



GH Research Reports Full Year 2022 Financial Results and Provides Business Updates

March 2, 2023

DUBLIN, Ireland, March 02, 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 full year ended December 31, 2022 and gave updates on its business.

Business Updates

We are pleased to report that we have recently initiated our multi-center, randomized, double-blind, placebo-controlled Phase 2b trial of GH001 in treatment-resistant depression (TRD) (GH001-TRD-201). GH001 is our proprietary inhalable mebufotenin (5-MeO-DMT) product candidate.

We expect to recruit approximately 80 patients for this trial across several European countries. The primary objective will be 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 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 status. Further trial design details are described in our updated corporate presentation, which is available in the investor section on our website.

Recent Business Highlights

In January 2023, we reported development progress in respect of our proprietary aerosol delivery device and our expectation that we will submit an IND for GH001, delivered with this proprietary device, in the third quarter of 2023. The IND-opening study is expected to be a Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-106), designed to support bridging to the clinical data generated with the third-party device we currently use in our clinical trials.

We also reported, in January 2023, the recent initiation of our randomized, double-blind, placebo-controlled, dose-ranging clinical pharmacology trial of GH002 in healthy volunteers (GH002-HV-105). GH002 is our mebufotenin (5-MeO-DMT) product candidate formulated for administration via a proprietary intravenous approach. We expect to complete this trial in the fourth quarter of 2023.

Furthermore, we reported the recent expansion of our patent portfolio, to include 11 patent families that relate to various aspects of mebufotenin (5-MeO-DMT) use in a therapeutic context, including but not limited to the use of mebufotenin (5-MeO-DMT) for treatment of various disorders when administered by inhalation, or by nasal, buccal, sublingual, intravenous, intramuscular or subcutaneous routes.

We also announced the selection of mebufotenin as the International Nonproprietary Name (INN) for 5-MeO-DMT by the World Health Organization (WHO) Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations.

Full Year 2022 Financial Highlights

Cash position

Cash, cash equivalents and marketable securities were \$251.7 million as of December 31, 2022, compared to cash of \$276.8 million as of December 31, 2021. Marketable securities are comprised of investment grade bonds. We believe that our existing cash, cash equivalents 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 \$20.5 million for the year ended December 31, 2022, compared to \$8.6 million for the full year 2021. The increase was primarily due to increased activities relating to our technical development, clinical trials and increased employee expenses to support these activities.

General and administrative expenses

G&A expenses were \$10.1 million for the year ended December 31, 2022, compared to \$6.5 million for the full year 2021. The increase was primarily due to higher insurance costs, an increase in professional costs as well as increased employee expenses.

Net loss

Net loss was \$22.5 million, or \$0.432 loss per share, for the year ended December 31, 2022, compared to \$9.2 million, or \$0.211 loss per share, for the full year 2021.

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).

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 treatment-resistant depression (TRD). 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 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, cash runway, business strategy, product candidates, proprietary medical devices, 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 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

Consolidated Statement of Comprehensive Income (Unaudited)

(in thousands, except share and per share amounts)

	Year ended December 31,	
	2022	2021
	\$'000	\$'000
Operating expenses		
Research and development	(20,484)	(8,553)
General and administration	(10,070)	(6,547)
Loss from operations	(30,554)	(15,100)
Net finance income/(expense)	922	(9)
Foreign exchange gain	7,176	5,907
Total finance income	8,098	5,898
Loss before tax	(22,456)	(9,202)
Tax charge/(credit)	—	—
Loss for the year	(22,456)	(9,202)
Other comprehensive income/(expense)		
<i>Items that may be reclassified to profit or loss</i>		
Fair value movement on marketable securities	558	—
Currency translation adjustment	(7,132)	(6,103)
Total comprehensive loss for the year	(29,030)	(15,305)
Attributable to owners:		
Loss for the year	(22,456)	(9,202)
Comprehensive loss for the year	(29,030)	(15,305)
Loss per share		
Basic and diluted loss per share (in USD)	(0.432)	(0.211)

GH RESEARCH PLC

Consolidated Balance Sheet (Unaudited)

(in thousands)

	At December 31,	
	2022	2021
	\$'000	\$'000
ASSETS		
Current assets		
Cash and cash equivalents	165,955	276,776
Other current assets	2,586	3,066
Total current assets	168,541	279,842
Non-current assets		
Marketable securities	85,724	—
Property, plant and equipment	97	82
Total non-current assets	85,821	82
Total assets	254,362	279,924
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	1,868	883
Other current liabilities	2,678	1,866
Total current liabilities	4,546	2,749
Total liabilities	4,546	2,749
Equity attributable to owners		
Share capital	1,301	1,301
Additional paid-in capital	291,448	291,448
Other reserves	2,595	366
Foreign currency translation reserve	(13,035)	(5,903)
Accumulated deficit	(32,493)	(10,037)
Total equity	249,816	277,175
Total liabilities and equity	254,362	279,924