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

November 6, 2025

- Engagement with FDA on GH001 IND complete response ongoing
- Full dataset from the Phase 2b clinical trial of GH001 in TRD reported in July 2025
- Long-term clinical data on safety and efficacy from Open-Label Extension presented at ECNP in October 2025
- Cash, cash equivalents and marketable securities of $293.9 million as of September 30, 2025

DUBLIN, Nov. 06, 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 September 30, 2025, and provided updates on its business.

Business Updates

GH001 Update

In July 2025, we announced that we received a communication from the U.S. Food and Drug Administration (FDA) relating to our complete response to the clinical hold of our Investigational New Drug Application (IND) for GH001, with only one hold topic remaining.

We are actively working with experts to address the remaining topic and engagement with the FDA on our IND complete response is ongoing.

Final Data from Fully Completed Phase 2b TRD

In July 2025, we reported on the full dataset from the Phase 2b clinical trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201).

The primary endpoint was met with a highly significant placebo adjusted reduction from baseline of -15.5 points in Montgomery-Åsberg Depression Rating Scale (MADRS) total score on Day 8 ($p<0.0001$).

The full analysis of the open-label extension (OLE) confirms a 73% remission rate at 6 months with infrequent treatment visits and no mandated psychotherapeutic intervention.

There were no treatment-related serious adverse events during the full 6-month duration of the trial. No treatment-emergent events of suicidal intent or suicidal behavior occurred during the 6-month duration of the trial.

In October 2025, we attended the 38th Annual European College of Neuropsychopharmacology Congress (ECNP) in Amsterdam, the Netherlands. At the conference, the long-term safety and efficacy data from the OLE of our randomized, double-blind, placebo-controlled Phase 2b clinical trial with GH001 in patients with TRD (GH001-TRD-201) were presented at the Novel Therapies Symposium by Professor Wiesław J. Cubała, MD, PhD, Department of Psychiatry, Faculty of Medicine, Medical University of Gdańsk. In addition, at the same conference, two posters were exhibited on the OLE safety and tolerability data as well as data on the psychoactive effects of GH001 in patients with TRD from GH001-TRD-201.

We continue to expect to initiate our global pivotal program in 2026.

Third Quarter 2025 Financial Highlights

Cash position

Cash, cash equivalents and marketable securities were $293.9 million as of September 30, 2025, compared to cash, cash equivalents, other financial assets and marketable securities of $182.6 million as of December 31, 2024. 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 $10.6 million for the quarter ended September 30, 2025, compared to $8.4 million for the same quarter in 2024. The increase is primarily due to increased expenses relating to technical development activities and employee expenses, partly offset by a decrease in clinical development expenses.

General and administrative expenses

G&A expenses were $6.0 million for the quarter ended September 30, 2025, compared to $4.2 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 $14.0 million, or $0.23 loss per share, for the quarter ended September 30, 2025, compared to $12.1 million, or $0.23 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 lives of patients by developing a practice-changing treatment in depression. 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). Based on the observed clinical activity in our Phase 2b 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 our mebufotenin product candidates have the potential to change the way TRD is treated today.

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 the 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 the clinical hold on GH001, including plans and expectations for progressing any nonclinical programs and any other work needed to lift the continuing clinical hold and the timing required for the FDA to lift such clinical hold; our targets regarding the initiation of our first global pivotal program; our business strategy, product candidates and cash runway, 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, the risk that the FDA does not accept our responses to the clinical hold issues and that we will be unable to fully address the FDA's concerns and lift the clinical hold on GH001; the risk that we may not be able to submit an IND for GH002, or to commence clinical trials in the United States on the timelines we are targeting; and those other risks described in our filings with the U.S. Securities and Exchange Commission from time to time. No assurance can be given that such future results, plans, or expectations or targets 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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Condensed Consolidated Interim Statement of Comprehensive Loss (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2025 $'000	2024 $'000	2025 $'000	2024 $'000
Operating expenses				
Research and development	(10,567)	(8,397)	(27,377)	(26,810)
General and administration	(5,998)	(4,224)	(16,624)	(10,558)
Loss from operations	**(16,565)**	**(12,621)**	**(44,001)**	**(37,368)**
Finance income	2,783	2,535	8,616	7,760
Finance expense	(21)	(181)	(373)	(538)
Movement of expected credit loss	30	(2)	24	45
Foreign exchange (loss)/gain	(247)	(1,845)	1,613	(58)
Total other income	**2,545**	**507**	**9,880**	**7,209**
Loss before tax	**(14,020)**	**(12,114)**	**(34,121)**	**(30,159)**
Tax charge/(credit)	-	-	-	-
Loss for the period	**(14,020)**	**(12,114)**	**(34,121)**	**(30,159)**
Other comprehensive (expense)/income				
Items that may be reclassified to profit or loss				
Fair value movement on marketable securities	(33)	908	(55)	258
Currency translation adjustment	(63)	1,622	926	(113)
Total comprehensive loss for the period	**(14,116)**	**(9,584)**	**(33,250)**	**(30,014)**

Attributable to owners:

Loss for the period	(14,020)	(12,114)	(34,121)	(30,159)
Total comprehensive loss for the period	(14,116)	(9,584)	(33,250)	(30,014)
Loss per share				
Basic and diluted loss per share (in USD)	(0.23)	(0.23)	(0.56)	(0.58)

GH RESEARCH PLC

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At September 30, 2025 $'000	At December 31, 2024 $'000
ASSETS		
Current assets		
Cash and cash equivalents	249,654	100,791
Other financial assets	-	19,387
Marketable securities	38,853	29,146
Other current assets	6,283	4,901
Total current assets	**294,790**	**154,225**
Non-current assets		
Marketable securities	5,378	33,300
Property, plant and equipment	692	748
Other non-current assets	1,162	-
Total non-current assets	**7,232**	**34,048**
Total assets	**302,022**	**188,273**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	3,837	3,741
Lease liability	365	255
Other current liabilities	6,206	4,957
Total current liabilities	**10,408**	**8,953**
Non-current liabilities		
Lease liability	217	369
Total non-current liabilities	**217**	**369**
Total liabilities	**10,625**	**9,322**
Equity attributable to owners		
Share capital	1,551	1,301
Additional paid-in capital	431,061	291,463
Other reserves	10,708	5,194
Foreign currency translation reserve	(11,635)	(12,561)
Accumulated deficit	(140,288)	(106,446)
Total equity	**291,397**	**178,951**
Total liabilities and equity	**302,022**	**188,273**