
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 January, 2026.

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 January 5, 2026, GH Research PLC (the “Company”) announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on GH001, provided further development updates, and made available an updated corporate presentation on its website. A copy of the press release is exhibited hereto as Exhibit 99.1 and a copy of the corporate presentation is attached hereto as Exhibit 99.2.

The fact that this press release and corporate presentation are being made available should not be deemed an admission as to the materiality of any information contained in the materials. The information contained in the press release and corporate presentation is being provided as of January 5, 2026, and the Company does not undertake any obligation to update the press release or the presentation 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 January 5, 2026
<u>99.2</u>	Corporate presentation for January 2026

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: January 5, 2026

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

GH Research Announces FDA Lifts Clinical Hold on GH001, Clearing Path for Global Phase 3 Initiation in 2026

- GH001 cleared by FDA for U.S. clinical investigation, enabling U.S. subject enrollment
- Company to seek FDA alignment on global Phase 3 program replicating Phase 2b design
- Phase 3 initiation targeted for 2026

Dublin, Ireland, January 5, 2026 – 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 the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on its Investigational New Drug Application (IND) for GH001.

This clearance enables U.S. subject enrollment and progresses the company toward alignment of its development across major jurisdictions.

“The FDA clearance is a major milestone and positions us to advance GH001 as a potential ultra-rapid and durable treatment option for TRD patients,” said Dr. Velichka Valcheva, Chief Executive Officer. “We continue to expect initiation of our global pivotal program in 2026. We look forward to meeting with the FDA to align on the design for the pivotal Phase 3 program.”

GH001 Phase 2b Profile Highlights from the Previously Reported Phase 2b trial (GH001-TRD-201):

- Primary endpoint met: -15.5 point placebo-adjusted MADRS reduction on Day 8 ($p < 0.0001$)
- Ultra-rapid remission (57.5% of patients on Day 8); 73% remission at 6 months with infrequent dosing (~4 treatments on average)
- Short psychoactive experience (median of ~11 minutes)
- No required psychotherapy
- 99% of patients discharge-ready within 1 hour of dosing
- Favorable safety: well-tolerated, no serious treatment-related adverse events

Recent presentations at scientific conferences reinforce GH001's potential for integration into existing interventional psychiatry practices through its convenient administration profile.

Michael E. Thase, MD, Professor of Psychiatry, Perelman School of Medicine at the University of Pennsylvania, said, “The large and rapid antidepressant effect observed with GH001 in the Phase 2b trial, combined with sustained remission through infrequent, short clinic visits, has the potential to be practice-changing for patients with treatment-resistant depression.”

About GH Research PLC

GH Research PLC is a clinical-stage biopharmaceutical company dedicated to transforming the lives of patients by developing a practice-changing treatment in depression. GH Research PLC's initial focus is on developing its novel and proprietary mebufotenin therapies for the treatment of patients with treatment-resistant depression (TRD).

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 the 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 expectations with regard to initiating our global pivotal program, and the expected timing of such initiation, 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

Julie Ryan
GH Research PLC
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Ultra-Rapid, Durable Remission in TRD with Minimal Clinic Burden

GH Research PLC (Nasdaq: GHRS)

January 2026

Disclaimer Regarding Forward-Looking Statements

This presentation has been prepared by GH Research PLC ("GH Research"). Nothing contained in this presentation is, or should be construed as, a recommendation, promise or representation by the presenter or GH Research or any director, employee, agent, or adviser of GH Research. This presentation does not purport to be all-inclusive or to contain all of the information you may desire.

This presentation does not constitute an offer to sell or the solicitation of an offer to buy securities, nor shall there be any sale of securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

This presentation contains forward-looking statements, all of which are qualified in their entirety by this cautionary statement. Many of the forward-looking statements contained herein can be identified by the use of forward-looking words such as "may", "anticipate", "believe", "could", "expect", "should", "plan", "intend", "estimate", "will", "potential" and "ongoing", among others, although not all forward-looking statements contain these identifying words.

