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

August 7, 2025

- Global pivotal program initiation on track for 2026
- Engagement with FDA on GH001 IND complete response ongoing
- The fully completed Open-Label Extension analysis confirms a 73% remission rate at 6 months with infrequent treatment visits and no psychotherapy
- Treatment was well tolerated and no treatment related serious adverse events were reported. There was no evidence of treatment-emergent suicidal ideation or behavior
- Cash, cash equivalents and marketable securities of $308.7 million as of June 30, 2025

DUBLIN, Aug. 07, 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 June 30, 2025, and provided updates on its business.

Business Updates

GH001 Update

We recently 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.

Engagement with the FDA on our IND complete response is ongoing. We are actively working on a plan with our respiratory, toxicology and regulatory experts to address the remaining topic.

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.

Final Data from Fully Completed Phase 2b TRD

We recently 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.

Safety analysis confirmed that 100% of patients from the double-blind part continued in the OLE and there were no treatment related serious adverse events across the full 6-month duration of the trial. No treatment-emergent events of suicidal intent or suicidal behavior occurred throughout the 6-month duration of the trial and lower rates of suicidal ideation were observed in comparison to baseline at any timepoint assessed during the study.

In May 2025, we attended the American Society of Clinical Psychopharmacology Annual Meeting (ASCP) in Arizona, United States from May 27 – 30. We were accepted for a Pharmaceutical Pipeline Presentation where Professor Michael E. Thase, MD, Professor of Psychiatry, Perelman School of Medicine, University of Pennsylvania presented clinical data from a randomized, double-blind, placebo-controlled Phase 2b clinical trial with GH001 in patients with TRD (GH001-TRD-201). Additionally, two late-breaking posters presenting safety and tolerability data from the double-blind part of the Phase 2b trial in TRD as well as data from a proof-of-concept trial with GH001 in postpartum depression were exhibited.

GH002 Update

We have previously announced the completion of a Phase 1, dose-ranging clinical pharmacology trial of GH002, our proprietary intravenous mebufotenin HBr product candidate, in healthy volunteers.

Top-line results demonstrate that GH002 was well-tolerated with no severe or serious adverse events and produced ultra-rapid psychoactive effects. The pharmacokinetic profile of GH002 was equivalent to that of GH001. We expect to submit an IND with the FDA for GH002 in Q4 2025.

Global Pivotal Program Plans

Pivotal program planning has been ongoing since Q1 2025:

- We have established a steering committee with KOLs to review Phase 2b results and assist with design of pivotal program;
- CRO and site selection process is ongoing and we are scaling our team for efficient execution; and

- We are in the process of getting regulatory input on phase 3 requirements and preparation for end-of-phase 2 meeting is underway.

On that basis, we expect to initiate our global pivotal program in 2026.

Second Quarter 2025 Financial Highlights

Cash position

Cash, cash equivalents and marketable securities were $308.7 million as of June 30, 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 $9.0 million for the quarter ended June 30, 2025, compared to $9.8 million for same quarter in 2024. The decrease is primarily due to decreased expenses relating to clinical development activities and the recognition of a research and development tax credit, partly offset by an increase in technical development expenses and employee expenses.

General and administrative expenses

G&A expenses were $5.7 million for the quarter ended June 30, 2025, compared to $3.5 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 $9.3 million, or $0.15 loss per share, for the quarter ended June 30, 2025, compared to $10.4 million, or $0.20 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 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 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 plans and expectations with respect to progressing development of GH002 including with respect to the timing, scope and likelihood of IND submission and approval with the FDA; our targets regarding the initiation of our first global pivotal program; 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 nonclinical studies and clinical trials, regulatory submissions and approvals and their effects on our business strategy, our expectations related to commencing trials in the US, 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, 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; those described in our filings with the U.S. Securities and Exchange Commission. 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.

Investor Relations:

Julie Ryan
GH Research PLC
investors@ghres.com

GH RESEARCH PLC

Condensed Consolidated Interim Statement of Comprehensive Loss (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2025 $'000	2024 $'000	2025 $'000	2024 $'000
Operating expenses				
Research and development	(8,958)	(9,755)	(16,810)	(18,413)
General and administration	(5,746)	(3,464)	(10,626)	(6,334)
Loss from operations	**(14,704)**	**(13,219)**	**(27,436)**	**(24,747)**
Finance income	3,074	2,555	5,833	5,225
Finance expense	(174)	(178)	(352)	(357)
Movement of expected credit loss	13	(3)	(6)	47
Foreign exchange gain	2,502	466	1,860	1,787
Total other income	**5,415**	**2,840**	**7,335**	**6,702**
Loss before tax	**(9,289)**	**(10,379)**	**(20,101)**	**(18,045)**
Tax charge/(credit)	-	-	-	-
Loss for the period	**(9,289)**	**(10,379)**	**(20,101)**	**(18,045)**
Other comprehensive (expense)/income				
Items that may be reclassified to profit or loss				
Fair value movement on marketable securities	(82)	(107)	(22)	(650)
Currency translation adjustment	457	(446)	989	(1,735)
Total comprehensive loss for the period	**(8,914)**	**(10,932)**	**(19,134)**	**(20,430)**
Attributable to owners:				
Loss for the period	(9,289)	(10,379)	(20,101)	(18,045)
Total comprehensive loss for the period	(8,914)	(10,932)	(19,134)	(20,430)
Loss per share				
Basic and diluted loss per share (in USD)	(0.15)	(0.20)	(0.33)	(0.35)

GH RESEARCH PLC

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At June 30,	At December 31,
	2025 $'000	2024 $'000
ASSETS		
Current assets		
Cash and cash equivalents	253,873	100,791
Other financial assets	-	19,387
Marketable securities	37,662	29,146
Other current assets	2,345	4,901
Total current assets	**293,880**	**154,225**
Non-current assets		
Marketable securities	17,151	33,300
Property, plant and equipment	739	748
Other non-current assets	1,658	-
Total non-current assets	**19,548**	**34,048**
Total assets	**313,428**	**188,273**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	3,447	3,741
Lease liability	364	255
Other current liabilities	6,155	4,957
Total current liabilities	**9,966**	**8,953**
Non-current liabilities		
Lease liability	283	369
Total non-current liabilities	**283**	**369**

Total liabilities	**10,249**	**9,322**
Equity attributable to owners		
Share capital	1,551	1,301
Additional paid-in capital	431,061	291,463
Other reserves	8,407	5,194
Foreign currency translation reserve	(11,572)	(12,561)
Accumulated deficit	(126,268)	(106,446)
Total equity	**303,179**	**178,951**
Total liabilities and equity	**313,428**	**188,273**