GH Research Reports Third Quarter 2022 Financial Results and Provides Business Updates

November 10, 2022

DUBLIN, Ireland, Nov. 10, 2022 (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, 2022 and gave updates on its business.

Third Quarter 2022 Financial Highlights

Cash position

Cash was $256.9 million as of September 30, 2022, compared to $276.8 million as of December 31, 2021. We believe that our existing cash will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2025.

Research and development expenses

R&D expenses were $4.6 million for the quarter ended September 30, 2022, compared to $2.6 million for the same quarter in 2021. The increase was primarily due to increased activities relating to our technical development and increases in employee expenses to support these activities.

General and administrative expenses

G&A expenses were $2.0 million for the quarter ended September 30, 2022, compared to $2.1 million for the same quarter in 2021. The decrease was primarily due to a decrease in insurance costs which has been partially offset by an increase in professional costs and employee expenses.

Net profit/loss

Net loss was $0.4 million, or $0.008 loss per share, for the quarter ended September 30, 2022, compared to a net loss of $1.8 million, or $0.035 loss per share, for the same quarter in 2021. The decrease was due to the foreign exchange gain in the quarter.

Business Updates

GH001 for the treatment of TRD

GH001 is our proprietary inhalable 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) product candidate.

We have recently submitted clinical trial applications in several European countries for a multi-center, randomized, controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201). Pending regulatory approval, we expect to initiate this trial in the first quarter of 2023. We expect to recruit approximately 80 patients for this trial. The primary objective will be to determine the efficacy of a 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 will be 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 response.

In May 2022, we also announced the positive outcome of our pre-IND meeting with the U.S. Food and Drug Administration (FDA), and we expect to submit our IND for GH001 in TRD in the first quarter of 2023. The planned IND-opening study is a Phase 1 imaging study in patients with TRD designed to further elucidate the mechanism of action of GH001 (GH001-TRD-104).

GH001 for the treatment of BDII and PPD

We have recently initiated Phase 2a proof-of-concept clinical trials of GH001 for the treatment of patients with bipolar II disorder and a current depressive episode (BDII) (GH001-BD-202) and for the treatment of patients with postpartum depression (PPD) (GH001-PPD-203). We expect to complete these studies by the end of 2023.

GH002 and GH003

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. GH002 has completed pre-clinical development to support early clinical trials and we have recently submitted a clinical trial application for a double-blind, placebo-controlled, randomized, dose-ranging clinical pharmacology trial in healthy volunteers (GH002-HV-105). Pending regulatory approval, we expect to initiate this trial in the fourth quarter of 2022.

GH003 is our 5-MeO-DMT product candidate formulated for administration via a proprietary intranasal administration approach. GH003 is currently in preclinical development.

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 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, 2021 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 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 single-day individualized dosing regimen in the Phase 2 part of the trial, we believe that GH001 has potential to change the way TRD is treated today. Across the GH001 program, no serious adverse events have been reported and GH001 was well tolerated at the investigated single dose levels and in the individualized dosing regimen.

About GH002 and GH003

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. GH002 has completed preclinical development to support early clinical trials. GH003 is our 5-MeO-DMT product candidate formulated for administration via a proprietary intranasal administration approach. GH003 is currently in preclinical development.

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, our cash runway, business strategy, product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals, research and development costs, 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 document speak only as of the date of this press release. 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,	
	2022	**2021**	**2022**	**2021**
	$'000	**$'000**	**$'000**	**$'000**
Operating expenses				
Research and development	(4,620)	(2,556)	(13,574)	(5,202)
General and administration	(2,006)	(2,110)	(7,808)	(3,277)
Loss from operations	**(6,626)**	**(4,666)**	**(21,382)**	**(8,479)**
Finance expense	-	(3)	-	(9)
Foreign exchange gain	6,185	2,832	15,512	3,377
Loss before tax	**(441)**	**(1,837)**	**(5,870)**	**(5,111)**
Tax charge/(credit)	-	-	-	-
Loss for the period	**(441)**	**(1,837)**	**(5,870)**	**(5,111)**
Other comprehensive expense				
Items that may be reclassified to profit or loss				
Currency translation adjustment	(6,464)	(2,845)	(15,779)	(3,533)
Total comprehensive loss for the period	**(6,905)**	**(4,682)**	**(21,649)**	**(8,644)**
Attributable to owners:				
Loss for the period	(441)	(1,837)	(5,870)	(5,111)
Comprehensive loss for the period	(6,464)	(2,845)	(15,779)	(3,533)
Loss per share				
Basic and diluted loss per share (in USD)	(0.008)	(0.035)	(0.113)	(0.125)

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At September 30, 2022 $'000	At December 31, 2021 $'000
ASSETS		
Current assets		
Cash and cash equivalents	256,939	276,776
Other current assets	3,100	3,066
Total current assets	**260,039**	**279,842**
Non-current assets		
Property, plant and equipment	84	82
Total non-current assets	84	**82**
Total assets	**260,123**	**279,924**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	1,750	883
Other current liabilities	1,635	1,866
Total current liabilities	**3,385**	**2,749**
Total liabilities	**3,385**	**2,749**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in-capital	291,448	291,448
Other reserves	1,578	366
Foreign currency translation reserve	(21,682)	(5,903)
Accumulated deficit	(15,907)	(10,037)
Total equity	**256,738**	**277,175**
Total liabilities and equity	**260,123**	**279,924**