Any statements contained herein that do not describe historical facts are forward-looking statements that are based on management's expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcomes, timing and performance to differ materially from those expressed or implied by such statements. These factors, risks and uncertainties include, but are not limited to: the costs and uncertainties associated with GH Research's research and development efforts; the inherent uncertainties associated with the conduct, timing and results of nonclinical and clinical studies of GH Research's product candidates; GH Research's expectations related to commencing trials in the US; GH Research's ability to obtain, maintain, enforce and defend issued patents; the adequacy of GH Research's capital resources, the availability of additional funding and GH Research's cash runway; and other factors, risks and uncertainties described in GH Research's filings with the U.S. Securities and Exchange Commission.

Except as otherwise noted, these forward-looking statements speak only as of the date of this presentation, and GH Research undertakes no obligation to update or revise any of such statements to reflect events or circumstances occurring after this presentation. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond GH Research's control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in any such forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. GH Research cautions you not to place undue reliance on the forward-looking statements contained in this presentation.

Pipeline



Product Candidate	Indication	Preclinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Current Status	Milestone
GH001 <i>Mebufotenin for inhalation administration</i>	Treatment-resistant depression (TRD)						Phase 2b RDBPC completed Phase 1 PK trial with proprietary device ongoing	Phase 3 initiation in 2026 Phase 1 PK trial completion
	Postpartum depression (PPD)						Phase 2a POC	Completed
	Bipolar II Disorder ^a (BDII)						Phase 2a POC	Completed
GH002 <i>Mebufotenin for i.v. administration</i>	Psychiatric disorder						Phase 1 HV trial completed	IND submission

Cash, cash equivalents and marketable securities were \$293.9 million as of September 30, 2025

Completed
In Planning

^aBipolar II disorder with a current major depressive episode.
 Abbreviations: HV = Healthy volunteer; IND= Investigational New Drug; i.v. = Intravenous; PK = Pharmacokinetics; POC = Proof-of-concept; RDBPC = Randomized, double-blind, placebo-controlled.

GH001 Key Milestones Achieved and Next Steps



Phase 2b Trial

Unprecedented Efficacy in TRD

Positioning GH001 as potentially practice-changing

New

US IND open



Pivotal Phase 3 Program

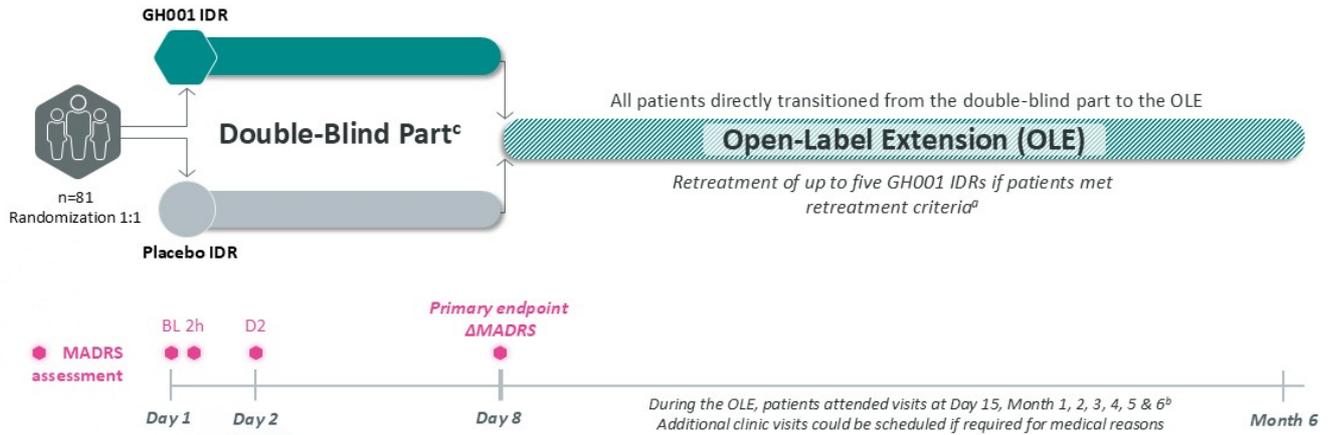
Designed in line with the FDA Guidelines and to replicate the Phase 2b data

