IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: GH RESEARCH IRELAND LIMITED
Serial No.: 18/851329
Filing or 371(c) Date: 3/27/2023
Entitled: TREATMENT OF POSTNATAL DEPRESSION

Confirmation No.: 6123
Group No.:
Examiner:

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.

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.

1. U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022)
2. ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." Lancet Public Health. 4(6):291-300
3. 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
4. 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
5. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022)
6. BUSNER (2009) "The Clinical Global Impressions scale: errors in understanding and use" Comprehensive Psychiatry. 50(3): 257-262
7. BARKIN (2014) "The Psychometric Properties of the Barkin Index of Maternal Functioning" Journal of Obstetric, Gynecologic & Neonatal Nursing. 43(6): 792–802.
8. 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
9. WO2018195455 "ASSESSING AND TREATING PSYCHEDELIC RESPONSIVE SUBJECTS" (Published Oct 25, 2018)
10. 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
11. 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/
12. 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

U.S.S.N. 18/679,917 Pending Claims	References
1. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in the treatment of a mental or nervous system disorder in a mother having a child of age 18 months or below, wherein the 5-MeO-DMT is administered via the intravenous, intramuscular or subcutaneous route.	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours,

	5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)." 4.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)."
2. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the mental or nervous system disorder involves one or more	4.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

symptoms selected from sleep disturbance, cognitive dysfunction, anxiety, psychomotor retardation, social/emotional withdrawal and negative thinking.	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/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour."

	From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)."
3. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 or 2, wherein the patient suffers from a treatment resistant form of the disorder.	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition."

From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. **In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased."

From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour."

From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg."

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3.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 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).” 4.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).”
4. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 3, wherein an improvement of the disorder, as reflected by a reduction in the CGI-S score, is observed after about 2 hours; on day 1, for instance after about 24 hours; on day 7; on day 14; and/or on day 28 after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	5.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." 6.BUSNER (2009) "The Clinical Global Impressions scale: errors in understanding and use" Comprehensive Psychiatry. 50(3): 257-262 From **page 258** "At present, **CGI-S and CGI-I data are part of the package insert of all major classes of marketed psychotropics** [13]. **CGI-S and CGI-I data are also relied upon by the scientific community at large.** An influential article in the Journal of the American Medication Association that examined published **antidepressant drug** and placebo response rates in publications across 2 decades characterized response as either 50% baseline to end point **reduction** on the Hamilton Depression Rating Scale or end point **CGI-I ratings** of 1 "very much improved" or 2 "much improved" [14]; this article further noted that such CGI-I classifications were routinely used to characterize treatment response." From **page 258** "Thus, for example, in a study of an investigational medication for the **treatment of major depressive disorder**, these investigators might assign a subject with a drug-related or drug-independent "adverse event" (side effect or physical illness, for example, upset stomach) a **lower CGI-I rating** than they would a subject with identical improvement in major depressive disorder who did not experience an adverse event." 1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022)

	From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg."

	2.ABEL (2019) “Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis.” *Lancet Public Health.* 4(6):291-300 From **page 291** “Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses.” 3.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 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).” 4.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).”
5. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 3, wherein an improvement of the disorder, as reflected by a reduction in the CGI-S score, occurs not later than about 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	5.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." 6.BUSNER (2009) "The Clinical Global Impressions scale: errors in understanding and use" Comprehensive Psychiatry. 50(3): 257-262 From **page 258** "At present, **CGI-S and CGI-I data are part of the package insert of all major classes of marketed psychotropics** [13]. **CGI-S and CGI-I data are also relied upon by the scientific community at large.** An influential article in the Journal of the American Medication Association that examined published **antidepressant drug** and placebo response rates in publications across 2 decades characterized response as either 50% baseline to end point **reduction** on the Hamilton Depression Rating Scale or end point **CGI-I ratings** of 1 "very much improved" or 2

	"much improved" [14]; this article further noted that such CGI-I classifications were routinely used to characterize treatment response." From **page 258** "Thus, for example, in a study of an investigational medication for the **treatment of major depressive disorder**, these investigators might assign a subject with a drug-related or drug-independent "adverse event" (side effect or physical illness, for example, upset stomach) a **lower CGI-I rating** than they would a subject with identical improvement in major depressive disorder who did not experience an adverse event." 1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased."

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6. 5-MeO-DMT or a pharmaceutically	5.CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022)

acceptable salt thereof for use as in claims 3 or 5, wherein an improvement of the disorder, as reflected by a reduction in the CGI-S score, persists until at least 6 days; in particular until at least 14 days; more preferably until at least 28 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	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." 6.BUSNER (2009) "The Clinical Global Impressions scale: errors in understanding and use" Comprehensive Psychiatry. 50(3): 257-262 From **page 258** "At present, **CGI-S and CGI-I data are part of the package insert of all major classes of marketed psychotropics** [13]. **CGI-S and CGI-I data are also relied upon by the scientific community at large.** An influential article in the Journal of the American Medication Association that examined published **antidepressant drug** and placebo response rates in publications across 2 decades characterized response as either 50% baseline to end point **reduction** on the Hamilton Depression Rating Scale or end point **CGI-I ratings** of 1 "very much improved" or 2 "much improved" [14]; this article further noted that such CGI-I classifications were routinely used to characterize treatment response." From **page 258** "Thus, for example, in a study of an investigational medication for the **treatment of major depressive disorder**, these investigators might assign a subject with a drug-related or drug-independent "adverse event" (side effect or physical illness, for example, upset stomach) a **lower CGI-I rating** than they would a subject with identical improvement in major depressive disorder who did not experience an adverse event." 1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg,

	once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)."

