IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: GH RESEARCH IRELAND LIMITED
Confirmation No.: 9216
Serial No.: 18/851,322
Group No.:
Filing or 371(c) Date: 9/26/2024
Examiner:
Entitled: 5-METHOXY-N,N-DIMETHYLTRYPTAMINE FOR THE TREATMENT OF POSTPARTUM DEPRESSION

THIRD-PARTY PRE-ISSUANCE SUBMISSION

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application.

1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022)
2. GERBASI (2020) "Associations between commonly used patient-reported outcome tools in postpartum depression clinical practice and the Hamilton Rating Scale for Depression" *Archives of Women's Mental Health*. 23: 727–735
3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Retrieved 6, December 2021. URL: https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html
4. BERGFELD (2018) "Treatment-resistant depression and suicidality" *Journal of Affective Disorders*. 235: 362-367
5. WALKER (2020) "The Long-Term Impact of Maternal Anxiety and Depression Postpartum and in Early Childhood on Child and Paternal Mental Health at 11–12 Years Follow-Up" *Frontier in Psychiatry*. 1: 562237
6. BARKIN (2014) "The Psychometric Properties of the Barkin Index of Maternal Functioning" *Journal of Obstetric, Gynecologic & Neonatal Nursing*. 43(6): 792–802.
7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671

8. BRAND (2022) “Psychedelics and Breastfeeding: What We Know—and Don’t Know—About a Taboo Subject” Double Blind, Retrieved 15, September 2022. URL: https://doubleblindmag.com/psychedelics-and-breastfeeding/
9. PROTOCOL 547-PPD-202 (2017) “A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO CONTROLLED STUDY EVALUATING THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF SAGE-547 INJECTION IN THE TREATMENT OF ADULT FEMALE SUBJECTS WITH SEVERE POSTPARTUM DEPRESSION AND ADULT FEMALE SUBJECTS WITH MODERATE POSTPARTUM DEPRESSION” Retrieved 16 March, 2017. URL: https://cdn.clinicaltrials.gov/large-docs/17/NCT02942017/Prot_000.pdf
10. RUCKER (2024) “Phase 1, placebo-controlled, single ascending dose trial to evaluate the safety, pharmacokinetics and effect on altered states of consciousness of intranasal BPL-003 (5-methoxy-N,N-dimethyltryptamine benzoate) in healthy participants” *Journal of Psychopharmacology*, 38(8): 712–723
11. KANES (2017) “Brexanolone (SAGE-547 injection) in post-partum depression: a randomised controlled trial” *Lancet*. 390: 480-489
12. TREVETHAN (2022) “The Barkin Index of Maternal Functioning: an evaluation and foundations for a new parental functioning scale” *Health Services and Outcomes Research Methodology*. 22: 416–434
13. CHAMGURDANI (2019) “The effect of counseling with a skill straining approach on maternal functioning: a randomized controlled clinical trial” *BMC Women’s Health*. 20:51
14. CA. Pat. App. Pub. No. CA3221280A1 “Enantiomeric entactogen compositions and methods of their use” (Published December 08, 2022)

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

U.S.S.N. 18/851,322 Pending Claims	References
1. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in treating a patient suffering from postpartum depression (PPD) wherein the 5-MeO-DMT is administered via the intravenous, intramuscular or subcutaneous route.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
2. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient has a Montgomery-Åsberg Depression Rating Scale (MADRS) score of 20 or more or a 17-item Hamilton Depression Rating Scale (HAM-D) score of 16 or more.	2. GERBASI (2020) "Associations between commonly used patient-reported outcome tools in postpartum depression clinical practice and the Hamilton Rating Scale for Depression" *Archives of Women's Mental Health*. 23: 727–735 From **page 728** "All trials enrolled female participants; aged 18–45 years; in good physical health; had a major depressive episode with onset no earlier than the third trimester and no later than 4 weeks after delivery, as determined by the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders-IV Axis I Disorders (First et al. 1996); **had a HAMD-17 total score ≥ 26 (severe PPD**, studies A and B) or 20–25 (moderate PPD, study C); and were 6 months postpartum or less at screening." From **page 727** "**Postpartum depression (PPD)** is one of the most common medical complications during and after pregnancy, **resulting in a substantial health-related quality of life burden for mothers, children**, and partners (Callaghan et al. 2010; Centers for Disease Control and Prevention 2018; Centers for Disease Control and Prevention 2019; De

	Sisto et al. 2014; Ko et al. 2017; Martin et al. 2019; Moore Simas et al. 2019; Roberts et al. 2013; Vismara et al. 2016). **In the USA, an estimated 11.5% of new mothers experience symptoms of PPD, with global estimates of 17.7%** (Hahn-Holbrook et al. 2017; Ko et al. 2017)." From **page 731** "The observed large associations between EPDS and PHQ-9 total score and **HAMD-17 total score**, as well as moderate associations of remission definitions, **suggest that patients' self-reports of their symptoms generally align with clinician-ratings, such as the HAMD-17**, that may be prohibitively time and training intensive to obtain and **further validate the ability of these screening tools to identify patients with PPD symptoms."** 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
3. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 2, wherein the patient has a MADRS score of 28 or	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Retrieved 6, December 2021. URL: https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html

more or a HAM-D score of 22 or more.	From **webpage** "The Phase 2 part of the clinical trial recruited 8 patients. The median age was 34 years. **The median baseline severity of depression by MADRS was 32**." From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." 2. GERBASI (2020) "Associations between commonly used patient-reported outcome tools in postpartum depression clinical practice and the Hamilton Rating Scale for Depression" *Archives of Women's Mental Health*. 23: 727–735 From **page 728** "All trials enrolled female participants; aged 18–45 years; in good physical health; had a major depressive episode with onset no earlier than the third trimester and no later than 4 weeks after delivery, as determined by the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders-IV Axis I Disorders (First et al. 1996); **had a HAMD-17 total score ≥ 26 (severe PPD**, studies A and B) or 20–25 (moderate PPD, study C); and were 6 months postpartum or less at screening." From **page 727** "**Postpartum depression (PPD)** is one of the most common medical complications during and after pregnancy, **resulting in a substantial health-related quality of life burden for mothers, children**, and partners (Callaghan et al. 2010; Centers for Disease Control and Prevention 2018; Centers for Disease Control and Prevention 2019; De Sisto et al. 2014; Ko et al. 2017; Martin et al. 2019; Moore Simas et al. 2019; Roberts et al. 2013; Vismara et al. 2016). **In the USA, an estimated 11.5% of new mothers experience symptoms of PPD, with global estimates of 17.7%** (Hahn-Holbrook et al. 2017; Ko et al. 2017)." From **page 731** "The observed large associations between EPDS and PHQ-9 total score and **HAMD-17 total score**, as well as moderate associations of remission definitions, **suggest that patients' self-reports of their symptoms generally align with clinician-ratings, such as the HAMD-17**, that may be prohibitively time and training intensive to obtain and **further validate the ability of these screening tools to identify patients with PPD symptoms."**

	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
4. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 2, wherein the patient has a MADRS score of 35 or more or by a HAM-D score of 27 or more.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Retrieved 6, December 2021. URL: https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "The Phase 2 part of the clinical trial recruited 8 patients. The median age was 34 years. **The median baseline severity of depression by MADRS was 32**." From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)."

