**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of May, 2024.

**Commission File Number: 001-40530**

# GH Research PLC

**(Exact name of registrant as specified in its charter)**

**Joshua Dawson House**
**Dawson Street**
**Dublin 2**
**D02 RY95**
**Ireland**
**(Address of principal executive office)**

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

Form 20-F ☒ Form 40-F ☐

**INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K**

On May 3, 2024, GH Research PLC (the "Company") reported its first quarter 2024 financial results and provided business updates.

On May 3, 2024, the Company made available an updated investor presentation on it's website. A copy of the investor presentation is attached hereto as Exhibit 99.4.

The fact that this press release and presentation are being made available and furnished herewith should not be deemed an admission as to the materiality of any information contained in the materials. The information contained in the press release and presentation is being provided as of May 3, 2024, and the Company does not undertake any obligation to update the press release and presentation in the future or to update forward-looking statements to reflect subsequent actual results.

**INCORPORATION BY REFERENCE**

This Report on Form 6-K (other than Exhibit 99.3 and Exhibit 99.4 hereto), including Exhibit 99.1 and Exhibit 99.2 hereto, shall be deemed to be incorporated by reference into the registration statement on Form S-8 (Registration No. 333-270422) and the registration statement on Form F-3 (Registration No. 333-270418) of GH Research PLC and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Unaudited Condensed Consolidated Interim Financial Statements for the three months ended March 31, 2024 |
| 99.2 | Management's Discussion and Analysis of Financial Condition and Results of Operations |
| 99.3 | Press release dated May 3, 2024 |
| 99.4 | Corporate Presentation for May 2024 |
| 101.INS | Inline XBRL Instance Document |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURE**

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

**GH Research PLC**

Date: May 3, 2024

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

**GH RESEARCH PLC**

**Unaudited condensed consolidated interim statement of comprehensive income**

| | Note | Three Months Ended March 31, 2024 $'000 | Three Months Ended March 31, 2023 $'000 |
|---|---|---|---|
| **Operating expenses** | | | |
| Research and development | 3 | (8,658) | (7,306) |
| General and administration | 3 | (2,870) | (3,113) |
| **Loss from operations** | | **(11,528)** | **(10,419)** |
| | | | |
| Finance income | 4 | 2,670 | 1,489 |
| Finance expense | 4 | (179) | (171) |
| Movement of expected credit loss | | 50 | (199) |
| Foreign exchange gain/(loss) | | 1,321 | (1,637) |
| **Total other income/(expense)** | | **3,862** | **(518)** |
| | | | |
| **Loss before tax** | | **(7,666)** | **(10,937)** |
| Tax charge/(credit) | | - | - |
| **Loss for the period** | | **(7,666)** | **(10,937)** |
| | | | |
| **Other comprehensive (expense)/income** | | | |
| *Items that may be reclassified to profit or loss* | | | |
| Fair value movement on marketable securities | | (543) | 724 |
| Currency translation adjustment | | (1,289) | 1,676 |
| **Total comprehensive loss for the period** | | **(9,498)** | **(8,537)** |
| | | | |
| **Attributable to owners:** | | | |
| Loss for the period | | (7,666) | (10,937) |
| Total comprehensive loss for the period | | (9,498) | (8,537) |
| | | | |
| **Loss per share** | | | |
| Basic and diluted loss per share (in USD) | 13 | (0.15) | (0.21) |

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

**GH RESEARCH PLC**

**Unaudited condensed consolidated interim statement of financial position**

| | Note | At March 31, 2024 $'000 | At December 31, 2023 $'000 |
|---|---|---|---|
| **ASSETS** | | | |
| **Current assets** | | | |
| Cash and cash equivalents | 5 | 77,483 | 78,420 |
| Other financial assets | | 51,346 | 55,615 |
| Marketable securities | 6 | 29,029 | 27,525 |
| Other current assets | 7 | 2,618 | 2,529 |
| **Total current assets** | | **160,476** | **164,089** |
| **Non-current assets** | | | |
| Marketable securities | 6 | 56,132 | 61,142 |
| Property, plant and equipment | | 975 | 1,069 |
| **Total non-current assets** | | **57,107** | **62,211** |
| **Total assets** | | **217,583** | **226,300** |
| | | | |
| **LIABILITIES AND EQUITY** | | | |
| **Current liabilities** | | | |
| Trade payables | 8 | 3,554 | 3,490 |
| Lease liability | | 336 | 343 |
| Other current liabilities | 9 | 3,385 | 2,868 |
| **Total current liabilities** | | **7,275** | **6,701** |
| **Non-current liabilities** | | | |
| Lease liability | | 561 | **631** |
| **Total non-current liabilities** | | **561** | **631** |
| **Total liabilities** | | **7,836** | **7,332** |
| | | | |
| **Equity attributable to owners** | | | |
| Share capital | | 1,301 | 1,301 |
| Additional paid-in capital | | 291,463 | 291,463 |
| Other reserves | | 4,293 | 4,651 |
| Foreign currency translation reserve | | (11,796) | (10,507) |
| Accumulated deficit | | (75,514) | (67,940) |
| **Total equity** | | **209,747** | **218,968** |
| **Total liabilities and equity** | | **217,583** | **226,300** |

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

**GH RESEARCH PLC**

**Unaudited condensed consolidated interim statement of changes in equity**

| | Attributable to owners | | | | | |
|---|---|---|---|---|---|---|
| | **Share capital** | **Additional paid-in capital** | **Other reserves** | **Foreign currency translation reserve** | **Accumulated deficit** | **Total** |
| | **$'000** | **$'000** | **$'000** | **$'000** | **$'000** | **$'000** |
| **At January 1, 2023** | **1,301** | **291,448** | **2,595** | **(13,035)** | **(32,493)** | **249,816** |
| Loss for the period | - | - | - | - | (10,937) | (10,937) |
| Other comprehensive income | - | - | 724 | 1,676 | - | 2,400 |
| **Total comprehensive loss for the period** | **-** | **-** | **724** | **1,676** | **(10,937)** | **(8,537)** |
| Share-based compensation expense | - | - | 551 | - | - | 551 |
| **Total transactions with owners** | **-** | **-** | **551** | **-** | **-** | **551** |
| **At March 31, 2023** | **1,301** | **291,448** | **3,870** | **(11,359)** | **(43,430)** | **241,830** |
| | | | | | | |
| **At January 1, 2024** | **1,301** | **291,463** | **4,651** | **(10,507)** | **(67,940)** | **218,968** |
| Loss for the period | - | - | - | - | (7,666) | (7,666) |
| Other comprehensive expense | - | - | (543) | (1,289) | - | (1,832) |
| **Total comprehensive loss for the period** | **-** | **-** | **(543)** | **(1,289)** | **(7,666)** | **(9,498)** |
| Share-based compensation expense | - | - | 277 | - | - | 277 |
| Transfer of share options | - | - | (92) | - | 92 | - |
| **Total transactions with owners** | **-** | **-** | **185** | **-** | **92** | **277** |
| **At March 31, 2024** | **1,301** | **291,463** | **4,293** | **(11,796)** | **(75,514)** | **209,747** |

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

**GH RESEARCH PLC**

**Unaudited condensed consolidated interim statement of cash flows**

| | Three months ended March 31, | |
|---|---|---|
| | **2024 $'000** | **2023 $'000** |
| **Cash flows from operating activities** | | |
| **Loss for the period** | **(7,666)** | **(10,937)** |
| Depreciation | 80 | 77 |
| Share-based compensation expense | 277 | 551 |
| Finance income | (2,670) | (1,489) |
| Finance expense | 179 | 171 |
| Movement of expected credit loss | (50) | 199 |
| Foreign exchange (gain)/loss | (1,321) | 1,637 |
| Movement in working capital | 557 | 2,473 |
| **Cash flows used in operating activities** | **(10,614)** | **(7,318)** |
| Finance expense paid | (169) | (246) |
| Finance income received | 1,187 | 679 |
| **Net cash used in operating activities** | **(9,596)** | **(6,885)** |
| | | |
| **Cash flows from/(used in) investing activities** | | |
| Purchase of other financial assets | - | (54,000) |
| Purchase of property, plant and equipment | (12) | (22) |
| Proceeds from sale of other financial assets | 5,000 | - |
| Proceeds from redemptions and disposals of marketable securities | 3,800 | - |
| **Cash flows from/(used in) investing activities** | **8,788** | **(54,022)** |
| | | |
| **Cash flows used in financing activities** | | |
| Payment of lease liability | **(71)** | **(70)** |
| | | |
| **Net decrease in cash and cash equivalents** | **(879)** | **(60,977)** |
| Cash and cash equivalents at the beginning of the period | 78,420 | 165,955 |
| Impact of foreign exchange on cash and cash equivalents | (58) | 104 |
| **Cash and cash equivalents at the end of the period** | **77,483** | **105,082** |

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

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

### 1. Corporate information

GH Research PLC (the "Company") was incorporated on March 29, 2021. The registered office of the Company is located at Joshua Dawson House, Dawson Street, Dublin 2, Ireland.

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

These unaudited condensed consolidated interim financial statements were presented to the board of directors and approved by them for issue on May 3, 2024.

### 2. Basis of preparation, significant judgments, and accounting policies

**Basis of preparation**

***Compliance with International Financial Reporting Standards***
The unaudited condensed consolidated interim financial statements for the three months ended March 31, 2024 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, 2023, which were prepared in accordance with IFRS Accounting Standards as adopted by the International Accounting Standards Board ("IASB"). These unaudited condensed consolidated interim financial statements are presented in U.S. dollar ("USD" or "$"), which is the Company's functional currency and the Group's presentation currency.

The financial information presented in this interim report does not represent full statutory accounts as defined by the Companies Act 2014. The statutory accounts of GH Research PLC for the year ended December 31, 2023, are expected to be filed with the Companies Registration Office by November 26, 2024.

***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, 2024 that are relevant to the Group and that have had any material impact in the interim period. The review of the impact of new standards on the Group's financial statements, including the recently issued IFRS 18 "Presentation and Disclosure in Financial Statements", which is not yet effective and which has not been early adopted by the Group is ongoing. There are no other amendments to standards and interpretations that are not yet effective which have been deemed relevant to the Group.

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

Since its incorporation, the Group has funded its growth through capital increases. The Group has no bank loans or other debt outstanding, except lease liabilities, as of March 31, 2024. As a result, the Group is not exposed to liquidity risk through requests for early repayment of loans.

