GH Research Reports Third Quarter 2021 Financial Results and Provides Business Updates

December 6, 2021

DUBLIN, Ireland, Dec. 06, 2021 (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, 2021 and gave updates on its business.

Third Quarter 2021 Financial Results

Cash position

Cash was $280.7 million as of September 30, 2021, compared to $5.9 million as of December 31, 2020.

Research and development expenses

R&D expenses were $2.6 million for the quarter ended September 30, 2021, compared to $55 thousand for the same quarter in 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 $2.1 million for the quarter ended September 30, 2021, compared to $5 thousand for the same quarter in 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 $1.8 million, or $0.035 loss per share, for the quarter ended September 30, 2021, compared to $60 thousand, or $0.002 loss per share, for the same quarter in 2020.

Business Updates

We announced today, in a separate press release, the successful outcome of the Phase 2 part of our Phase 1/2 clinical trial of GH001 in treatment-resistant depression (TRD), where the primary endpoint was met with 7 of 8 patients (87.5%) in remission (Montgomery–Åsberg Depression Rating Scale (MADRS) ≤10) at day 7 after dosing ($p<0.0001$).

We plan to request a pre-IND meeting with the FDA and a Scientific Advice meeting with the EMA in the first quarter of 2022 and, pending the outcome of these meetings, we plan to initiate a multi-center, randomized, controlled Phase 2b trial of GH001 in TRD.

Given GH001's mechanism of action, we believe that GH001 may confer beneficial effects in other psychiatric and neurological disorders with unmet medical needs. We have recently initiated the development in two undisclosed psychiatric disorders which are expected to be announced in Q1 2022.

GH002, our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach, and GH003, our recently added 5-MeO-DMT product candidate formulated for administration via a proprietary intranasal administration approach, are currently in preclinical development. We anticipate developing them in subpopulations and confined use scenarios within our focus area of psychiatric and neurological disorders.

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, 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,	
	2021 $'000	2020 $'000	2021 $'000	2020 $'000
Operating expenses				
Research and development	(2,556)	(55)	(5,202)	(105)
General and administration	(2,110)	(5)	(3,277)	(16)
Loss from operations	**(4,666)**	**(60)**	**(8,479)**	**(121)**
Finance expense	(3)	-	(9)	-
Foreign currency translation differences	2,832	-	3,377	-
Loss for the period	**(1,837)**	**(60)**	**(5,111)**	**(121)**
Other comprehensive income/(expense)				
Items that may be reclassified to profit or loss				
Currency translation adjustment	(2,845)	15	(3,533)	15
Total comprehensive loss for the period	**(4,682)**	**(45)**	**(8,644)**	**(106)**
Attributable to owners:				
Loss for the period	(1,837)	(60)	(5,111)	(121)
Comprehensive loss for the period	(2,845)	15	(3,533)	15
Loss per share				
Basic and diluted loss per share (in USD)	(0.035)	(0.002)	(0.125)	(0.004)

GH RESEARCH PLC

Condensed Consolidated Interim Statement of Financial Position (Unaudited)

(in thousands)

	At September 30,	At December 31,
	2021 $'000	2020 $'000
ASSETS		
Current assets		
Cash	280,745	5,895
Other current assets	4,816	17
Total current assets	**285,561**	**5,912**
Non-current assets		
Property, plant and equipment	73	-
Total non-current assets	**73**	**-**
Total assets	**285,634**	**5,912**

LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	1,214	1
Other current liabilities	819	245
Total current liabilities	**2,033**	**246**
Total liabilities	**2,033**	**246**
Equity attributable to owners		
Share capital	1,301	871
Share premium	291,448	5,430
Other reserves	131	-
Foreign currency translation reserve	(3,333)	200
Accumulated deficit	(5,946)	(835)
Total equity	**283,601**	**5,666**
Total liabilities and equity	**285,634**	**5,912**