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

May 18, 2022

DUBLIN, Ireland, May 18, 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 first quarter ended March 31, 2022 and gave updates on its business.

First Quarter 2022 Financial Highlights

Cash position

Cash was $270.8 million as of March 31, 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 $4.7 million for the quarter ended March 31, 2022, compared to $692 thousand for the same quarter in 2021. 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 $3.3 million for the quarter ended March 31, 2022, compared to $448 thousand for the same quarter in 2021. The increase was primarily due to higher legal, professional and compliance fees, as well as increased employee expenses.

Net loss

Net loss was $5.8 million, or $0.111 loss per share, for the quarter ended March 31, 2022, compared to $1.1 million, or $0.038 loss per share, for the same quarter in 2021.

Business Updates

GH001 for the treatment of TRD

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

We recently announced our plan to submit 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) in the third quarter of 2022. Preparation of those submissions is ongoing.

On May 11, 2022, we held a pre-IND meeting with the U.S. Food and Drug Administration (FDA), the planning of which had been previously announced. In preparation for this meeting, we had provided the FDA with a detailed description of the development status and plans for GH001 including clinical, non-clinical, and chemistry, manufacturing and controls activities. The outcome of the meeting was positive and positions us for an anticipated IND submission not later than 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).

The data from our previously reported Phase 1/2 clinical trial of GH001 in patients with TRD (GH001-TRD-102) has been recently accepted for oral presentation at the American Society of Clinical Psychopharmacology 2022 Annual Meeting in Scottsdale, AZ, and will be presented during the Pharmaceutical Pipelines session on May 31, 2022. The primary endpoint of the Phase 2 part of the trial was met with 7 of 8 patients (87.5%) in remission (Montgomery–Asberg Depression Rating Scale (MADRS) ≤10) at day 7 after dosing ($p<0.0001$). Patients followed a proprietary individualized dosing regimen with up to three increasing GH001 doses (6 mg, 12 mg and 18 mg) on a single day. No serious and no severe adverse events, no clinically significant changes in any of the safety laboratory analyses, vital signs, psychiatric safety assessments or measures of cognitive function and no signal for suicidal ideation or behavior were observed.

GH001 for the treatment of BDII and PPD

We recently submitted additional clinical trial applications in further European countries for the planned Phase 2a proof-of-concept clinical trial of GH001 for the treatment of patients with bipolar II disorder and a current depressive episode (BDII) (GH001-BD-202) and for the planned Phase 2a proof-of-concept clinical trial of GH001 for the treatment of patients with postpartum depression (PPD) (GH001-PPD-203). Pending regulatory clearance, we expect to initiate these trials in the third quarter of 2022.

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 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. 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. GH003 is our 5-MeO-DMT product candidate formulated for administration via a proprietary intranasal administration approach. GH002 and GH003 are currently in preclinical development, and we anticipate developing them 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 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 March 31,	
	2022	**2021**
	$'000	**$'000**
Operating expenses		
Research and development	(4,714)	(692)
General and administration	(3,292)	(448)
Loss from operations	**(8,006)**	**(1,140)**
Foreign currency translation differences	2,243	(9)
Loss before tax	**(5,763)**	**(1,149)**
Tax charge/(credit)	-	-
Loss for the period	**(5,763)**	**(1,149)**
Other comprehensive expense		
Items that may be reclassified to profit or loss		
Currency translation adjustment	(2,261)	(202)
Total comprehensive loss for the period	**(8,024)**	**(1,351)**
Attributable to owners:		
Loss for the period	(5,763)	(1,149)
Comprehensive loss for the period	(2,261)	(202)

Loss per share		
Basic and diluted loss per share (in USD)	(0.111)	(0.038)

GH RESEARCH PLC

Condensed Consolidated Interim Balance Sheet (Unaudited)

(in thousands)

	At March 31, 2022 $'000	At December 31, 2021 $'000
ASSETS		
Current assets		
Cash and cash equivalents	270,750	276,776
Other current assets	2,713	3,066
Total current assets	**273,463**	**279,842**
Non-current assets		
Property, plant and equipment	81	82
Total non-current assets	81	**82**
Total assets	**273,544**	**279,924**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	1,545	883
Other current liabilities	2,521	1,866
Total current liabilities	**4,066**	**2,749**
Total liabilities	**4,066**	**2,749**
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,448	291,448
Other reserves	693	366
Foreign currency translation reserve	(8,164)	(5,903)
Accumulated deficit	(15,800)	(10,037)
Total equity	**269,478**	**277,175**
Total liabilities and equity	**273,544**	**279,924**