As of March 31, 2024, the Group's cash and cash equivalents amounted to $77.5 million (December 31, 2023: $78.4 million). The Group also held marketable securities of $85.2 million and other financial assets of $51.3 million as of March 31, 2024 (December 31, 2023: marketable securities of $88.7 million and other financial assets of $55.6 million). The marketable securities held by the Group are quoted in active markets and are an additional source of liquidity.

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

**Use of estimates and judgments**

The preparation of the unaudited condensed consolidated interim financial statements requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

In preparing these unaudited condensed consolidated interim financial statements, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty are consistent with those that applied in the preparation of the consolidated financial statements for the year ended December 31, 2023.

**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.

**Current and deferred income tax**

The interim income tax expense is calculated based on the Company's estimate of the weighted average effective annual income tax rate expected for the full year. The current and deferred income tax charge was $nil for the three months ended March 31, 2024 and 2023, 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.

**Research and development tax credits**

As explained in the Group's consolidated financial statements for the year ended December 31, 2023, an amount of $1.3 million had remained unrecognized with respect to research and development tax credit claims for the year ended December 31, 2022 and 2021. In the period to March 31, 2024, an amount of $0.8 million has been received by the Group which has been recognized as a deduction from research and development expenses under the Group's relevant accounting policy. At March 31, 2024, a balance of $0.5 million remains unrecognized as it has been concluded that reasonable assurance has not been achieved. Judgment was applied in this determination.

**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 March 31, | |
|---|---|---|
| | 2024 $'000 | 2023 $'000 |
| External research and development expenses | 7,047 | 5,825 |
| Employee expenses[1] | 1,548 | 1,419 |
| Depreciation | 6 | 10 |
| Other expenses | 57 | 52 |
| **Total research and development expenses** | **8,658** | **7,306** |
| | | |
| External costs | 1,915 | 2,270 |
| Employee expenses[2] | 881 | 776 |
| Depreciation | 74 | 67 |
| **Total general and administrative expenses** | **2,870** | **3,113** |
| **Total operating expenses** | **11,528** | **10,419** |

[1]Included in employee expenses is share based compensation expense of $0.2 million and $0.3 million for the three months ended March 31, 2024 and 2023, respectively, relating to employees in the research and development department.

[2] Included in employee expenses is share based compensation expense of $0.1 million and $0.2 million for the three months ended March 31, 2024 and 2023, respectively, relating to employees in the general and administrative department.

**Foreign exchange gain/loss**

Foreign exchange gain of $1.3 million for the three months ended March 31, 2024 (foreign exchange loss of $1.6 million for the three months ended March 31, 2023) consists primarily of gains (2023: losses) related to the translation of the U.S. dollar cash and other financial assets balance into euro in the accounts of the Company's subsidiary, GH Research Ireland Limited, whose functional currency is euro as explained in the Group's consolidated financial statements for the year ended December 31, 2023.

At March 31, 2024, if the U.S. dollar had weakened/strengthened by 10% against the euro with all other variables held constant, the loss before tax for the three months ended March 31, 2024, would have been $5.6 million higher/lower, mainly related to the translation of cash and other financial assets held in U.S. dollar in the Company's subsidiary, GH Research Ireland Limited. This would be offset by an equivalent amount within Other Comprehensive Income.

## 4. Finance income and expense

| | Three Months Ended March 31, | |
|---|---|---|
| | 2024 $'000 | 2023 $'000 |
| **Finance income** | | |
| Finance income on cash, cash equivalents and other financial assets | 558 | - |
| Gain on cash equivalents and other financial assets at fair value through profit and loss ("FVTPL") | 1,057 | 465 |
| Interest income under effective interest rate method at fair value through other comprehensive income ("FVOCI") | 1,055 | 1,024 |
| **Finance income** | **2,670** | **1,489** |
| | | |
| **Finance expense** | | |
| Finance expense on investments | (166) | (153) |
| Finance expense on lease liability | (13) | (18) |
| **Finance expense** | **(179)** | **(171)** |

## 5. Cash and cash equivalents

| | March 31, 2024 $'000 | December 31, 2023 $'000 |
|---|---|---|
| Cash at bank and in hand | 39,026 | 41,390 |
| Cash equivalents | 38,457 | 37,030 |
| | **77,483** | **78,420** |

During the three months ended March 31, 2024, proceeds of $5.0 million were received from the sale of a portion of other financial assets and proceeds of $3.8 million were received from the redemption of marketable securities.

## 6. Marketable securities

| | Marketable securities $'000 |
|---|---|
| **Fair value** | |
| **At January 1, 2024** | **88,667** |
| Accrued interest | 1,055 |
| Interest received | (268) |
| Redemptions and disposals of marketable securities | (3,800) |
| Revaluation adjustment | (493) |
| **At March 31, 2024** | **85,161** |

The Group holds government and corporate listed bonds which comprise marketable securities measured at FVOCI. These marketable securities had a fair value of $85.2 million at March 31, 2024 (December 31, 2023: $88.7 million). During the period to March 31, 2024, a number of marketable securities were redeemed. This resulted in proceeds of $3.8 million in the period. The impairment loss allowance for expected credit losses at the reporting date was $0.1 million (December 31, 2023: $0.1 million). At March 31, 2024, the maturity of the Group's marketable securities ranges from one month to three years. This maturity has been reflected in the allocation of current and non-current assets in the unaudited condensed consolidated interim statement of financial position.

The movement through OCI for the three months ended March 31, 2024, and March 31, 2023, is shown in the table below:

| | Three Months Ended March 31, | |
|---|---|---|
| | **2024 $'000** | **2023 $'000** |
| Revaluation adjustments | (493) | 525 |
| Movement of expected credit losses on assets measured at FVOCI | (50) | 199 |
| **Movement on marketable securities through OCI** | **(543)** | **724** |

## 7. Other current assets

Other current assets primarily represent prepayments.

## 8. Trade payables

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

## 9. Other current liabilities

Other current liabilities primarily represent accruals for operating expenses and employee tax payable and are expected to be settled within one year.

## 10. Contingencies

As of March 31, 2024, there were no material contingencies which required adjustment or disclosure in the unaudited condensed consolidated interim financial statements (2023: none).

## 11. Share based compensation

***Share Options***

In June 2021, the Company adopted a share option plan referred to herein as the Share Option Plan under which grants of options are made to eligible participants. The Company had reserved 1,202,734 ordinary shares for future issuance under the Share Option Plan, which include ordinary shares pursuant to share-based equity awards issued to date. As of March 31, 2024, the Company has 368,741 ordinary shares available for the future issuance of share-based equity awards.

Under the Share Option Plan, the options may be settled only in ordinary shares of the Company. Therefore, the grants of share options under the Share Option Plan have been accounted for as equity-settled under IFRS 2. As such, the Company records a charge for the vested portion of award grants and for partially earned but non-vested portions of award grants.

During the three months ended March 31, 2024, the Company granted the option to purchase 68,000 ordinary shares to employees which were in line with the general terms of the Share Option Plan. All share options granted during the three months ended March 31, 2024, had a contractual term (expiration) of eight years from the grant date with an exercise price at the closing market price on the day prior to the grant.

The following table summarizes the share option awards outstanding as of March 31, 2024:

| | Average exercise price per share in USD | Number of awards | Weighted average remaining life in years |
|---|---|---|---|
| **At December 31, 2023** | **10.35** | **790,720** | **6.57** |
| Granted | 6.96 | 68,000 | 7.81 |
| Forfeited | 12.82 | (32,023) | 6.12 |
| **At March 31, 2024**[1] | **9.98** | **826,697** | **6.45** |

[1] 149,207 of the awards outstanding as of March 31, 2024, were exercisable.

The weighted average grant date fair value of awards granted during the three months ended March 31, 2024, was $5.21 per award.

The fair values of the options granted were determined on the date of the grant using the Black-Scholes option-pricing model. The Company used an independent valuation firm to assist in calculating the fair value of the award grants per participant.

The fair values of the options granted during the three months ended March 31, 2024 and 2023 were determined on the date of the grant using the following assumptions:

| | Three Months Ended March 31, 2024 | Three Months Ended March 31, 2023 |
|---|---|---|
| Share price, in USD | 5.80 - 8.00 | 8.77 - 10.40 |
| Strike price, in USD – employees (weighted average) | 6.96 | 9.66 |
| Expected volatility | 87% - 88% | 87% |
| Award life (weighted average) | 6 | 6 |
| Expected dividends | - | - |
| Risk-free interest rate | 3.82% - 4.26% | 3.63% - 4.22% |

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

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

As of March 31, 2024, Other Reserves within equity includes $4.4 million (December 31, 2023: $4.2 million) relating to the Group's Share Option Plan. Balances which relate to forfeited awards which had previously vested are transferred from Other Reserves to Accumulated Deficit. The amount of expense for all awards recognized for services received during the three months ended March 31, 2024 was $0.3 million (three months ended March 31, 2023: $0.6 million).

## 12. Related party disclosures

There have been no transactions in the three months ended March 31, 2024 and ended March 31, 2023 with related parties that had a material effect on the financial position or performance of the Group.

## 13. Loss per share

| | Three Months Ended March 31, | |
|---|---|---|
| | 2024 | 2023 |
| Loss attributable to shareholders (in $'000) | (7,666) | (10,937) |
| Weighted average number of shares in issue | 52,028,145 | 52,020,849 |
| Basic and diluted loss per share (in USD) | (0.15) | (0.21) |

For the three months ended March 31, 2024 and 2023, 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.

## 14. Events after the reporting date

There were no events after the reporting date requiring disclosure in the Group's consolidated 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 months ended March 31, 2024. 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, 2023 titled "Item 3. Key Information—D. Risk Factors."

Our unaudited condensed consolidated interim financial statements for the three months ended March 31, 2024, were prepared in accordance with International Accounting Standard 34, Interim Financial Reporting. The terms "dollar," "USD" or "$" refer to U.S. dollars. We have made rounding adjustments to some of the figures included in this discussion. Accordingly, any numerical discrepancies in any table between totals and sums of the amounts listed are due to rounding.

