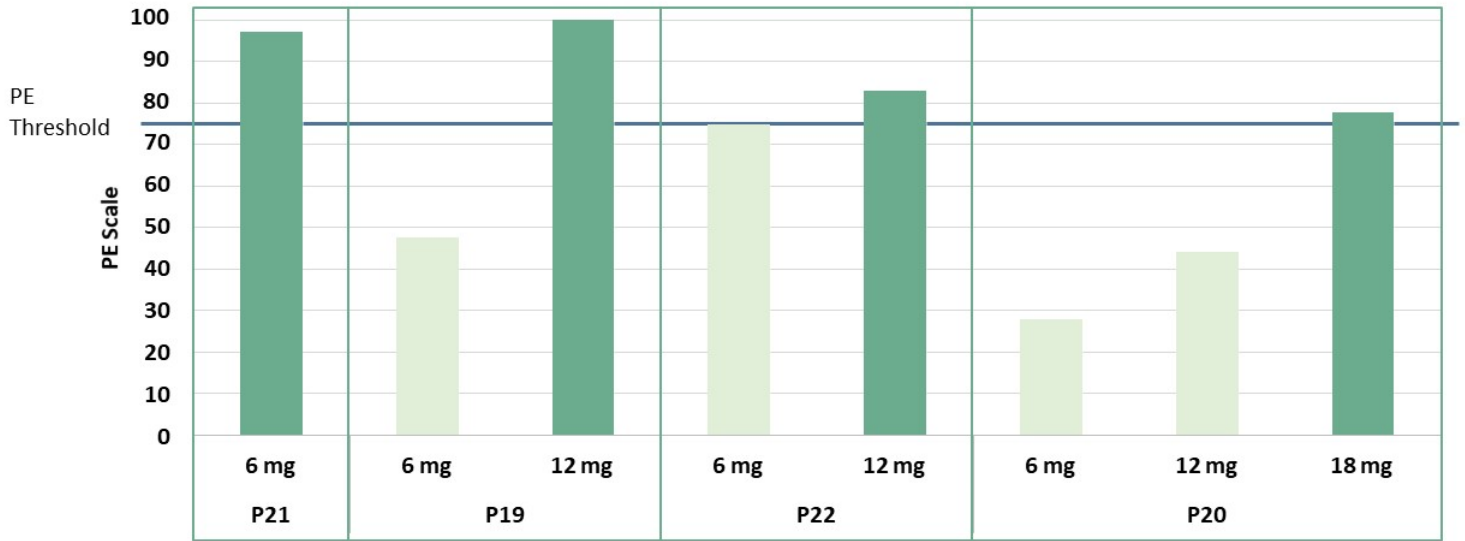
<sup>1</sup> 6 mg (N=1); 6-12 mg (N=2); 6-12-18 mg (N=1)

