
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 September, 2024.

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

GH Research PLC (the "Company") will attend the 37th ECNP Congress, which is scheduled to take place in Milan, Italy between September 21 – 24, 2024 (the "Congress").

The Company will sponsor an industry mini session during the Congress.

A copy of the presentation prepared by Wieslaw J. Cubala to be delivered during the industry mini session is attached hereto as [Exhibit 99.1](#).

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.

Date: September 20, 2024

GH Research PLC

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

Review of Ongoing Phase 2b Treatment-Resistant Depression Clinical Trial (GH001-TRD-201)

Wiesław J. Cudała

Medical University of Gdańsk

19/09/2024

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Author Disclosure



Conflict of interest statement regarding my presentation in the 'Industry session financially supported by GH Research during the 37th ECNP congress.' Review of Ongoing Phase 2b TRD Clinical Trial (GH001-TRD-201) on 22 September 2024.

I have an interest in relation to one or more organisations that could be perceived as a possible conflict of interest in the context of the subject of this presentation. The relationships are summarised below^a:

<u>Interests</u>	<u>Name of Organisation</u>
Grants	Acadia, Angelini, Beckley Psytech, GH Research, HMNC Brain Health, IntraCellular Therapies, Janssen, MSD, Novartis, Otsuka, Recognify Life Sciences
Honoraria	Angelini, Janssen, Novartis
Shares	-
Paid positions	Professor of Psychiatry (full-time), Medical University of Gdańsk, Poland
Advisory boards	Douglas Pharmaceuticals, GH Research, Janssen, MSD, Novartis
Other involvement	-

^a Relationships reported within the last three years.

Overview of GH001 Clinical Trial Aspects^{1,2}



A synthetic formulation of the **serotonergic psychedelic mebufotenin^{a,b}** administered via **pulmonary inhalation**



Rapid onset (within seconds) and **short duration** (<30mins) of psychoactive effects



Single-dose administration OR an **individualized dosing regimen (IDR)** with up to three escalating doses administered on a single day; escalation guided by **peak experience^c**



No additional structured psychological support visits before or after dosing in clinical trial protocol



GH Research is also developing an **intravenous formulation** of mebufotenin: **GH002**

Abbreviations: PES = Peak experience scale.

^a Mebufotenin is not currently authorized as a treatment for any therapeutic indications. ^b Mebufotenin is more commonly known as 5-MeO-DMT (5-methoxy-N,N-dimethyltryptamine). ^c Peak experience is defined as achieving a score of ≥ 75 on the proprietary PES.

1. Reckweg JT, et al. *Eur Psychiatry*. 2022;65(suppl 1):S716. 2. Reckweg JT, et al. *Front. Psychiatry*. 2023;14:1133414. doi: 10.3389/fpsyt.2023.1133414.



GH001 (Inhaled)

Three completed trials

- Two Phase 1 trials in **HV** (GH001-HV-101, GH001-HV-103)
- One Phase 1/2 trial in patients with **TRD** (GH001-TRD-102)
- **78 subjects dosed to date** (completed studies only; 62 HV, 16 TRD)

Four ongoing trials

- Phase 1 trial in **HV** (GH001-HV-106-2) using GH Research's proprietary aerosol delivery device
- Phase 2b trial in patients with **TRD** (GH001-TRD-201)
- Phase 2a trial in patients with **bipolar II disorder**^a (GH001-BD-202)
- Phase 2a trial in patients with **PPD** (GH001-PPD-203)

GH002 (Intravenous)