	4.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)."
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.	4.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)." 3.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 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)." 1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major

depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition."

From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased."

From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour."

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2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300

From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses."

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.	7.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.**" 4.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)." 3.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 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)." 1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant**

	depression (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%,

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9. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 8, wherein the treatment improves maternal functioning.	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0027]** "In embodiments, the methods and compositions may be used to **treat** a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour."

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	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.**”
10. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 9, 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.	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 2** “More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment).” 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.**” 4.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

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	mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses."
11. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 8 to 10, wherein the BIMF score is improved by 10% or more, preferably by 20% or more.	8.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** "P**ost-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)."

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From **page 2** “More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment).”

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12. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 11, 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.	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg,

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3.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 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)."

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15. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 12, 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.	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder,

substance/medication-induced depressive disorder, and depressive disorder due to another medical condition.”

From **[0057]** “In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. I**n embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased.”

From **[0058]** “In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour.”

From **[0061]** “In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg.”

2.ABEL (2019) “Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis.” *Lancet Public Health.* 4(6):291-300

From **page 291** “Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses.”

3.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 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)." 4.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)." 8.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** "P**ost-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)." 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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take**

	care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management). During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment).” 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.**”
16. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 13, 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 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.	1.U.S. Pat. App. Pub. No. US/2022/0041551 “METHODS OF TREATING MOOD DISORDERS” (Published February 10, 2022) From **[0003]** “Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations.” From **[0027]** “In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition.” From **[0057]** “In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg,

	0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)." 4.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)." 8.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** "P**ost-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)." 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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment)." 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.**"
17. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 13 or 16, 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.	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. **In embodiments, the subject may be started at a low dose and the dosage is escalated.** In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours,

5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour."

From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg."

2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300

From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses."

3.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

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8.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** “P**ost-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).” 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 2** “More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment).” 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.**”
18. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 17, wherein the first dosage	1.U.S. Pat. App. Pub. No. US/2022/0041551 “METHODS OF TREATING MOOD DISORDERS” (Published February 10, 2022) From **[0003]** “Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms,

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.	even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300

	From **page 291** “Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses.” 3.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 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).” 4.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).” 8.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** “P**ost-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).”

	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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment)." 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.**"
19. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 13 or 16, 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	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder,

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.	substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)." 4.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)." 8.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** "P**ost-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; $p < 0.001$)." 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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take**

	care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management). During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment).” 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.**”
20. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 19, 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/2022/0041551 “METHODS OF TREATING MOOD DISORDERS” (Published February 10, 2022) From **[0003]** “Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations.” From **[0027]** “In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition.” From **[0057]** “In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour**

	period is, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)." 4.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)." 8.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** "P**ost-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)." 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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment)." 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.**”
21. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 16 to 20, 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.	1.U.S. Pat. App. Pub. No. US/2022/0041551 “METHODS OF TREATING MOOD DISORDERS” (Published February 10, 2022) From **[0003]** “Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations.” From **[0027]** “In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition.” From **[0057]** “In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased.” From **[0058]** “In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound

	disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, **4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour**, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)." 4.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)." 8.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

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22. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 12 to	9.WO2018195455 "ASSESSING AND TREATING PSYCHEDELIC RESPONSIVE SUBJECTS" (Published Oct 25, 2018)

21, 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 Consciousness (ASC) questionnaire or is identified through achievement of a Peak Experience Scale (PES) Total Score of at least 75.	From **[page 15, lines 11-16]** “Characteristics of ME can be self-reported, e.g., using the Mystical Experience Questionnaire (MEQ-43; Griffiths et al., Psychopharmacology 2006, 187:268-283) or equivalent variant thereof (e.g., **MEQ-30**; MacLean et al, Journal for the Scientific Study of Religion 2012, 51 :721 -737; Barret et al., Journal of Psychopharmacology 2015, 29:1 182-1 190). ME can be approximated using a correlate. For example, the "**ocean boundlessness**" dimension of the **5D-ASC** provided by Studerus et al. (PLoS ONE 2012, 7) can be used as a correlate **measure of ME**.” From **[page 38, lines 17-26]** “Although this model predicted strength of ME as measured on a continuum, ME is often measured as complete or less than complete using threshold scores. Barrett et al. (Journal of Psychopharmacology 20^, 29:1 182-1 190), for example, used 60% on all of the subscales as the **threshold for a complete ME in their work.** Because the 4-point scale used in our study allowed for far less variability in scores when compared with the 1 0-point scale in the MEQ30, ME was dichotomized at the 50% point such that those individuals reaching **>2.5 (of the maximum possible mean of 4)** on all four subscales were identified as having had a complete ME. Within this sample, 58% met criteria for having a complete ME. Proportions experiencing complete ME did not vary by sex, but a chi-square revealed that a significantly larger proportion of experienced psychedelic users had a full ME (63%, n=70) when compared to novice users (42%, n=13) (x2=4.21 6; p=.04).” From **[page 38, lines 34-35]** “Complete ME significantly predicted significantly higher levels of **positive change after the psychedelic experience.**” 1.U.S. Pat. App. Pub. No. US/2022/0041551 “METHODS OF TREATING MOOD DISORDERS” (Published February 10, 2022) From **[0003]** “Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations.” From **[0027]** “In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition.”