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



PE, Peak Experience

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

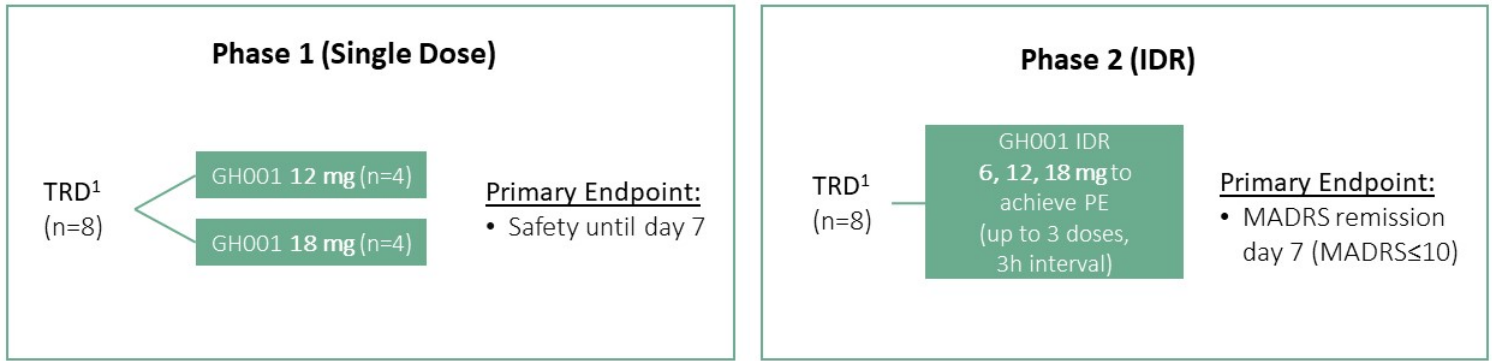


PE, Peak Experience

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

Clinicaltrials.gov ID NCT04698603

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



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

<sup>1</sup> Defined as inadequate response to at least two adequate courses of pharmacological therapy or one adequate course of pharmacological therapy and at least one adequate course of evidence-based psychotherapy

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

## Study Safety Group review

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

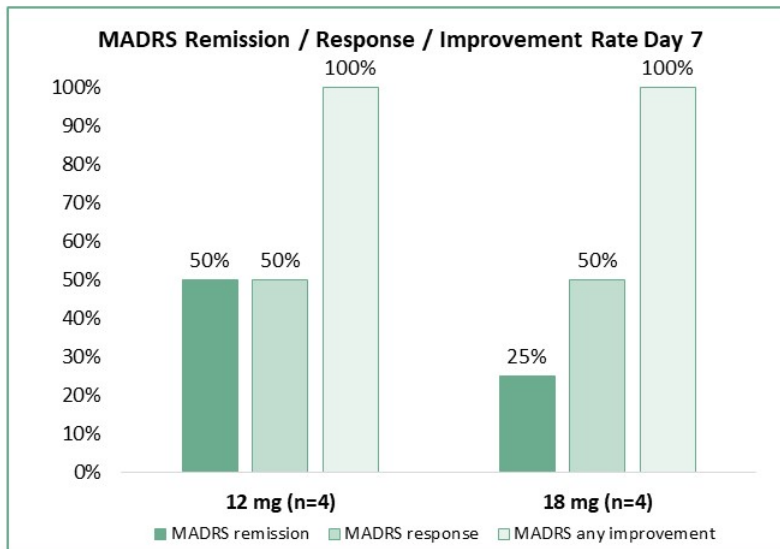
ADRs	Phase 1 (Single Dose)		Phase 2 (IDR)
	12 mg (N=4)	18 mg (N=4)	IDR <sup>1</sup> (N=8)
MedDRA Preferred Term	n	n	n
Abdominal discomfort			1
Anxiety			2
Depressive symptom			1*
Dizziness	1		
Feeling abnormal	1	1	
Flashback	1	1	2
Headache	2	1	3
Muscle discomfort			1
Muscle spasms		1	
Nausea			2*
Paresthesia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

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

<sup>1</sup>6-12 mg (N=6); 6-12-18 mg (N=2)



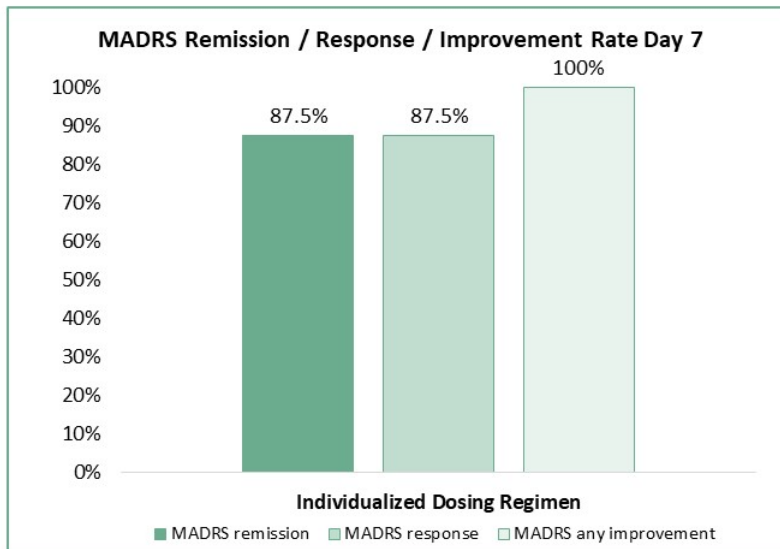
## Phase 1 (Single Dose) – Efficacy (MADRS)



