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 October, 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 October 17, 2022, at the European College of Neuropsychopharmacology Conference 2022 ("ECNP 2022"), an investigator will present data related to a Phase 1/2 clinical trial of GH001 (GH001-TRD-102) conducted by GH Research PLC (the "Company") in the form of a poster session and presentation. A copy of the poster is attached hereto as Exhibit 99.1 and a copy of the presentation is attached hereto as Exhibit 99.2.

Additionally, on October 17, 2022, at ECNP 2022, an investigator will present data related to a Phase 1 clinical trial of GH001 (GH001-HV-101) conducted by the Company in the form of a poster session and presentation. A copy of the poster is attached hereto as Exhibit 99.3 and a copy of the presentation is attached hereto as Exhibit 99.4.

The fact that these materials are 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 these materials is being provided as of October 14, 2022 and the Company does not undertake any obligation to update these materials in the future or to update forward-looking statements to reflect subsequent actual results.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Poster for a Phase 1/2 clinical trial of GH001 (GH001-TRD-102), for October 2022
99.2	Presentation for a Phase 1/2 clinical trial of GH001 (GH001-TRD-102), for October 2022
99.3	Poster for a Phase 1 clinical trial of GH001 (GH001-HV-101), for October 2022
99.4	Presentation for a Phase 1 clinical trial of GH001 (GH001-HV-101), for October 2022

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: October 14, 2022

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

Maastricht University | GH Research

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

Reckweg JT[1]*, van Leeuwen C[1], Henquet C[2], van Amelsvoort T[2], Mason NL[1], Terwey TH[3], Ramaekers JG[1]
*presenting author
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[3]GH Research, Dublin, Ireland

Poster # P.0450

INTRODUCTION

Current established treatments for depression are slow-acting, often taking several weeks before potential effects appear, and about one third of patients do not reach remission even after 4 treatment steps[1].

5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) is a potent, fast-acting, naturally-occurring psychoactive tryptamine[2]. It acts on the 5-HT1A and 5-HT2A receptors and has a high propensity in eliciting so called peak experiences (PE). These are states during an intense psychedelic experience that are defined by feelings of ego dissolution and experiences of oneness or unity. PEs can be very profound and meaningful experiences, which may correlate with therapeutic outcomes.

The current study tested if 5-MeO-DMT, in a proprietary vaporized formulation (GH001), could function as a rapid treatment option for patients with treatment-resistant depression (TRD). TRD was defined as an 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.

AIMS

1. To investigate the safety and tolerability of GH001 in patients with TRD (Phase 1 part).
2. To assess the therapeutic efficacy of GH001 in patients with TRD (Phase 2 part).

METHODS

The study was comprised of two single-arm parts, where the Phase 1 part (n=8) consisted of two single dose levels (12 mg and 18 mg) and the Phase 2 part (n=8) was comprised of an individualized dosing regimen (IDR) of up to three increasing doses on a single day (6 mg, 12 mg, 18 mg). The Phase 2 part consecutive doses were only administered if the previous dose did not elicit a PE. This was assessed using a proprietary novel PE scale (PES), consisting of 3 visual analogue scales. Aside from a pre-screening, a thorough medical and psychiatric screening, and the single administration day, follow up visits were conducted on day 1 and day 7 after the dosing day. No specific psychotherapeutic interventions, besides interactions for the screening and outcome assessments, were included at any of the visits.

A total of 16 patients with TRD (7 female, 9 male) aged 21 to 51 years (*Mdn*=29.5) participated in the study. To avoid expectancy effects, participants were not informed about the identity of the study drug until completion of the study.

The primary endpoint of the Phase 1 part of the study was to assess the safety and tolerability of GH001 administered via inhalation after vaporization. The primary endpoint of the Phase 2 part of the study was to assess the effect of GH001 on the severity of depression, as evaluated by the proportion of patients in remission (MADRS≤10) at 7 days after dosing. For this primary endpoint the one-sided null hypothesis assumed a remission probability ≤ 0·01 and was tested by an exact binomial test with one-sided significance level α = 0·025. The secondary endpoints of mean change in MADRS total score from baseline to 2 hours, 1 day, and 7 days after dosing were evaluated by a paired t-test comparing the mean MADRS total score at the respective time point with the mean MADRS total score at baseline, each time point being evaluated separately.