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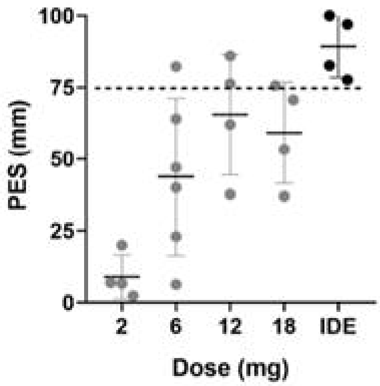
23. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 22, wherein the occurrence of a peak psychedelic experience is identified through achievement of a Peak Experience Scale (PES) Total Score of at least 75.	10. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety 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 experienceas 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"



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	support), and as if they were adjusting to their added responsibilities (adjustment)." 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.**" 9.WO2018195455 "ASSESSING AND TREATING PSYCHEDELIC RESPONSIVE SUBJECTS" (Published Oct 25, 2018) From **[page 15, lines 11-16]** "Characteristics of ME can be self-reported, e.g., using the Mystical Experience Questionnaire (MEQ-43; Griffiths et al., Psychopharmacology 2006, 187:268-283) or equivalent variant thereof (e.g., **MEQ-30**; MacLean et al, Journal for the Scientific Study of Religion 2012, 51 :721 -737; Barret et al., Journal of Psychopharmacology 2015, 29:1 182-1 190). ME can be approximated using a correlate. For example, the "**ocean boundlessness**" dimension of the **5D-ASC** provided by Studerus et al. (PLoS ONE 2012, 7) can be used as a correlate **measure of ME**." From **[page 38, lines 17-26]** "Although this model predicted strength of ME as measured on a continuum, ME is often measured as complete or less than complete using threshold scores. Barrett et al. (Journal of Psychopharmacology 20^, 29:1 182-1 190), for example, used 60% on all of the subscales as the **threshold for a complete ME in their work.** Because the 4-point scale used in our study allowed for far less variability in scores when compared with the 1 0-point scale in the MEQ30, ME was dichotomized at the 50% point such that those individuals reaching **>2.5 (of the maximum possible mean of 4)** on all four subscales were identified as having had a complete ME. Within this sample, 58% met criteria for having a complete ME. Proportions experiencing complete ME did not vary by sex, but a chi-square revealed that a significantly larger proportion of experienced psychedelic users had a full ME (63%, n=70) when compared to novice users (42%, n=13) (x2=4.21 6; p=.04)." From **[page 38, lines 34-35]** "Complete ME significantly predicted significantly higher levels of **positive change after the psychedelic experience.**"

	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, **4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour**, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g.,

	12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)." 4.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)."
24. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 23, wherein the 5-MeO-DMT or a pharmaceutically acceptable salt thereof is administered via intravenous injection.	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0068]** "**Pharmaceutical compositions include** those suitable for oral, rectal, nasal, topical (including transdermal, buccal and sublingual), vaginal or parenteral (including subcutaneous, intramuscular, **intravenous** and intradermal) administration or administration via an implant. The compositions **may be prepared by any method well known in the art of pharmacy.**" From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of

	antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, **4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour**, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300

From **page 291** “Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses.”

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9.WO2018195455 “ASSESSING AND TREATING PSYCHEDELIC RESPONSIVE SUBJECTS” (Published Oct 25, 2018)

From **[page 15, lines 11-16]** “Characteristics of ME can be self-reported, e.g., using the Mystical Experience Questionnaire (MEQ-43; Griffiths et al., Psychopharmacology 2006, 187:268-283) or equivalent variant thereof (e.g., **MEQ-30**; MacLean et al, Journal for the Scientific Study of Religion 2012, 51 :721 -737; Barret et al., Journal of Psychopharmacology 2015, 29:1 182-1 190). ME can be approximated using a correlate. For example, the "**ocean boundlessness**" dimension of the **5D-ASC** provided by Studerus et al. (PLoS ONE 2012, 7) can be used as a correlate **measure of ME**.”