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

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

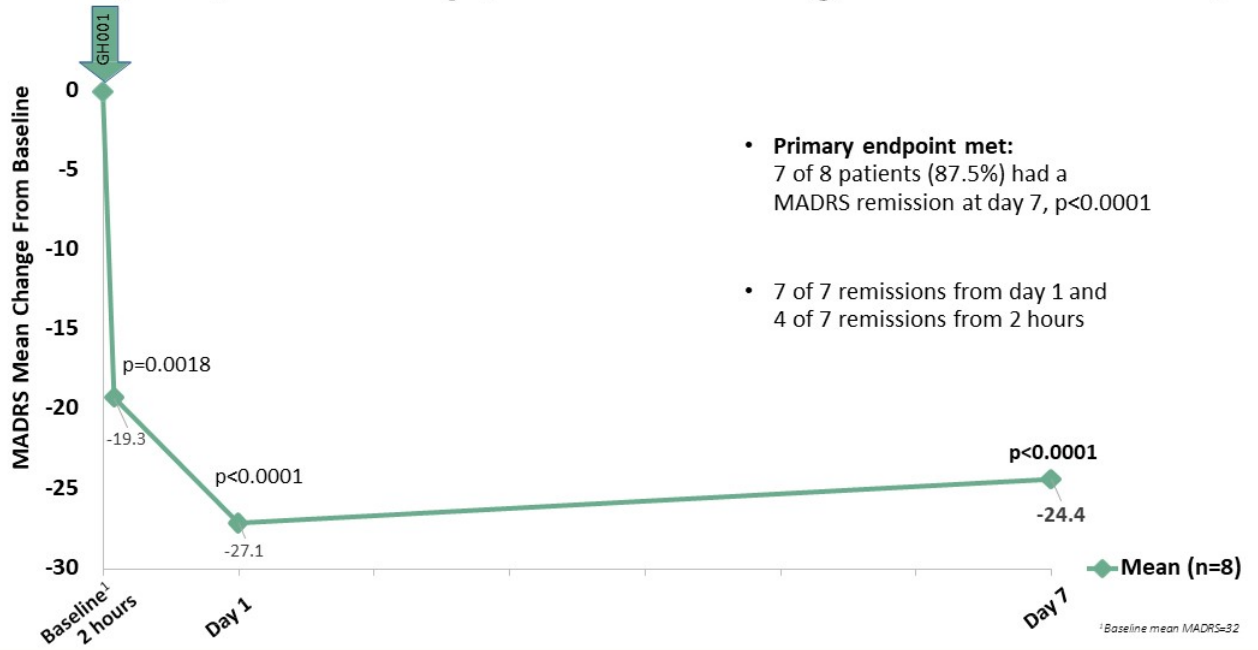
## Phase 2 (IDR) – Efficacy (MADRS)



- **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  $\leq 10$ ; 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)