RESULTS

In the Phase 1 part, 2 out of 4 patients achieved a PE (i.e., PES rating ≥75) in the 12 mg dose group, and 0 out of 4 patients achieved a PE in the 18 mg dose group. In the Phase 2 Part, applying the IDR, 7 out of 8 patients achieved a PE, whereby 6 patients achieved a PE after the second administration (6 mg + 12 mg), and one patient achieved a PE after the third administration (6 mg + 12 mg + 18 mg).

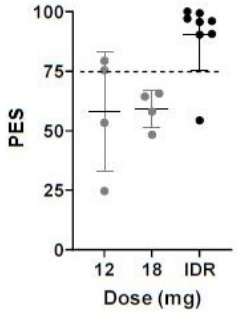

Figure 1. *Mean (SE) and individual ratings of the PES per dose level. Average of ≥75 on PES indicated a PE.*

The proportion of patients with MADRS remission (MADRS≤10) at day 7 was 2 out of 4 (50%) and 1 out of 4 (25%) in the 12 mg and 18 mg groups in the Phase 1 part, respectively, and 7 out of 8 (87.5%) in the IDR group in the Phase 2 part, meeting its primary endpoint (remission probability=0.875; 95% CI=0.473-0.997; Mid-p 95% CI=0.520-0.994; p<0.0001).

The mean MADRS change from baseline to day 7 was -21.0 (-65%) and -12.5 (-40%) in the 12 and 18 mg groups, respectively, and -24.4 (-76%) for the IDR. Paired t-tests revealed a significant decrease in MADRS ratings at 2 hours (t=-4.71; p=.0022), 1 day (t=-8.08; p<.0001) and 7 days (t=-5.31; p=.0011) after single dose administrations in the Phase 1 part, and at 2 hours (t=-4.88; p=.0018), 1 day (t=-14.54; p<.0001) and 7 days (t=-9.98; p<.0001) after administration of the IDR in Part B.

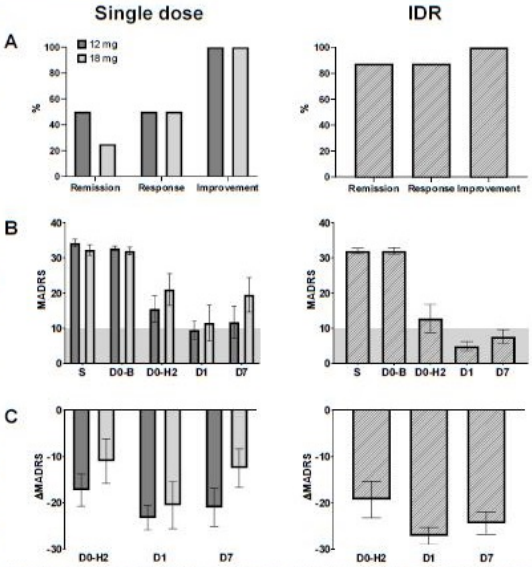

Figure 2. *Panel A shows remission, response and improvement rates after single doses of GH001 and after an IDR of GH001. Panel B shows mean (SE) MADRS ratings at screening (S), at baseline (D0-B) before dosing, at 2 hours after dosing of GH001 (D0-H2), and at 1 (D1) and 7 (D7) days follow-up in the Phase 1 part (single dose) and phase 2 Part (IDR). Grey planes indicate remission as indicated by MADRS ≤ 10. Panel C shows mean (SE) MADRS change from baseline at D0-H2, D1 and D7.*

Safety

Safety measures, such as measures of cognitive function and psychiatric safety, did not show any clinically significant change at any post-dose assessment as compared to their values at baseline. Further, no clinically significant changes in vital parameters, ECG and safety laboratory analyses were observed.
There were 3 adverse drug reactions of moderate intensity (2x nausea, 1x depressive symptom) with all other adverse drug reactions being mild, and all resolved spontaneously. There were no serious adverse events (SAE).