From **[page 38, lines 17-26]** “Although this model predicted strength of ME as measured on a continuum, ME is often measured as complete or less than complete using threshold scores. Barrett et al. (Journal of Psychopharmacology 20^, 29:1 182-1 190), for example, used 60% on all of the subscales as the **threshold for a complete ME in their work.** Because the 4-point scale used in our study allowed for far less variability

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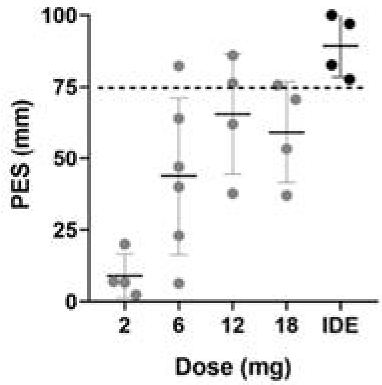

8.CHAMGURDANI (2019) “The effect of counseling with a skills training approach on maternal functioning: a randomized controlled clinical trial” *BMC Women’s Health*. 20:51

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** “P**ost-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).”

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 2** “More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment).”

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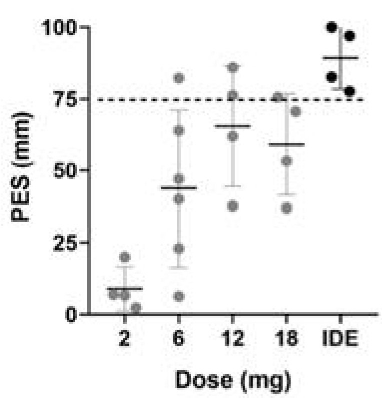
25. 5-MeO-DMT for use as in claims 1 to 24, wherein the disorder is a disorder characterized by depressive episodes, for example, Major Depressive Disorder (MDD), Persistent Depressive Disorder, Seasonal Affective Disorder and Bipolar Disorder (BD), such as Bipolar I Disorder and Bipolar II Disorder; Anxiety Disorder, for example, Separation Anxiety Disorder, Agoraphobia, Generalised Anxiety Disorder (GAD), Social Anxiety Disorder (SAD), Panic Disorder, Phobia, and Substance/Medication Induced Anxiety Disorder; Somatic Symptom Disorder; Obsessive compulsive and Related Disorders, for example, Obsessive Compulsive Disorder (OCD) and Body Dysmorphic Disorder (BDD); Post-Traumatic Stress Disorder (PTSD); Pain Disorders, for	1.U.S. Pat. App. Pub. No. US/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at

example Chronic Pain, Fibromyalgia, and Migraine; Mental and Behavioural Disorders due to Psychoactive Substance Use, for example, Substance Use Disorder (SUD); Psychotic Disorders, for example Schizophrenia; an Eating Disorder; Attention Deficit Hyperactivity Disorder (ADHD); a Personality Disorder, for example Schizotypal Personality Disorder and Borderline Personality Disorder; Autism Spectrum Disorder; Chronic Fatigue Syndrome; a mental disorder or a nervous system disorder associated with HIV, with Post COVID Condition or with Traumatic Brain Injury.	a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses." 3.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 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)." 4.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)."

	10. 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 experienceas 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” 

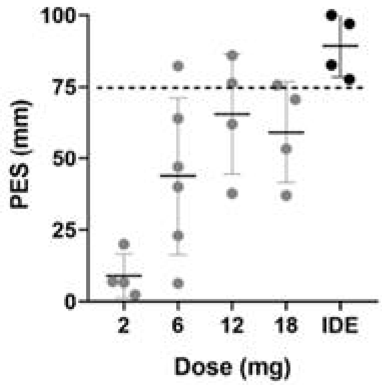
	8.CHAMGURDANI (2019) "The effect of counseling with a skills training approach on maternal functioning: a randomized controlled clinical trial" *BMC Women's Health*. 20:51 From **page 3** "In studies in which the IFSAC was used, **maternal functional status was found to be associated with maternal depression** 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** "P**ost-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; $p < 0.001$)." 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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment)." 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.**"

	9.WO2018195455 “ASSESSING AND TREATING PSYCHEDELIC RESPONSIVE SUBJECTS” (Published Oct 25, 2018) From **[page 15, lines 11-16]** “Characteristics of ME can be self-reported, e.g., using the Mystical Experience Questionnaire (MEQ-43; Griffiths et al., Psychopharmacology 2006, 187:268-283) or equivalent variant thereof (e.g., **MEQ-30**; MacLean et al, Journal for the Scientific Study of Religion 2012, 51 :721 -737; Barret et al., Journal of Psychopharmacology 2015, 29:1 182-1 190). ME can be approximated using a correlate. For example, the "**ocean boundlessness**" dimension of the **5D-ASC** provided by Studerus et al. (PLoS ONE 2012, 7) can be used as a correlate **measure of ME**.” From **[page 38, lines 17-26]** “Although this model predicted strength of ME as measured on a continuum, ME is often measured as complete or less than complete using threshold scores. Barrett et al. (Journal of Psychopharmacology 20^, 29:1 182-1 190), for example, used 60% on all of the subscales as the **threshold for a complete ME in their work.** Because the 4-point scale used in our study allowed for far less variability in scores when compared with the 1 0-point scale in the MEQ30, ME was dichotomized at the 50% point such that those individuals reaching **>2.5 (of the maximum possible mean of 4)** on all four subscales were identified as having had a complete ME. Within this sample, 58% met criteria for having a complete ME. Proportions experiencing complete ME did not vary by sex, but a chi-square revealed that a significantly larger proportion of experienced psychedelic users had a full ME (63%, n=70) when compared to novice users (42%, n=13) (x2=4.21 6; p=.04).” From **[page 38, lines 34-35]** “Complete ME significantly predicted significantly higher levels of **positive change after the psychedelic Experience.**”
26. 5-MeO-DMT for use as in claims 1 to 25, wherein the patient suffers from sleep disturbance.	1.U.S. Pat. App. Pub. No. US/2022/0041551 “METHODS OF TREATING MOOD DISORDERS” (Published February 10, 2022) From **[0030]** “In some embodiments, **symptoms associated** with depression include, but are not limited to, persistent anxious or sad feelings, feelings of helplessness, hopelessness, pessimism, and/or worthlessness, low energy, restlessness, irritability, fatigue, loss of interest in pleasurable activities or hobbies, **excessive sleeping**, overeating, appetite loss, **insomnia**, thoughts of suicide, or suicide attempts.” From **[0003]** “Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations.”