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

### Overview

We are a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders. Our initial focus is on developing our novel and proprietary mebufotenin (5-methoxy-N,N-dimethyltryptamine, or 5-MeO-DMT) therapies for the treatment of patients with treatment-resistant depression, or TRD. Mebufotenin was selected as the International Nonproprietary Name (INN) for 5-MeO-DMT by the World Health Organization (WHO) Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

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

We have incurred losses since inception, including losses of $7.7 million for the three months ended March 31 2024, and losses of $35.6 million and $22.5 million for the years ended December 31, 2023 and 2022, respectively. As of March 31, 2024, we had an accumulated deficit of $75.5 million. We expect to incur significant expenses and operating losses for the foreseeable future as we expand our research and development activities. In addition, our losses from operations may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials, our expenditures on other research and development activities and based on foreign currency translation differences. We anticipate that our expenses will increase significantly in connection with our ongoing activities, if and as we:

- continue to develop and conduct clinical trials, including in expanded geographies such as the United States, for GH001, our inhalable mebufotenin product candidate, GH002, our intravenous mebufotenin product candidate, and GH003, our intranasal mebufotenin product candidate, for our initial indications and additional indications;

- continue both the technical development and expansion of our external manufacturing capabilities for our current product candidates GH001, GH002 and GH003 and of the medical devices required to deliver these product candidates, such as our proprietary aerosol delivery device for GH001;
- initiate and continue research and development, including nonclinical, clinical, and discovery efforts for any future product candidates;
- seek to identify additional product candidates;
- seek regulatory approvals for our product candidates GH001, GH002 and GH003, including the medical devices required to deliver these product candidates, such as our proprietary aerosol delivery device, or any other product candidates that successfully complete clinical development;
- progress any nonclinical programs and any other work that may be required to lift the clinical hold on the study we proposed in our IND for GH001;
- 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;
- acquire or in-license other product candidates, medical devices to deliver our product candidates, and other technologies; and
- incur increased costs as a result of operating as a public company.

In addition, as we progress toward marketing approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our product candidates or other research and development initiatives, which could have a material adverse effect on our business, results of operations, and financial condition. We will need to generate significant revenue to achieve profitability, and we may never do so.

We are subject to a number of risks comparable to those of other similar companies, including dependence on key individuals; the need to develop product candidates with the required safety and efficacy profile and which support regulatory approval and are commercially viable; competition from other companies, many of which are larger and better capitalized; and the need to obtain adequate additional financing to fund the development of our product candidates.

**Business Updates**

*GH001 in Patients with TRD*

GH001, our proprietary inhaled mebufotenin (5-MeO-DMT) product candidate, is currently being investigated in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in approximately 80 patients with treatment-resistant depression (TRD) (GH001-TRD-201) with approximately 20 sites across seven European countries.

We continue to recruit according to plan, supporting the expected completion of the double-blind phase of this trial in the third quarter of 2024, with top-line data expected to be available in the third or the fourth quarter of 2024. The completion of the 6-month open-label extension of this trial is expected in the first quarter of 2025.

In this trial, GH001 is administered using a commercially available inhalation device. Consistent with previously completed trials, GH001 is administered on a single initial dosing day, without additional mandated visits for psychotherapy or psychological support before or after dosing.

*GH001 in Patients with PPD and BDII*

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

We continue to expect GH001-PPD-203 completion and availability of top-line data in the third quarter of 2024. The BDII (GH001-BD-202) trial is recruiting slower than previously anticipated. We have recently initiated 6 additional sites in 3 European countries for this trial, and have implemented certain additional measures to support recruitment, but we need to further assess the impact of these measures on recruitment before we can provide an updated timeline.

*GH002*

GH002 is our proprietary intravenous mebufotenin (5-MeO-DMT) product candidate. With GH002, we have recently completed a Phase 1, dose-ranging clinical pharmacology trial in healthy volunteers (GH002-HV-105). This trial demonstrated that GH002 was well-tolerated and produced potent pharmacodynamic (PD) effects, as assessed by psychoactive effect intensity, with an ultra-rapid onset and short duration psychoactive experience. The pharmacokinetic (PK) profile of GH002 correlated with the ultra-rapid profile of the psychoactive effects.

The analyses of the PK/PD relationship, and various other secondary endpoints, are ongoing and will inform the further clinical development strategy for GH002.

*Update on IND for GH001*

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

As previously announced, we have initiated the requested nonclinical studies and are preparing the requested device design verification information. With regard to the device design verification matters, we requested a meeting with the FDA to seek input on certain aspects of our response, which was granted. That interaction with the FDA will be dealt with by way of written responses, which we expect to receive from the FDA this month.

We have now submitted a clinical trial application for our planned Phase 1 healthy volunteer clinical pharmacology trial (GH001-HV-106) in Europe. This trial uses our proprietary aerosol delivery device for administration of GH001 and is designed to support bridging to the clinical data generated with the commercial device we have used, and are using, in our clinical trials to date.

**Results of Operations**

***Comparison of the Three Months Ended March 31, 2024 and 2023***

*The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:*

| | Three Months Ended March 31 | | |
|---|---|---|---|
| | **2024** | **2023** | **Change** |
| | | **(in USD thousands)** | |
| Operating Expenses: | | | |
| Research and development | (8,658) | (7,306) | (1,352) |
| General and administrative | (2,870) | (3,113) | 243 |
| **Loss from operations** | **(11,528)** | **(10,419)** | **(1,109)** |
| Net finance income[1] | 2,541 | 1,119 | 1,422 |
| Foreign exchange gain/(loss) | 1,321 | (1,637) | 2,958 |
| **Loss for the period** | **(7,666)** | **(10,937)** | **3,271** |

[1]Net finance income for the three months ended March 31, 2024, comprises finance income, finance expense and expected credit losses.

*Research and Development Expenses*

The following table summarizes our research and development expenses for the three months ended March 31, 2024 and 2023:

| | Three Months Ended March 31 | | |
|---|---|---|---|
| | **2024** | **2023** | **Change** |
| | | **(in USD thousands)** | |
| External research and development expenses | (7,047) | (5,825) | (1,222) |
| Employee expenses[1] | (1,548) | (1,419) | (129) |
| Depreciation | (6) | (10) | 4 |
| Other expenses | (57) | (52) | (5) |
| **Research and development** | **(8,658)** | **(7,306)** | **(1,352)** |

[1] Includes share based compensation expense of $0.2 million and $0.3 million for the three months ended March 31, 2024 and 2023, respectively.

The following table summarizes our research and development expenses for our product candidates for the three months ended March 31, 2024 and 2023:

| | Three Months Ended March 31 | | |
|---|---|---|---|
| | **2024** | **2023** | **Change** |
| | | **(in USD thousands)** | |
| GH001 | (6,021) | (4,663) | (1,358) |
| GH002 | (586) | (535) | (51) |
| GH003 | (18) | (8) | (10) |
| Related to multiple product candidates (GH001, GH002 and GH003) and exploratory work for potential future product candidates [1] | (2,033) | (2,100) | 67 |
| **Research and development** | **(8,658)** | **(7,306)** | **(1,352)** |

[1] Includes expenses that relate to any combination of GH001, GH002 and/or GH003 and exploratory work for potential future candidates.

Research and development expenses increased by $1.4 million to $8.7 million for the three months ended March 31, 2024, from $7.3 million for the three months ended March 31, 2023. The increase is primarily due to increased expenses relating to nonclinical activities, active pharmaceutical ingredient and drug product development and manufacturing and increased clinical trial expenses. These increases have been partly offset by a decrease in expenses relating to our technical development including device development.

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 $1.4 million in the three months ended March 31, 2024, primarily due to an increase in clinical trial expenses, an increase in expenses related to nonclinical activities and active pharmaceutical ingredient and drug product development and manufacturing, partly offset by a decrease in expenses relating to technical development including device development.

Research and development expenses relating to GH002 increased by $0.1 million in the three months ended March 31, 2024, primarily due to an increase in active pharmaceutical ingredient and drug product development and manufacturing and partly offset by decreased clinical trial expenses.

*General and Administrative Expenses*

The following table summarizes our general and administrative expenses for the three months ended March 31, 2024 and 2023:

| | Three Months Ended March 31 | | |
|---|---|---|---|
| | **2024** | **2023** | **Change** |
| | | **(in USD thousands)** | |
| External costs | (1,915) | (2,270) | 355 |
| Employee expenses[1] | (881) | (776) | (105) |
| Depreciation | (74) | (67) | (7) |
| **General and administrative** | **(2,870)** | **(3,113)** | **243** |

[1] Includes share based compensation expense of $0.1 million and $0.2 million for the three months ended March 31, 2024 and 2023, respectively.

General and administrative expenses decreased by $0.2 million to $2.9 million for the three months ended March 31, 2024, from $3.1 million for the three months ended March 31, 2023. The decrease is primarily due to a reduction in professional fees and insurance costs offset by an increase in employee expenses in our general and administrative functions to support our growth initiatives.

*Net Finance Income*

Our net finance income increased to $2.5 million for the three months ended March 31, 2024, from $1.1 million for the three months ended March 31, 2023. The increase is primarily due to an increase in finance income of $0.6 million relating to cash, cash equivalents and other financial assets, as well as an increase in the fair value gain of $0.6 million relating to our cash equivalents and other financial assets.

*Foreign Exchange Gain/(Loss)*

Foreign exchange gain is $1.3 million for the three months ended March 31, 2024, a movement of $3.0 million from a loss of $1.6 million for the three months ended March 31, 2023. This movement is primarily as a result of the translation of the U.S. dollar cash and other financial assets balance in the accounts of our subsidiary into its functional currency, which is the euro. During the three months ended March 31, 2024, the U.S. dollar strengthened compared to the euro, which resulted in the foreign exchange gain.

**Liquidity and Capital Resources**

***Sources of Liquidity***

We have incurred 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 March 31, 2024, we had cash, cash equivalents, other financial assets and marketable securities of $214.0 million, compared to cash, cash equivalents and marketable securities of $222.7 million as of December 31, 2023.

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

*Cash Flows*

The following table provides information regarding our cash flows for the three months ended March 31, 2024 and 2023:

| | Three Months Ended March 31 | | |
|---|---|---|---|
| | **2024** | **2023** | **Change** |
| | | **(in USD thousands)** | |
| Net cash flows used in operating activities | (9,596) | (6,885) | (2,711) |
| Net cash flows from/(used in) investing activities | 8,788 | (54,022) | 62,810 |
| Net cash flows used in financing activities | (71) | (70) | (1) |
| **Net decrease in cash and cash equivalents** | **(879)** | **(60,977)** | **60,098** |

*Net Cash Flows Used in Operating Activities*

Net cash flows used in operating activities increased by $2.7 million to $9.6 million for the three months ended March 31, 2024 from $6.9 million for the three months ended March 31, 2023, due to an increase in loss from operations for the period and movement in working capital.

