GH Research Reports Second Quarter 2023 Financial Results and Provides Business Updates

August 23, 2023

DUBLIN, Ireland, Aug. 23, 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 second quarter ended June 30, 2023 and provided business updates.

Second Quarter 2023 Financial Highlights

Cash position

Cash, cash equivalents, other financial assets and marketable securities were $238.1 million as of June 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 $7.2 million for the quarter ended June 30, 2023, compared to $4.2 million for the same quarter in 2022. The increase was primarily due to increased activities relating to our technical development and clinical trials and increases in employee expenses to support these activities.

General and administrative expenses

G&A expenses were $2.7 million for the quarter ended June 30, 2023, compared to $2.5 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 $7.7 million, or $0.15 loss per share, for the quarter ended June 30, 2023, compared to a net profit of $0.3 million, or $0.01 earnings per share, for the same quarter in 2022. The net profit in the prior year quarter was due to a foreign exchange gain which was not repeated in 2023.

Business Updates

GH001

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). Patient enrollment for this trial is underway, with expected recruitment of approximately 80 patients across several European countries. The primary objective is to determine the efficacy of our single-day individualized dosing regimen (IDR) of GH001 compared with placebo in improving depressive symptoms as assessed by the mean change from baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) at the end of the 7-day double-blind phase. The double-blind phase is followed by a 6-month open-label extension phase where all patients can receive treatment with the GH001 IDR as-needed, based on the patient's clinical status. Further trial design details are described in our corporate presentation, which is available in the investor section on our website.

As previously announced, we expect to submit an IND with the U.S. FDA for GH001 in TRD, delivered with our proprietary aerosol delivery device, in the third quarter of 2023. Pending clearance by the FDA, we expect to initiate a Phase 1 clinical pharmacology trial of GH001 delivered with our proprietary aerosol delivery device in healthy volunteers (GH001-HV-106) in the fourth quarter of 2023. The trial is designed to support bridging to the clinical data generated with the third-party device we currently use in our clinical trials.

Our Phase 2a proof-of-concept clinical trial of GH001 in postpartum depression (GH001-PPD-203) is ongoing and, as previously announced, is expected to be completed in the fourth quarter of 2023. Our Phase 2a proof-of-concept clinical trial of GH001 in bipolar II disorder with a current depressive episode (GH001-BD-202) is recruiting slower than previously projected and we now expect this trial to be completed 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.

Expansion of Executive Management Team

We are pleased to announce the recent expansion of our Executive Management Team, with the appointment of Velichka (Villy) Valcheva, MD, MSc as VP Clinical Research and Medical Affairs. Villy has more than 20 years' experience in various leadership roles, with global exposure in pharmaceutical and biotech companies, including Global Senior Medical Director positions at Ipsen and Sanofi. Villy joins us from Albireo, where, in her position as VP and Head of Medical Affairs International, she was responsible for all international medical activities, played a pivotal role in gaining market access across multiple countries, was deeply involved in driving the company's strategic decisions, and significantly contributed to the recent acquisition of Albireo by Ipsen.

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 treatment-resistant depression (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 of GH001 in TRD.

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, 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 June 30,		Six months ended June 30,	
	2023	**2022**	**2023**	**2022**
	$'000	**$'000**	**$'000**	**$'000**
Operating expenses				
Research and development	(7,176)	(4,240)	(14,482)	(8,954)
General and administration	(2,749)	(2,510)	(5,862)	(5,802)
Loss from operations	**(9,925)**	**(6,750)**	**(20,344)**	**(14,756)**
Finance income	2,122	-	3,611	-
Finance expense	(179)	-	(350)	-
Movement of expected credit loss	217	-	18	-
Foreign exchange gain/(loss)	36	7,084	(1,601)	9,327
Total other income	**2,196**	**7,084**	**1,678**	**9,327**
(Loss)/profit before tax	**(7,729)**	**334**	**(18,666)**	**(5,429)**
Tax charge/(credit)	-	-	-	-

(Loss)/profit for the period	**(7,729)**	**334**	**(18,666)**	**(5,429)**
Other comprehensive (expense)/income				
Items that may be reclassified to profit or loss				
Fair value movement on marketable securities	(1,512)	-	(788)	-
Currency translation adjustment	(57)	(7,054)	1,619	(9,315)
Total comprehensive loss for the period	**(9,298)**	**(6,720)**	**(17,835)**	**(14,744)**
Attributable to owners:				
(Loss)/profit for the period	(7,729)	334	(18,666)	(5,429)
Total comprehensive loss for the period	(9,298)	(6,720)	(17,835)	(14,744)
(Loss)/earnings per share				
Basic and diluted (loss)/earnings per share (in USD)	(0.15)	0.01	(0.36)	(0.10)

GH RESEARCH PLC

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At June 30, 2023 $'000	At December 31, 2022 $'000
ASSETS		
Current assets		
Cash and cash equivalents	96,895	165,955
Other financial assets	54,728	-
Marketable securities	13,761	-
Other current assets	1,015	2,586
Total current assets	**166,399**	**168,541**
Non-current assets		
Marketable securities	72,697	85,724
Property, plant, and equipment	1,176	97
Total non-current assets	**73,873**	**85,821**
Total assets	**240,272**	**254,362**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	2,912	1,868
Lease liability	267	-
Other current liabilities	3,378	2,678
Total current liabilities	**6,557**	**4,546**
Non-current liabilities		
Lease liability	732	-
Total non-current liabilities	**732**	**-**
Total liabilities	**7,289**	**4,546**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,448	291,448
Other reserves	2,809	2,595
Foreign currency translation reserve	(11,416)	(13,035)
Accumulated deficit	(51,159)	(32,493)
Total equity	**232,983**	**249,816**
Total liabilities and equity	**240,272**	**254,362**