	From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg." 2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300 From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses."

	3.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 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)." 4.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)." 9.WO2018195455 "ASSESSING AND TREATING PSYCHEDELIC RESPONSIVE SUBJECTS" (Published Oct 25, 2018) From **[page 15, lines 11-16]** "Characteristics of ME can be self-reported, e.g., using the Mystical Experience Questionnaire (MEQ-43; Griffiths et al., Psychopharmacology 2006, 187:268-283) or equivalent variant thereof (e.g., **MEQ-30**; MacLean et al, Journal for the Scientific Study of Religion 2012, 51 :721 -737; Barret et al., Journal of Psychopharmacology 2015, 29:1 182-1 190). ME can be approximated using a correlate. For example, the "**ocean boundlessness**" dimension of the **5D-ASC** provided by Studerus et al. (PLoS ONE 2012, 7) can be used as a correlate **measure of ME**." From **[page 38, lines 17-26]** "Although this model predicted strength of ME as measured on a continuum, ME is often measured as complete or less than complete using threshold scores. Barrett et al. (Journal of Psychopharmacology 20^, 29:1 182-1 190), for example, used 60% on all of the subscales as the **threshold for a complete ME in their work.** Because the 4-point scale used in our study allowed for far less variability in scores when compared with the 1 0-point scale in the MEQ30, ME was dichotomized at the 50% point such that those individuals reaching **>2.5 (of the maximum possible mean of 4)** on all four subscales were identified as having had a complete ME. Within this sample, 58% met criteria for having a complete ME. Proportions experiencing complete ME did not vary by sex, but a chi-square revealed that a significantly larger proportion

	of experienced psychedelic users had a full ME (63%, n=70) when compared to novice users (42%, n=13) (x2=4.21 6; p=.04).” From **[page 38, lines 34-35]** “Complete ME significantly predicted significantly higher levels of **positive change after the psychedelic Experience.**” 10. 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 experienceas 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”



8.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** “P**ost-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; $p < 0.001$).”

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 2** “More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment).”

	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.**"
27. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 26, 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.	11.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")." 12.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/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0030]** "In some embodiments, **symptoms associated** with depression include, but are not limited to, persistent anxious or sad feelings, feelings of helplessness, hopelessness, pessimism, and/or worthlessness, low energy, restlessness, irritability, fatigue, loss of interest

	in pleasurable activities or hobbies, **excessive sleeping**, overeating, appetite loss, **insomnia**, thoughts of suicide, or suicide attempts." From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour." From **[0061]** "In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g.,

12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg."

2.ABEL (2019) "Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis." *Lancet Public Health.* 4(6):291-300

From **page 291** "Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses."

3.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 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)."

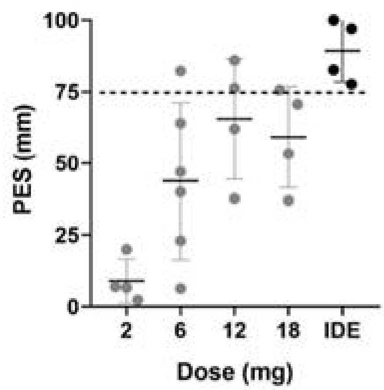
4.WALKER (2020) "The Long-Term Impact of Maternal Anxiety and Depression Postpartum and in Early Childhood on Child and Paternal Mental Health at 11–12 Years Follow-Up" Frontier in Psychiatry. 1: 562237

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)."

9.WO2018195455 "ASSESSING AND TREATING PSYCHEDELIC RESPONSIVE SUBJECTS" (Published Oct 25, 2018)

From **[page 15, lines 11-16]** "Characteristics of ME can be self-reported, e.g., using the Mystical Experience Questionnaire (MEQ-43; Griffiths et al., Psychopharmacology 2006, 187:268-283) or equivalent variant thereof (e.g., **MEQ-30**; MacLean et al, Journal for the Scientific Study of Religion 2012, 51 :721 -737; Barret et al., Journal of Psychopharmacology 2015, 29:1 182-1 190). ME can be approximated using a correlate. For example, the "**ocean boundlessness**" dimension of the **5D-ASC** provided by Studerus et al. (PLoS ONE 2012, 7) can be used as a correlate **measure of ME**."