*Net Cash Flows From/(Used in) Investing Activities*

Net cash flows from investing activities for the three months ended March 31, 2024, is $8.8 million, a movement of $62.8 million from net cash flows used in investing activities of $54.0 million for the three months ended March 31, 2023. The net cash from investing activities during the three months ended March 31, 2024, comprised the receipt of proceeds from the sale of financial assets of $5.0 million and the redemption of marketable securities of $3.8 million. The net cash used in investing activities during the three months ended March 31, 2023, was primarily due to an investment in a money market fund of $54.0 million.

***Funding Requirements***

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance the technical development work, nonclinical studies and clinical trials of our product candidates and the medical devices required to deliver such product candidates, such as our proprietary aerosol delivery device for GH001. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, convertible debt financings, strategic collaborations and licensing arrangements. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our future capital requirements will depend on many factors, which are outlined in our annual report on Form 20-F for the year ended December 31, 2023, and this discussion and analysis. We believe that we have sufficient financial resources available to cover our planned cash outflows for at least the next twelve months.

**Critical Accounting Estimates**

There have been no material changes to the significant accounting policies and significant judgments and estimates from those referred to in the section in our annual report on Form 20-F for the year ended December 31, 2023, titled “Item 5. Operating and Financial Review and Prospects—E. Critical Accounting Estimates.”

**Emerging Growth Company Status**

On April 5, 2012, the Jumpstart our Business Act of 2012 (“JOBS Act”) was enacted. As an emerging growth company, or EGC, we rely on exemptions and reduced reporting requirements under the JOBS Act including exemptions from (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

We will remain classified as an EGC until the earlier of (1) the last day of the fiscal year (i) in which we have total annual gross revenue of $1.235 billion; (ii) following the fifth anniversary of the completion of our initial public offering; or (iii) in which we are deemed to be a “large accelerated filer,” which requires the market value of our ordinary shares that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three-year period.

**Recently Issued Accounting Pronouncements**

As disclosed in note 2 to our unaudited condensed consolidated interim financial statements, there are no standards that are mandatory for the financial year beginning on January 1, 2024, that are relevant to and have had any material impact on our unaudited condensed consolidated interim financial statements. The review of the impact of new standards on our unaudited condensed consolidated interim financial statements, including the recently issued IFRS 18 “Presentation and Disclosure in Financial Statements”, which is not yet effective and which has not been early adopted by us is ongoing.

**Risk Factors**

There have been no material changes in our risk factors from those disclosed in our annual report on Form 20-F for the year ended December 31, 2023.

**Cautionary Statement Regarding Forward-Looking Statements**

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

Forward-looking statements appear in a number of places in this discussion and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section in our annual report on Form 20-F for the year ended December 31, 2023, 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, such as our proprietary aerosol delivery device for GH001, for our initial and any additional indications;
- our efforts to expand into other jurisdictions such as the United States and in the European Union;
- our expectations related to the technical development and expansion of our external manufacturing capabilities for our GH001, GH002 and GH003 product candidates as well as the medical devices required to deliver these product candidates, such as our proprietary aerosol delivery device for GH001;
- our reliance on the success of our GH001, GH002 and GH003 product candidates;
- the timing, scope or likelihood of regulatory filings and approvals by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other comparable foreign regulatory authorities, for our GH001, GH002 and GH003 product candidates and our initial and any additional indications;
- our expectations related to the clinical hold imposed by the FDA on the study we proposed in our IND for GH001, including our plans and expectations for progressing any nonclinical programs and any other work to lift the clinical hold, the timing required to lift such clinical hold and for discussions with the FDA and the outcomes and resolution of such discussions;
- our expectations regarding the size of the eligible patient populations for our GH001, GH002 and GH003 product candidates, if approved for commercial use;
- our ability to identify third-party clinical trial sites to conduct trials and our ability to identify and train appropriately qualified therapists to administer our investigational therapy;
- the effect of pandemics, such as the COVID-19 pandemic, epidemics, outbreaks of an infectious disease or similar events on aspects of our business operations, including delays in the regulatory approval process, contracting with clinical trial sites and engaging in clinical trials;
- our ability to implement our business model and our strategic plans for our business and GH001, GH002 and GH003 product candidates;
- our ability to identify, develop or acquire and obtain approval by the FDA, EMA or other comparable foreign regulatory authorities of medical devices required to deliver our GH001, GH002 and GH003 product candidates, such as our proprietary aerosol delivery device for GH001;
- our commercialization and marketing capabilities and strategy;

- the effects of undesirable clinical trial outcomes and potential adverse public perception regarding the use of mebufotenin (5-MeO-DMT) and psychedelics generally on the regulatory approval process and future development of our product;
- the pricing, coverage and reimbursement of our GH001, GH002 and GH003 product candidates, if approved;
- the scalability and commercial viability of our manufacturing methods and processes;
- the rate and degree of market acceptance and clinical utility of our GH001, GH002 and GH003 product candidates;
- our reliance on third-party suppliers for our nonclinical study and clinical trial drug substance and product candidate supplies, as well as key raw materials used in our manufacturing processes;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;
- our expectations regarding potential benefits of our GH001, GH002 and GH003 product candidates and our approach generally;
- our expectations around regulatory development paths and with respect to Controlled Substances Act, or CSA, classification;
- the scope of protection we and any current or future licensors or collaboration partners are able to establish and maintain for intellectual property rights covering our GH001, GH002 and GH003 product candidates;
- our ability to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights and proprietary technology of third parties;
- our ability to protect our intellectual property rights, including enforcing and defending intellectual property-related claims;
- regulatory developments in the United States, under the laws and regulations of the European Union and other jurisdictions;
- continuing inflation, interest rates and foreign currency exchange rates, disruptions in global supply chains and labor markets, volatility and stress within the banking sector and the measures governments and financial services companies have taken in response, and geopolitical risks and global hostilities, including any direct or indirect economic impacts resulting from Russia's invasion of Ukraine, the ongoing military conflict between Israel and Hamas and any resulting conflicts in the region, or increased tensions between China and Taiwan;
- 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, cash equivalents, other financial assets and marketable securities 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;
- the future trading price of the ordinary shares and impact of securities analysts' reports on these prices; and
- other risks and uncertainties, including those listed under "Item 3. Key Information—D. Risk Factors."

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 sections in our annual report on Form 20-F for the year ended December 31, 2023, titled "Item 3. Key Information—D. Risk Factors" and "Item 5. Operating and Financial Review and Prospects" and elsewhere in our annual report and this discussion. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this discussion, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

**GH Research Reports First Quarter 2024 Financial Results and Provides Business Updates**

- Phase 2b clinical trial of GH001 in patients with treatment-resistant depression on track for expected completion of double-blind phase in Q3 2024 and of 6-month open-label extension phase in Q1 2025
- Phase 2a clinical trial of GH001 in postpartum depression on track for expected completion in Q3 2024
- Cash, cash equivalents, other financial assets and marketable securities of $214.0 million expected to provide cash runway into 2026

DUBLIN, Ireland, May 3, 2024 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported financial results for the first quarter ended March 31, 2024, and provided updates on its business.

**Business Updates**

*GH001 in Patients with TRD*

GH001, our proprietary inhaled mebufotenin (5-MeO-DMT) product candidate, is currently being investigated in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in approximately 80 patients with treatment-resistant depression (TRD) (GH001-TRD-201) with approximately 20 sites across seven European countries.

We continue to recruit according to plan, supporting the expected completion of the double-blind phase of this trial in the third quarter of 2024, with top-line data expected to be available in the third or the fourth quarter of 2024. The completion of the 6-month open-label extension of this trial is expected in the first quarter of 2025.

In this trial, GH001 is administered using a commercially available inhalation device. Consistent with previously completed trials, GH001 is administered on a single initial dosing day, without additional mandated visits for psychotherapy or psychological support before or after dosing.

*GH001 in Patients with PPD and BDII*

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

We continue to expect GH001-PPD-203 completion and availability of top-line data in the third quarter of 2024. The BDII (GH001-BD-202) trial is recruiting slower than previously anticipated. We have recently initiated 6 additional sites in 3 European countries for this trial, and have implemented certain additional measures to support recruitment, but we need to further assess the impact of these measures on recruitment before we can provide an updated timeline.

*GH002*

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The analyses of the PK/PD relationship, and various other secondary endpoints, are ongoing and will inform the further clinical development strategy for GH002.

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As previously announced, we have initiated the requested nonclinical studies and are preparing the requested device design verification information. With regard to the device design verification matters, we requested a meeting with the FDA to seek input on certain aspects of our response, which was granted. That interaction with the FDA will be dealt with by way of written responses, which we expect to receive from the FDA this month.

We have now submitted a clinical trial application for our planned Phase 1 healthy volunteer clinical pharmacology trial (GH001-HV-106) in Europe. This trial uses our proprietary aerosol delivery device for administration of GH001 and is designed to support bridging to the clinical data generated with the commercial device we have used, and are using, in our clinical trials to date.

**First Quarter 2024 Financial Highlights**

*Cash position*

Cash, cash equivalents, other financial assets and marketable securities were $214.0 million as of March 31, 2024, compared to cash, cash equivalents, other financial assets and marketable securities of $222.7 million as of December 31, 2023. Other financial assets are comprised of money market funds, and marketable securities are comprised of investment grade bonds. We believe that our existing cash, cash equivalents, other financial assets and marketable securities will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2026.

*Research and development expenses*

R&D expenses were $8.7 million for the quarter ended March 31, 2024, compared to $7.3 million for same quarter in 2023. The increase was primarily due to increased expenses relating to nonclinical activities, increased expenses relating to our technical development and increased clinical trial expenses. These were partly offset by a decrease in expenses relating to our device development.

*General and administrative expenses*

G&A expenses were $2.9 million for the quarter ended March 31, 2024, compared to $3.1 million for the same quarter in 2023. The decrease is primarily due to a decrease in professional fees and insurance costs, partly offset by increased employee expenses.

*Net loss*

Net loss was $7.7 million, or $0.15 loss per share, for the quarter ended March 31, 2024, compared to $10.9 million, or $0.21 loss per share, for the same quarter in 2023.

**About GH Research PLC**

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

GH Research PLC's annual report on Form 20-F filed with the U.S. Securities and Exchange Commission for the year ended December 31, 2023, is available at www.ghres.com and shareholders may receive a hard copy free of charge upon request.

**About GH001**

Our lead product candidate, GH001, is formulated for mebufotenin (5-MeO-DMT) administration via a proprietary inhalation approach. With GH001, we have completed two Phase 1 healthy volunteer clinical trials and a Phase 1/2 clinical trial in patients with TRD. Based on the observed clinical activity, where 87.5% of patients with TRD achieved ultra-rapid remission with our GH001 individualized single-day dosing regimen in the Phase 2 part of the trial, we believe that GH001 has the potential to change the way TRD is treated today. GH001 is currently in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in patients with TRD and in two Phase 2a proof-of-concept trials in patients with postpartum depression and in patients with bipolar II disorder suffering from a current depressive episode.