Global Phase 3 start in 2026

Abbreviations: TRD = Treatment Resistant Depression; IND = Investigational New Drug; FDA = Food and Drug Administration



GH001-TRD-201: A Randomized, Double-Blind, Placebo-Controlled, Phase 2b Trial with an Open-Label Extension

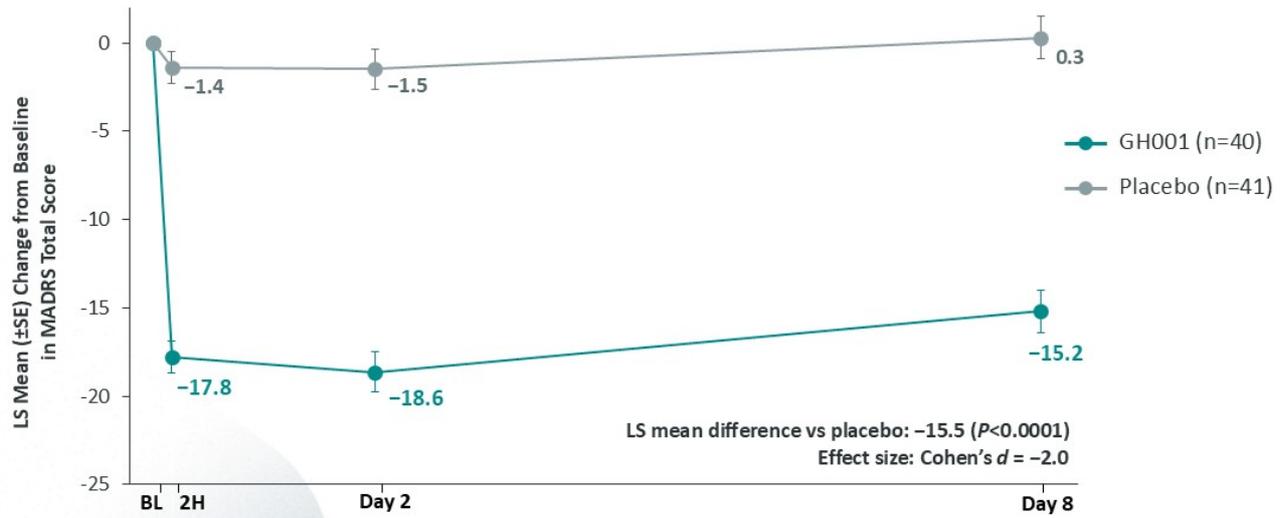


This trial was conducted under the supervision of qualified healthcare professionals, providing psychological support per standard of care, but without any planned psychotherapeutic intervention before, during, or after dosing

^aRetreatment criteria: MADRS score >18, or MADRS score >10 and ≤18 and MADRS score ≤10 not observed at Day 8 of the prior treatment or at any visit since, or MADRS score >10 and ≤18 and MADRS score >18 observed since the most recent observation of MADRS score ≤10. ^bPatients also attended assessment visits on Day 2 (phone call) and Day 8 after each retreatment. ^cEfficacy assessments were carried out by independent blinded raters in the double-blind part. Abbreviations: BL = Baseline; D = Day; h = Hour; IDR = Individualized dosing regimen; MADRS = Montgomery-Åsberg Depression Rating Scale. ClinicalTrials.gov. <https://clinicaltrials.gov/study/NCT05800860>, Accessed March 13, 2025.

