
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

For the month of June, 2025.

Commission File Number: 001-40530

GH Research PLC

(Exact name of registrant as specified in its charter)

Joshua Dawson House
Dawson Street
Dublin 2
D02 RY95
Ireland
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of
Form 20-F or Form 40-F:

Form 20-F



Form 40-F



INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On June 20, 2025, GH Research PLC (the "Company") announced that, in June, it submitted its complete response to the previously announced clinical hold of its Investigational New Drug Application ("IND") for GH001 to the U.S. Food and Drug Administration ("FDA"). A copy of the press release is exhibited hereto as Exhibit 99.1.

The fact that this press release is being made available and furnished herewith should not be deemed an admission as to the materiality of any information contained in the materials. The information contained in the press release is being provided as of June 20, 2025, and the Company does not undertake any obligation to update the press release in the future or to update forward-looking statements to reflect subsequent actual results.

EXHIBIT INDEX

Exhibit No.	Description
<u>99.1</u>	Press release dated June 20, 2025

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GH Research PLC

Date: June 20, 2025

By: /s/ Julie Ryan
Name: Julie Ryan
Title: Vice President, Finance

GH Research Submits Complete IND Hold Response to FDA Ahead of Schedule

Dublin, Ireland, June 20, 2025 – GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the lives of patients by developing a practice-changing treatment in depression, today announced that, in June, it submitted its complete response to the previously announced clinical hold of its Investigational New Drug Application (IND) for GH001 to the U.S. Food and Drug Administration (FDA).

“We are thrilled to have submitted our response to the FDA ahead of schedule, addressing their clear requests with comprehensive data and completed toxicology studies. We remain fully committed to working closely with the agency to bring GH001 to patients,” said Dr. Velichka Valcheva, Chief Executive Officer.

About GH001

Our lead product candidate, GH001, is formulated for mebufotenin administration via a proprietary inhalation approach. Based on the observed clinical activity in our Phase 2b GH001-TRD-201 trial, where the primary endpoint was met with a MADRS reduction from baseline of -15.5 points compared with placebo on Day 8 ($p<0.0001$), we believe that GH001 has potential to change the way TRD is treated today.

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, medical devices required to deliver these product candidates, research pipeline, ongoing and currently planned preclinical studies and clinical trials, regulatory submissions and approvals and their effects on our business strategy, including our plans and expectations for discussions with the FDA and the outcomes and resolution of such discussions related to the clinical hold on the GH001 IND, research and development costs, cash runway, 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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