**About GH002 and GH003**

GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach. We have completed a Phase 1 trial of GH002 in healthy volunteers. GH003 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intranasal administration approach. GH003 is currently in preclinical development. We anticipate developing GH002 and GH003 within our focus areas of psychiatric and neurological disorders.

**Forward-Looking Statements**

This press release contains statements that are, or may be deemed to be, forward-looking statements. All statements other than statements of historical fact included in this press release, including statements regarding our future results of operations and financial position, business strategy, product candidates, medical devices required to deliver these product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals and their effects on our business strategy, including our plans and expectations for discussions with the FDA and the outcomes and resolution of such discussions related to the clinical hold on the GH001 IND, research and development costs, cash runway, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. Forward-looking statements appear in a number of places in this press release and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those described in our filings with the U.S. Securities and Exchange Commission. No assurance can be given that such future results will be achieved. Such forward-looking statements contained in this press release speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update these forward-looking statements contained in this press release to reflect any change in our expectations or any change in events, conditions, or circumstances on which such statements are based unless required to do so by applicable law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

**Investor Relations:**
Julie Ryan
GH Research PLC
investors@ghres.com

**GH RESEARCH PLC**

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

(in thousands, except share and per share amounts)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2024 $'000** | **2023 $'000** |
| **Operating expenses** | | |
| Research and development | (8,658) | (7,306) |
| General and administration | (2,870) | (3,113) |
| **Loss from operations** | **(11,528)** | **(10,419)** |
| | | |
| Finance income | 2,670 | 1,489 |
| Finance expense | (179) | (171) |
| Movement of expected credit loss | 50 | (199) |
| Foreign exchange gain/(loss) | 1,321 | (1,637) |
| **Total other income/(expense)** | **3,862** | **(518)** |
| | | |
| **Loss before tax** | **(7,666)** | **(10,937)** |
| Tax charge/(credit) | — | — |
| **Loss for the period** | **(7,666)** | **(10,937)** |
| | | |
| **Other comprehensive (expense)/income** | | |
| ***Items that may be reclassified to profit or loss*** | | |
| Fair value movement on marketable securities | (543) | 724 |
| Currency translation adjustment | (1,289) | 1,676 |
| **Total comprehensive loss for the period** | **(9,498)** | **(8,537)** |
| | | |
| **Attributable to owners:** | | |
| Loss for the period | (7,666) | (10,937) |
| Total comprehensive loss for the period | (9,498) | (8,537) |
| | | |
| **Loss per share** | | |
| Basic and diluted loss per share (in USD) | (0.15) | (0.21) |

**GH RESEARCH PLC**

**Condensed Consolidated Interim Balance Sheet (Unaudited)**

(in thousands)

| | At March 31, 2024 $'000 | At December 31, 2023 $'000 |
|---|---|---|
| **ASSETS** | | |
| **Current assets** | | |
| Cash and cash equivalents | 77,483 | 78,420 |
| Other financial assets | 51,346 | 55,615 |
| Marketable securities | 29,029 | 27,525 |
| Other current assets | 2,618 | 2,529 |
| **Total current assets** | **160,476** | **164,089** |
| **Non-current assets** | | |
| Marketable securities | 56,132 | 61,142 |
| Property, plant and equipment | 975 | 1,069 |
| **Total non-current assets** | **57,107** | **62,211** |
| **Total assets** | **217,583** | **226,300** |
| | | |
| **LIABILITIES AND EQUITY** | | |
| **Current liabilities** | | |
| Trade payables | 3,554 | 3,490 |
| Lease liability | 336 | 343 |
| Other current liabilities | 3,385 | 2,868 |
| **Total current liabilities** | **7,275** | **6,701** |
| **Non-current liabilities** | | |
| Lease liability | 561 | 631 |
| **Total non-current liabilities** | **561** | **631** |
| **Total liabilities** | **7,836** | **7,332** |
| | | |
| **Equity attributable to owners** | | |
| Share capital | 1,301 | 1,301 |
| Additional paid-in capital | 291,463 | 291,463 |
| Other reserves | 4,293 | 4,651 |
| Foreign currency translation reserve | (11,796) | (10,507) |
| Accumulated deficit | (75,514) | (67,940) |
| **Total equity** | **209,747** | **218,968** |
| **Total liabilities and equity** | **217,583** | **226,300** |


GH
RESEARCH
Corporate Presentation
GH Research PLC (NASDAQ: GHRS)
May 2024
2024© GH Research PLC
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# 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 expectations related to the clinical hold on the GH001 IND, including plans and expectations for progressing any nonclinical programs and any other work to lift the clinical hold, the timing required to lift such clinical hold and for discussions with the FDA and the outcomes and resolution of such discussions; GH Research's ability to obtain, maintain, enforce and defend issued patents; the adequacy of GH Research's capital resources, the availability of additional funding and GH Research's cash runway; and other factors, risks and uncertainties described in GH Research's filings with the U.S. Securities and Exchange Commission.

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

GH RESEARCH

# Seeking Ultra-Rapid, Durable Remissions in Depression

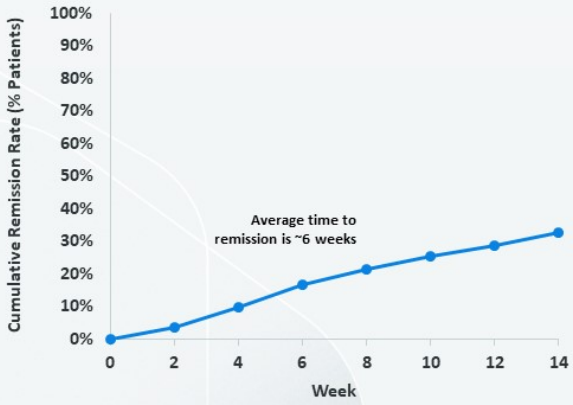
# Pipeline


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

# The Problem for Patients with Depression

## Established Therapies are Slow-Acting

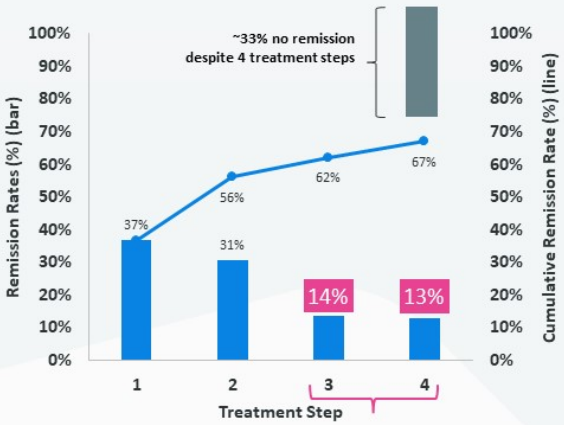
(STAR*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)




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

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

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




2 or more prior therapies = TRD

# Large and Open Depression Market in the EU and US

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

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

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

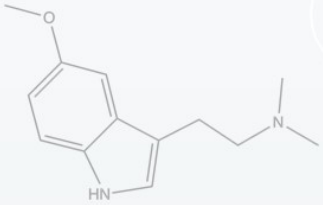
Patients cycle through ineffective therapies for TRD

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

# Mebufotenin (5-MeO-DMT) and GH001

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

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



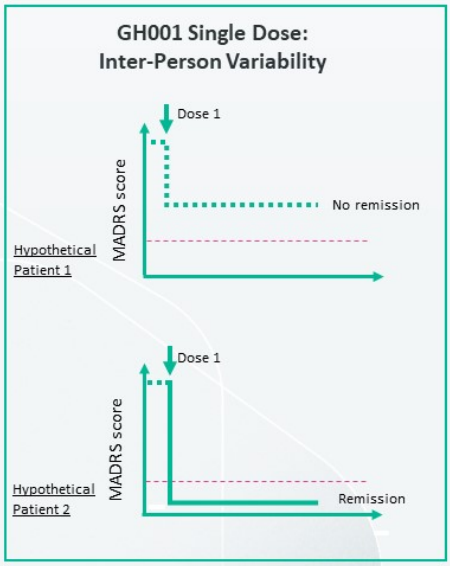

Mebufotenin (5-MeO-DMT)

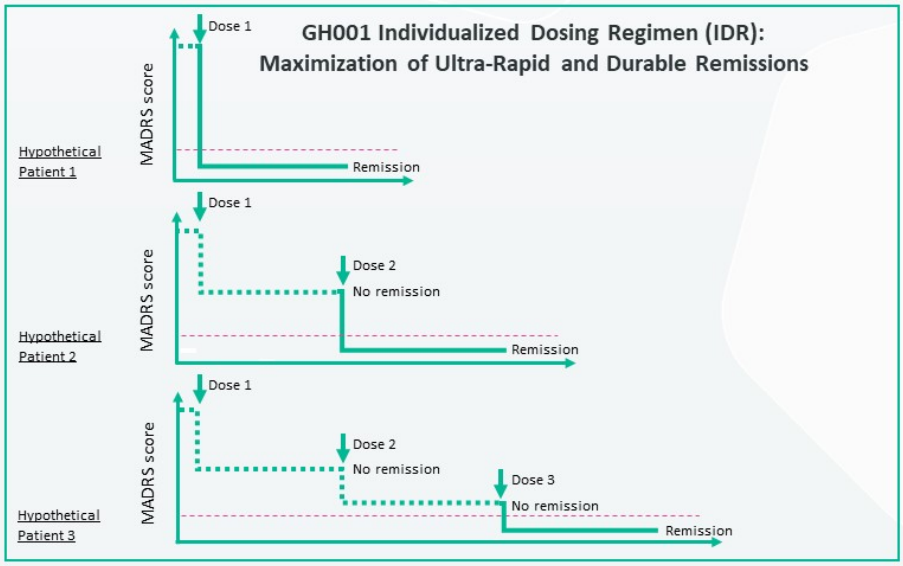
GH001 (Mebufotenin administration via a proprietary pulmonary inhalation approach)

- **Psychoactive effects with ultra-rapid onset** (within seconds) **and short duration** (5 to 30 min)
- **High propensity to induce peak experiences (PE), which may be a surrogate marker for therapeutic effects**
- **Intraday individualized dosing regimen (IDR)** for **maximization of ultra-rapid and durable remissions**
- **Single visit initial treatment,** without additional mandated visits for psychotherapy or psychological support before or after dosing
- Potential for **convenient and infrequent retreatment**