	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."
5. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 4, wherein the patient is diagnosed with a treatment-resistant form of postpartum depression.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Retrieved 6, December 2021. URL: https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include, but is not limited to**, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and **treatment-resistant depression**), headache disorder (including cluster headaches and migraine headache)…"

	From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."
6. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 5, wherein the patient suffers in addition from suicidal ideation.	4. BERGFELD (2018) "Treatment-resistant depression and suicidality" *Journal of Affective Disorders.* 235: 362-367 From **page 362** "Even more important, **TRD is a life-threatening disorder**, given the extremely high suicide risk: **approximately 30% of the patients attempt suicide at least once in their life time** (Dunner et al., 2006; Hantouche et al., 2010; Nelsen and Dunner, 1995)." 3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Retrieved 6, December 2021. URL: https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include, but is not limited to**, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and **treatment-resistant depression**), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-**

	dimethyltryptamine (5-MeO-DMT), dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."
7. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 6, wherein the patient suffers in addition from slightly compromised, compromised or severely compromised maternal functioning.	5. WALKER (2020) "The Long-Term Impact of Maternal Anxiety and Depression Postpartum and in Early Childhood on Child and Paternal Mental Health at 11–12 Years Follow-Up" *Frontier in Psychiatry*. 1: 562237 From **page 2** "Both **maternal postpartum** anxiety and **depression** are **associated with** personal suffering, psychosocial and occupational dysfunctioning, and **poor family functioning and both conditions have been shown to negatively affect mother-infant interactions** (2, 5–7)." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…" 2. GERBASI (2020) "Associations between commonly used patient-reported outcome tools in postpartum depression clinical practice and the

	Hamilton Rating Scale for Depression" *Archives of Women's Mental Health*. 23: 727–735 From **page 728** "All trials enrolled female participants; aged 18–45 years; in good physical health; had a major depressive episode with onset no earlier than the third trimester and no later than 4 weeks after delivery, as determined by the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders-IV Axis I Disorders (First et al. 1996); **had a HAMD-17 total score ≥ 26 (severe PPD**, studies A and B) or **20–25 (moderate PPD**, study C); and were 6 months postpartum or less at screening." From **page 727** "**Postpartum depression (PPD)** is one of the most common medical complications during and after pregnancy, **resulting in a substantial health-related quality of life burden for mothers, children**, and partners (Callaghan et al. 2010; Centers for Disease Control and Prevention 2018; Centers for Disease Control and Prevention 2019; De Sisto et al. 2014; Ko et al. 2017; Martin et al. 2019; Moore Simas et al. 2019; Roberts et al. 2013; Vismara et al. 2016). **In the USA, an estimated 11.5% of new mothers experience symptoms of PPD, with global estimates of 17.7%** (Hahn-Holbrook et al. 2017; Ko et al. 2017)**."**
8. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 7, wherein the patient has a Barkin Index of Maternal Functioning (BIMF) score of 95 or below such as 80 or below, in particular 65 or below.	6. BARKIN (2014) "The Psychometric Properties of the Barkin Index of Maternal Functioning" *Journal of Obstetric, Gynecologic & Neonatal Nursing*. 43(6): 792–802. From **page** 5 "Participant Characteristics The characteristics of the study sample are displayed in Table 1. The majority of the sample was White (68%), unmarried (56%), and utilizing public health insurance (53%). On average, the mothers were age 28.2 years and infants were age 6.2 weeks. The average (SD) SIGH-ADS-29 score was 22 (6.3), which is indicative of **depression of moderate severity. On average, women had a BIMF average (SD) total score of 79.6** (16.2)." From **page 1** "**Conclusions: The BIMF** may be administered in its 18-item version, as two separate subscales, or in its original 20-item format. **A clinical threshold should be developed to facilitate accurate identification of mothers who are struggling with functioning during the postpartum period**." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post**

	partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
9. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 8, wherein the 5-MeO-DMT or salt thereof is administered at a dose or in a dosage regimen that causes the patient to experience a peak psychedelic experience.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, **6**, 12, and 18 **mg 5-MeO-DMT administered via inhalation as well as individualized dose escalation (IDE) of 5- MeO-DMT at doses ranging from 6 to 18 mg**. The overall aim of the study was to **determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, **because strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines**"
10. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 9, wherein a dosage of about 1 mg to about 10 mg 5-MeO-DMT is administered, or wherein equimolar amounts of the pharmaceutically acceptable salt are	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, **6**, 12, and 18 **mg 5-MeO-DMT administered via inhalation as well as individualized dose escalation (IDE) of 5- MeO-DMT at doses ranging from 6 to 18 mg**. The overall aim of the study was to **determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience**

administered instead of 5-MeO-DMT.	in healthy volunteers. That aim is relevant for future dose selection in clinical populations, **because strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines**"
11. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 9, wherein a dosage of about 2 mg; or of about 5 mg; or of about 8 mg is administered, or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, **6**, 12, and 18 **mg 5-MeO-DMT administered via inhalation as well as individualized dose escalation (IDE) of 5- MeO-DMT at doses ranging from 6 to 18 mg**. The overall aim of the study was to **determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, **because strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines**"
12. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 9, wherein a dosage of about 1 mg; or of about 2 mg; or of about 3 mg is administered, or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, 6, 12, and 18 **mg 5-MeO-DMT administered via inhalation** as well as individualized dose escalation (IDE) of 5- MeO-DMT at doses ranging from 6 to 18 mg. The overall aim of the study was to **determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, **because strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines**"
13. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 10, wherein the 5-MeO-DMT or salt thereof is administered in a first dosage amount for a first administration; and the 5-MeO-DMT or salt	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 3** "The phase 1 study was comprised of two single-arm parts, where Part A was a single-ascending dose study and **Part B used an individualized dose escalation regimen (IDE)**... **In Part B, an IDE regimen of 6, 12, and 18 mg was applied, where at least one and up to**

thereof is administered in zero to six subsequent administrations; wherein each subsequent administration uses a dosage amount higher than the previous administration unless the patient experiences a peak psychedelic experience.	**three doses of 5-MeO-DMT** (as GH001) interspaced at 3 h were given on a single day. **The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously administered dose** and whether the previously administered dose was safe. **If no PE had been achieved, the next dose was administered, up to the maximum of three doses**, after consultation with and consent from the participant." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months."

14. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 10 or 13, wherein the 5-MeO-DMT is administered in a dosage from about 1 mg to about 3 mg for a first administration, and then increased, unless the patient has already experienced a peak psychedelic experience, to a dosage from about 4 mg to about 6 mg for a second administration, and then increased, unless the patient has already experienced a peak psychedelic experience, to a dosage from about 7 mg to about 9 mg for a third administration, or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 3** "The phase 1 study was comprised of two single-arm parts, where Part A was a single-ascending dose study and **Part B used an individualized dose escalation regimen (IDE)**... **In Part B, an IDE regimen of 6, 12, and 18 mg was applied, where at least one and up to three doses of 5-MeO-DMT** (as GH001) **interspaced at 3 h were given on a single day**. **The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously administered dose** and whether the previously administered dose was safe. **If no PE had been achieved, the next dose was administered, up to the maximum of three doses**, after consultation with and consent from the participant." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin

	can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months."
15. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 14, wherein the first dosage of 5-MeO-DMT is about 2 mg, the second dosage of 5-MeO-DMT is about 5 mg, and the third dosage of 5-MeO-DMT is about 8 mg; or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."
16. 5-MeO-DMT or a pharmaceutically acceptable salt thereof	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022)

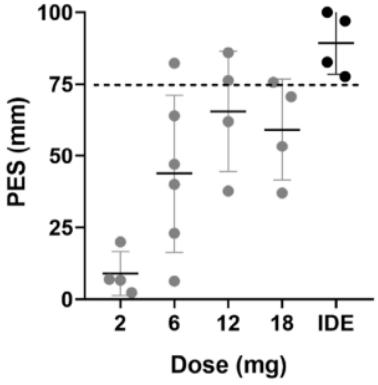
for use as in claims 1 to 10 or 13, wherein the 5-MeO-DMT is administered in a dosage from about 0.5 mg to about 1.5 mg for a first administration, and then increased, unless the patient has already experienced a peak psychedelic experience, to a dosage from about 1.5 mg to about 2.5 mg for a second administration, and then increased, unless the patient has already experienced a peak psychedelic experience, to a dosage from about 2.5 mg to about 3.5 mg for a third administration, or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." 7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 3** "The phase 1 study was comprised of two single-arm parts, where **Part A was a single-ascending dose study** and Part B used an individualized dose escalation regimen (IDE)... In Part B, an IDE regimen of 6, 12, and 18 mg was applied, where at least one and up to three doses of 5-MeO-DMT (as GH001) interspaced at 3 h were given on a single day. **The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously**

	administered dose and whether the previously administered dose was safe. **If no PE had been achieved, the next dose was administered, up to the maximum of three doses**, after consultation with and consent from the participant."
17. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 16, wherein the first dosage of 5-MeO-DMT is about 1 mg, the second dosage of 5-MeO-DMT is about 2 mg, and the third dosage of 5-MeO-DMT is about 3 mg; or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." 7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671

	From **page 3** "The phase 1 study was comprised of two single-arm parts, where **Part A was a single-ascending dose study** and Part B used an individualized dose escalation regimen (IDE)... In Part B, an IDE regimen of 6, 12, and 18 mg was applied, where at least one and up to three doses of 5-MeO-DMT (as GH001) interspaced at 3 h were given on a single day. **The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously administered dose** and whether the previously administered dose was safe. **If no PE had been achieved, the next dose was administered, up to the maximum of three doses**, after consultation with and consent from the participant."
18. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 13 to 17, wherein the interval between two administrations is not less than 1 hour and not more than 24 hours, such as about 1 to 4 hours, preferably about 1 to 2 hours.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 3** "The phase 1 study was comprised of two single-arm parts, where Part A was a single-ascending dose study and Part B used an individualized dose escalation regimen (IDE)... In Part B, an IDE regimen of 6, 12, and 18 mg was applied, **where at least one and up to three doses of 5-MeO-DMT** (as GH001) **interspaced at 3 h were given on a single day**. The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously administered dose and whether the previously administered dose was safe. If no PE had been achieved, the next dose was administered, up to the maximum of three doses, after consultation with and consent from the participant." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-

	dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months."
19. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 9 to 18, wherein the occurrence of a peak psychedelic experience is identified through achievement of at least 60% of the maximum possible score in each of the four subscales (mystical, positive mood, transcendence of time and space, and ineffability) of the 30-item revised Mystical Experience Questionnaire (MEQ30) or is identified through achievement of at least 60% of the maximum possible score of the Oceanic Boundlessness (OBN) dimension of the Altered States of	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 7-8** "For example, in the present study, only **three individuals achieved a rating >60% across all subscores of the MEQ (i.e., MEQ rating >3), which is the MEQ threshold for a mystical experience (Barrett et al., 2015; Barsuglia et al., 2018).** …The MEQ, EDI and 5D-ASC scales capture many aspects of a psychedelic experience that seem not to be typical for the intense, short-lasting psychoactive effects of 5-MeO-DMT when used in the clinical setting, and those scores may be more appropriate in the spiritual or self-exploratory contexts of naturalistic use. For example, among visitors of a psychospiritual retreat program in Mexico (Barsuglia et al., 2018) who received 50 mg of toad venom containing 5-MeO-DMT, over 75% had "a complete mystical experience" (≥60% on all MEQ subscales)." From **page 2** "The overall aim of the study was **to determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, because **strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines** (Garcia-Romeu et al., 2014; Johnson et al., 2014; Bogenschutz et al., 2015; Griffiths et al., 2016; Ross et al., 2016; Roseman et al., 2018)."

Consciousness (ASC) questionnaire or is identified through achievement of a Peak Experience Scale (PES) Total Score of at least 75.	From **page 3** "**Subjective ratings included the** Peak Experience Scale (PES), duration of experience, the Ego Dissolution Inventory (EDI) (Nour et al., 2016), the **Mystical Experiences Questionnaire (MEQ)** (Studerus et al., 2010; Barrett et al., 2015), the Challenging Experiences Questionnaire (CEQ) (Barrett et al., 2016) and the 5-Dimensional Altered States of Consciousness Questionnaire (5D-ASC) (Studerus et al., 2010)." From **page 6** "Overall, **5-MeO-DMT elicited a substantial psychedelic experience as retrospectively assessed with all questionnaires**, except the CEQ. **All doses elicited significantly higher** PES and **MEQ ratings as compared to the lowest dose of 2 mg**. In total, eight 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, and **all four participants in the individualized dose escalation group**."
20. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 19, wherein the occurrence of a peak psychedelic experience is identified through achievement of a Peak Experience Scale (PES) Total Score of at least 75.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The overall aim of the study was **to determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, because **strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines** (Garcia-Romeu et al., 2014; Johnson et al., 2014; Bogenschutz et al., 2015; Griffiths et al., 2016; Ross et al., 2016; Roseman et al., 2018)." From **page 3** "**Subjective ratings included the** Peak Experience Scale (PES), duration of experience, the Ego Dissolution Inventory (EDI) (Nour et al., 2016), the **Mystical Experiences Questionnaire (MEQ)** (Studerus et al., 2010; Barrett et al., 2015), the Challenging Experiences Questionnaire (CEQ) (Barrett et al., 2016) and the 5-Dimensional Altered States of Consciousness Questionnaire (5D-ASC) (Studerus et al., 2010)." From **page 6** "Overall, **5-MeO-DMT elicited a substantial psychedelic experience as retrospectively assessed with all questionnaires**, except the CEQ. **All doses elicited significantly higher** PES and **MEQ ratings as compared to the lowest dose of 2 mg**. In total, eight 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, and **all four participants in the individualized dose escalation group**."