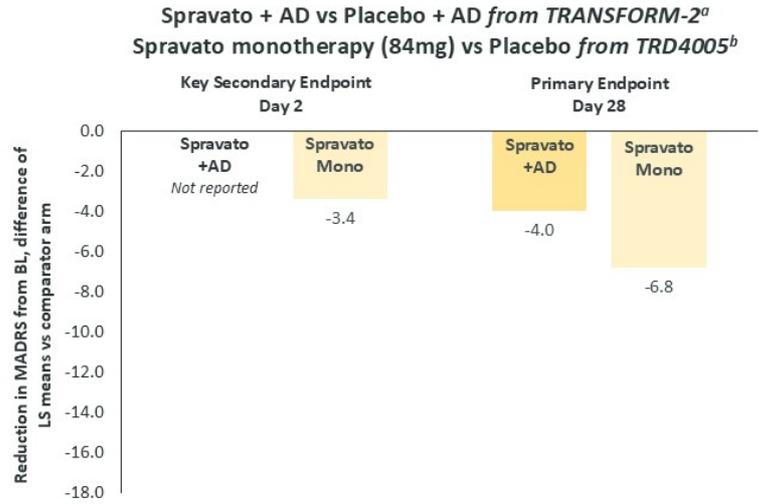
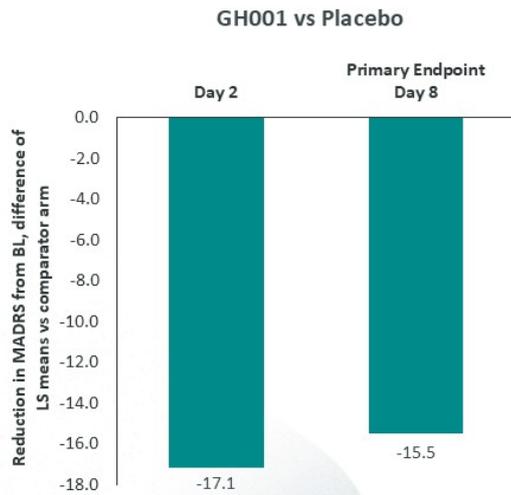


Primary Endpoint: GH001 Led to Mean MADRS Reduction from Baseline of -15.5 on Day 8^a vs Placebo ($P < 0.0001$)



^aFDA Guidance notes that efficacy with rapid-acting antidepressants generally should be demonstrated within 1 week, supporting a primary efficacy endpoint within this timeframe. Abbreviations: BL = Baseline, FDA = Food and Drug Administration, H = Hours, LS = Least squares, MADRS = Montgomery-Åsberg Depression Rating Scale, SE = Standard error. FDA Guidance: Major Depressive Disorder: Developing Drugs for Treatment. <https://www.fda.gov/media/113988/download>. Accessed on 26 June 2025.

MADRS Total Score Change from Baseline: GH001 and Spravato at Day 2 and Primary Endpoint (Difference from Comparator Arm)

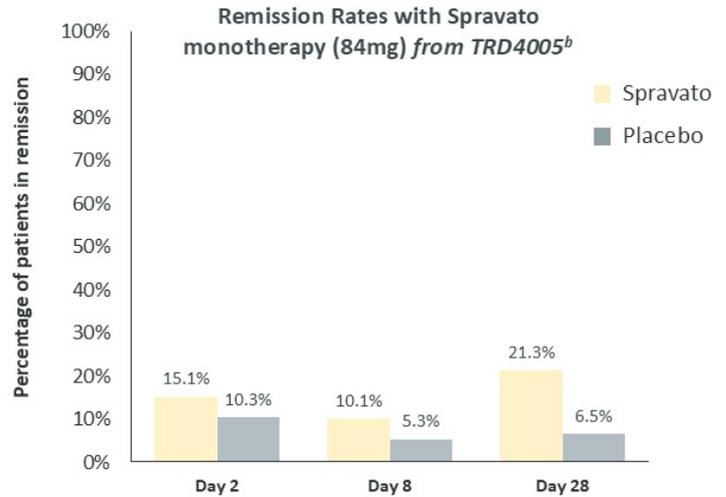
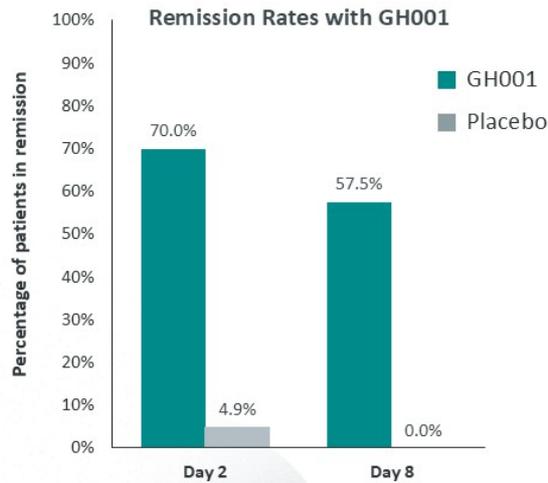


Note: To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable.