Foundational IP

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



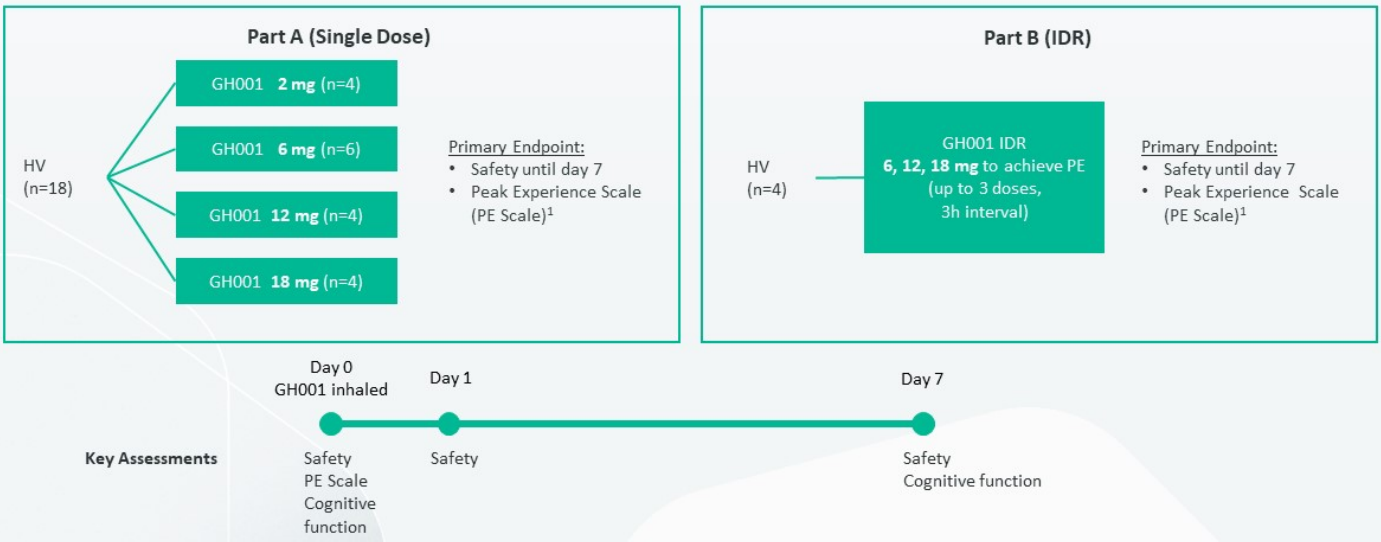

*MADRS, Montgomery-Åsberg Depression Rating Scale*

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

(Completed)

Clinicaltrials.gov ID: NCT04640831

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




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

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

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

Study Safety Group review

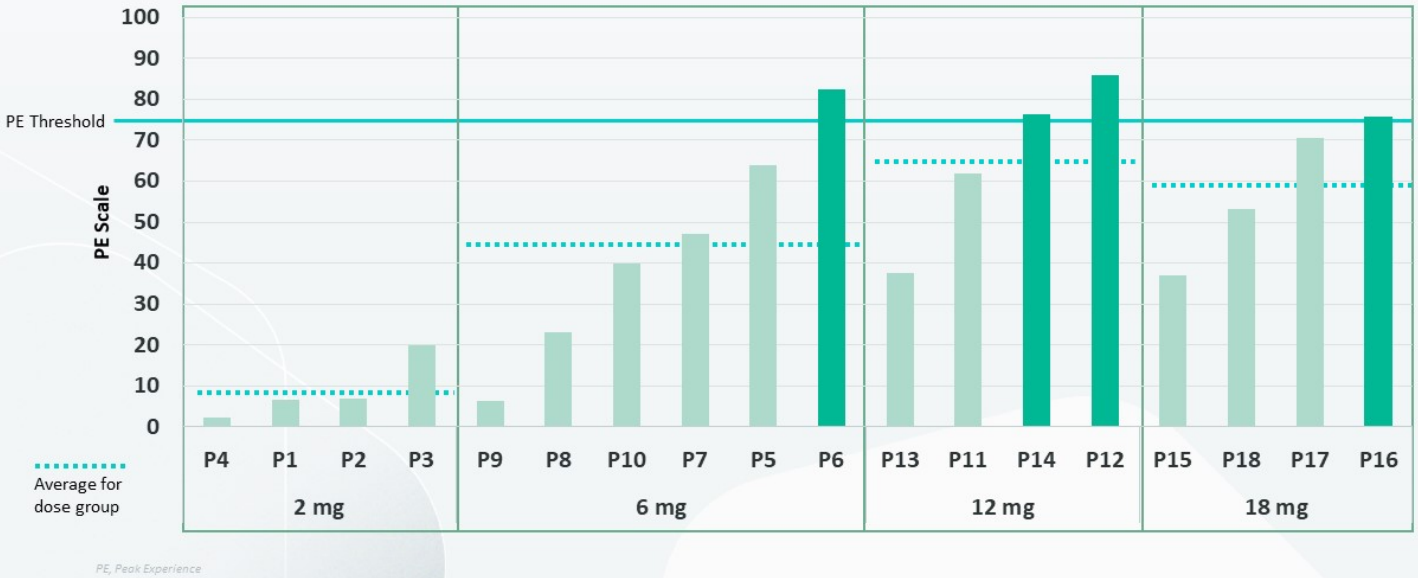
- **No SAEs**
- **All ADRs mild, except two moderate** (*)
- **All ADRs resolved spontaneously**
- **Inhalation well-tolerated**
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
-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

| ADRs | Part A (Single Dose) | | | | Part B (IDR) |
|---|---|---|---|---|---|
| | 2 mg (n=4) | 6 mg (n=6) | 12 mg (n=4) | 18 mg (n=4) | IDR[1] (n=4) |
| MedDRA Preferred Term | Number of Events | | | | |
| Abnormal dreams | | | | 1 | |
| Anxiety | | 1 | 1 | | |
| Clumsiness | | 1 | | | |
| Confusional state | | 1 | | | |
| Euphoric mood | | 1 | | | |
| Fatigue | | | | 1 | 1* |
| Feeling hot | | 1 | | | |
| Flashback | | | | 1 | |
| Hallucination | | | | 1 | |
| Head discomfort | | | | | 1 |
| Headache | | 2 | | 1 | 1 |
| Heart rate increased | | | 1* | | |
| Hyperacusis | | | | 1 | |
| Insomnia | | | | 1 | |
| Mental fatigue | | | | 1 | |
| Nausea | 2 | 1 | | 1 | 2 |
| Vision blurred | 1 | | | | |

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

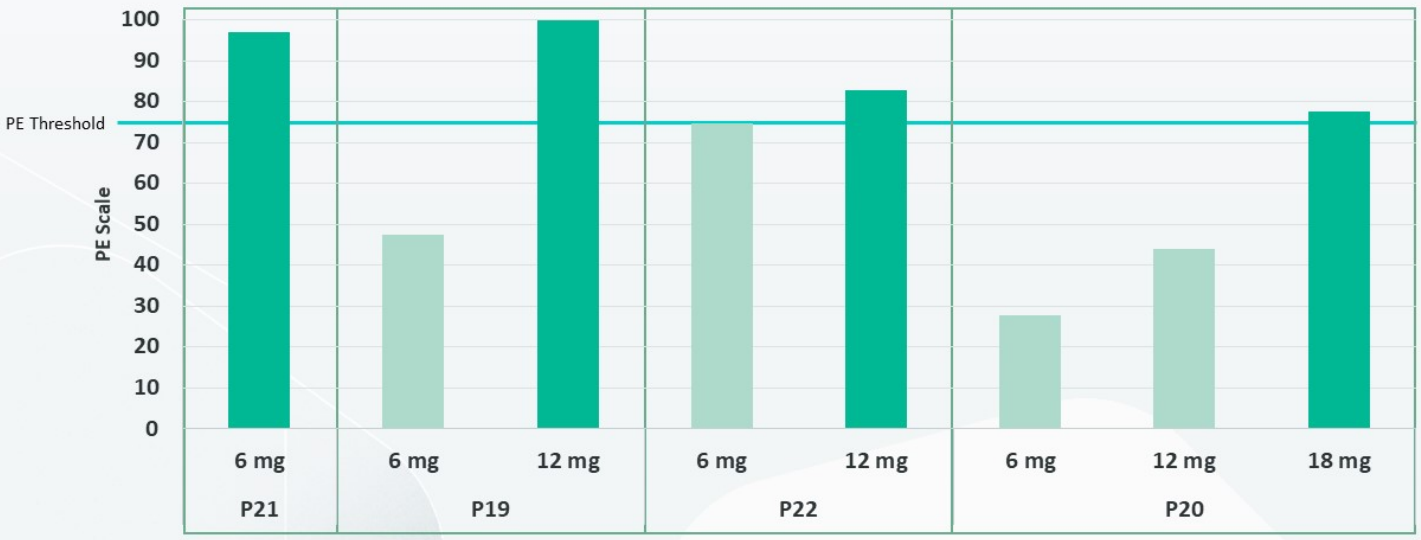
[1] *6 mg (n=1); 6-12 mg (n=2); 6-12-18 mg (n=1)*