	From **page 4-5** "n Part A, **one participant achieved a PE (i.e., PES rating ≥75%) in the 6 mg dose group**…**FIGURE 1 | Mean (SE) and individual retrospective ratings of the acute psychedelic experience (PES**, EDI, MEQ, CEQ) per dose level" 
21. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 20, wherein the 5-MeO-DMT or a pharmaceutically acceptable salt thereof is administered via intravenous injection.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0022]** "When administering the compound of the present invention orally, it will generally be formulated in an immediate release capsule, immediate release tablet, modified release capsule or tablet (including enteric coatings), solution, or suspension. When administering the compound of the present invention parenterally, it will generally be formulated in a sublingual or buccal orally dissolving tablet, dissolving film, intranasal powder, intranasal solution, inhaled powder, inhaled solution, transdermal patch, transdermal patch with microneedles or other permeation enhancers, or as a unit dosage injectable form (solution, suspension, emulsion). **The pharmaceutical formulations suitable for injection** include sterile aqueous solutions or dispersions and sterile powders for reconstitution into sterile injectable solutions or dispersions. The carrier can be a solvent or dispersing medium containing, for example, water, ethanol, polyol (for example, glycerol, propylene glycol, liquid polyethylene glycol, and the like), suitable mixtures thereof, and vegetable oils. From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-**

	dimethyltryptamine (5-MeO-DMT), dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."
22. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 21, wherein a clinical response, as reflected by a reduction in the Clinical Global Impression—Severity (CGI-S) score, occurs not later than about 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	14. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0254]** A variety of methods for screening or assessing a subject for a mental health disorder may be used in accordance with the methods described herein, such as to identify a subject in need of a disclosed compound, such as R-MDMA, S-MDMA, and non-racemic mixtures thereof, such as comprising R-MDMA in enantiomeric excess, and/or to determine a reduction in symptom severity. In some embodiments, a diagnosis of a mental health disorder is facilitated with use of the Diagnostic and Statistical Manual of Mental Disorders, such as the DSM-5. … The Mood Disorder Questionnaire (MDQ), and other similar questionnaires. **In some embodiments, alternative questionnaires, such as the Clinical Global Impression ¨ Improvement scale (CGI-I), may be used to assess improvement of a subject's mental health state, such as by comparing baseline responses to responses after a treatment intervention.** In some embodiments, any of the diagnostic manuals and assessments described, and other similar tools, may be used to confirm a reduction in symptoms, a reduction in symptom severity, or elimination of symptoms and/or a previous diagnosis." From [0027] "In some embodiments, the method treats a mental disorder in the subject. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (1V1DD), **treatment-resistant depression (TRD)**, atypical depression, **postpartum depression**, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder,…" From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),**

	mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA), racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12-4 SUBSTITUTE SHEET (RULE 26) administration. In some embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."
23. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 22, wherein a clinical response, as reflected by a reduction in the Clinical Global Impression—Severity (CGI-S) score, occurs on day 1, for instance, about 24 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	14. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0254]** A variety of methods for screening or assessing a subject for a mental health disorder may be used in accordance with the methods described herein, such as to identify a subject in need of a disclosed compound, such as R-MDMA, S-MDMA, and non-racemic mixtures thereof, such as comprising R-MDMA in enantiomeric excess, and/or to determine a reduction in symptom severity. In some embodiments, a diagnosis of a mental health disorder is facilitated with use of the Diagnostic and Statistical Manual of Mental Disorders, such as the DSM-5. … The Mood Disorder Questionnaire (MDQ), and other similar questionnaires. **In some embodiments, alternative questionnaires, such as the Clinical Global Impression ¨ Improvement scale (CGI-I), may be used to assess improvement of a subject's mental health state, such as by comparing baseline responses to responses after a treatment intervention.** In some embodiments, any of the diagnostic manuals and assessments described, and other similar tools, may be used to confirm a reduction in symptoms, a reduction in symptom severity, or elimination of symptoms and/or a previous diagnosis." From [0027] "In some embodiments, the method treats a mental disorder in the subject. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (1V1DD), **treatment-resistant depression (TRD)**, atypical depression, **postpartum depression**, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder,…" From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-

	fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),** mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA), racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12-4 SUBSTITUTE SHEET (RULE 26) administration. In some embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."
24. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 23, wherein a clinical response, as reflected by a reduction in the Clinical Global Impression—Severity (CGI-S) score, persists until at least 6 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	14. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0254]** A variety of methods for screening or assessing a subject for a mental health disorder may be used in accordance with the methods described herein, such as to identify a subject in need of a disclosed compound, such as R-MDMA, S-MDMA, and non-racemic mixtures thereof, such as comprising R-MDMA in enantiomeric excess, and/or to determine a reduction in symptom severity. In some embodiments, a diagnosis of a mental health disorder is facilitated with use of the Diagnostic and Statistical Manual of Mental Disorders, such as the DSM-5. … The Mood Disorder Questionnaire (MDQ), and other similar questionnaires. **In some embodiments, alternative questionnaires, such as the Clinical Global Impression ¨ Improvement scale (CGI-I), may be used to assess improvement of a subject's mental health state, such as by comparing baseline responses to responses after a treatment intervention.** In some embodiments, any of the diagnostic manuals and assessments described, and other similar tools, may be used to confirm a reduction in symptoms, a reduction in symptom severity, or elimination of symptoms and/or a previous diagnosis." From [0027] "In some embodiments, the method treats a mental disorder in the subject. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (1V1DD), **treatment-resistant depression (TRD)**, atypical depression,

	postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder,…" From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),** mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA), racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12-4 SUBSTITUTE SHEET (RULE 26) administration. In some embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."
25. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 24, wherein a clinical response, as reflected by a reduction in the Clinical Global Impression—Severity (CGI-S) score, persists until at least 14 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	14. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0254]** A variety of methods for screening or assessing a subject for a mental health disorder may be used in accordance with the methods described herein, such as to identify a subject in need of a disclosed compound, such as R-MDMA, S-MDMA, and non-racemic mixtures thereof, such as comprising R-MDMA in enantiomeric excess, and/or to determine a reduction in symptom severity. In some embodiments, a diagnosis of a mental health disorder is facilitated with use of the Diagnostic and Statistical Manual of Mental Disorders, such as the DSM-5. … The Mood Disorder Questionnaire (MDQ), and other similar questionnaires. **In some embodiments, alternative questionnaires, such as the Clinical Global Impression ¨ Improvement scale (CGI-I), may be used to assess improvement of a subject's mental health state, such as by comparing baseline responses to responses after a treatment intervention.** In some embodiments, any of the diagnostic manuals and

	assessments described, and other similar tools, may be used to confirm a reduction in symptoms, a reduction in symptom severity, or elimination of symptoms and/or a previous diagnosis." From [0027] "In some embodiments, the method treats a mental disorder in the subject. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (1V1DD), **treatment-resistant depression (TRD)**, atypical depression, **postpartum depression**, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder,…" From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),** mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA), racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12-4 SUBSTITUTE SHEET (RULE 26) administration. In some embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."
26. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 25, wherein a clinical response, as reflected by a reduction in the Clinical Global Impression—Severity	14. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0254]** A variety of methods for screening or assessing a subject for a mental health disorder may be used in accordance with the methods described herein, such as to identify a subject in need of a disclosed compound, such as R-MDMA, S-MDMA, and non-racemic mixtures thereof, such as comprising R-MDMA in enantiomeric excess, and/or to determine a reduction in symptom severity. In some embodiments, a

