
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 May, 2022.

Commission File Number: 001-40530

GH Research PLC

(Exact name of registrant as specified in its charter)

28 Baggot Street Lower
Dublin 2
D02 NX43
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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

On May 31, 2022, at the American Society of Clinical Psychopharmacology 2022 Annual Meeting, the principal investigator presented data related to a Phase 1/2 clinical trial of GH001 (GH001-TRD-102) conducted by GH Research PLC (the “Company”). A copy of the presentation is attached hereto as Exhibit 99.1.

The fact that this presentation 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 presentation is being provided as of May 31, 2022 and the Company does not undertake any obligation to update the presentation in the future or to update forward-looking statements to reflect subsequent actual results.

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: May 31, 2022

GH Research PLC

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Presentation for May 2022

A Phase 1/2 Trial of GH001, a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation, in Patients with Treatment-Resistant Depression (TRD)

Johannes Reckweg¹, Cees van Leeuwen¹, Cécile Henquet², Therese van Amelsvoort², Natasha Mason¹, Riccardo Paci¹, Theis Terwey³, Johannes G Ramaekers¹

1. Faculty of Psychology and Neuroscience, Maastricht University, Maastricht, Netherlands
2. School Mental Health and Neuroscience, Maastricht University, Maastricht, Netherlands
3. GH Research, Dublin, Ireland

Clinicaltrials.gov ID NCT04698603

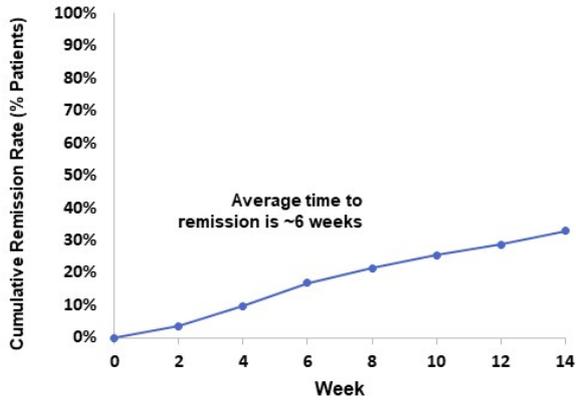
GH001-TRD-102
ASCP 2022

1

The Problem for Patients with Depression

Established Therapies are **Slow-Acting**

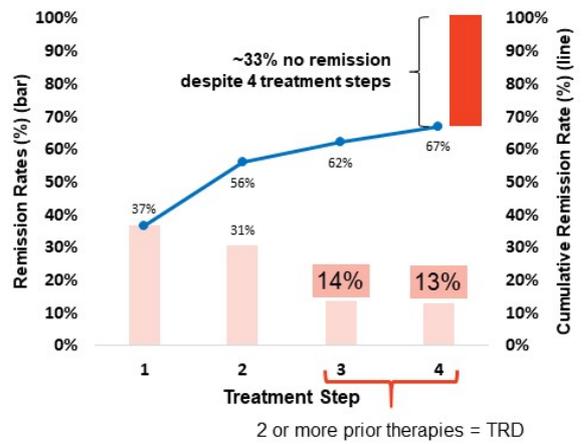
(STAR*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



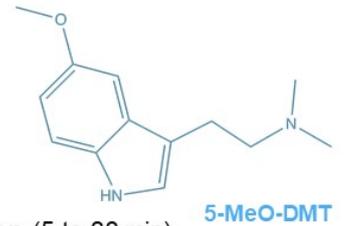
Adapted from Trivedi et al., Am J Psychiatry 2006 and Rush et al., Am J Psychiatry 2006

... Remission Rates in TRD < 15%

(STAR*D study, Remission Rates Treatment Steps 1 to 4)



5-MeO-DMT and GH001

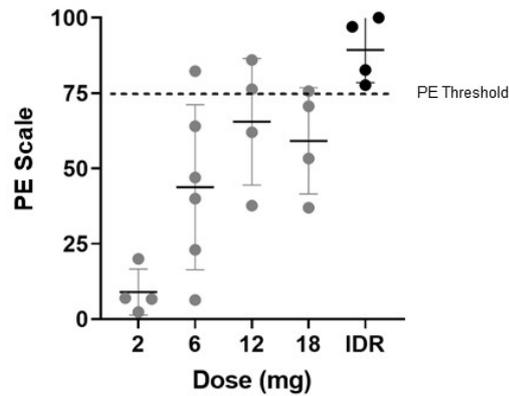


- **5-MeO-DMT** (5-Methoxy-N,N-Dimethyltryptamine)
 - Naturally-occurring psychoactive substance from tryptamine class
 - **Highly potent** agonist on 5-HT_{1A} and 5-HT_{2A} receptors
 - **Psychoactive effects with ultra-rapid onset** (within seconds) and **short duration** (5 to 30 min)
 - **High propensity to induce peak experiences (PE), which may be a surrogate marker for therapeutic effects**