CONCLUSION

- GH001 allows rapid and individualized dosing optimization
- GH001 administered without specific structured psychotherapeutic interventions before, during and after dosing was well tolerated, and no SAE were reported
- The GH001 IDR administered on a single day achieved a rapid and sustained (7 days) full remission in 7/8 patients with TRD.

References

[1]Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. *Am J Psychiatry*. 2006;163(11):1905-1917.
[2]Reckweg JT, Uthaug MV, Szabo A, et al. The clinical pharmacology and potential therapeutic applications of 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT). *J Neurochem*. 2022; 162(1):128-146.

Disclosure statement: The study was funded by GH Research, Dublin, Ireland

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Psychopharmacology in Maastricht

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

Johannes Reckweg[1], Cees van Leeuwen[1], Cécile Henquet[2], Thérèse van Amelsvoort[2], Natasha Mason[1], Riccardo Paci[1], Theis Terwey[3], Johannes G Ramaekers[1]

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Clinicaltrials.gov ID NCT04698603

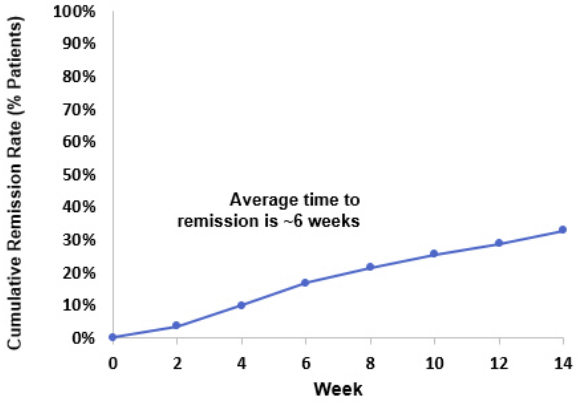
Disclosures

Grants	The study was funded by GH Research
Advisory Board/Consultant	Johannes Reckweg and Jan Ramaekers work as consultants for GH Research

The Problem for Patients with Depression

Established Therapies are Slow-Acting

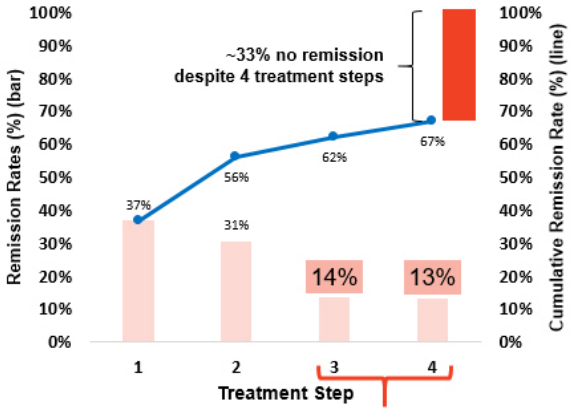
(STAR*D study, Remission Rate Over Time, Treatment Step 1 = Citalopram)