(CGI-S) score, persists until at least 28 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	diagnosis of a mental health disorder is facilitated with use of the Diagnostic and Statistical Manual of Mental Disorders, such as the DSM-5. … The Mood Disorder Questionnaire (MDQ), and other similar questionnaires. **In some embodiments, alternative questionnaires, such as the Clinical Global Impression ¨ Improvement scale (CGI-I), may be used to assess improvement of a subject's mental health state, such as by comparing baseline responses to responses after a treatment intervention.** In some embodiments, any of the diagnostic manuals and assessments described, and other similar tools, may be used to confirm a reduction in symptoms, a reduction in symptom severity, or elimination of symptoms and/or a previous diagnosis." From [0027] "In some embodiments, the method treats a mental disorder in the subject. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (1V1DD), **treatment-resistant depression (TRD)**, atypical depression, **postpartum depression**, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder,…" From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),** mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA), racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12-4 SUBSTITUTE SHEET (RULE 26) administration. In some embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."

27. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims **1** to **27**, wherein a clinical response, as assessed by at least 50% improvement of the MADRS or HAM-D score, compared to the respective score prior to treatment, occurs not later than about 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** ($p<0.0001$)"
28. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 27, wherein a clinical response, as assessed by at least 75% improvement of the MADRS or HAM-D score, compared to the respective score prior to treatment, occurs not later than about 2 hours after the last administration of 5-MeO-DMT or a	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)."

pharmaceutically acceptable salt thereof.	From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** ($p<0.0001$)"
29. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 24, wherein a remission of depressive symptoms, as assessed by a MADRS score equal to or less than 10, or a HAM-D score equal to or less than 7, occurs not later than about 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** ($p<0.0001$)"
30. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 29, wherein a remission	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.co

of depressive symptoms, as assessed by a MADRS score equal to or less than 10, or a HAM-D score equal to or less than 7, occurs on day 1, for instance, about 24 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	m/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** ($p<0.0001$)"
31. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 30, wherein the clinical response, as assessed by at least 50% improvement of the MADRS or HAM-D score, compared to the respective score prior to treatment, persists until at least 6 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**."

	From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing (p<0.0001) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** (p<0.0001)"
32. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 31, wherein there is a clinical response, as assessed by at least 75% improvement of the MADRS or HAM-D score, compared to the respective score prior to treatment, on day 7 after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing (p<0.0001) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** (p<0.0001)"
33. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 32, wherein the patient is in remission of depressive symptoms, as assessed by a MADRS score equal to or less	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html

than 10, or a HAM-D score equal to or less than 7, on day 7 after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** ($p<0.0001$)"
34. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 33, wherein the clinical response, as assessed by at least 50% improvement of the MADRS or HAM-D score, compared to the respective score prior to treatment, persists until at least 14 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met

	Mean change from baseline in **MADRS** at day 7 after dosing was -**24.4 points (-76%)** (p<0.0001)"
35. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 34, wherein there is a clinical response, as assessed by at least 75% improvement of the MADRS or HAM-D score, compared to the respective score prior to treatment, on day 14 after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing (p<0.0001) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was -**24.4 points (-76%)** (p<0.0001)"
36. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 35, wherein the patient is in remission of depressive symptoms, as assessed by a MADRS score equal to or less than 10, or a HAM-D score equal to or less than 7, on day 14 after the last administration of 5-MeO-DMT or a	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT**

pharmaceutically acceptable salt thereof.	**product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** ($p<0.0001$)"
37. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 36, wherein the clinical response, as assessed by at least 50% improvement of the MADRS or HAM-D score, compared to the respective score prior to treatment, persists until at least 28 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** ($p<0.0001$)"
38. 5-MeO-DMT or a pharmaceutically	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in

acceptable salt thereof for use as in claims 1 to 37, wherein there is a clinical response, as assessed by at least 75% improvement of the MADRS or HAM-D score, compared to the respective score prior to treatment, on day 28 after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)." From **webpage** "Of the 7 patients who had a remission at day 7, all were in remission beginning on day 1, with **5 in remission as early as 2 hours after dosing**." From **webpage** "Primary endpoint met in Phase 2 part of clinical trial for GH001 in TRD **7 of 8 patients (87.5%) were in remission (MADRS ≤10)** at day 7 after dosing ($p<0.0001$) Secondary endpoints met Mean change from baseline in **MADRS** at day 7 after dosing was **-24.4 points (-76%)** ($p<0.0001$)"
39. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 38, wherein the patient is in remission of depressive symptoms, as assessed by a MADRS score equal to or less than 10, or a HAM-D score equal to or less than 7, on day 28 after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	3. GH RESEARCH PLC (2021) "GH Research Announces Successful Outcome of the Phase 2 part of its Phase 1/2 Clinical Trial of GH001 in Treatment-Resistant Depression" GlobeNewswire, Web Archives, Retrieved 6, December 2021. URL: https://web.archive.org/web/20221007093800/https://www.globenewswire.com/en/news-release/2021/12/06/2346425/0/en/GH-Research-Announces-Successful-Outcome-of-the-Phase-2-part-of-its-Phase-1-2-Clinical-Trial-of-GH001-in-Treatment-Resistant-Depression.html From **webpage** "DUBLIN, Ireland, Dec. 06, 2021 (GLOBE NEWSWIRE) -- GH Research PLC (Nasdaq: GHRS), a clinical-stage biopharmaceutical company dedicated to transforming the treatment of psychiatric and neurological disorders, today reported the successful outcome of the Phase 2 part of a Phase 1/2 clinical trial of GH001, **an inhalable 5-MeO-DMT product candidate, in patients with treatment-resistant depression (TRD)** (GH001-TRD-102)."