^aSpravato + AD data from TRANSFORM-2, Popova et al., 2019; ^bSpravato monotherapy data for 84mg dose from TRD4005 trial, Janik et al., 2025; Spravato 56mg MADRS total score change from baseline difference of LS means from PBO was -5.1 at Day 28 and -3.8 at Day 2

Abbreviations: AD = Antidepressant; BL = Baseline; D = Day; LS = Least Squares; MADRS = Montgomery-Åsberg Depression Rating Scale; Mono = Monotherapy.

Secondary Endpoints: Remissions^a GH001 Day 2 and Day 8 and Spravato Monotherapy (84 mg) Day 2, Day 8 and Day 28

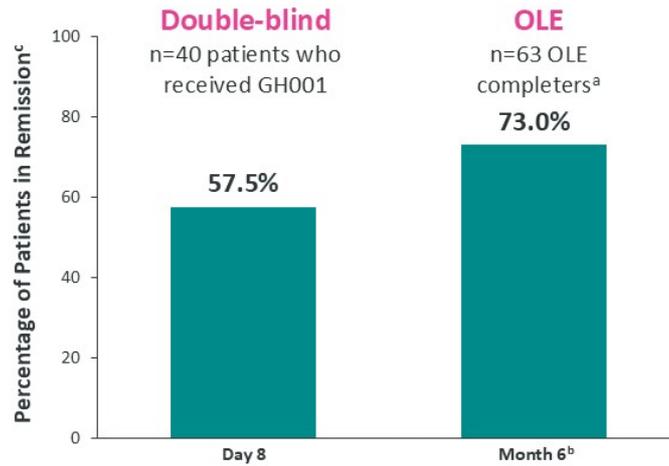


Note: To-date, no head-to-head comparisons of any other products to any of our product candidates in any clinical trial have been completed; results have been obtained from different trials with different designs, endpoints and patient populations; results may not be comparable.

^aRemission defined as MADRS total score ≤ 10 for both GH001 and Spravato. ^bSource: Spravato monotherapy data for 84mg dose from TRD4005 trial, Janik et al. 2025; Spravato 56mg participants in the TRD4005 trial achieved remission rates of 13.1% at Day 2, 7.1% at Day 8 and 14.6% at Day 28 (MADRS ≤ 10)

Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale

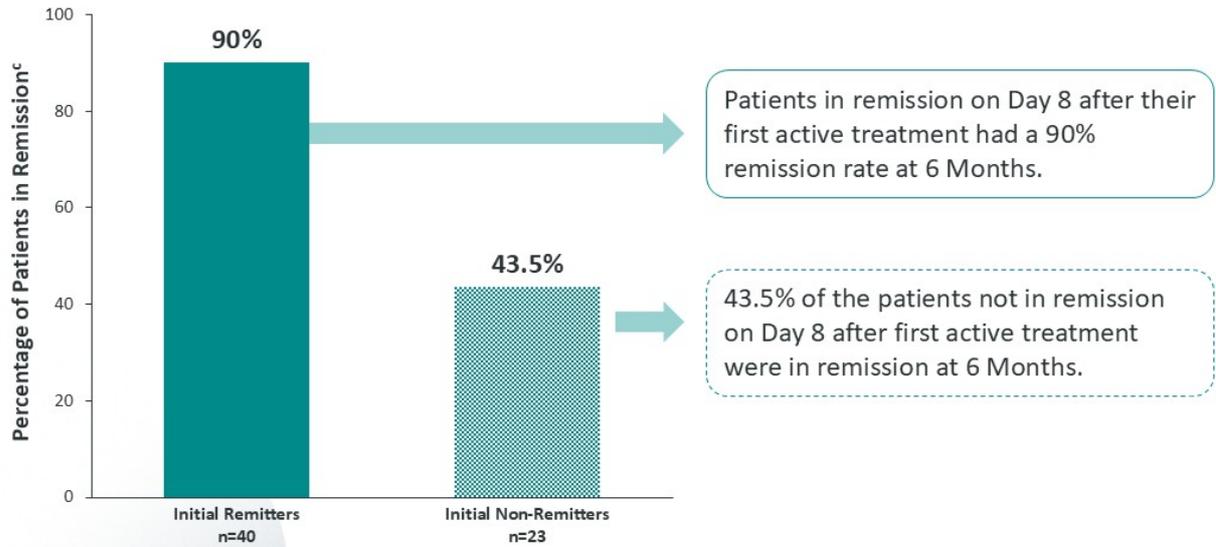
73% Remission Rate at 6 Months in OLE Completers