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

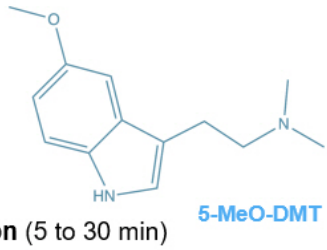
... Remission Rates in TRD < 15%

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



2 or more prior therapies = TRD

5-MeO-DMT and GH001

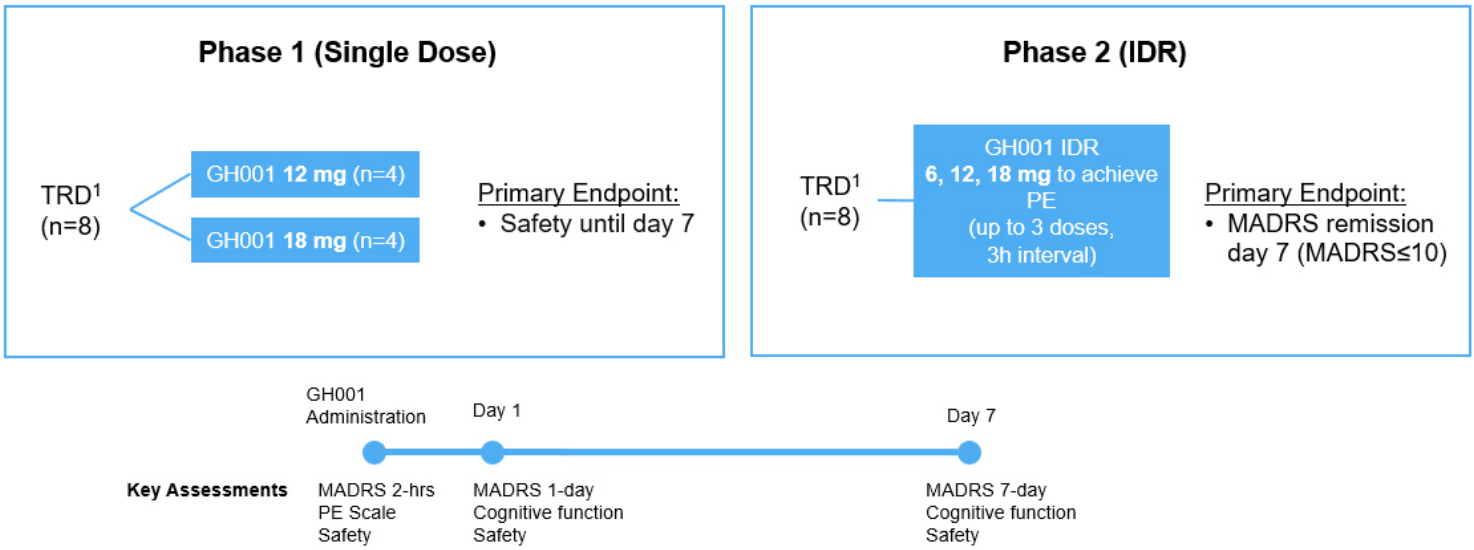


5-MeO-DMT

- **5-MeO-DMT** (5-Methoxy-N,N-Dimethyltryptamine)
  - Naturally-occurring psychoactive substance from tryptamine class
  - **Highly potent** agonist on 5-HT1A and 5-HT2A receptors
  - **Psychoactive effects with ultra-rapid onset** (within seconds) **and short duration** (5 to 30 min)
    - High propensity to induce **peak experiences**; markers for **therapeutic effect**

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

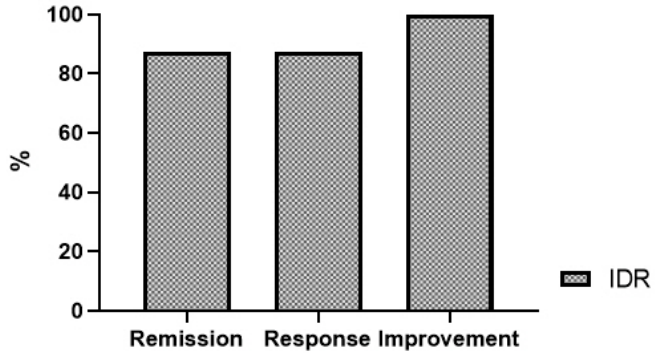


PE, Peak Experience; MADRS, Montgomery-Åsberg Depression Rating Scale; IDR, Individualized Dosing Regimen

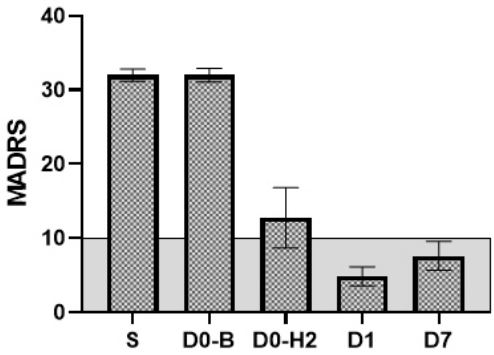
[1] *Defined as inadequate response to at least two adequate courses of pharmacological therapy or one adequate course of pharmacological therapy and at least one adequate course of evidence-based psychotherapy*