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40. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 39, wherein the patient is a breastfeeding mother who is advised to discontinue breastfeeding until 48 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	8. BRAND (2022) "Psychedelics and Breastfeeding: What We Know—and Don't Know—About a Taboo Subject" Double Blind, Retrieved 15, September 2022. URL: https://doubleblindmag.com/psychedelics-and-breastfeeding/ From **webpage** "Dr. James Abbey of Infant Risk, **an organization that informs lactating mothers on matters around pharmaceutical drugs and breastfeeding, has written that four half-lives is "usually enough to render all but the most toxic drugs safe for breastfeeding." Some sources recommend refraining from breastfeeding for five half-lives of the drug to reach an even greater level of safety.** To maintain milk levels, breast-or-chest-feeding people can pump and dispose of breastmilk during the waiting period (a practice known as "pump and dump")." 9. PROTOCOL 547-PPD-202 (2017) "A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO CONTROLLED STUDY EVALUATING THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF SAGE-547 INJECTION IN THE TREATMENT OF ADULT FEMALE SUBJECTS WITH SEVERE POSTPARTUM DEPRESSION AND ADULT FEMALE SUBJECTS WITH MODERATE POSTPARTUM DEPRESSION" Retrieved 16 March, 2017. URL: https://cdn.clinicaltrials.gov/large-docs/17/NCT02942017/Prot_000.pdf From **page 39** "Inclusion Criteria 5. **Subject either must have ceased lactating at screening**; **or if still lactating or actively breastfeeding at screening, must agree to temporarily cease giving breastmilk to their infant(s)** from just prior to receiving study drug through 4 days (Study Day 7) after the end of the infusion." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022)

	From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
41. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 39, wherein the patient is a breastfeeding mother who is advised to discontinue breastfeeding until 24 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	10. RUCKER (2024) "Phase 1, placebo-controlled, single ascending dose trial to evaluate the safety, pharmacokinetics and effect on altered states of consciousness of intranasal BPL-003 (5-methoxy-N,N-dimethyltryptamine benzoate) in healthy participants" *Journal of Psychopharmacology*, 38(8): 712–723 From **abstrac**t "**5-MeO-DMT** was rapidly absorbed and eliminated; the median time to peak plasma concentration was approximately 8–10 min and the mean terminal elimination **half-life was <27 min**." From **page 715** "**Plasma PK parameters included** maximum plasma concentration (*C*max), time to reach *C*max (*t*max), area under the plasma concentration–time curve (AUC) from time 0 to time of the last quantifiable concentration (AUClast), AUC extrapolated to infinity (AUCinf) and **terminal elimination half-life (*t*½) for** both analytes, plus clearance (CL/F) for **5-MeO-DMT** only." 8. BRAND (2022) "Psychedelics and Breastfeeding: What We Know—and Don't Know—About a Taboo Subject" Double Blind, Retrieved 15, September 2022. URL: https://doubleblindmag.com/psychedelics-and-breastfeeding/

	From **webpage** "Dr. James Abbey of Infant Risk, **an organization that informs lactating mothers on matters around pharmaceutical drugs and breastfeeding, has written that four half-lives is "usually enough to render all but the most toxic drugs safe for breastfeeding." Some sources recommend refraining from breastfeeding for five half-lives of the drug to reach an even greater level of safety.** To maintain milk levels, breast-or-chest-feeding people can pump and dispose of breastmilk during the waiting period (a practice known as "pump and dump")." 9. PROTOCOL 547-PPD-202 (2017) "A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO CONTROLLED STUDY EVALUATING THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF SAGE-547 INJECTION IN THE TREATMENT OF ADULT FEMALE SUBJECTS WITH SEVERE POSTPARTUM DEPRESSION AND ADULT FEMALE SUBJECTS WITH MODERATE POSTPARTUM DEPRESSION" Retrieved 16 March, 2017. URL: https://cdn.clinicaltrials.gov/large-docs/17/NCT02942017/Prot_000.pdf From **page 39** "Inclusion Criteria 5. **Subject either must have ceased lactating at screening**; **or if still lactating or actively breastfeeding at screening, must agree to temporarily cease giving breastmilk to their infant(s)** from just prior to receiving study drug through 4 days (Study Day 7) after the end of the infusion." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."

	From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
42. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 39, wherein the patient is a breastfeeding mother who is advised to discontinue breastfeeding until 6 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	10. RUCKER (2024) "Phase 1, placebo-controlled, single ascending dose trial to evaluate the safety, pharmacokinetics and effect on altered states of consciousness of intranasal BPL-003 (5-methoxy-N,N-dimethyltryptamine benzoate) in healthy participants" *Journal of Psychopharmacology*, 38(8): 712–723 From **abstrac**t "**5-MeO-DMT** was rapidly absorbed and eliminated; the median time to peak plasma concentration was approximately 8–10 min and the mean terminal elimination **half-life was <27 min**." From **page 715** "**Plasma PK parameters included** maximum plasma concentration (*C*max), time to reach *C*max (*t*max), area under the plasma concentration–time curve (AUC) from time 0 to time of the last quantifiable concentration (AUClast), AUC extrapolated to infinity (AUCinf) and **terminal elimination half-life (*t*½) for** both analytes, plus clearance (CL/F) for **5-MeO-DMT** only." 8. BRAND (2022) "Psychedelics and Breastfeeding: What We Know—and Don't Know—About a Taboo Subject" Double Blind, Retrieved 15, September 2022. URL: https://doubleblindmag.com/psychedelics-and-breastfeeding/ From **webpage** "Dr. James Abbey of Infant Risk, **an organization that informs lactating mothers on matters around pharmaceutical drugs and breastfeeding, has written that four half-lives is "usually enough to render all but the most toxic drugs safe for breastfeeding." Some sources recommend refraining from breastfeeding for five half-lives of the drug to reach an even greater level of safety.** To maintain milk levels, breast-or-chest-feeding people can pump and dispose of breastmilk during the waiting period (a practice known as "pump and dump")." 9. PROTOCOL 547-PPD-202 (2017) "A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO CONTROLLED STUDY EVALUATING THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF SAGE-547 INJECTION IN THE

	TREATMENT OF ADULT FEMALE SUBJECTS WITH SEVERE POSTPARTUM DEPRESSION AND ADULT FEMALE SUBJECTS WITH MODERATE POSTPARTUM DEPRESSION" Retrieved 16 March, 2017. URL: https://cdn.clinicaltrials.gov/large-docs/17/NCT02942017/Prot_000.pdf From **page 39** "Inclusion Criteria 5. **Subject either must have ceased lactating at screening**; **or if still lactating or actively breastfeeding at screening, must agree to temporarily cease giving breastmilk to their infant(s)** from just prior to receiving study drug through 4 days (Study Day 7) after the end of the infusion." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
43. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims	10. RUCKER (2024) "Phase 1, placebo-controlled, single ascending dose trial to evaluate the safety, pharmacokinetics and effect on altered states of consciousness of intranasal BPL-003 (5-methoxy-N,N-dimethyltryptamine benzoate) in healthy participants" *Journal of Psychopharmacology*, 38(8): 712–723

