GH Research Reports Full Year 2024 Financial Results and Provides Business Updates

February 27, 2025

- Phase 2b clinical trial of GH001 in patients with treatment-resistant depression on track for completion of last patient visit in the open-label extension in Q1 2025
- Phase 1 clinical trial to evaluate proprietary aerosol delivery device in healthy volunteers is ongoing in the UK
- Full response to the IND hold on track for submission in mid-2025
- Cash, cash equivalents, other financial assets and marketable securities of $182.6 million as of December 31, 2024
- Net cash proceeds of an additional $139.8 million from public offering received in February 2025

DUBLIN, Feb. 27, 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 year ended December 31, 2024, and provided updates on its business.

Business Updates

GH001 in Patients with TRD

GH001, our proprietary inhalable mebufotenin 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 recently announced that 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 open label extension (OLE) as it remains ongoing, but as of January 22, 2025, no SAEs have been 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.

The OLE is on track for completion of last patient visit in the open-label extension in Q1 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.

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 have recently announced the completion of all FDA requests to address IND hold.

The requested additional inhalation toxicology study in a non-rodent species has now been completed. The pathology report concludes that there are no histology findings in the respiratory tract of any dogs at any dose level evaluated in the study.

The requested additional inhalation toxicology study in rats has now been completed which showed histology findings consistent with our previously completed study in rats. This supports our position that these findings are rat specific.

Based on previously announced FDA interactions, the response to their request for additional device design verification information is being prepared and, together with the completion of the inhalation toxicology studies, provides the final piece of information requested by the agency.

We are preparing to engage with the FDA in advance of providing a full response to the IND hold which we are on track to submit in mid-2025.

Proof-of-Concept Trials with GH001

We have recently announced the completion of and results from two Phase 2a proof-of-concept (POC) trials with GH001 in postpartum depression (PPD) and bipolar II disorder with a current major depressive episode (BDII).

The primary endpoint of the Phase 2a POC trial for GH001 in PPD was met with a significant reduction from baseline of –35.4 points (96.3%) in MADRS total score on Day 8 after administration of GH001 ($p<0.0001$, $n=10$). On Day 8, 100% of patients were in remission (MADRS ≤ 10). GH001 was well tolerated and no treatment-related serious adverse events were reported. All treatment-emergent adverse events (TEAEs) were mild or moderate.

The primary endpoint of the Phase 2a POC trial for GH001 in BDII was met with a significant reduction from baseline of –16.8 points (51.9%) in MADRS total score on Day 8 after administration of GH001 (p=0.0099, n=6). On Day 8, 33.3% of patients were in remission (MADRS ≤ 10). GH001 was well tolerated and no treatment-related serious adverse events were reported. The majority of TEAEs were mild or moderate and there were no reported TEAEs of hypomania or mania.

Full Year 2024 Financial Highlights

Cash position

Cash, cash equivalents, other financial assets and marketable securities were $182.6 million as of December 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.

Research and development expenses

R&D expenses were $35.0 million for the year ended December 31, 2024, compared to $29.8 million for the full year 2023. The increase is primarily due to increased expenses relating to clinical development activities including clinical trial and non-clinical activities. These increases have been partly offset by the recognition of a research and development tax credit and a decrease in technical development expenses. Employee expenses also increased primarily due to the hiring of personnel to support our research and development activities.

General and administrative expenses

G&A expenses were $15.3 million for the year ended December 31, 2024, compared to $11.4 million for the full year 2023. The increase was primarily due to higher professional fees, which has been partly offset by a decrease in insurance costs. Employee expenses increased due to an increase in headcount to support our growth initiatives.

Net loss

Net loss was $39.0 million, or $0.75 loss per share, for the year ended December 31, 2024, compared to $35.6 million, or $0.68 loss per share, for the full year 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 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.

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

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

	Year ended December 31,	
	2024	**2023**
	$'000	**$'000**
Operating expenses		

Research and development	(35,016)	(29,821)
General and administration	(15,296)	(11,401)
Loss from operations	**(50,312)**	**(41,222)**
Finance income	9,873	8,978
Finance expense	(717)	(723)
Movement of expected credit loss	66	1
Foreign exchange gain/(loss)	2,129	(2,621)
Total other income	**11,351**	**5,635**
Loss before tax	**(38,961)**	**(35,587)**
Tax charge/(credit)	—	—
Loss for the year	**(38,961)**	**(35,587)**
Other comprehensive (expense)/income		
Items that may be reclassified to profit or loss		
Fair value movement on marketable securities	(173)	(95)
Currency translation adjustment	(2,054)	2,528
Total comprehensive loss for the year	**(41,188)**	**(33,154)**
Attributable to owners:		
Loss for the year	(38,961)	(35,587)
Total comprehensive loss for the year	(41,188)	(33,154)
Loss per share		
Basic and diluted loss per share (in USD)	(0.75)	(0. 68)

GH RESEARCH PLC
Consolidated Balance Sheet
(in thousands)

	At December 31,	
	2024	**2023**
	$'000	**$'000**
ASSETS		
Current assets		
Cash and cash equivalents	100,791	78,420
Other financial assets	19,387	55,615
Marketable securities	29,146	27,525
Other current assets	4,901	2,529
Total current assets	**154,225**	**164,089**
Non-current assets		
Marketable securities	33,300	61,142
Property, plant and equipment	748	1,069
Total non-current assets	**34,048**	**62,211**
Total assets	**188,273**	**226,300**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	3,741	3,490
Lease liability	255	343
Other current liabilities	4,957	2,868
Total current liabilities	**8,953**	**6,701**
Non-current liabilities		
Lease liability	369	631
Total non-current liabilities	**369**	**631**
Total liabilities	**9,322**	**7,332**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,463	291,463
Other reserves	5,194	4,651
Foreign currency translation reserve	(12,561)	(10,507)
Accumulated deficit	(106,446)	(67,940)

Total equity	**178,951**	**218,968**
Total liabilities and equity	**188,273**	**226,300**