Phase 2 (IDR) – Efficacy (MADRS)

MADRS Remission, Response, Improvement Rate at Day 7



MADRS from Screening to Day 7



- **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 ≥50% from baseline in MADRS; S, Screening; D0-B, Day 0 Baseline; D0-H2, Day 0 2 hours; D1, Day 1; D7, Day 7.

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	Phase 1 (Single Dose)		Phase 2 (IDR)
	12 mg (N=4)	18 mg (N=4)	IDR[1] (N=8)
MedDRA Preferred Term	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

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
IDR, Individualized Dosing Regimen; C-SSRS, Columbia-Suicide Severity Rating Scale

[1] *6-12 mg (N=6); 6-12-18 mg (N=2)*

Conclusions

- GH001 was **well tolerated,** and no serious adverse events were reported
  - **No clinically significant changes** in vital signs, cognitive function, psychiatric safety assessment
- 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

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Maastricht University

GH Research

A Phase 1, Dose-Ranging Trial to Assess the Safety and Psychoactive Effects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers

Reckweg JT[1]*, Mason NL[1], van Leeuwen C[1], Toennes SW[2], Terwey TH[3], Ramaekers JG[1]

*presenting author

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[2]Institute of Legal Medicine, University of Frankfurt, Frankfurt, Germany
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Poster # P.0665

INTRODUCTION

5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) is a potent, fast-acting, naturally-occurring psychoactive tryptamine[1]. It is predominantly found in the bufotoxin of the Sonoran Desert toad[2] and was first synthesized in 1936[3]. It acts on the 5-HT1A and 5-HT2A receptors, and it has been suggested that the 5-HT1A subtype is functionally dominant[4]. 5-MeO-DMT has been used in recreational or self-exploratory contexts[2].

5-MeO-DMT has been reported to be proficient in eliciting so called peak psychedelic experiences (PE). These are states during an intense psychedelic experience that are defined by feelings of ego dissolution and experiences of oneness or unity. These can be very profound and meaningful experiences, which may correlate with therapeutic outcomes.

In the current study, 5-MeO-DMT was administered via inhalation as GH001, a novel vaporized 5-MeO-DMT formulation.

AIMS

The primary aim of the study was to investigate safety, tolerability and dose-related psychoactive effects of GH001 in healthy volunteers. Additional aims were to assess the impact of GH001 on cognition, mood, and well-being, as well as to determine the best dosing regimen to reliably elicit a PE.

METHODS

The study was comprised of two single-arm parts, where Part A (n=18) consisted of four single dose levels (2 mg, 6 mg, 12 mg, 18 mg).
Part B (n=4) was comprised of an individualized dosing regimen (IDR), of up to three increasing doses on a single day (6 mg, 12 mg, 18 mg). The part B consecutive doses were only administered if the previous dose did not elicit a PE. This was assessed using a proprietary novel PE scale (PES), consisting of 3 visual analogue scales. Aside from a (medical) screening and the single administration day, follow up visits were conducted on day 1 and day 7 after the dosing day.

A total of 22 healthy volunteers (9 female, 13 male) aged 18 to 42 years (M=29, SD=6.08) with a history of prior psychedelic use participated in the study.
To avoid expectancy effects, participants were not informed about the identity of the study drug until completion of the study.

Measures of the psychedelic experience (PES, EDI, MEQ, CEQ, 5D-ASC) were analyzed using ANOVAs with single factor *Dose* (5 levels: 2, 6, 12, 18 mg and IDR).
The cognitive tests (DSST, PVT, PMT), measures of well-being (DASS-21, SWLS, FFMQ, CADSS, BPRS), and vital signs were analysed using GLM RM-ANOVAs with the factors *Dose* (5 levels) and *Time* (3 levels: Baseline, post-administration, 7-day follow up).