1 to 39, wherein the patient is a breastfeeding mother who is advised to discontinue breastfeeding until 3 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	From **abstrac**t "**5-MeO-DMT** was rapidly absorbed and eliminated; the median time to peak plasma concentration was approximately 8–10 min and the mean terminal elimination **half-life was <27 min**." From **page 715** "**Plasma PK parameters included** maximum plasma concentration (*C*max), time to reach *C*max (*t*max), area under the plasma concentration–time curve (AUC) from time 0 to time of the last quantifiable concentration (AUClast), AUC extrapolated to infinity (AUCinf) and **terminal elimination half-life (*t*½) for** both analytes, plus clearance (CL/F) for **5-MeO-DMT** only." 8. BRAND (2022) "Psychedelics and Breastfeeding: What We Know—and Don't Know—About a Taboo Subject" Double Blind, Retrieved 15, September 2022. URL: https://doubleblindmag.com/psychedelics-and-breastfeeding/ From **webpage** "Dr. James Abbey of Infant Risk, **an organization that informs lactating mothers on matters around pharmaceutical drugs and breastfeeding, has written that four half-lives is "usually enough to render all but the most toxic drugs safe for breastfeeding." Some sources recommend refraining from breastfeeding for five half-lives of the drug to reach an even greater level of safety.** To maintain milk levels, breast-or-chest-feeding people can pump and dispose of breastmilk during the waiting period (a practice known as "pump and dump")." 9. PROTOCOL 547-PPD-202 (2017) "A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO CONTROLLED STUDY EVALUATING THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF SAGE-547 INJECTION IN THE TREATMENT OF ADULT FEMALE SUBJECTS WITH SEVERE POSTPARTUM DEPRESSION AND ADULT FEMALE SUBJECTS WITH MODERATE POSTPARTUM DEPRESSION" Retrieved 16 March, 2017. URL: https://cdn.clinicaltrials.gov/large-docs/17/NCT02942017/Prot_000.pdf From **page 39** "Inclusion Criteria 5. **Subject either must have ceased lactating at screening**; **or if still lactating or actively breastfeeding at screening, must agree to temporarily cease giving breastmilk to their infant(s)** from just prior to receiving study drug through 4 days (Study Day 7) after the end of the infusion." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022)

	From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
44. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 39, wherein the patient is a breastfeeding mother who is advised to discontinue breastfeeding until 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	10. RUCKER (2024) "Phase 1, placebo-controlled, single ascending dose trial to evaluate the safety, pharmacokinetics and effect on altered states of consciousness of intranasal BPL-003 (5-methoxy-N,N-dimethyltryptamine benzoate) in healthy participants" *Journal of Psychopharmacology*, 38(8): 712–723 From **abstrac**t "**5-MeO-DMT** was rapidly absorbed and eliminated; the median time to peak plasma concentration was approximately 8–10 min and the mean terminal elimination **half-life was <27 min**." From **page 715** "**Plasma PK parameters included** maximum plasma concentration (*C*max), time to reach *C*max (*t*max), area under the plasma concentration–time curve (AUC) from time 0 to time of the last quantifiable concentration (AUClast), AUC extrapolated to infinity (AUCinf) and **terminal elimination half-life (*t*½) for** both analytes, plus clearance (CL/F) for **5-MeO-DMT** only." 8. BRAND (2022) "Psychedelics and Breastfeeding: What We Know—and Don't Know—About a Taboo Subject" Double Blind, Retrieved 15, September 2022. URL: https://doubleblindmag.com/psychedelics-and-breastfeeding/

	From **webpage** "Dr. James Abbey of Infant Risk, **an organization that informs lactating mothers on matters around pharmaceutical drugs and breastfeeding, has written that four half-lives is "usually enough to render all but the most toxic drugs safe for breastfeeding." Some sources recommend refraining from breastfeeding for five half-lives of the drug to reach an even greater level of safety.** To maintain milk levels, breast-or-chest-feeding people can pump and dispose of breastmilk during the waiting period (a practice known as "pump and dump")." 9. PROTOCOL 547-PPD-202 (2017) "A MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO CONTROLLED STUDY EVALUATING THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF SAGE-547 INJECTION IN THE TREATMENT OF ADULT FEMALE SUBJECTS WITH SEVERE POSTPARTUM DEPRESSION AND ADULT FEMALE SUBJECTS WITH MODERATE POSTPARTUM DEPRESSION" Retrieved 16 March, 2017. URL: https://cdn.clinicaltrials.gov/large-docs/17/NCT02942017/Prot_000.pdf From **page 39** "Inclusion Criteria 5. **Subject either must have ceased lactating at screening**; **or if still lactating or actively breastfeeding at screening, must agree to temporarily cease giving breastmilk to their infant(s)** from just prior to receiving study drug through 4 days (Study Day 7) after the end of the infusion." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."

	From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
45. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 44, wherein the treatment improves maternal functioning.	11. KANES (2017) "Brexanolone (SAGE-547 injection) in post-partum depression: a randomised controlled trial" *Lancet*. 390: 480-489 From **page 483** "**Additional prespecified secondary and exploratory endpoints** are detailed in the appendix, **including** the Generalised Anxiety Disorder Questionnaire,36 Edinburgh Postnatal Depression Scale,37Patient Health Questionnaire-9,38 and **Barkin Index of Maternal Function**.39" From **page 480** "**Post-partum depression** is a serious mood disorder in women that might be triggered by peripartum fluctuations in reproductive hormones. This phase 2 study investigated brexanolone (USAN; formerly SAGE-547 injection), an intravenous formulation of allopregnanolone, a positive allosteric modulator of γ-aminobutyric acid (GABAA) receptors, for the treatment of post-partum depression" 12. TREVETHAN (2022) "The Barkin Index of Maternal Functioning: an evaluation and foundations for a new parental functioning scale" *Health Services and Outcomes Research Methodology*. 22: 416–434 From **page 420** "From thematic analysis of focus-group transcripts, Barkin et al. (2010) proposed the existence of seven domains that they attempted to ensure were subsequently represented when they created the **BIMF**. They labeled these domains self-care, infant care, **mother–child interaction, psychological well-being of the mother**, social support, management, and adjustment." 6. BARKIN (2014) "The Psychometric Properties of the Barkin Index of Maternal Functioning" *Journal of Obstetric, Gynecologic & Neonatal Nursing*. 43(6): 792–802. From **page** 5 "Participant Characteristics The characteristics of the study sample are displayed in Table 1. The majority of the sample was White (68%), unmarried (56%), and utilizing public health insurance (53%). On average, the mothers were age 28.2 years and infants were age 6.2 weeks. The average (SD) SIGH-ADS-29

	score was 22 (6.3), which is indicative of **depression of moderate severity. On average, women had a BIMF average (SD) total score of 79.6** (16.2)." From **page 1** "**Conclusions: The BIMF** may be administered in its 18-item version, as two separate subscales, or in its original 20-item format. **A clinical threshold should be developed to facilitate accurate identification of mothers who are struggling with functioning during the postpartum period**."
46. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 45, wherein the improvement relates to one or more, in particular two or more functional domains according to the Barkin Index of Maternal Functioning (BIMF) selected from self-care, infant care, mother-child interaction, psychological wellbeing of the mother, social support, management, and adjustment.	11. KANES (2017) "Brexanolone (SAGE-547 injection) in post-partum depression: a randomised controlled trial" *Lancet*. 390: 480-489 From **page 483** "**Additional prespecified secondary and exploratory endpoints** are detailed in the appendix, **including** the Generalised Anxiety Disorder Questionnaire,36 Edinburgh Postnatal Depression Scale,37Patient Health Questionnaire-9,38 and **Barkin Index of Maternal Function**.39" From **page 480** "**Post-partum depression** is a serious mood disorder in women that might be triggered by peripartum fluctuations in reproductive hormones. This phase 2 study investigated brexanolone (USAN; formerly SAGE-547 injection), an intravenous formulation of allopregnanolone, a positive allosteric modulator of γ-aminobutyric acid (GABAA) receptors, for the treatment of post-partum depression" 12. TREVETHAN (2022) "The Barkin Index of Maternal Functioning: an evaluation and foundations for a new parental functioning scale" *Health Services and Outcomes Research Methodology*. 22: 416–434 From **page 420** "From thematic analysis of focus-group transcripts, Barkin et al. (2010) proposed the existence of seven domains that they attempted to ensure were subsequently represented when they created the **BIMF**. They labeled these domains self-care, infant care, **mother–child interaction, psychological well-being of the mother**, social support, management, and adjustment." 6. BARKIN (2014) "The Psychometric Properties of the Barkin Index of Maternal Functioning" *Journal of Obstetric, Gynecologic & Neonatal Nursing*. 43(6): 792–802. From **page** 5 "Participant Characteristics The characteristics of the study sample are displayed in Table 1. The majority of the sample was White (68%), unmarried (56%), and utilizing public health insurance (53%). On average, the mothers were age 28.2