	From **[page 38, lines 17-26]** "Although this model predicted strength of ME as measured on a continuum, ME is often measured as complete or less than complete using threshold scores. Barrett et al. (Journal of Psychopharmacology 20^, 29:1 182-1 190), for example, used 60% on all of the subscales as the **threshold for a complete ME in their work.** Because the 4-point scale used in our study allowed for far less variability in scores when compared with the 1 0-point scale in the MEQ30, ME was dichotomized at the 50% point such that those individuals reaching **>2.5 (of the maximum possible mean of 4)** on all four subscales were identified as having had a complete ME. Within this sample, 58% met criteria for having a complete ME. Proportions experiencing complete ME did not vary by sex, but a chi-square revealed that a significantly larger proportion of experienced psychedelic users had a full ME (63%, n=70) when compared to novice users (42%, n=13) (x2=4.21 6; p=.04)." From **[page 38, lines 34-35]** "Complete ME significantly predicted significantly higher levels of **positive change after the psychedelic Experience.**" 10. 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 experienceas 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"  8.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** "P**ost-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; $p < 0.001$)." 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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social

	support), and as if they were adjusting to their added responsibilities (adjustment).” 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.**”
28. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 26, 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.	11.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”).” 12.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/2022/0041551 “METHODS OF TREATING MOOD DISORDERS” (Published February 10, 2022)

	From **[0030]** "In some embodiments, **symptoms associated** with depression include, but are not limited to, persistent anxious or sad feelings, feelings of helplessness, hopelessness, pessimism, and/or worthlessness, low energy, restlessness, irritability, fatigue, loss of interest in pleasurable activities or hobbies, **excessive sleeping**, overeating, appetite loss, **insomnia**, thoughts of suicide, or suicide attempts." From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour."

From **[0061]** “In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg.”

2.ABEL (2019) “Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis.” *Lancet Public Health.* 4(6):291-300

From **page 291** “Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses.”

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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).”

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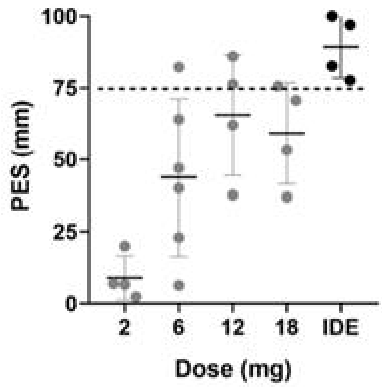
	two participants at the 12 mg dose, one participant at the 18 mg dose, and **all four participants in the individualized dose escalation group**." From **page 4-5** "n Part A, **one participant achieved a PE (i.e., PES rating ≥75%) in the 6 mg dose group**…**FIGURE 1 | Mean (SE) and individual retrospective ratings of the acute psychedelic experience (PES**, EDI, MEQ, CEQ) per dose level"  8.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** "P**ost-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)." 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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take**

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29. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 26, 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.	11.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")." 12.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/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0030]** "In some embodiments, **symptoms associated** with depression include, but are not limited to, persistent anxious or sad feelings, feelings of helplessness, hopelessness, pessimism, and/or worthlessness, low energy, restlessness, irritability, fatigue, loss of interest in pleasurable activities or hobbies, **excessive sleeping**, overeating, appetite loss, **insomnia**, thoughts of suicide, or suicide attempts." From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased." From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For

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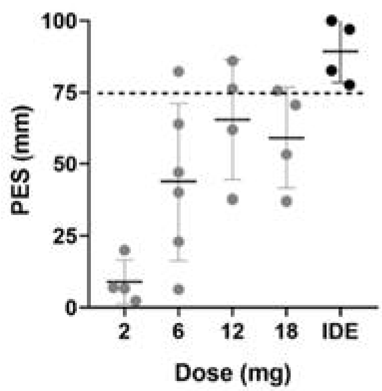
	e.g., using the Mystical Experience Questionnaire (MEQ-43; Griffiths et al., Psychopharmacology 2006, 187:268-283) or equivalent variant thereof (e.g., **MEQ-30**; MacLean et al, Journal for the Scientific Study of Religion 2012, 51 :721 -737; Barret et al., Journal of Psychopharmacology 2015, 29:1 182-1 190). ME can be approximated using a correlate. For example, the "**ocean boundlessness**" dimension of the **5D-ASC** provided by Studerus et al. (PLoS ONE 2012, 7) can be used as a correlate **measure of ME**." From **[page 38, lines 17-26]** "Although this model predicted strength of ME as measured on a continuum, ME is often measured as complete or less than complete using threshold scores. Barrett et al. (Journal of Psychopharmacology 20^, 29:1 182-1 190), for example, used 60% on all of the subscales as the **threshold for a complete ME in their work.** Because the 4-point scale used in our study allowed for far less variability in scores when compared with the 1 0-point scale in the MEQ30, ME was dichotomized at the 50% point such that those individuals reaching **>2.5 (of the maximum possible mean of 4)** on all four subscales were identified as having had a complete ME. Within this sample, 58% met criteria for having a complete ME. Proportions experiencing complete ME did not vary by sex, but a chi-square revealed that a significantly larger proportion of experienced psychedelic users had a full ME (63%, n=70) when compared to novice users (42%, n=13) (x2=4.21 6; p=.04)." From **[page 38, lines 34-35]** "Complete ME significantly predicted significantly higher levels of **positive change after the psychedelic Experience.**" 10. 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 experienceas 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"  8.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** "P**ost-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)." 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 2** "More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological**

