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

November 14, 2024

- Phase 2b clinical trial of GH001 in patients with treatment-resistant depression completed enrolment of the double-blind phase in Q3 2024
- Phase 1 clinical trial to evaluate proprietary aerosol delivery device in healthy volunteers is ongoing in the UK
- Cash, cash equivalents, other financial assets and marketable securities of $193.8 million

DUBLIN, Nov. 14, 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 third quarter ended September 30, 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). GH001 is administered on a single dosing day, without mandated in-trial psychotherapeutic intervention, consistent with our previously completed trials.

We completed enrolment of the double-blind phase in the third quarter of 2024, with top-line data expected to be available in the fourth quarter of 2024 or the first quarter of 2025. This trial includes a 6-month open-label extension which is on track for completion in the first quarter of 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 was placed on clinical hold by the U.S. Food and Drug Administration (FDA). Based on interactions with the FDA, we believe we have a path to respond on the device element of the hold. The nonclinical studies to address the inhalation toxicology aspect are ongoing.

Proof-of-Concept Trials with GH001

GH001 is being investigated in a proof-of-concept clinical trial in bipolar II disorder in patients with a current depressive episode (BDII) (GH001-BD-202). While increasing the number of sites has improved enrolment, recruitment has continued to be difficult and, for these reasons, the trial will end in the fourth quarter of 2024.

GH001 is also being investigated in a proof-of-concept clinical trial in patients with postpartum depression (PPD) (GH001-PPD-203). We continue to expect GH001-PPD-203 completion in the fourth quarter of 2024.

Third Quarter 2024 Financial Highlights

Cash position

Cash, cash equivalents, other financial assets and marketable securities were $193.8 million as of September 30, 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 $8.4 million for the quarter ended September 30, 2024, compared to $7.1 million for same quarter in 2023. The increase is primarily due to increased expenses relating to our clinical development activities including clinical trials and nonclinical activities.

General and administrative expenses

G&A expenses were $4.2 million for the quarter ended September 30, 2024, compared to $2.6 million for the same quarter in 2023. The increase is primarily due to an increase in professional fees and employee expenses in our general and administrative functions to support our growth initiatives.

Net loss

Net loss was $12.1 million, or $0.23 loss per share, for the quarter ended September 30, 2024, compared to $5.6 million, or $0.11 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.

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 related to addressing 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:

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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 September 30,		Nine months ended September 30,	
	2024 $'000	2023 $'000	2024 $'000	2023 $'000
Operating expenses				
Research and development	(8,397)	(7,088)	(26,810)	(21,570)
General and administration	(4,224)	(2,631)	(10,558)	(8,493)
Loss from operations	**(12,621)**	**(9,719)**	**(37,368)**	**(30,063)**
Finance income	2,535	2,438	7,760	6,049
Finance expense	(181)	(184)	(538)	(534)
Movement of expected credit loss	(2)	(17)	45	1
Foreign exchange (loss)/gain	(1,845)	1,833	(58)	232
Total other income	**507**	**4,070**	**7,209**	**5,748**
Loss before tax	**(12,114)**	**(5,649)**	**(30,159)**	**(24,315)**
Tax charge/(credit)	-	-	-	-
Loss for the period	**(12,114)**	**(5,649)**	**(30,159)**	**(24,315)**
Other comprehensive income/(expense)				
Items that may be reclassified to profit or loss				
Fair value movement on marketable securities	908	(428)	258	(1,216)
Currency translation adjustment	1,622	(1,780)	(113)	(161)
Total comprehensive loss for the period	**(9,584)**	**(7,857)**	**(30,014)**	**(25,692)**
Attributable to owners:				
Loss for the period	(12,114)	(5,649)	(30,159)	(24,315)
Total comprehensive loss for the period	(9,584)	(7,857)	(30,014)	(25,692)

Loss per share				
Basic and diluted loss per share (in USD)	(0.23)	(0.11)	(0.58)	(0.47)

GH RESEARCH PLC
Condensed Consolidated Interim Balance Sheet (Unaudited)
(in thousands)

	At September 30, 2024 $'000	At December 31, 2023 $'000
ASSETS		
Current assets		
Cash and cash equivalents	90,059	78,420
Other financial assets	32,517	55,615
Marketable securities	27,461	27,525
Other current assets	4,909	2,529
Total current assets	**154,946**	**164,089**
Non-current assets		
Marketable securities	43,806	61,142
Property, plant and equipment	859	1,069
Total non-current assets	**44,665**	**62,211**
Total assets	**199,611**	**226,300**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	2,946	3,490
Lease liability	275	343
Other current liabilities	6,566	2,868
Total current liabilities	**9,787**	**6,701**
Non-current liabilities		
Lease liability	458	631
Total non-current liabilities	**458**	**631**
Total liabilities	**10,245**	**7,332**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,463	291,463
Other reserves	4,866	4,651
Foreign currency translation reserve	(10,620)	(10,507)
Accumulated deficit	(97,644)	(67,940)
Total equity	**189,366**	**218,968**
Total liabilities and equity	**199,611**	**226,300**