GH Research Reports Third Quarter Financial Results and Provides Business Updates

November 9, 2023

DUBLIN, Ireland, Nov. 09, 2023 (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, 2023, and provided business updates.

Third Quarter 2023 Financial Highlights

Cash position

Cash, cash equivalents, other financial assets and marketable securities were $228.7 million as of September 30, 2023, compared to cash, cash equivalents and marketable securities of $251.7 million as of December 31, 2022. Cash equivalents and other financial assets comprise money market funds. Marketable securities comprise investment grade bonds. We believe that our existing cash, cash equivalents, other financial assets and marketable securities will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2026.

Research and development expenses

R&D expenses were $7.1 million for the quarter ended September 30, 2023, compared to $4.6 million for the same quarter in 2022. The increase was primarily due to increased activities relating to our clinical trials and increases in employee expenses to support these activities.

General and administrative expenses

G&A expenses were $2.6 million for the quarter ended September 30, 2023, compared to $2.0 million for the same quarter in 2022. The increase was primarily due to an increase in professional fees and employee expenses offset by lower insurance costs.

Net loss

Net loss was $5.6 million, or $0.11 loss per share, for the quarter ended September 30, 2023, compared to a net loss of $0.4 million, or $0.01 loss per share, for the same quarter in 2022.

Business Updates

GH001 in TRD

GH001, our proprietary inhalable mebufotenin (5-MeO-DMT) product candidate, is currently being investigated in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in patients with treatment-resistant depression (TRD) (GH001-TRD-201). The trial has been approved in seven European countries and is expected to recruit approximately 80 patients across approximately 20 sites. Patient enrollment is on schedule and we continue to expect completion of the double-blind phase of this trial in the third quarter of 2024, with availability of top-line data in the third or the fourth quarter of 2024. In this trial, GH001 is administered using an externally-sourced inhalation device.

Update on IND for GH001

In August 2023, we submitted an Investigational New Drug Application (IND) for GH001 with the U.S. Food and Drug Administration (FDA), with the purpose to initiate a Phase 1 healthy volunteer clinical pharmacology trial, where GH001 is administered using our proprietary aerosol delivery device (GH001-HV-106). The trial is designed to support bridging to the clinical data generated with the third-party device we currently use in our clinical trials. As previously announced in September, the FDA advised that it had placed our IND on clinical hold.

We have now received a formal clinical hold letter from the FDA. To remove the hold, they have requested that we provide (i) an inhalation toxicology study in a non-rodent species and an additional inhalation toxicology study in rats, related to respiratory tract histology findings from a previously completed inhalation toxicology study in rats, (ii) additional device design verification information and (iii) updates to our investigator brochure. We are working to respond to the FDA's requests, including by initiating the requested nonclinical studies. We intend to request a meeting with the FDA, expected to take place in the first quarter of 2024, if granted, to discuss the feedback, provide clarifications, and discuss our plan to address their comments. We intend to provide an update regarding the IND response submission and the planned Phase 1 healthy volunteer clinical pharmacology trial (GH001-HV-106) in due course after taking into account the conclusions of that meeting.

GH001 in BD and PPD

GH001 is also currently being investigated in a proof-of-concept clinical trial in patients with bipolar II disorder with a current depressive episode (GH001-BD-202) and in a proof-of-concept clinical trial in patients with postpartum depression (GH001-PPD-203).

Recently, the clinical research organization that manages one of our clinical trial sites informed us that the site will be closed for business reasons. As this is one of two sites activated in each trial, and because both trials have been recruiting slower than previously projected, we expect a delay in the completion of the trials. We are in the process of putting measures in place to support recruitment of both trials, including the addition of further clinical trial sites, and we plan to provide an updated timeline for expected trial completion in the first quarter of 2024.

GH002

As previously announced, our randomized, double-blind, placebo-controlled, dose-ranging clinical pharmacology trial of GH002, our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach, in healthy volunteers (GH002-HV-105) is expected to be completed in the fourth quarter of 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/A filed with the U.S. Securities and Exchange Commission for the year ended December 31, 2022 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 were brought into an ultra-rapid remission with our GH001 individualized single-day dosing regimen in the Phase 2 part of the trial, we believe that GH001 has potential to change the way TRD is treated today. GH001 is currently in a multi-center, randomized, double-blind, placebo-controlled Phase 2b trial in patients with TRD and in two Phase 2a proof-of-concept trials in patients with bipolar II disorder and a current depressive episode and in patients with postpartum depression.

About GH002 and GH003

GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach. GH002 is currently in Phase 1 clinical development. 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 in subpopulations and confined use scenarios within our focus area 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, 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 Income (Unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023 $'000	2022 $'000	2023 $'000	2022 $'000
Operating expenses				
Research and development	(7,088)	(4,620)	(21,570)	(13,574)
General and administration	(2,631)	(2,006)	(8,493)	(7,808)
Loss from operations	**(9,719)**	**(6,626)**	**(30,063)**	**(21,382)**
Finance income	2,438	-	6,049	-
Finance expense	(184)	-	(534)	-
Movement of expected credit loss	(17)	-	1	-
Foreign exchange gain	1,833	6,185	232	15,512
Total other income	**4,070**	**6,185**	**5,748**	**15,512**
Loss before tax	**(5,649)**	**(441)**	**(24,315)**	**(5,870)**
Tax charge/(credit)	-	-	-	-
Loss for the period	**(5,649)**	**(441)**	**(24,315)**	**(5,870)**
Other comprehensive expense				
Items that may be reclassified to profit or loss				
Fair value movement on marketable securities	(428)	-	(1,216)	-
Currency translation adjustment	(1,780)	(6,464)	(161)	(15,779)

Total comprehensive loss for the period	**(7,857)**	**(6,905)**	**(25,692)**	**(21,649)**
Attributable to owners:				
Loss for the period	(5,649)	(441)	(24,315)	(5,870)
Total comprehensive loss for the period	(7,857)	(6,905)	(25,692)	(21,649)
Loss per share				
Basic and diluted loss per share (in USD)	(0.11)	(0.01)	(0.47)	(0.11)

GH RESEARCH PLC

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At September 30, 2023 $'000	At December 31, 2022 $'000
ASSETS		
Current assets		
Cash and cash equivalents	86,439	165,955
Other financial assets	55,494	-
Marketable securities	19,343	-
Other current assets	2,765	2,586
Total current assets	**164,041**	**168,541**
Non-current assets		
Marketable securities	67,449	85,724
Property, plant, and equipment	1,078	97
Total non-current assets	**68,527**	**85,821**
Total assets	**232,568**	**254,362**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	2,707	1,868
Lease liability	260	-
Other current liabilities	3,167	2,678
Total current liabilities	**6,134**	**4,546**
Non-current liabilities		
Lease liability	661	-
Total non-current liabilities	**661**	**-**
Total liabilities	**6,795**	**4,546**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,448	291,448
Other reserves	2,888	2,595
Foreign currency translation reserve	(13,196)	(13,035)
Accumulated deficit	(56,668)	(32,493)
Total equity	**225,773**	**249,816**
Total liabilities and equity	**232,568**	**254,362**