Completed trial

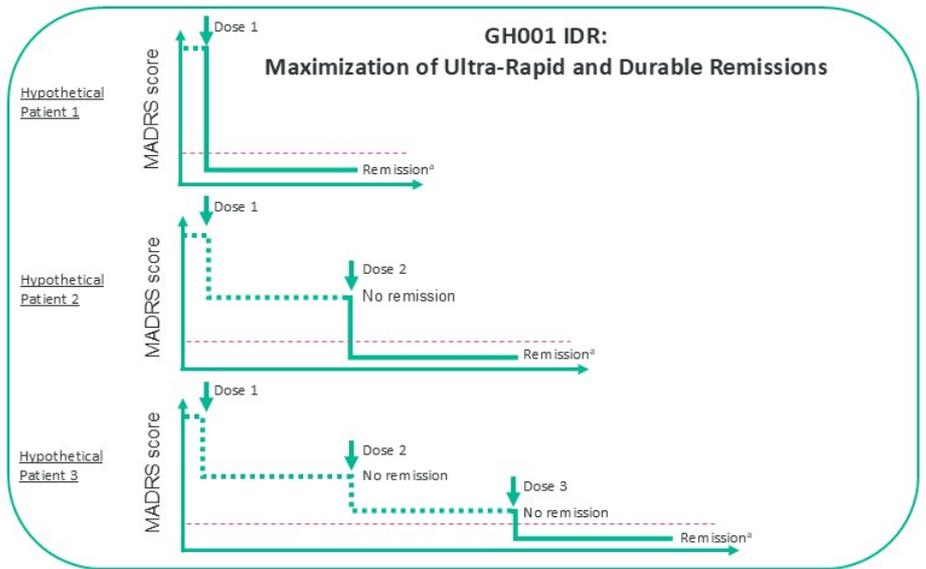
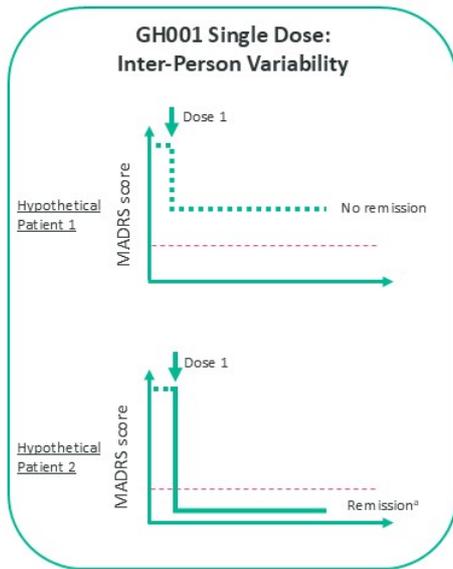
- One Phase 1 trial in **HV** (GH002-HV-105)
- 50 subjects dosed with GH002 to date

Abbreviations: HV = Healthy volunteers; PPD = Postpartum depression; TRD = Treatment-resistant depression.

^a Patients must be diagnosed with bipolar II disorder with a current major depressive episode.

1. Reckweg JT, et al. *Eur Psychiatry*. 2022;65(suppl 1):S716. 2. GH Research, Data on file. 3. Reckweg JT, et al. *Front. Psychiatry*. 2023;14:1133414. doi: 10.3389/fpsyt.2023.1133414.

Utilization of IDR Dose Escalations to Maximize Therapeutic Response^{1,2}



Abbreviations: IDR = Individualized dosing regimen; MADRS = Montgomery-Åsberg Depression Rating Scale; PE = Peak experience; PsE = Psychoactive effects.

^a Remission defined as a MADRS score ≤ 10 .

1. Reckweg JT, et al. *Eur Psychiatry*. 2022;65(suppl 1):S716. 2. Reckweg JT, et al. *Front. Psychiatry*. 2023;14:1133414. doi: 10.3389/fpsyt.2023.1133414.

Safety and Tolerability of GH001 in Completed Trials

GH001-HV-101¹, GH001-HV-103², and GH001-TRD-102³



Safety Parameters, n	Overall Population N=78
Any TEAE, n	50
Headache, no. of events	19
Anxiety, no. of events	12
Nausea, no. of events	8
Fatigue, no. of events	7
Any Serious AE	0
Any AE leading to trial/drug withdrawal	0
Death	0

TEAEs by Severity, no. of events	Overall Population N=78
Total number of TEAEs	105
Mild TEAEs	97
Moderate TEAEs	8
Severe TEAEs	0

- Overall, inhalation of GH001 was well tolerated across completed trials with no severe or serious adverse events reported and with TEAEs observed in 64.1% of subjects
- Most TEAEs were mild in severity (92.4%) and resolved spontaneously
- No noteworthy changes in vital signs were observed; transient increases in heart rate and blood pressure shortly after GH001 administration were not clinically significant
- Safety assessments, including laboratory analyses, psychiatric scales, electrocardiogram, and cognitive function tests, showed no clinically meaningful changes

Abbreviations: AE = Adverse event; TEAE = Treatment-emergent adverse event.