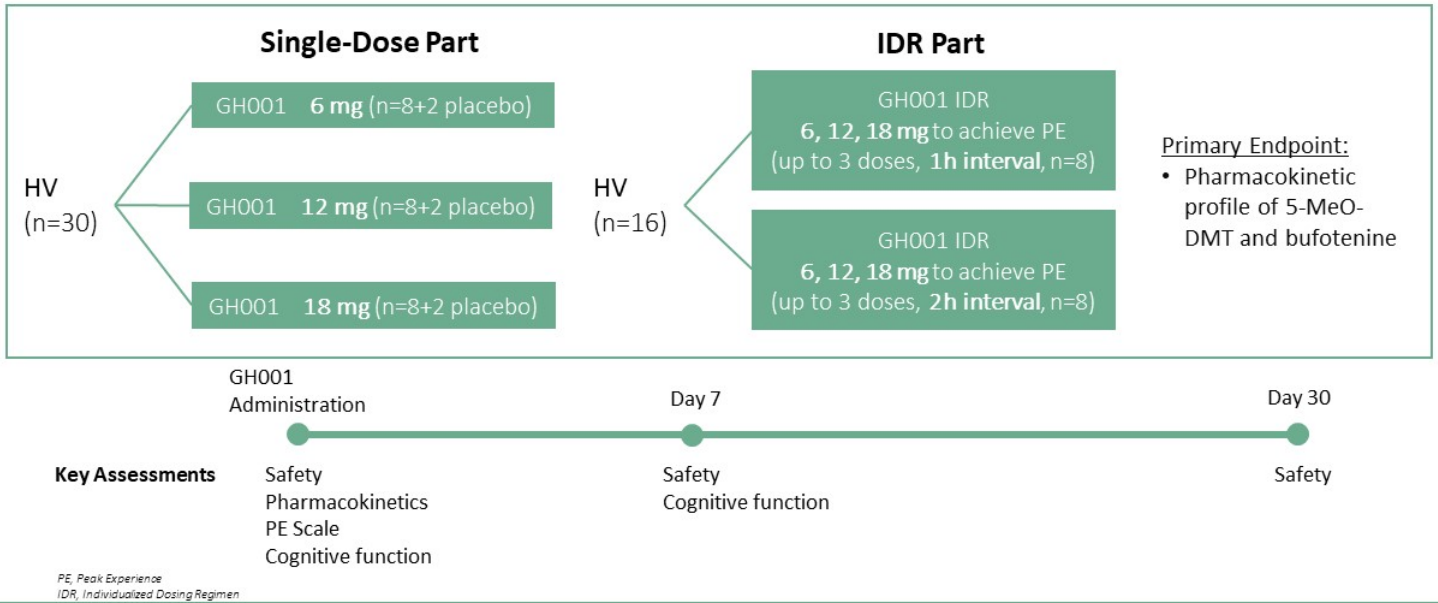
	Phase 2 (IDR)	Phase 1 (Single Dose) 12 mg	Phase 1 (Single Dose) 18 mg
<b>MADRS Remission Rate Day 7</b>	87.5% (7 of 8)	50% (2 of 4)	25% (1 of 4)
<b>Mean MADRS Change Day 7</b>	-24.4 (-76%)	-21.0 (-65%)	-12.5 (-40%)
<b>Rate of PE</b>	87.5% (7 of 8)	50% (2 of 4)	0% (0 of 4)
<b>Mean PE Score</b>	90.4 (at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

# 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) <sup>1</sup>	2h interval (N=8) <sup>2</sup>
MedDRA Preferred Term	n	n	n	n	N	n
Abnormal dreams						1
Chest discomfort		1				
Crying			2		2	
Dizziness			1			
Dry mouth	1					
Dyskinesia			1			
Fatigue		1			2	1
Headache	3		1		1	1
Hypoesthesia oral		1				
Paresthesia oral						1
Retching			1			
Somnolence		1				
Tachycardia			2			
Tension						1
Tremor			1			

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

<sup>1</sup>6 mg (N=1), 6-12 mg (N=3), 6-12-18 mg (N=4)  
<sup>2</sup>6-12 mg (N=3), 6-12-18 mg (N=5)

# Three-Layer Protection Strategy

## LAYER 1: REGULATORY EXCLUSIVITY

FDA: 5 years (+2.5 years paragraph IV stay)

EMA: 10 years (+1 year for new indication)

## LAYER 2: PATENTS

Several patent applications filed:

- Novel aerosol compositions of matter of 5-MeO-DMT
- Novel manufacturing methods and novel salt forms of 5-MeO-DMT
- Novel uses of 5-MeO-DMT in various disorders (including inhaled, nasal, buccal, sublingual, i.v., i.m., s.c. routes)

## LAYER 3: TECHNICAL

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



# Board of Directors & Management



**Florian Schönharting**  
MSc  
Chairman of the Board, Co-founder



**Michael Forer**  
BA, LLB  
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



**Julie Ryan**  
ACA, MAcc, BComm  
VP, Finance




**Magnus Halle**  
BSc  
Managing Director, Ireland, Co-founder



# Scientific Advisors



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





**Michael Thase**  
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Professor of Psychiatry, Perelman School of Medicine  
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**Mark Zimmerman**  
M.D.  
Professor of Psychiatry and Human Behavior,  
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**Eduard Vieta**  
Prof. Dr.  
Head, Psychiatry Unit,  
Hospital Clínic de Barcelona  