	well-being, (e) social support, (f) management, and (g) adjustment (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment)." 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.**"
30. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 26, 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.	11.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")." 12.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/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0030]** "In some embodiments, **symptoms associated** with depression include, but are not limited to, persistent anxious or sad feelings, feelings of helplessness, hopelessness, pessimism, and/or worthlessness, low energy, restlessness, irritability, fatigue, loss of interest in pleasurable activities or hobbies, **excessive sleeping**, overeating, appetite loss, **insomnia**, thoughts of suicide, or suicide attempts." From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg, 300 mg, 400 mg, or 500 mg. In embodiments, the subject may be started at a low dose and the dosage is escalated. In embodiments, the subject may be started at a high dose and the dosage is decreased."

From **[0058]** “In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour.”

From **[0061]** “In embodiments, a compound of the present disclosure is administered to a patient under the supervision of a healthcare provider at a high dose intended to induce a **psychedelic experience** in the subject, e.g., 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 125 mg, or 150 mg.”

2.ABEL (2019) “Prevalence of maternal mental illness among children and adolescents in the UK between 2005 and 2017: a national retrospective cohort analysis.” *Lancet Public Health.* 4(6):291-300

From **page 291** “Overall prevalence of **maternal mental illness** was 23·2% (95% CI 23·1–23·4), which increased during childhood (21·9%, 21·7–22·1 among the **0–<2 year** age group vs 27·3%, 26·8–27·8 among the 14–<16 year age group). **Depression and anxiety** were the most prevalent maternal mental illnesses.”

3.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 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).”

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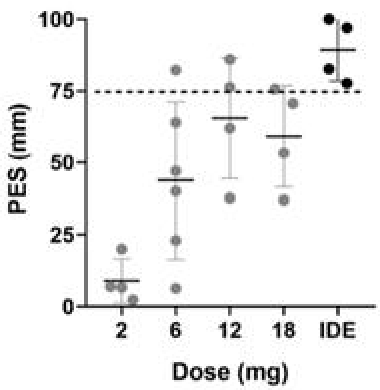
	Questionnaire (CEQ) (Barrett et al., 2016) and the 5-Dimensional Altered States of Consciousness Questionnaire (5D-ASC) (Studerus et al., 2010)." From **page 6** "Overall, **5-MeO-DMT elicited a substantial psychedelic experienceas retrospectively assessed with all questionnaires**, except the CEQ. **All 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"  8.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** "P**ost-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)." 6.BARKIN (2014) "The Psychometric Properties of the Barkin Index of Maternal Functioning" Journal of Obstetric, Gynecologic & Neonatal Nursing. 43(6): 792–802.

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31. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in any of claims 1 to 26, 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.	11.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")." 12.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/2022/0041551 "METHODS OF TREATING MOOD DISORDERS" (Published February 10, 2022) From **[0030]** "In some embodiments, **symptoms associated** with depression include, but are not limited to, persistent anxious or sad feelings, feelings of helplessness, hopelessness, pessimism, and/or worthlessness, low energy, restlessness, irritability, fatigue, loss of interest in pleasurable activities or hobbies, **excessive sleeping**, overeating, appetite loss, **insomnia**, thoughts of suicide, or suicide attempts." From **[0003]** "Approximately **one third of patients with major depressive disorder** (MDD) fail to achieve remission of their symptoms, even after multiple rounds of treatment with several known classes of antidepressants, including selective serotonin reuptake inhibitors (SSRIs) (Rush et al. 2006). This **high prevalence of treatment-resistant depression** (TRD) makes clear the need for new, more efficacious pharmacotherapies for depression that will target new mechanisms and/or patient populations." From **[0027]** "In embodiments, the methods and compositions may be used to treat a mood disorder including depressive disorders, e.g., major depressive disorder, persistent depressive disorder, **postpartum depression**, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, and depressive disorder due to another medical condition." From **[0057]** "In embodiments, the dosage of a compound disclosed herein is 0.0005-5 mg/kg, 0.001-1 mg/kg, 0.01-1 mg/kg or 0.1-5 mg/kg **once, twice, three times or four times daily**. For example, in embodiments, the dosage is 0.0005 mg/kg, 0.001 mg/kg, 0.005 mg/kg, 0.01 mg/kg, 0.025 mg/kg, 0.05 mg/kg, 0.1 mg/kg, 0.15 mg/kg, 0.2 mg/kg, 0.25 mg/kg, 0.3 mg/kg, 0.4 mg/kg, 0.5 mg/kg, 0.75 mg/kg, 1 mg/kg, 2.5 mg/kg, or 5 mg/kg, once, twice, three times or four times daily. **In embodiments, a subject is administered a total daily dose of 0.01 mg to 500 mg of a compound disclosed herein once, twice, three times, or four times daily. In embodiments, the total amount administered to a subject in a 24-hour period is**, e.g., 0.01 mg, 0.025 mg, 0.05 mg, 0.075 mg, 0.1 mg, 0.125 mg, 0.15 mg, 0.175 mg, 0.2 mg, 0.25 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.75 mg, **1 mg, 1.5 mg, 2 mg**, 2.5 mg, 3 mg, 4 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 17.5 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 60 mg, 75 mg, 80 mg, 90 mg, 100 mg, 125 mg, 150 mg, 175 mg, 200 mg, 250 mg,