- **GH001** (5-MeO-DMT administration via a proprietary inhalation approach)
 - **Intraday individualized dosing regimen (IDR) for maximization of ultra-rapid remissions**
 - **Single visit initial treatment**, with no structured psychotherapy

Phase 1 Trial in Healthy Volunteers (GH001-HV-101, n=22)

- GH001 single doses of 2 mg, 6 mg, 12 mg, 18 mg and GH001 IDR (6, 12, 18 mg intra-subject dose escalation)
- **No SAEs, all ADRs mild (except two moderate), all ADRs resolved spontaneously, inhalation well-tolerated**
- GH001 single dose with psychoactive effect dose response but high inter-subject variability
- **GH001 IDR controls inter-subject variability achieving a PE¹ in all healthy volunteers**

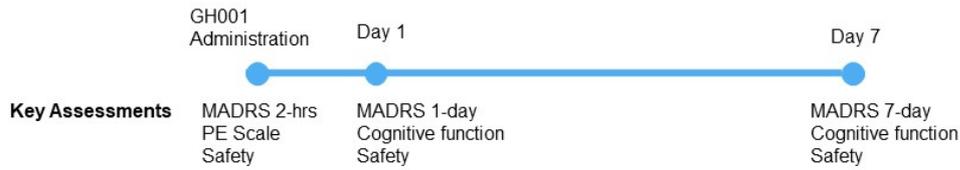
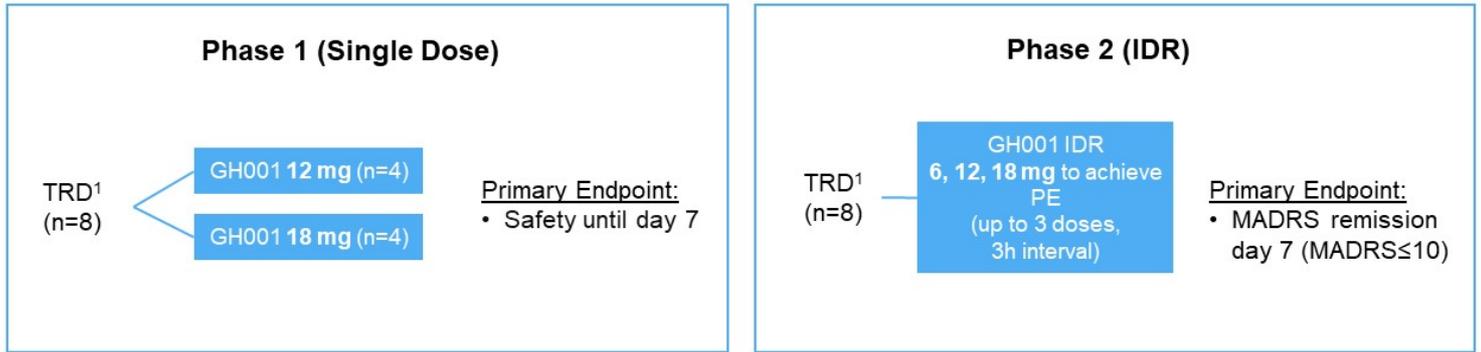


Clinicaltrials.gov ID NCT04640832; Reckweget al, 2021

¹The occurrence of a Peak Experience (PE) is assessed using the proprietary PE Scale, which averages answers scored by the patient from 0 to 100 on a visual analog scale for three parameters of the experience: intensity, feelings of loss of control and profoundness. A PE is defined as an average score across these three parameters of at least 75. PE ratings shown for IDR group represent values for the final administration of GH001.

IDR, Individualized Dosing Regimen; SAE, Serious Adverse Event; ADR, Adverse Drug Reaction (an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing).

Phase 1/2 Trial in TRD (GH001-TRD-102, n=16)

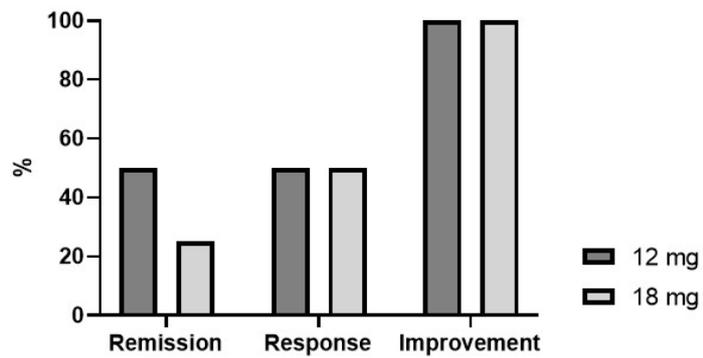


PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen

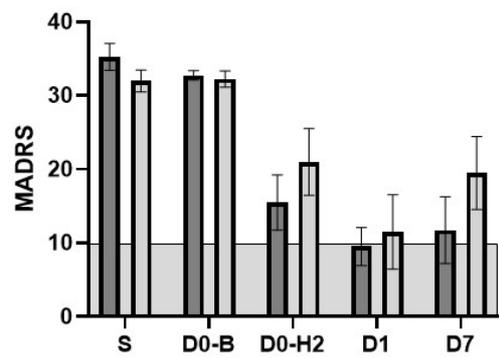
¹Defined as inadequate response to at least two adequate courses of pharmacological therapy or one adequate course of pharmacological therapy and at least one adequate course of evidence-based psychotherapy

