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

February 29, 2024

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

DUBLIN, Ireland, Feb. 29, 2024 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported financial results for the year ended December 31, 2023, and provided updates on its business.

Business Updates

GH001 in Patients with TRD

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

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

GH001 in Patients with PPD and BDII

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

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

GH002

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

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

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

Intellectual Property Updates

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

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

Update on IND for GH001

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

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

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

Full Year 2023 Financial Highlights

Cash position

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

Research and development expenses

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

General and administrative expenses

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

Net loss

Net loss was $35.6 million, or $0.68 loss per share, for the year ended December 31, 2023, compared to $22.5 million, or $0.43 loss per share, for the full year 2022.

About GH Research PLC

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

About GH001

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

About GH002 and GH003

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

Forward-Looking Statements

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

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GH RESEARCH PLC
Consolidated Statement of Comprehensive Income (Unaudited)
(in thousands, except share and per share amounts)

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

GH RESEARCH PLC
Consolidated Balance Sheet (Unaudited)
(in thousands)

	At December 31, 2023 $'000	At December 31, 2022 $'000
ASSETS		
Current assets		
Cash and cash equivalents	78,420	165,955
Other financial assets	55,615	—
Marketable securities	27,525	—
Other current assets	2,529	2,586
Total current assets	**164,089**	**168,541**
Non-current assets		
Marketable securities	61,142	85,724
Property, plant and equipment	1,069	97
Total non-current assets	**62,211**	**85,821**
Total assets	**226,300**	**254,362**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	3,490	1,868
Lease liability	343	—
Other current liabilities	2,868	2,678
Total current liabilities	**6,701**	**4,546**

Non-current liabilities		
Lease liability	631	—
Total non-current liabilities	**631**	**—**
Total liabilities	**7,332**	**4,546**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,463	291,448
Other reserves	4,651	2,595
Foreign currency translation reserve	(10,507)	(13,035)
Accumulated deficit	(67,940)	(32,493)
Total equity	**218,968**	**249,816**
Total liabilities and equity	**226,300**	**254,362**