RESULTS

Psychedelic experience

ANOVAs indicated a significant effect of 5-MeO-DMT *Dose* on ratings of the PES ($F_{4,17}$ = 9.302, p < .001, η_p^2 = 0.686), EDI ($F_{4,17}$ = 6.925, p = .002, η_p^2 = 0.62), MEQ ($F_{4,17}$ = 8.026, p = .001, η_p^2 = 0.654), and Reduction of Vigilance as assessed with the 5D-ASC ($F_{4,17}$ = 4.023, p = .018, η_p^2 = 0.486). The effects of dose on ratings of Oceanic Boundlessness approached significance ($F_{4,17}$ = 2.901, p = .053, η_p^2 = 0.406). Planned contrasts indicated higher mean ratings of the psychedelic experience at higher doses compared to the lowest dose of 2 mg.

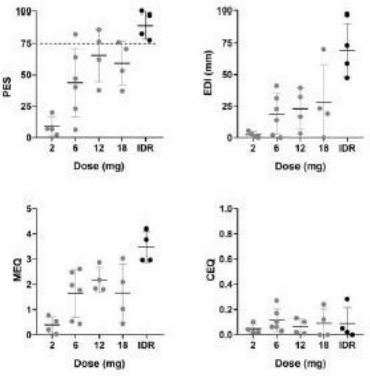

Figure 1 Mean (SE) and individual retrospective ratings of the acute psychedelic experience (PES, EDI, MEQ, CEQ) per dose level. *Average of ≥75 on PES indicated a PE.*

In part A, four participants reported a peak experience (i.e., PES rating ≥75%): one participant at the 6 mg dose, two participants at the 12 mg dose, one participant at the 18 mg dose. In part B, all four participants in the IDR group reached a PE; one participant after first dose (6 mg), two after second dose (6 mg + 12 mg), and one participant after three doses (6 mg + 12 mg + 18 mg).

Cognition and well-being

For the measures on cognition and well-being, no clinically relevant effects of *Dose* or *Time*x*Dose* were observed. The factor *Time* reached significance for the SLWS, BPRS, and the Amnesia and Derealization subscales of the CADSS.

Safety and tolerability

All doses were considered safe and well-tolerated. There were no dropouts and no serious adverse events (AEs) reported. There were two AEs of moderate severity (fatigue, heart rate increase) with all other AEs being mild (e.g. nausea, headache, anxiety), and all AEs resolved spontaneously.
There were no significant effects of *Dose* on measures of systolic/diastolic blood pressure or heart rate and only a non-clinically significant effect of *Time* (p=.003), reflecting a mild decrease in heart rate from baseline to 3 hours post-administration (heart rate remained within normal range).

Plasma concentrations

Plasma concentrations of 5-MeO-DMT were very low at 1 hour post-administration and barely measureable at 3 hours post-administration. Bufotenin concentrations were below limit of detection (0.006 ng/ml) at all time points.

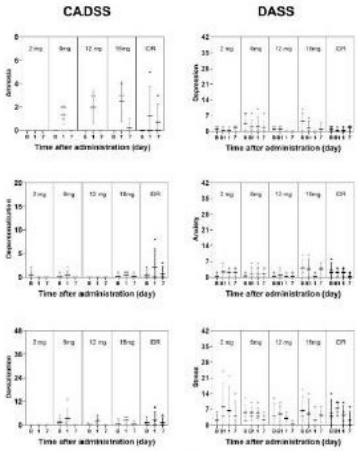

Figure 2 Mean (SE) and individual CADSS and DASS ratings per dose level.