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




*PE, Peak Experience*

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



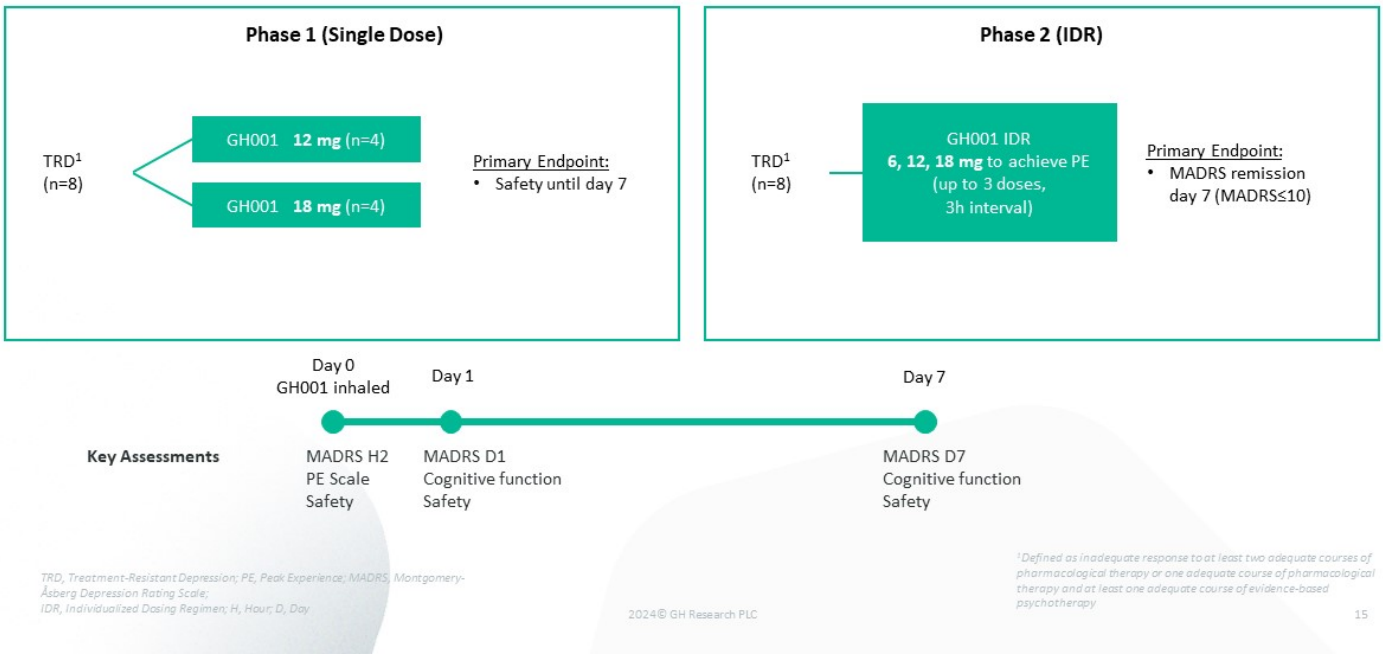

*PE, Peak Experience*

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

(Completed)

Clinicaltrials.gov ID: NCT04698603

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




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

*[1]Defined as inadequate response to at least two adequate courses of pharmacological therapy or one adequate course of pharmacological therapy and at least one adequate course of evidence-based psychotherapy*

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

Study Safety Group review

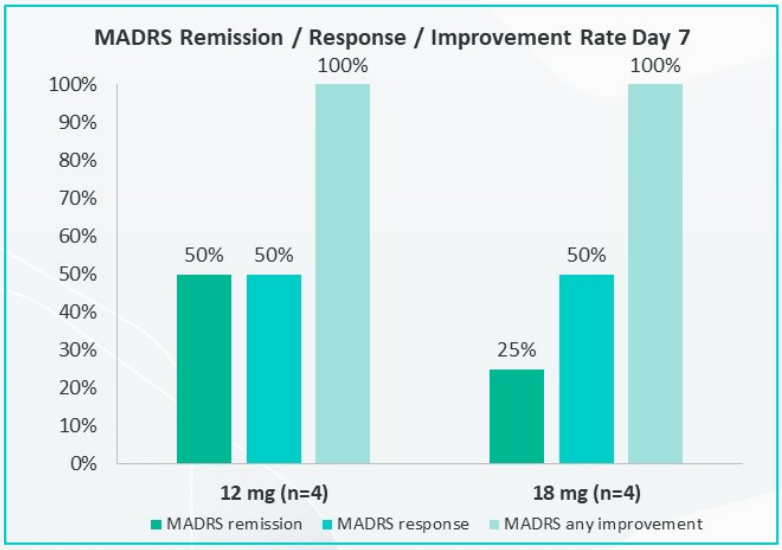
- **No SAEs**
- **All ADRs mild, except three moderate** (*)
- **All ADRs resolved spontaneously**
- **Inhalation well-tolerated**
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001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

| ADRs | Phase 1 (Single Dose) | | Phase 2 (IDR) |
|---|---|---|---|
| | 12 mg (n=4) | 18 mg (n=4) | IDR[1] (n=8) |
| MedDRA Preferred Term | Number of Events | | |
| Abdominal discomfort | | | 1 |
| Anxiety | | | 2 |
| Depressive symptom | | | 1* |
| Dizziness | 1 | | |
| Feeling abnormal | 1 | 1 | |
| Flashback | 1 | 1 | 2 |
| Headache | 2 | 1 | 3 |
| Muscle discomfort | | | 1 |
| Muscle spasms | | 1 | |
| Nausea | | | 2* |
| Paresthesia | | | 1 |
| Sensory disturbance | | | 3 |

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

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

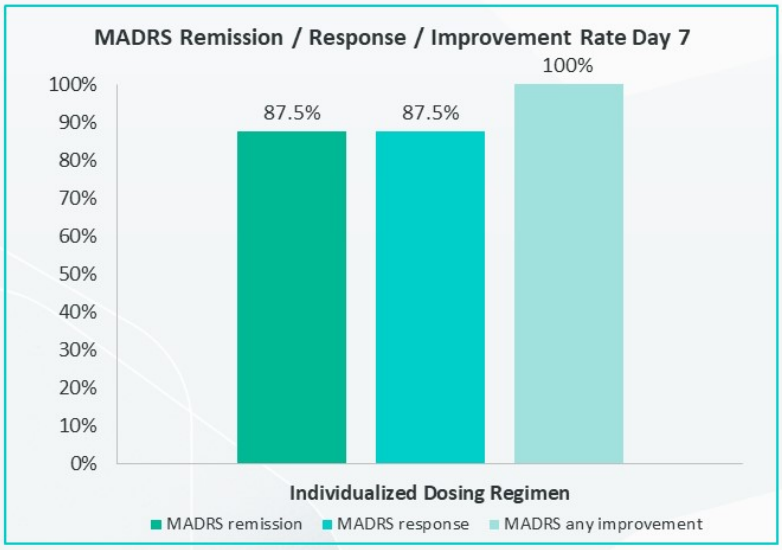
# Phase 1 (Single Dose) – Efficacy (MADRS)




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

*PE, Peak Experience; MADRS, Montgomery–Åsberg Depression Rating Scale*
*MADRS remission = MADRS of ≤10; MADRS response = Reduction of ≥50% from baseline in MADRS; MADRS any improvement = any reduction from baseline in MADRS*

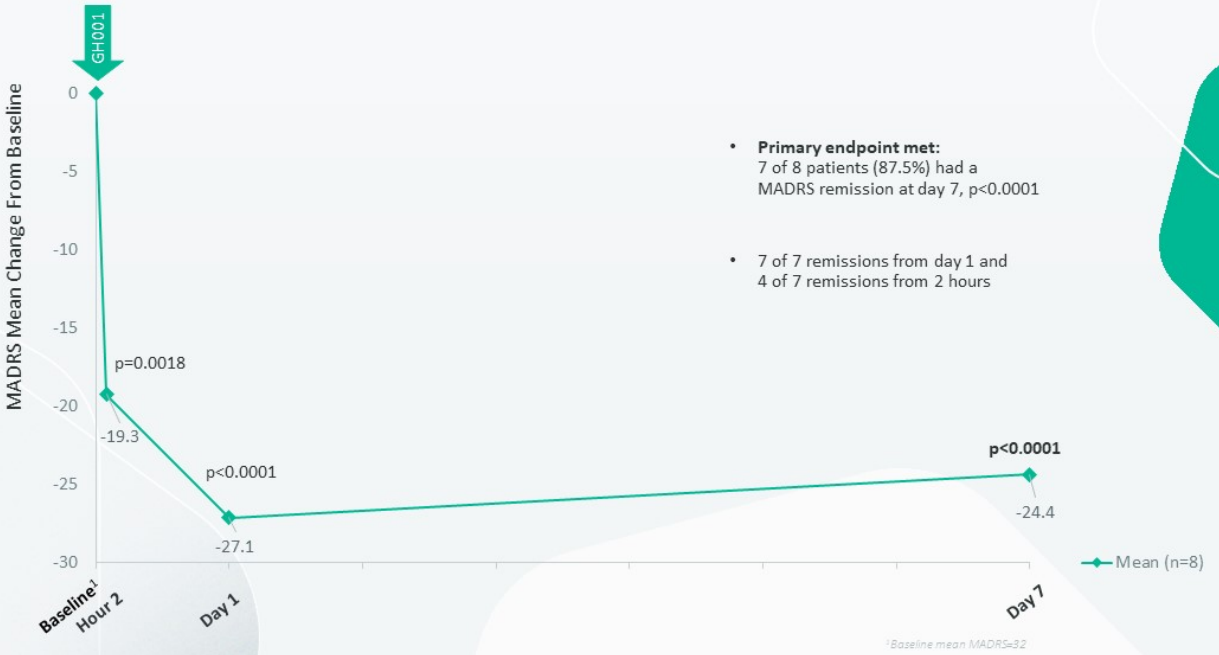
# Phase 2 (IDR) – Efficacy (MADRS)




- **Primary endpoint met:**
  7 of 8 patients (87.5%) had a MADRS remission at day 7, p<0.0001
- 7 of 8 patients had a PE and 6 of those had a MADRS remission at day 7

*PE, Peak Experience; MADRS, Montgomery–Åsberg Depression Rating Scale*
*MADRS remission = MADRS of ≤10; MADRS response = Reduction of ≥50% from baseline in MADRS; MADRS any improvement = any reduction from baseline in MADRS*

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




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

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

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

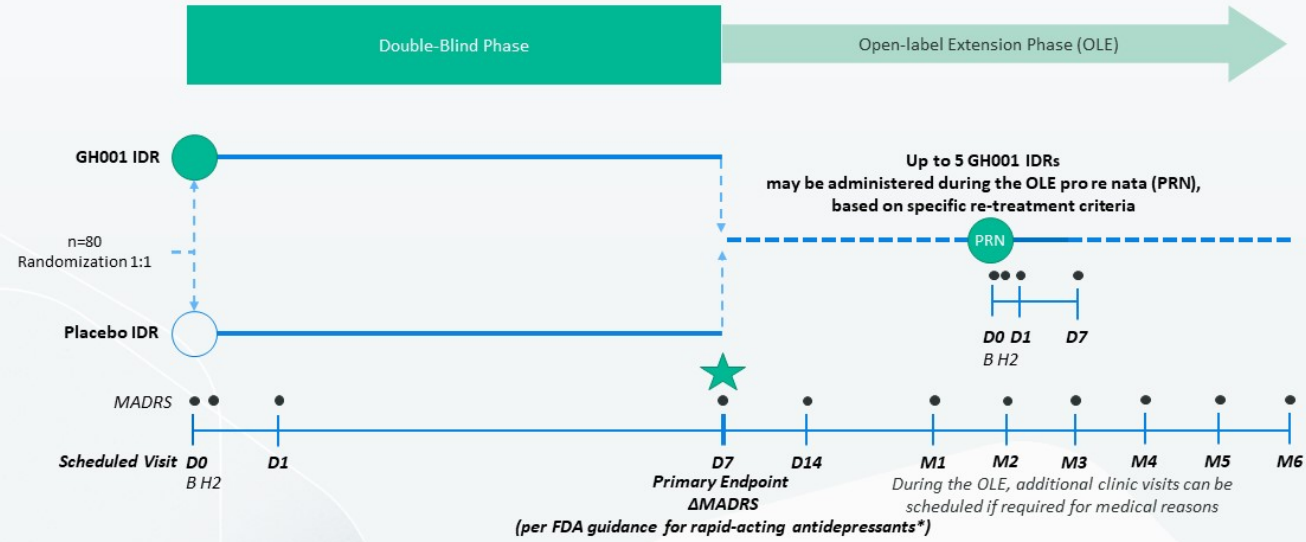
*PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen*