	years and infants were age 6.2 weeks. The average (SD) SIGH-ADS-29 score was 22 (6.3), which is indicative of **depression of moderate severity. On average, women had a BIMF average (SD) total score of 79.6** (16.2)." From **page 1** "**Conclusions: The BIMF** may be administered in its 18-item version, as two separate subscales, or in its original 20-item format. **A clinical threshold should be developed to facilitate accurate identification of mothers who are struggling with functioning during the postpartum period**."
47. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 45 or 46, wherein the BIMF score is improved by 10% or more, preferably by 20% or more.	13. CHAMGURDANI (2019) "The effect of counseling with a skills training approach on maternal functioning: a randomized controlled clinical trial" *BMC Women's Health*. 20:51 From **page 3** "In studies in which the IFSAC was used, **maternal functional status was found to be associated with maternal depression** and low self-efficacy **in the postpartum period** [18], high levels of anxiety in women after childbirth [30], impaired infant development [15] and lactation difficulties [16]…**The BIMF is a more recently developed and patient-centered measure of postpartum functioning** [14]." From **page 6** "Post-intervention, the mean total score (SD) of the BIMF in the counseling group was 95.8 (11.8) and in the control group it was 70.3 (4.5). Based on the ANCOVA test, and after adjusting for the baseline score, the mean score of the **BIMF was significantly higher in the counseling group than in the control group (Mean Difference (MD): 22.9**; 95% CI: 18.2 to 27.6; $p < 0.001$). In summary, there was no significant difference between the two groups related to the seven BIMF domains before the intervention ($p > 0.05$). However, the post intervention scores of all BIMF domains including self-care (MD: 3.8; 95% CI: 2.8 to 4.8), infant care (MD: 2.0; 95% CI: 1.4 to 2.6), **mother-child interaction (MD: 4.8**; 95% CI: 3.9 to 5.7), psychological wellbeing (MD: 8.4; 95% CI: 6.8 to 9.9), social support (MD: 4.0; 95% CI: 3.1 to 4.8), management (MD: 6.8; 95% CI: 5.1 to 8.4), and adjustment (MD: 3.2; 95% CI: 2.4 to 3.9) were significantly higher in the intervention group compared to the control group ($P < 0.001$)"

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/851,322	**11/14/2025 11:56:36 AM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	SISI LI
PATENT CENTER #	73182810	FILING DATE	09/26/2024
CUSTOMER #	–	FIRST NAMED INVENTOR	
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 13

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
Concise-description-generated.pdf		3	Concise Description of Relevance	41 KB
third-party-preissuance-submission.pdf		3	Third-Party Submission Under 37 CFR 1.290	75 KB
2_GERBASI.pdf		9	-	299 KB
2_GERBASI-NPL.pdf	(1-9)	9	Non Patent Literature	262 KB
3_GH RESEARCH PLC.pdf		8	-	1380 KB
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Claims_Chart.pdf		46	-	525 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-46)	46	Concise Description of Relevance	479 KB
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Digest

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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/851,322	**11/14/2025 11:56:36 AM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	SISI LI
PATENT CENTER #	73182810	AUTHORIZED BY	-
CUSTOMER #	–	FILING DATE	09/26/2024
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 0642	**E2025ADB57316014**	**SISI LI**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2818	DOCUMENT FEE FOR THIRD-PARTY SUBMISSIONS (SEE 37 CFR 1.290(F))	78.00	1	78.00
			TOTAL AMOUNT:	**$78.00**

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New Applications Under 35 U.S.C. 111

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National Stage of an International Application under 35 U.S.C. 371

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371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/851,322	**11/14/2025 12:03:29 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	SISI LI
PATENT CENTER #	73180198	FILING DATE	09/26/2024
CUSTOMER #	–	FIRST NAMED INVENTOR	
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 8

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
third-party-preissuance-submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	52 KB
Concise-description-generated.pdf		2	Concise Description of Relevance	28 KB
Claims_Chart.pdf		46	-	525 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-46)	46	Concise Description of Relevance	479 KB
11_KANES.pdf		10	-	460 KB
11_KANES-NPL.pdf	(1-10)	10	Non Patent Literature	448 KB

12_TREVETHAN.pdf		19	-	2680 KB
12_TREVETHAN-NPL.pdf	(1-19)	19	Non Patent Literature	2667 KB
13_CHAMGURDANI.pdf		10	-	682 KB
13_CHAMGURDANI-NPL.pdf	(1-10)	10	Non Patent Literature	639 KB
14_CA3221280A1.pdf		128	-	6831 KB
14_CA3221280A1-FOR.pdf	(1-128)	128	Foreign Reference	6806 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
Third-party-notification-request.pdf	378C89EF826DF7DAF10D902B7AFF9D64E7D2A921D4C2AFCD796DD01F9F13FD5AF9A8AF50A8356E36F3AEE12A3A57EC86A0A90AC6469FEAF8F855144470213BCC
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Claims_Chart-3P.RELEVANCE.pdf	81336D2D18A1E10BEF70AF348E3A93E778678CB8C0D20DEAF502F451C6DC4CC5632B167243B9135B10516EC92F260CF6235EE47F90FA6A35CD4620FEACFE27DE
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12_TREVETHAN.pdf	AA342C827FB9113A5945D44D1AE43C2C78F3A15752FF44C7DC23E583E0FBC25C8FA5F8A0E19EC7C84A9F903CBE85D6609A09595436F52D48551211D6FD9F004D
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13_CHAMGURDANI.pdf	43C291CF8B1A8327E2297CC25DA69F449796E8DA76F700F4F73E5E5A574C614575299AFCB2BCA51913DAB05D8EBAFA44D7B1860DC119F40419FB5C0D087A181D
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/851,322	**11/14/2025 12:03:29 PM Z ET**	

Title of Invention

Application Information

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CONFIRMATION #		FILED BY	SISI LI
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CUSTOMER #	–	FILING DATE	09/26/2024
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 0642	**E2025ADC04226418**	**SISI LI**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
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