CONCLUSION

- Administration of GH001 was well tolerated
- Short duration of effects support safety profile
- Individual variability for dose-related effects
  → IDR may be preferable for clinical applications that aim to optimize therapeutic response

References
[1]Shulgin, A., and Shulgin, A. (1997). *Tryptamines I Have Known and Loved: The Chemistry Continues*. Berkeley, CA: Transform Press.
[2]Weil, A. T., & Davis, W. (1994). Bufo alvarius: A potent hallucinogen of animal origin. *Journal of Ethnopharmacology*, **41**, 1–8.
[3]Hoshino, T., and Shimodaira, K. (1936). Über Die Synthese Des Bufotenin-Methyl-Äthers (5-Methoxy-N-Dimethyl-Tryptamin) Und Bufotenins (Synthesen in Der Indol-Gruppe. Xv). *Bull. Chem. Soc. Jpn.* 11, 221–224. doi:10.1246/bcsj.11.221
[4]Krebs-Thomson, K., Ruiz, E. M., Masten, V., Buell, M., and Geyer, M. A. (2006). The Roles of 5-HT1A and 5-HT2 Receptors in the Effects of 5-MeO-DMT on Locomotor Activity and Prepulse Inhibition in Rats. *Psychopharmacology (Berl)*. 189, 319–329. doi:10.1007/s00213-006-0566-1

Disclosure statement: The study was funded by GH Research, Dublin, Ireland

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Psychopharmacology in Maastricht

A Phase 1, Dose-Ranging Study to Assess Safety and Psychoactive Effects of a Vaporized 5-Methoxy-N, N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers

Johannes Reckweg[1], Natasha Mason[1], Cees van Leeuwen[1], Stefan Toennes[2], Theis Terwey[3], Johannes G Ramaekers[1]

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2. Institute of Legal Medicine, University of Frankfurt, Frankfurt, Germany
3. GH Research, Dublin, Ireland

Clinicaltrials.gov ID NCT04698603

Disclosures

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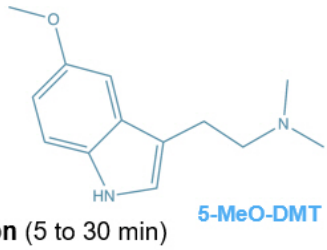
5-MeO-DMT and GH001



5-MeO-DMT

- **5-MeO-DMT** (5-Methoxy-N,N-Dimethyltryptamine)
  - Naturally-occurring psychoactive substance from tryptamine class
  - **Highly potent** agonist on 5-HT1A and 5-HT2A receptors
  - **Psychoactive effects with ultra-rapid onset** (within seconds) **and short duration** (5 to 30 min)

- **GH001** (5-MeO-DMT administration via a proprietary inhalation approach)
  - **Intraday individualized dosing regimen (IDR) for maximization of ultra-rapid remissions**

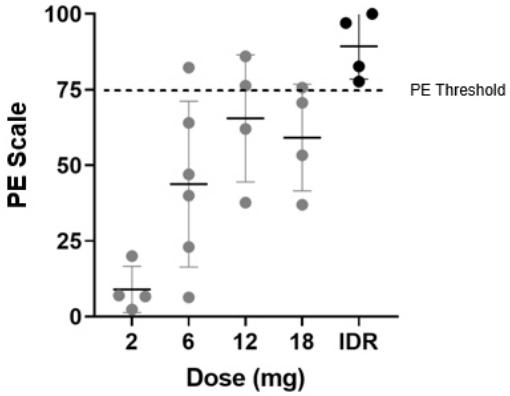
5-MeO-DMT and Peak Experiences

- High propensity to induce **peak experiences (PE)**
  - Feelings of **ego dissolution**
  - Experience of **unity** or **oneness**
  - **Profound** and **meaningful**
- May be a surrogate marker for therapeutic effects

- Assessed through proprietary Peak Experience Scale
  - Three visual analogue scales (0 – 100):
    - Intensity
    - Loss of control
    - Profoundness
  - PE defined as total average of ≥ 75

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 PE in all healthy volunteers**



Clinicaltrials.gov ID NCT04640831; Reckweg et al, 2021
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).

Conclusions

- GH001 has promising safety profile
- GH001 allows **rapid and individualized dosing optimization**
- IDR could be used in clinical applications

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IDR, Individualized Dosing Regimen