GH Research Reports Full Year 2021 Financial Results and Provides Business Updates

March 28, 2022

DUBLIN, Ireland., March 28, 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 full year ended December 31, 2021 and gave updates on its business.

Fourth Quarter 2021 Business Highlights

In December 2021, we reported the successful outcome of the Phase 2 part of our Phase 1/2 clinical trial of GH001, our proprietary inhalable 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT) product candidate, in patients with treatment-resistant depression (TRD) (GH001-TRD-102). 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 (IDR) 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.

Furthermore, we reported positive preliminary safety results from a Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-103), which supported the safety profile of GH001 single doses (6 mg, 12 mg and 18 mg) and the proprietary GH001 IDR with up to three increasing GH001 doses (6 mg, 12 mg and 18 mg) on a single day, given in two dose intervals (1 hour, 2 hours).

Full Year 2021 Financial Highlights

Cash position

Cash was $276.8 million as of December 31, 2021, compared to $5.9 million as of December 31, 2020.

Research and development expenses

R&D expenses were $8.6 million for the year ended December 31, 2021, compared to $338 thousand for the full year 2020. The increase was primarily due to increased activities relating to our technical developments and clinical trials and increases in employee expenses to support these activities.

General and administrative expenses

G&A expenses were $6.5 million for the year ended December 31, 2021, compared to $108 thousand for the full year 2020. The increase was primarily due to higher professional and compliance fees associated with being a public company, as well as increased employee expenses.

Net loss

Net loss was $9.2 million, or $0.211 loss per share, for the year ended December 31, 2021, compared to $446 thousand, or $0.016 loss per share, for the full year 2020.

Business Updates

GH001 for the treatment of TRD

We plan to submit clinical trial applications in several European countries for a multi-center, randomized, controlled Phase 2b trial of GH001 in TRD (GH001-TRD-201) in the third quarter of 2022.

GH001 for the treatment of additional disorders

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

GH001 in healthy volunteers

We now have the final safety results of our Phase 1 clinical pharmacology trial in healthy volunteers (GH001-HV-103) and the data continue to support the safety profile of GH001 single doses and the proprietary GH001 IDR. Results from pharmacokinetic analyses were aligned with the ultra-rapid onset and short duration of observed psychoactive effects. Results of cognitive function tests as well as psychoactive effect assessments were aligned with results of previous trials. The full results of the trial support that an interval down to 1 hour between individual doses of the IDR is feasible for use in future clinical trials.

Other GH001 regulatory interactions

We have recently submitted a request for a pre-IND meeting with the FDA to discuss our planned filing of a U.S. IND for GH001 in TRD. The meeting has been granted by the FDA for the second quarter of 2022. The proposed 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). There are no current plans for additional regulatory meetings with other agencies.

Intellectual property

We have recently filed a number of new patent applications, which have not yet been published, that relate to further aspects of 5-MeO-DMT use in a therapeutic context, including novel manufacturing methods of 5-MeO-DMT, novel salt forms of 5-MeO-DMT and novel uses of 5-MeO-DMT.

Financial

Cash was approximately $273.8 million as of February 28, 2022, and we believe that our existing cash will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2025.

Filing of Annual Report on Form 20-F

In connection with the announcement of our full year 2021 financial highlights, we have filed our annual report on Form 20-F with the U.S. Securities and Exchange Commission. The annual report is available on our website at www.ghres.com and shareholders may receive a hard copy free of charge upon request.

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).

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

Consolidated Statement of Comprehensive Income

(in thousands, except share and per share amounts)

	Year ended December 31,		
	2021	**2020**	**2019**
	$'000	**$'000**	**$'000**
Operating expenses			

Research and development	(8,553)	(338)	(296)
General and administration	(6,547)	(108)	(14)
Loss from operations	**(15,100)**	**(446)**	**(310)**
Finance expense	(9)	—	—
Foreign currency translation differences	5,907	—	—
Loss before tax	**(9,202)**	**(446)**	**(310)**
Tax charge/(credit)	—	—	—
Loss for the year	**(9,202)**	**(446)**	**(310)**
Other comprehensive income/(expense)			
Items that may be reclassified to profit or loss			
Currency translation adjustment	(6,103)	212	(12)
Total comprehensive loss for the year	**(15,305)**	**(234)**	**(322)**
Attributable to owners:			
Loss for the year	(9,202)	(446)	(310)
Comprehensive loss for the year	(15,305)	(234)	(322)
Loss per share			
Basic and diluted loss per share (in USD)	(0.211)	(0.016)	(0.011)

GH RESEARCH PLC

Consolidated Balance Sheet

(in thousands)

	At December 31,	
	2021	**2020**
	$'000	**$'000**
ASSETS		
Current assets		
Cash and cash equivalents	276,776	5,895
Other current assets	3,066	17
Total current assets	**279,842**	**5,912**
Non-current assets		
Property, plant and equipment	82	—
Total non-current assets	**82**	**—**
Total assets	**279,924**	**5,912**
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	883	1
Other current liabilities	1,866	245
Total current liabilities	**2,749**	**246**
Total liabilities	**2,749**	**246**
Equity attributable to owners		
Share capital	1,301	871
Additional paid-in capital	291,448	5,430
Other reserves	366	—
Foreign currency translation reserve	(5,903)	200
Accumulated deficit	(10,037)	(835)
Total equity	**277,175**	**5,666**
Total liabilities and equity	**279,924**	**5,912**