Patients who completed the OLE received a **mean of four treatments**, with 63.5% (40/63) requiring one to four treatments during the **6 months**

^aIncludes 63 patients who completed the 6-month OLE per protocol (18 patients terminated early are excluded). ^bApproximately 6 months post-study start (median 168 days from Day 1 of double-blind part). ^cRemission defined as MADRS total score ≤ 10 . Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension.

Remission Rate at 6 Months^a in OLE Completers^b



^a6 Months' or 'Month 6' (end of trial) was at approximately 6 months post-study start (median 168 days from Day 1 of double-blind part). ^bIncludes 63 patients who completed the 6-month OLE per protocol (18 patients terminated early are excluded). ^cRemission defined as a MADRS total score ≤ 10 .
Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension.

83% Fewer Treatment Visits with GH001 than with Spravato®



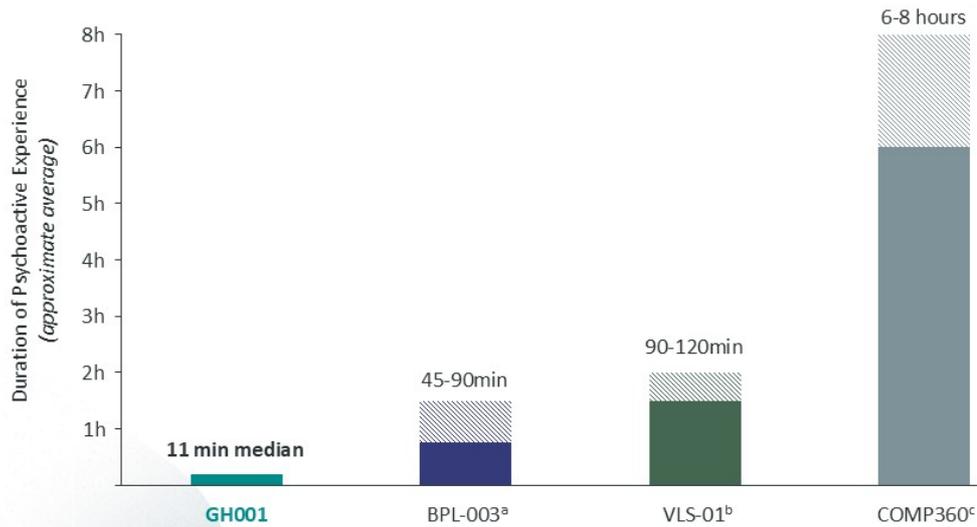
Note: To-date, no head-to-head comparisons of any other products to any of our product candidates have been completed in any clinical trial; results have been obtained from different trials with different designs, endpoints, and patient populations; results may not be comparable.

^aFour GH001 visits deduced from the mean total number of treatments received by patients who completed the OLE and were in remission at 6-months of the GH001-TRD-201 trial. ^b'6 months' (end of trial) was at approximately 6 months post-study start (median 168 days from Day 1 of double-blind part). ^cSPRAVATO® Assumes 23 treatment visits, as per standard initiation protocol of eight and four sessions in Months 1 and 2, respectively, and ICER assumed maintenance treatment frequency of 2.86 treatments per month for Months 3-6. ^dRemission defined as MADRS ≤10; Spravato® 32-Week remission rates from ESCAPE-TRD trial were 49.1% remission at 32 weeks (55.0% with LOCF method)⁴. Abbreviations: ICER = Institute for Clinical and Economic Review; LOCF = Last observation carried forward; MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension; TRD = Treatment-resistant depression.