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



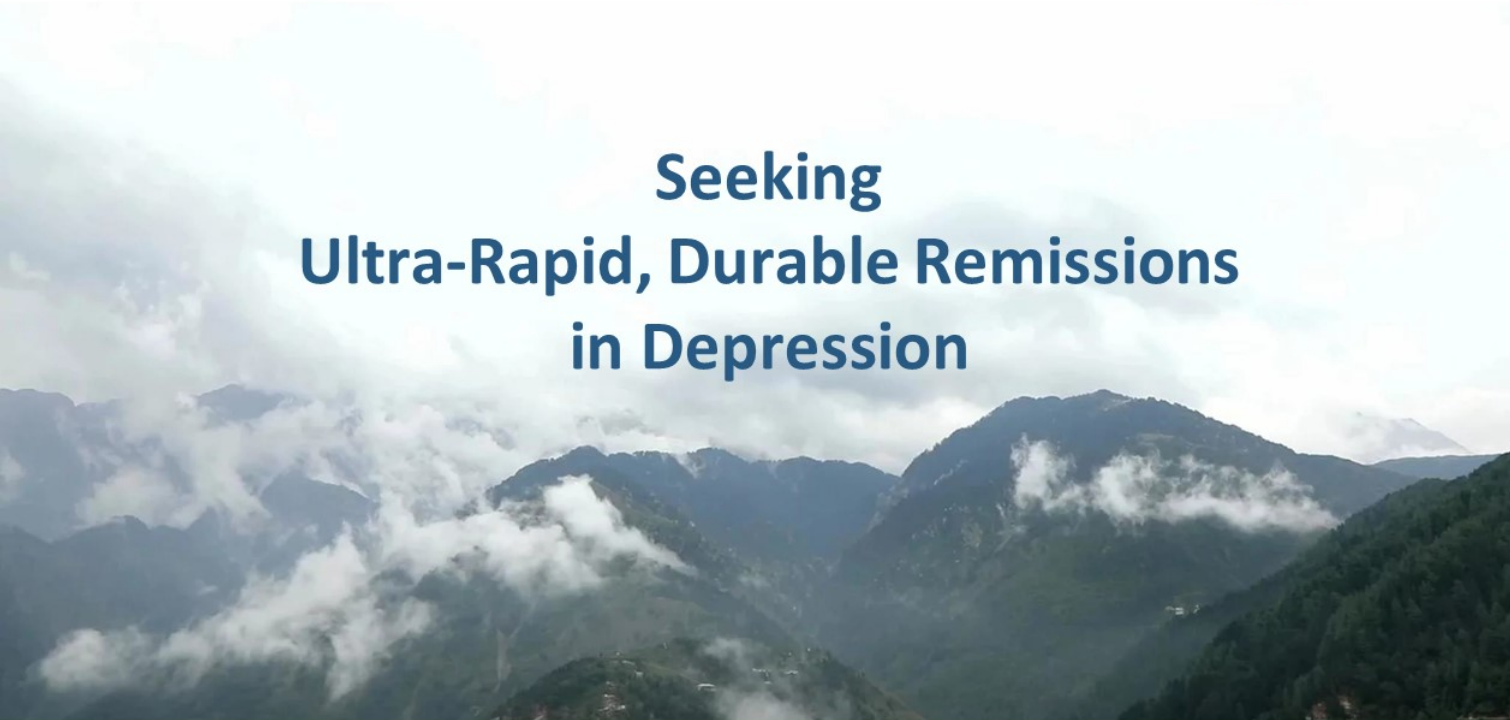

**Malek Bajbouj**  
Prof. Dr. med.  
Head, Center for Affective Neuroscience,  
Charité, Berlin  




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


# Anticipated Milestones and Financial Overview

- **GH001**
  - Initiate multi-center, randomized, controlled Phase 2b trial in TRD in 1Q.2023
  - Submit U.S. IND for GH001 in TRD in 1Q.2023
  - Complete proof-of-concept Phase 2a trials in BDII and in PPD by the end of 2023
- **GH002**
  - Initiate Phase 1 clinical pharmacology trial in healthy volunteers in 4Q.2022
- **GH003**
  - Complete preclinical development
- **Financial Overview**
  - Cash was \$256.9 million as of September 30, 2022
  - We believe existing cash will be sufficient to fund operating expenses and capital expenditure requirements into 2025



# Seeking Ultra-Rapid, Durable Remissions in Depression