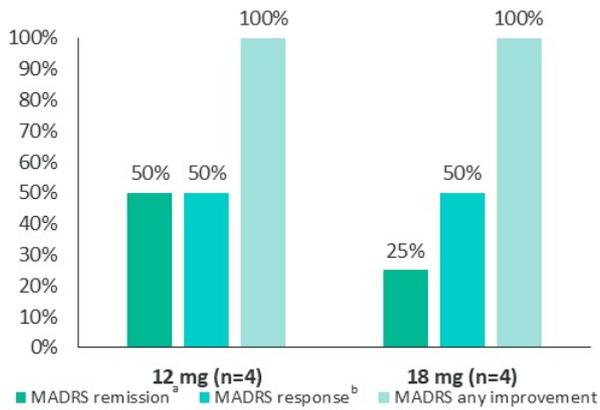
1. Reckweg JT, et al. *Eur Psychiatry*. 2022;65(suppl 1):S716. 2. GH Research, *Data on file*. 3. Reckweg JT, et al. *Front. Psychiatry*. 2023;14:1133414. doi: 10.3389/fpsy.2023.1133414.

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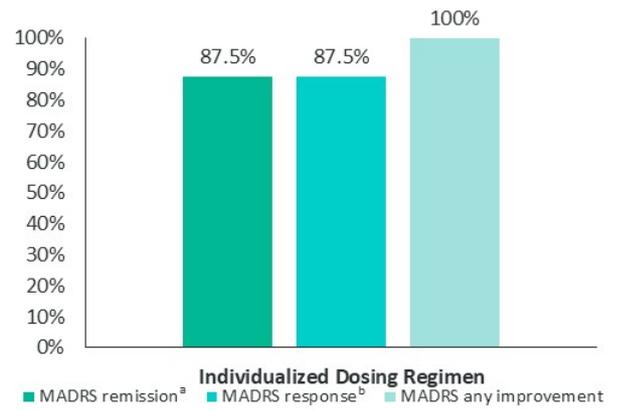


Single Dose (Day 7)



- 2/4 (50%) patients in the 12 mg group and 1/4 (25%) in the 18 mg group had a MADRS remission at Day 7
- 2/8 patients had a PE^c and both had a MADRS remission at Day 7

Individualized Dosing Regimen (Day 7)



- 7/8 (87.5%) patients had a MADRS remission at Day 7
- 7/8 patients had a PE^c and 6 of those had a MADRS remission at Day 7

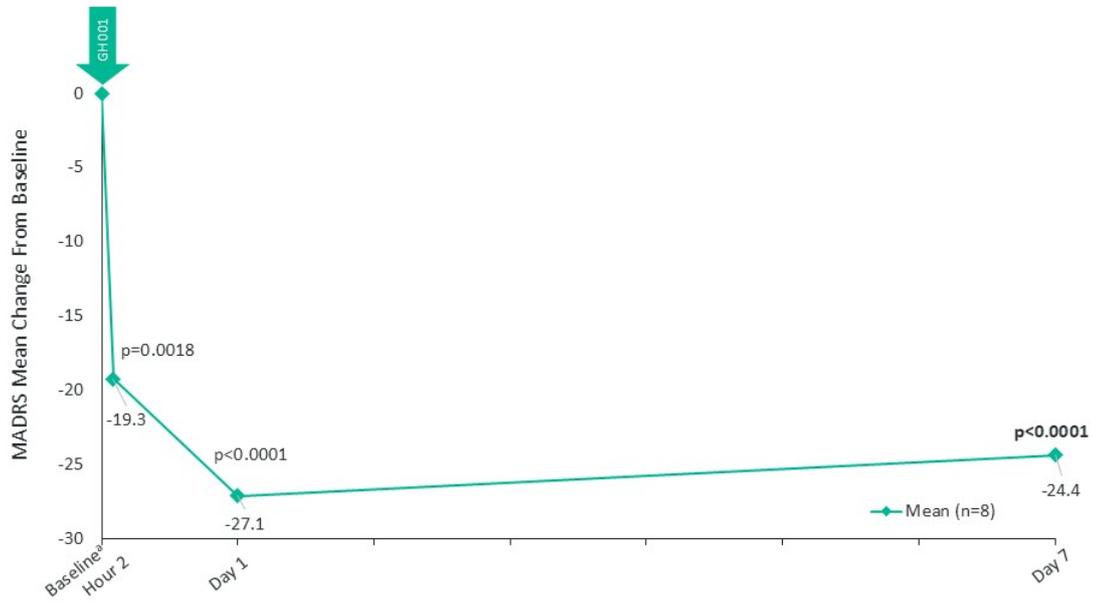
Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; PE = Peak experience; PES = Peak experience scale.