1. Johnson & Johnson Spravato Access, Coding and Reimbursement Guide. 2. ICER Spravato® Final Evidence Report. 3. Janssen-science.com, Dosage and Administration of Spravato, Duration of Therapy. 4. Reif et al. New Engl J Med 2023.



Median Duration of the Psychoactive Experience of 11 minutes (Double-Blind & OLE treatments)



Note: To-date, no head-to-head comparisons of any other products to any of our product candidates have been completed in any clinical trial; results have been obtained from different trials with different designs, endpoints, and patient populations; results may not be comparable.

^aAssumption of BPL-003 duration of ~90min in psychoactive phase from Phase 1 SDI results as reported in Rucker et al., 2024. ^bVLS-01 duration of 90-120 minutes psychoactive experience from Phase 1b results, mean SIRS scores graph, (atal Life Sciences Corporate Presentation, October 2025). ^cCOMP360 duration of ~6h from Compass Pathways website, which states "The psilocybin experience typically lasts 6 to 8 hours".

Abbreviations: h = Hours; min = Minutes; OLE = Open-label extension; SDI = Subjective drug intensity; SIRS = Subjective Intensity Rating Scale; TRD = Treatment-resistant depression.



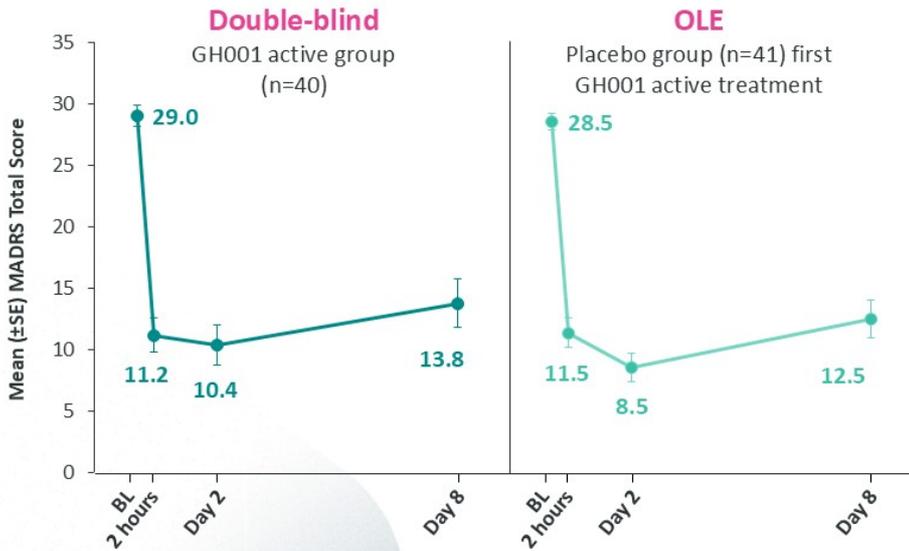
➤ **There were no treatment-related SAEs during the 6-month duration of the trial.**

➤ All patients completed the double-blind part and automatically transitioned to the OLE

➤ No TEAEs of suicidal intent or suicidal behavior occurred

➤ Across the double-blind and OLE, patients were deemed discharge ready by 1 hour from dose administration at 99% of treatment visits (>250 GH001 treatments in 81 patients)

Reproducibility of MADRS Reduction Demonstrated in Phase 2b Trial



- MADRS reduction in the Placebo group following first active treatment^a after entering the OLE, was comparable to the results observed in the GH001 group in the DB part, showing **reproducibility of effects**.
- OLE data shows GH001 leads to a **consistent and rapid reduction in MADRS after each GH001 treatment**, as in the DB part

^aAn active treatment refers to treatment with GH001.

Abbreviations: BL = Baseline; DB = Double-blind; MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension; PBO = Placebo; SE = Standard error; SEM = Standard error of mean.

