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

May 3, 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 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 03, 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

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.

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.

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GH RESEARCH PLC

Condensed Consolidated Interim Statement of Comprehensive Income (Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	**2023**
	$'000	**$'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**