



GH Research PLC Provides Business Updates and Reports Second Quarter 2021 Financial Results

September 23, 2021

DUBLIN, Ireland, Sept. 23, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (NASDAQ: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today provided business updates and reported financial results for the second quarter ended June 30, 2021.

Business Updates

Corporate Updates

In June 2021, we completed our initial public offering, in which we issued and sold an aggregate of 11,499,999 ordinary shares, including those issued and sold pursuant to the exercise in full of the underwriters' option to purchase additional ordinary shares, at a price of \$16.00 per share. The net proceeds of the offering were \$167.7 million, after deducting underwriting discounts and offering expenses payable by us.

Today we announced that Dermot Hanley and Dr. Duncan Moore have been appointed to our Board of Directors as non-executive directors effective September 24, 2021, expanding the Board to five members. Mr. Hanley and Dr. Moore will also serve as members of the Audit Committee. Mr. Hanley is an experienced independent non-executive director and investment banker, having previously served as Co-Head of Coverage for Barclays Bank Ireland and having spent 16 years in international investment banking and capital markets roles with major global firms, including Claret Capital, JP Morgan, Deutsche Bank and Citibank. Dr. Moore is currently a partner at East West Capital Partners. Prior roles included 17 years as a top-ranked pharmaceutical analyst at Morgan Stanley, including 11 years as a Managing Director leading the firm's global healthcare equity research team.

Clinical Development Updates

GH001, our inhalable 5-Methoxy-N,N-Dimethyltryptamine (5-MeO-DMT) product candidate, is currently being investigated in the Phase 2 part of an ongoing open-label, single-arm Phase 1/2 clinical trial in patients with Treatment-Resistant Depression (TRD). Based on the observed clinical activity in the Phase 1 part of the trial, we believe that administration of a single dose of GH001 has the potential to induce ultra-rapid remissions as measured by the Montgomery-Åsberg Depression Rating Scale, or MADRS, in certain patients. The goal of the ongoing Phase 2 part, which we expect to complete in the fourth quarter of 2021, is to assess whether an individualized dosing regimen with intra-subject dose escalation within a single day can further increase the MADRS remission rate as compared to a single dose of GH001.

We have previously announced the plan to conduct a clinical pharmacology trial in healthy volunteers to further elucidate the pharmacokinetic profile of GH001. This trial has been initiated and is expected to be completed in the fourth quarter of 2021.

Pending completion of the aforementioned studies, we plan to request a pre-IND meeting with the FDA and a Scientific Advice meeting with the EMA and plan to initiate a multi-center, randomized, controlled Phase 2b trial in TRD.

Given GH001's mechanism of action, we believe that GH001 may confer beneficial effects as an earlier line of treatment in MDD, including potential to serve as a front-line treatment, as well as in other psychiatric and neurological disorders with unmet medical need. We plan to initiate proof-of-concept Phase 2a trials in two such disorders.

GH002, our injectable 5-MeO-DMT product candidate, is currently in preclinical development. We anticipate developing GH002 in indications within our focus area of psychiatric and neurological disorders.

Second Quarter 2021 Financial Results

Cash position

Cash was \$292.6 million as of June 30, 2021, compared to \$5.9 million as of December 31, 2020.

Research and development expenses

R&D expenses were \$2 million for the quarter ended June 30, 2021, compared to \$39 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 \$719 thousand for the quarter ended June 30, 2021, compared to \$3 thousand for the same quarter in 2020. The increase was primarily due to costs incurred in preparation for our initial public offering and increased employee expenses.

Net loss

Net loss was \$2.1 million, or \$0.053 loss per share, for the quarter ended June 30, 2021, compared to \$42 thousand, or \$0.002 loss per share, for the same quarter in 2020.

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.

About GH001

Our lead product candidate, GH001, is formulated for 5-MeO-DMT administration via a proprietary inhalation approach. We are currently investigating administration of GH001 as a single-dose induction regimen and in an individualized dosing regimen where up to three escalating doses of GH001 are given on the same day. With GH001, we have completed a Phase 1 healthy volunteer clinical trial, in which administration of GH001 via inhalation was observed to be well tolerated at the investigated single dose levels and in the individualized dosing regimen. GH001 is currently being investigated in the Phase 2 part of an ongoing Phase 1/2 clinical trial in patients with TRD. In the completed Phase 1 part of this ongoing trial, no serious adverse events were observed and all adverse drug reactions were mild and resolved spontaneously. Based on observed clinical activity, we believe that administration of a single dose of GH001 has the potential to induce ultra-rapid remissions as measured by the Montgomery-Åsberg Depression Rating Scale, or MADRS, in certain patients. The goal of the ongoing Phase 2 part of the trial is to assess whether an individualized dosing regimen with intra-subject dose escalation within a single day can further increase the MADRS remission rate as compared to a single dose of GH001.