Phase 1 (Single Dose) – Efficacy (MADRS)

MADRS Remission, Response, Improvement Rate at Day 7



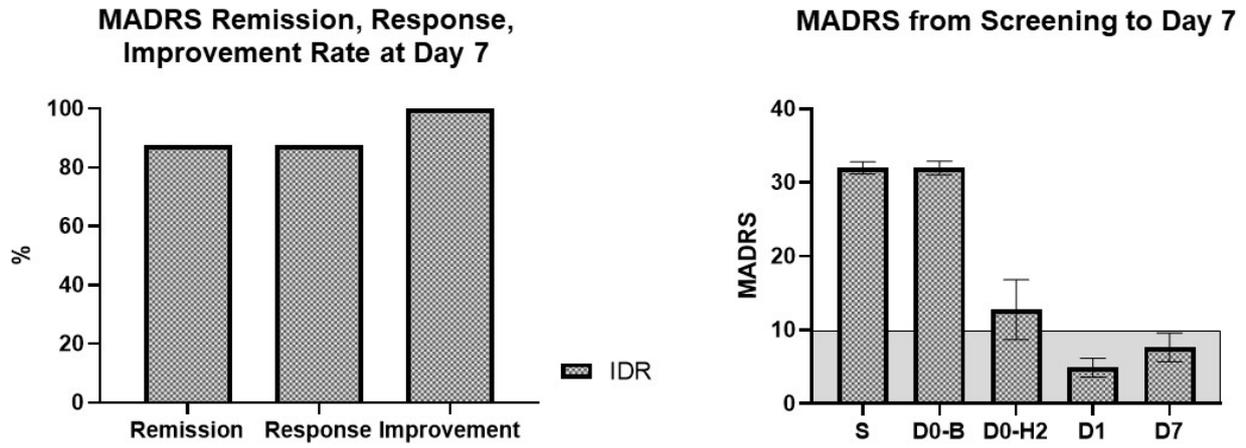
MADRS from Screening to Day 7



- 2 of 4 patients in the 12 mg group and 1 of 4 patients in the 18 mg group had a MADRS remission at day 7
- 2 of 4 patients in the 12 mg group had a PE and both had a MADRS remission at day 7, 0 of 4 patients in the 18 mg group had a PE

PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale, MADRS remission, MADRS of ≤ 10 ; MADRS response, Reduction of $\geq 50\%$ from baseline in MADRS; S, Screening; D0-B, Day 0 Baseline; D0-H2, Day 0 2 hours.

Phase 2 (IDR) – Efficacy (MADRS)



- **Primary endpoint met:** 7 of 8 patients (87.5%) had a MADRS remission at day 7, $p < 0.0001$
- 7 of 8 patients had a PE and 6 of those had a MADRS remission at day 7

PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; MADRS remission, MADRS of ≤ 10 ; MADRS response, Reduction of $\geq 50\%$ from baseline in MADRS; S, Screening; D0-B, Day 0 Baseline; D0-H2, Day 0 2 hours.

Phase 1 (Single Dose) and Phase 2 (IDR) – Safety

Study Safety Group review

- No SAEs
- All ADRs mild, except three moderate*
- All ADRs resolved spontaneously
- Inhalation well-tolerated
- No noteworthy changes in vital parameters, except for temporary, non-clinically relevant increase in heart rate and blood pressure shortly after administration of GH001
- No clinically significant changes in safety laboratory analyses, psychiatric safety assessments or measures of cognitive function
- No safety signal relating to suicidal ideation or suicidal behavior, based on C-SSRS and MADRS subscore item "suicidal thoughts"

ADRs MedDRA Preferred Term	Phase 1 (Single Dose)		Phase 2 (IDR)
	12 mg (N=4)	18 mg (N=4)	IDR ¹ (N=8)
	n	n	n
Abdominal discomfort			1
Anxiety			2
Depressive symptom			1*
Dizziness	1		
Feeling abnormal	1	1	
Flashback	1	1	2
Headache	2	1	3
Muscle discomfort			1
Muscle spasms		1	
Nausea			2*
Paresthesia			1
Sensory disturbance			3

Adverse Drug Reaction, or ADR, an adverse event with a relationship code to the investigational product of definite, probable, or possible, or where code is missing
IDR, Individualized Dosing Regimen; C-SSRS, Columbia-Suicide Severity Rating Scale

¹6-12 mg (N=6); 6-12-18 mg (N=2)

Conclusions

- GH001 allows **rapid and individualized dosing optimization**
- A single dosing day with GH001 IDR achieved a **rapid (within 24 hours) and sustained full remission (7 days)** of symptoms of depression in 7/8 patients (87.5%) with TRD
- GH001 was **well tolerated**, and no serious adverse events were reported

Contacts

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