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

(Initiated)

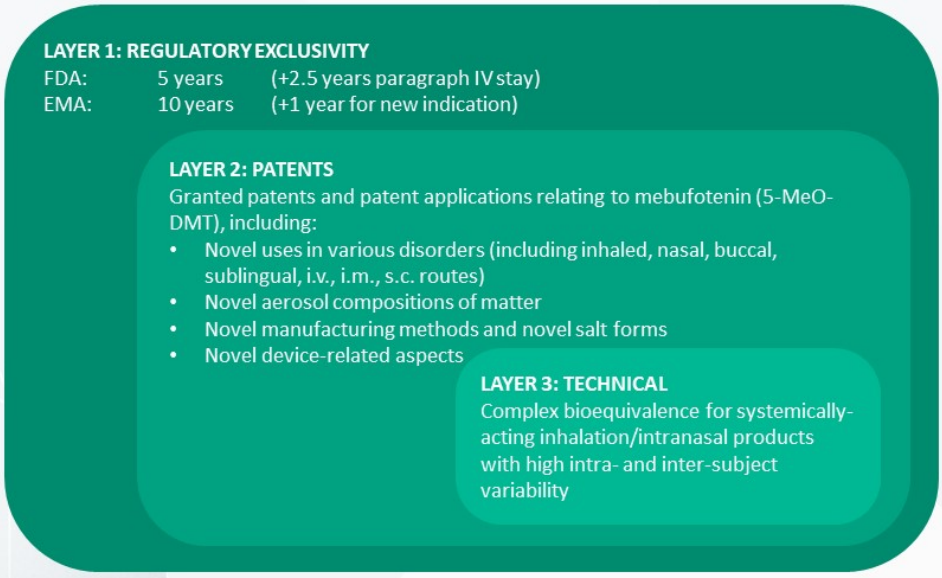
EudraCT Number: 2022-000574-26

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




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

# Three-Layer Protection Strategy



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MSc
Chairman of the Board, Co-founder

**Michael Forer**
BA, LLB
Vice-Chairman of the Board

**Dermot Hanley**
BSc, MBA
Board Member

**Duncan Moore**
MPhil, PhD
Board Member

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

**Velichka (Villy) Valcheva**
MD, MSc
Chief Medical Officer

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

**Aaron Cameron**
MSc, MBA
Chief Operating Officer

**Magnus Halle**
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UT Southwestern Medical Center

**Michael Thase**
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Professor of Psychiatry, Perelman School of Medicine
University of Pennsylvania

**Mark Zimmerman**
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Professor of Psychiatry and Human Behavior,
Brown University

**Eduard Vieta**
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# Anticipated Milestones and Financial Overview

### GH001

- Complete double-blind phase of European Phase 2b trial in TRD in Q3 2024 and provide top-line data in Q3 or Q4 2024; complete open-label extension phase in Q1 2025
- Complete Phase 2a trial in PPD and provide top-line data in Q3 2024
- Complete nonclinical studies and prepare device design verification information to support response to clinical hold on U.S. IND for GH001 administered using our proprietary aerosol delivery
- Initiate Phase 1 clinical pharmacology trial with proprietary aerosol delivery device in Europe

### GH002

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

### GH003

- Complete preclinical development

### Financial Overview

- Cash, cash equivalents, other financial assets and marketable securities were $214.0 million as of March 31, 2024
- We believe existing cash, cash equivalents, other financial assets and marketable securities will be sufficient to fund operating expenses and capital expenditure requirements into 2026

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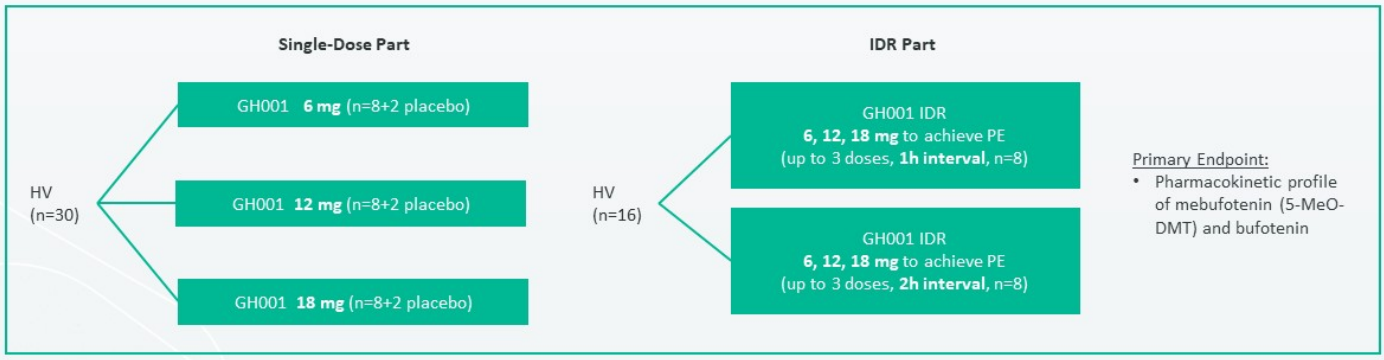
# Appendix
# Additional Completed Trials

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

(Completed)

Clinicaltrials.gov ID: NCT05163691

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





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

# Single Dose and IDR – Safety and Further Results

## Safety Review

- **No SAEs**
- **All ADRs mild**
- **All ADRs resolved spontaneously**
- **Inhalation well-tolerated**
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically relevant changes in ECG, safety laboratory analyses, peak flow, cognitive function or psychiatric symptom scales, including the C-SSRS

## Further Results

- Pharmacokinetic analyses and psychoactive effect assessments (PE Scale) support that an interval down to 1 hour between individual doses of the IDR is feasible for future clinical trials

| ADRs | Single-dose | | | | IDR | |
|---|---|---|---|---|---|---|
| | 6 mg (n=8) | 12 mg (n=8) | 18 mg (n=8) | Placebo (n=6) | 1h interval (n=8)[1] | 2h interval (n=8)[2] |
| MedDRA Preferred Term | Number of Events | | | | | |
| Abnormal dreams | | | | | | 1 |
| Chest discomfort | | 1 | | | | |
| Crying | | | 2 | | 2 | |
| Dizziness | | | 1 | | | |
| Dry mouth | 1 | | | | | |
| Dyskinesia | | | 1 | | | |
| Fatigue | | 1 | | | 2 | 1 |
| Headache | 3 | | 1 | | 1 | 1 |
| Hypoesthesia oral | | 1 | | | | |
| Paresthesia oral | | | | | | 1 |
| Retching | | | 1 | | | |
| Somnolence | | 1 | | | | |
| Tachycardia | | | 2 | | | |
| Tension | | | | | | 1 |
| Tremor | | | 1 | | | |

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

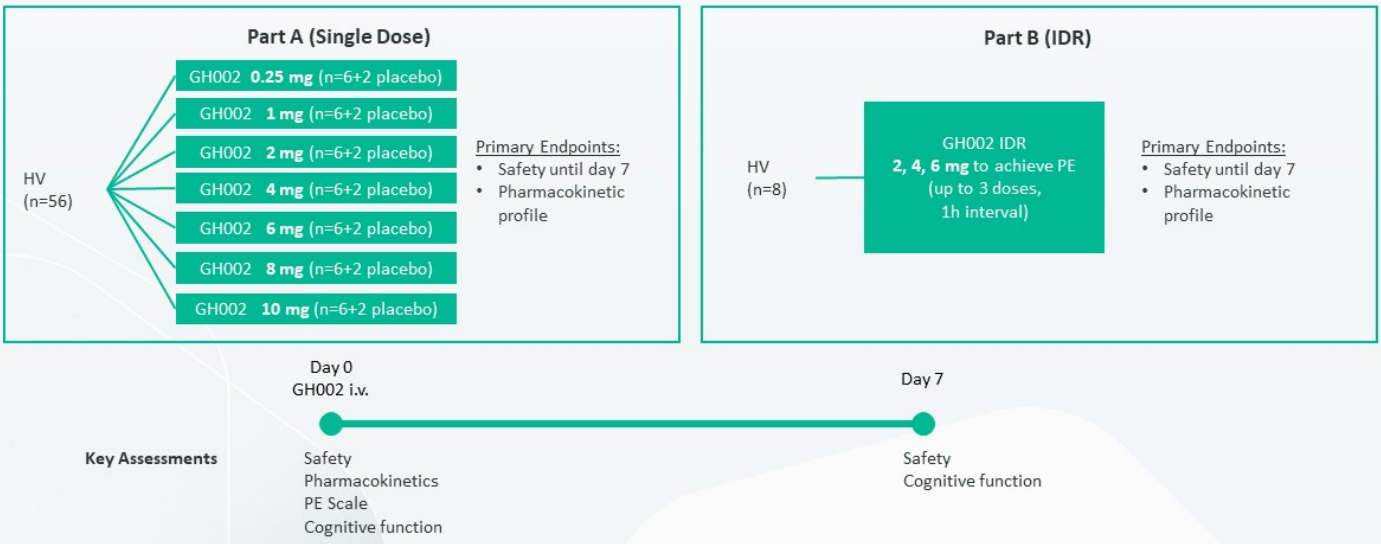
*[1] 6 mg (n=1), 6-12 mg (n=3); 6-12-18 mg (n=4)*
*[2] 6-12 mg (n=3); 6-12-18 mg (n=5)*

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

(Completed)

Clinicaltrials.gov ID: NCT05753956

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




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

# Single Dose and IDR – Safety and Further Results

## Safety review

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

## Further Results

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

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

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

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

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# Seeking Ultra-Rapid, Durable Remissions in Depression