About GH002

GH002 is our 5-MeO-DMT product candidate formulated for administration via a proprietary injectable approach. GH002 is currently in preclinical development, and we anticipate developing GH002 in indications within our focus area of psychiatric and neurological disorders.

About Dermot Hanley

Mr. Hanley is an experienced independent non-executive director and investment banker. He is currently a non-executive board member of numerous private equity backed companies and regulated financial investment funds. These include Killiney Maritime since September 2018, Larix Opportunities Master ICAV since February 2020, Varagon Capital Credit Strategies ICAV since October 2020. Additionally, he has served as Chairperson of RTW Investments ICAV since January 2021 and CVP Credit Value Fund (Europe) V GP Limited since May 2021. He founded Nusli in 2012. Previously, Mr. Hanley was Co-Head of Coverage for Barclays Bank Ireland and spent 16 years in international investment banking and capital markets roles with major global firms, including Claret Capital, JP Morgan, Deutsche Bank and Citibank. He is a member of the Governance Advisory Council for The Corporate Governance Institute and is also a longstanding member of the Finance and Economics Committee (Ecotax) at The Irish Business and Employers Confederation. He is a graduate of University College Dublin (BSc) and The Queens University of Belfast (MBA) and holds a diploma in corporate governance from The Governance Institute/Glasgow Caledonia University.

About Duncan Moore

Dr. Moore is a partner at East West Capital Partners since May 2008. Previously, Dr. Moore was a top-ranked pharmaceutical analyst at Morgan Stanley from 1991 to 2008 and was a Managing Director from 1997 to 2008 leading the firm's global healthcare equity research team. Whilst at the University of Cambridge, he co-founded a medical diagnostics company, Ultra Clone, with two colleagues which led to the beginnings of a 20-year career in healthcare capital markets analysis. In 1986, he was involved in establishing the BankInvest biotechnology funds and was on their scientific advisory board. Dr. Moore was educated in Edinburgh and attended the University of Leeds where he studied Biochemistry and Microbiology. He has a M.Phil. and Ph.D. from the University of Cambridge where he was also a post-doctoral research fellow. Currently, he is an active investor in biomedical companies as Chairman of Lamellar Biomedical and Allarity Therapeutics A/S (previously Oncology Venture A/S). In addition, he has a board position at Forward Pharma A/S and Cycle Pharma. He is also the Chairman of the Scottish Life Sciences Association and serves on the Board of Governors of Merchiston Castle School in Edinburgh and the International School in Shenzhen in the Peoples Republic of China.

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, 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.

Investor Relations:

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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 June 30,		Six months ended June 30,	
2021	2020	2021	2020

	\$'000	\$'000	\$'000	\$'000
Operating expenses				
Research and development	(1,954)	(39)	(2,646)	(50)
General and administration	(719)	(3)	(1,167)	(11)
Loss from operations	(2,673)	(42)	(3,813)	(61)
Finance expense	(6)	-	(6)	-
Foreign currency translation differences	554	-	544	-
Loss for the period	(2,125)	(42)	(3,275)	(61)
Other comprehensive income/(expense) <i>Items that may be reclassified to profit or loss</i>				
Currency translation adjustment	(486)	6	(688)	-
Total comprehensive loss for the period	(2,611)	(36)	(3,963)	(61)
Attributable to owners:				
Loss for the period	(2,125)	(42)	(3,275)	(61)
Comprehensive loss for the period	(486)	6	(688)	-
Loss per share				
Basic and diluted loss per share (in USD)	(0.053)	(0.002)	(0.093)	(0.002)

GH RESEARCH PLC
Condensed Consolidated Interim Balance Sheet (Unaudited)
(in thousands)

	At June 30, 2021 \$'000	At December 31, 2020 \$'000
ASSETS		
Current assets		
Cash	292,625	5,895
Other current assets	164	17
Total current assets	292,789	5,912
Non-current assets		
Property, plant and equipment	30	-
Total non-current assets	30	-
Total assets	292,819	5,912
LIABILITIES AND EQUITY		
Current liabilities		
Trade payables	1,002	1
Other current liabilities	3,590	245
Total current liabilities	4,592	246
Total liabilities	4,592	246
Equity attributable to owners		
Share capital	1,301	871
Share premium	291,512	5,430
Other reserves	12	-
Foreign currency translation reserve	(488)	200
Accumulated deficit	(4,110)	(835)
Total equity	288,227	5,666
Total liabilities and equity	292,819	5,912