GH Research Reports First Quarter 2025 Financial Results and Provides Business Updates

May 8, 2025

- Primary endpoint met in Phase 2b trial with GH001 in TRD demonstrating -15.5 Point placebo-adjusted MADRS reduction
- Full response to the IND hold on track for submission in mid-2025
- Cash, cash equivalents, other financial assets and marketable securities of $315.3 million as of March 31, 2025

DUBLIN, May 08, 2025 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the lives of patients by developing a practice-changing treatment in depression, today reported financial results for the quarter ended March 31, 2025, and provided updates on its business.

Business Updates

GH001 in Patients with TRD

Our multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of GH001 in 81 patients with treatment-resistant depression (TRD) (GH001-TRD-201) has completed, with last patient visit in the open-label extension (OLE) occurring in Q1 2025.

As recently announced, the trial met its primary endpoint with a significant placebo-adjusted Montgomery-Åsberg Depression Rating Scale (MADRS) reduction from baseline of -15.5 on Day 8 ($p<0.0001$). The majority of the patients treated with GH001 achieved remission (MADRS≤10) with a 57.5% remission rate on Day 8 compared with 0% in the placebo group ($p<0.0001$). All other secondary endpoints were met with clinically and statistically significant improvements on Day 8, compared with placebo. During the double-blind part, GH001 was well tolerated and no serious adverse events (SAE) were reported. There was no evidence of treatment-emergent suicidal ideation or behavior.

Safety analysis has not yet been completed for the OLE, but as of January 22, 2025, no SAEs were reported throughout the OLE. As of January 22, 2025, 77.8% of the OLE completers were in remission at the 6-month visit, with infrequent treatments. Patients who had remission on Day 8 after their first active treatment had a 91.7% remission rate at 6 months. Further clinical trial results from the double-blind part and open-label extension of the trial are expected to be provided at upcoming scientific conferences.

Proof-of-Concept Trials with GH001

We previously announced that the primary endpoint was met in two Phase 2a proof-of-concept trials with GH001, one in bipolar II disorder in patients with a current depressive episode (BDII) (GH001-BD-202) and, separately, another in patients with postpartum depression (PPD) (GH001-PPD-203). Close out activities and data analysis for both trials are ongoing and further clinical trial results are expected to be provided at upcoming scientific conferences.

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 recently announced the completion of all FDA requests to address IND hold. We are working to prepare the full response and are on track to submit in mid-2025.

GH001 Administered with Proprietary Aerosol Delivery Device

Our Phase 1 clinical pharmacology trial to evaluate our proprietary aerosol delivery device for administration of GH001 in healthy volunteers (GH001-HV-106) is ongoing in the United Kingdom. This trial is designed to support our global program for GH001, by bridging to the clinical data generated with the commercially available device that we have used in our clinical trials to date.

First Quarter 2025 Financial Highlights

Cash position

Cash, cash equivalents, other financial assets and marketable securities were $315.3 million as of March 31, 2025, compared to cash, cash equivalents, other financial assets and marketable securities of $182.6 million as of December 31, 2024. Gross proceeds from public offering in Q1 2025 were $150.0 million. Other financial assets are comprised of money market funds, and marketable securities are comprised of investment grade bonds.

Research and development expenses

R&D expenses were $7.9 million for the quarter ended March 31, 2025, compared to $8.7 million for same quarter in 2024. The decrease was primarily due to decreased clinical development and technical development activities and the recognition of a research and development tax credit, partly offset by increases in nonclinical activities and employee expenses.

General and administrative expenses

G&A expenses were $4.9 million for the quarter ended March 31, 2025, compared to $2.9 million for the same quarter in 2024. The increase is primarily due to an increase in professional fees and employee expenses.

Net loss

Net loss was $10.8 million, or $0.19 loss per share, for the quarter ended March 31, 2025, compared to $7.7 million, or $0.15 loss per share, for the same quarter in 2024.

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 therapies for the treatment of patients with treatment-resistant depression (TRD).

About GH001

Our lead product candidate, GH001, is formulated for mebufotenin administration via a proprietary inhalation approach. Based on the observed clinical activity in our Phase 2b GH001-TRD-201 trial, where the primary endpoint was met with a MADRS reduction from baseline of -15.5 points compared with placebo on Day 8 ($p<0.0001$), we believe that GH001 has potential to change the way TRD is treated today.

About GH002

GH002 is our mebufotenin product candidate formulated for administration via a proprietary intravenous approach. We have completed a Phase 1 trial of GH002 in healthy volunteers.

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 Loss (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2025 $'000	**2024 $'000**
Operating expenses		
Research and development	(7,852)	(8,658)
General and administration	(4,880)	(2,870)
Loss from operations	**(12,732)**	**(11,528)**
Finance income	2,759	2,670
Finance expense	(178)	(179)
Movement of expected credit loss	(19)	50
Foreign exchange (loss)/gain	(642)	1,321
Total other income	**1,920**	**3,862**
Loss before tax	**(10,812)**	**(7,666)**
Tax charge/(credit)	-	-
Loss for the period	**(10,812)**	**(7,666)**
Other comprehensive income/(expense)		
Items that may be reclassified to profit or loss		
Fair value movement on marketable securities	60	(543)

Currency translation adjustment	532	(1,289)
Total comprehensive loss for the period	**(10,220)**	**(9,498)**
Attributable to owners:		
Loss for the period	(10,812)	(7,666)
Total comprehensive loss for the period	(10,220)	(9,498)
Loss per share		
Basic and diluted loss per share (in USD)	(0.19)	(0.15)

GH RESEARCH PLC

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At March 31, 2025 $'000	At December 31, 2024 $'000
ASSETS		
Current assets		
Cash and cash equivalents	244,954	100,791
Other financial assets	12,558	19,387
Marketable securities	33,835	29,146
Other current assets	3,321	4,901
Total current assets	**294,668**	**154,225**
Non-current assets		
Marketable securities	23,991	33,300
Property, plant and equipment	705	748
Other non-current assets	1,090	-
Total non-current assets	**25,786**	**34,048**
Total assets	**320,454**	**188,273**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	4,774	3,741
Lease liability	336	255
Other current liabilities	4,808	4,957
Total current liabilities	**9,918**	**8,953**
Non-current liabilities		
Lease liability	322	369
Total non-current liabilities	**322**	**369**
Total liabilities	**10,240**	**9,322**
Equity attributable to owners		
Share capital	1,551	1,301
Additional paid-in capital	431,061	291,463
Other reserves	6,671	5,194
Foreign currency translation reserve	(12,029)	(12,561)
Accumulated deficit	(117,040)	(106,446)
Total equity	**310,214**	**178,951**
Total liabilities and equity	**320,454**	**188,273**