- All patients enrolled in the DB part of the trial directly transitioned into the OLE at the end of the DB period.
- Once a patient completed the Day 8 visit of the DB part, if re-treatment criteria were met, a GH001 treatment could be administered.
- All patients allocated placebo in the DB part received at least one treatment with GH001 in the OLE.



Potential Value-Add for GH001 in TRD

Best in Therapeutic Category (TRD)

- **Efficacy:** Pbo-adj MADRS Δ of **-15.5** with GH001 vs **-6.8** with Spravato monotherapy^a vs **~-4** with oral AD^b
- **Length of PsE:** Median of **11 mins** with GH001 vs **~1.5 hours** with Spravato^c
- No additional psychotherapy/therapist visits with GH001; **83% fewer treatment visits** with GH001 than with Spravato^d

Best in Class (Psychedelics)

- **Efficacy:** Pbo-adj MADRS Δ of **-15.5** with GH001 vs **-3.6** with COMP360 (Phase 3 data)^e
- **Length of PsE:** Median of **11 mins** with GH001 vs **6-8 hours** for COMP360^e vs **45-90 mins** for BPL-003^f
- No additional psychotherapy/therapists visits with GH001

Best in Molecule (Mebufotenin; 5-MeO-DMT)

- **Efficacy:** Day 8 remission rate of **57.5%** with GH001 vs **26%** with BPL-003 8 mg dose^h
- **Length of PsE:** Median of **11 mins** with GH001 vs **45-90 mins** for BPL-003^f
- No additional psychotherapy/therapists visits with GH001

Note: To-date, no head-to-head comparisons of any other products to any of our product candidates have been completed in any clinical trial; results have been obtained from different trials with different designs, endpoints, and patient populations; results may not be comparable. While Spravato has been approved by the FDA, GH001 has not been approved by the FDA or any other regulatory authority.

^aSpravato[®] monotherapy data for 84mg dose from TRD4005 trial, presented at ECNP 2024. ^bAuvelity, data at Week 6 GEMINI trial, Iosifescu et al., 2022. ^cDissociative effects/perceptual disturbances, Popova et al., Am J Psychiatry 2019. ^dAssumes 23 treatment visits, as per standard initiation protocol of 8 & 4 sessions in Months 1 and 2, respectively, and ICER assumed maintenance treatment frequency of 2.86 treatments per month for Months 3-6. See slide.11. ^eCompass Pathways press release June 23, 2025. ^fBPL-003 duration assumption from Phase 1 SDI results as reported in Rucker et al., 2024. ^gCOMP360 duration assumption from Compass Pathways website, which states "The psilocybin experience typically lasts 6 to 8 hours". ^hAtai Corporate Deck, July 2025.

Abbreviations: ICER = Institute for Clinical and Economic Review; MADRS = Montgomery-Åsberg Depression Rating Scale; PsE = Psychoactive effect; SDI = Subjective drug intensity; TRD = Treatment-resistant depression; AD = antidepressant; Pbo-adj = placebo-adjusted.

Three-Layer Protection Strategy



LAYER 1: REGULATORY EXCLUSIVITY

FDA:	5 years	(+2.5 years paragraph IV stay)
EMA:	10 years	(+1 year for new indication)

LAYER 2: PATENTS

Granted patents and patent applications relating to mebufotenin, including:

- Novel uses in various disorders (including inhaled, nasal, buccal, sublingual, i.v., i.m., s.c. routes)
- Novel aerosol compositions of matter
- Novel manufacturing methods and novel salt forms
- Novel device-related aspects

LAYER 3: TECHNICAL

Complex bioequivalence for systemically-acting inhalation/intranasal products with high intra- and inter-subject variability



Phase 2b Trial

Unprecedented Efficacy in TRD

Positioning GH001 as potentially practice-changing

New
US IND open



Pivotal Phase 3 Program

Designed in line with the FDA Guidelines and to replicate the Phase 2b data

Global Phase 3 start in 2026

Abbreviations: TRD = Treatment Resistant Depression; IND = Investigational New Drug; FDA = Food and Drug Administration