^a Remission is defined as a patient achieving a MADRS score of ≤ 10 after dosing. ^b Response is defined as a patient achieving $\geq 50\%$ reduction from baseline in MADRS total score after dosing. ^c PE is defined as achieving a score of ≥ 75 on the proprietary PES.

1. Reckweg JT, et al. *Front. Psychiatry*. 2023;14:1133414. doi: 10.3389/fpsyt.2023.1133414.

Efficacy of GH001 (MADRS Change from Baseline)

GH001-TRD-102: Individualized Dosing Regimen¹



Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale.

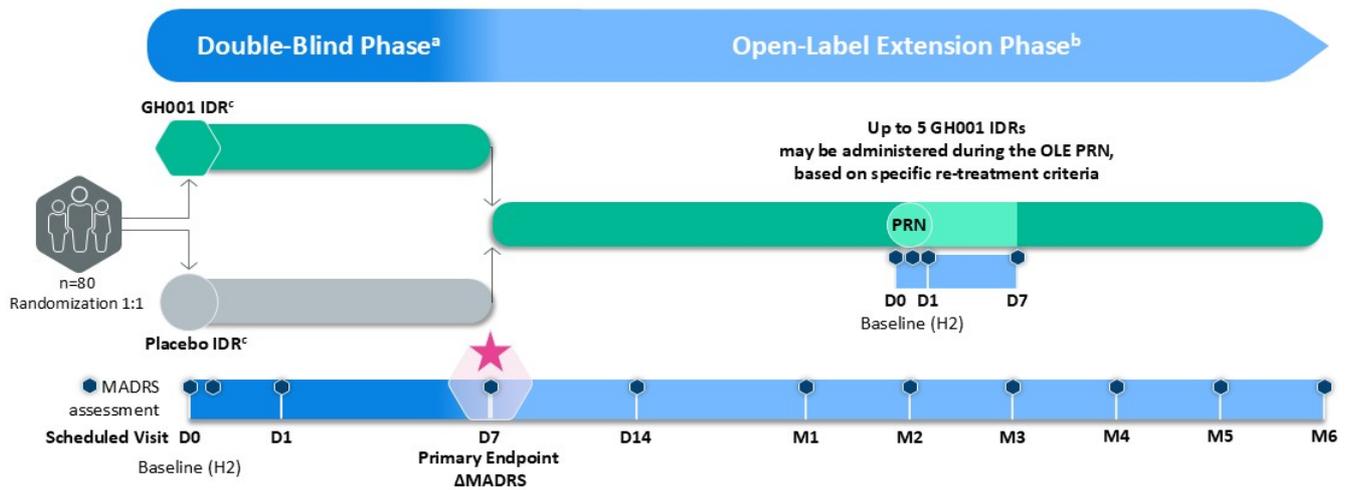
^a Baseline mean MADRS = 32.

1. Reckweg JT, et al. *Front. Psychiatry*. 2023;14:1133414. doi: 10.3389/fpsyt.2023.1133414.

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GH001-TRD-201 Trial Design

Phase 2b trial in patients with TRD¹



Abbreviations: D = Day; H = Hour; IDR = Individualized dosing regimen; M = Month; MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension; PRN = Pro re nata (as needed); TRD = Treatment-resistant depression.

^aThe double-blind phase was a fixed duration of 7 days (\pm 1 day) after an IDR with visits on D0, D1 and D7. After the double-blind phase there was a variable duration until a potential GH001 IDR in the OLE. ^bDuring the OLE, additional clinic visits can be scheduled if required for medical reasons. ^cThe GH001 IDR consists of up to 3 increasing doses (6, 12, 18 mg) and the placebo IDR consists of up to three placebo doses. As in previously completed trials, the GH001-TRD-201 trial will be conducted under the supervision of a healthcare provider, but without any planned psychotherapeutic interventions before, during, or after dosing.

1. NCT05800860. (2024). A Trial of GH001 in Patients With Treatment-Resistant Depression. ClinicalTrials.gov. Accessed August 23, 2024. <https://clinicaltrials.gov/ct2/show/NCT05800860>.



Thank you for your attention!