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From **[0058]** "In embodiments, a compound disclosed herein may be administered, e.g., via inhalation or orally, at specified intervals. For example, during treatment a patient may be **administered** a compound disclosed herein **at intervals of every**, e.g., 1 year, 6 months, 90 days, 60 days, 30 days, 14 days, 7 days, 3 days, 24 hours, 12 hours, 8 hours, 6 hours, 5 hours, 4 hours, 3 hours, 2.5 hours, 2.25 hours, 2 hours, 1.75 hours, 1.5 hours, 1.25 hours, 1 hour, 0.75 hour, 0.5 hour, or 0.25 hour."

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4.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

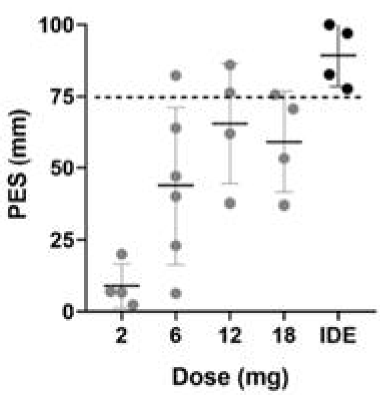
From **page 2** "Both **maternal postpartum anxiety** and **depression** are **associated with** personal suffering, psychosocial and occupational

	dysfunctioning, and **poor family functioning** and **both conditions have been shown to negatively affect mother-infant interactions** (2, 5–7).” 9.WO2018195455 “ASSESSING AND TREATING PSYCHEDELIC RESPONSIVE SUBJECTS” (Published Oct 25, 2018) From **[page 15, lines 11-16]** “Characteristics of ME can be self-reported, e.g., using the Mystical Experience Questionnaire (MEQ-43; Griffiths et al., Psychopharmacology 2006, 187:268-283) or equivalent variant thereof (e.g., **MEQ-30**; MacLean et al, Journal for the Scientific Study of Religion 2012, 51 :721 -737; Barret et al., Journal of Psychopharmacology 2015, 29:1 182-1 190). ME can be approximated using a correlate. For example, the "**ocean boundlessness**" dimension of the **5D-ASC** provided by Studerus et al. (PLoS ONE 2012, 7) can be used as a correlate **measure of ME**.” From **[page 38, lines 17-26]** “Although this model predicted strength of ME as measured on a continuum, ME is often measured as complete or less than complete using threshold scores. Barrett et al. (Journal of Psychopharmacology 20^, 29:1 182-1 190), for example, used 60% on all of the subscales as the **threshold for a complete ME in their work.** Because the 4-point scale used in our study allowed for far less variability in scores when compared with the 1 0-point scale in the MEQ30, ME was dichotomized at the 50% point such that those individuals reaching **>2.5 (of the maximum possible mean of 4)** on all four subscales were identified as having had a complete ME. Within this sample, 58% met criteria for having a complete ME. Proportions experiencing complete ME did not vary by sex, but a chi-square revealed that a significantly larger proportion of experienced psychedelic users had a full ME (63%, n=70) when compared to novice users (42%, n=13) (x2=4.21 6; p=.04).” From **[page 38, lines 34-35]** “Complete ME significantly predicted significantly higher levels of **positive change after the psychedelic Experience.**” 10. 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 experienceas 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"



8.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** "P**ost-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)."

	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 2** “More specifically, researchers have shown that new mothers are concerned with their **functioning across seven domains**, including **(a) self-care, (b) infant care, (c) mother/child interaction, (d) psychological well-being, (e) social support, (f) management, and (g) adjustment** (Barkin et al., 2010b). These researchers conducted focus groups with 31 new mothers and asked them to explain the circumstances around their low and high functioning periods. **Women described peak or optimal performance in the maternal role as times where they were able to take care of themselves (self-care), take care of their infants (infant care), bond with their infants (mother/child interaction), and manage their households (management)**. During these times they also felt generally emotionally healthy (psychological well-being), well supported (social support), and as if they were adjusting to their added responsibilities (adjustment).” 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.”**

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/851,329	**11/24/2025 01:20:35 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	NASTASSJA MATUS
PATENT CENTER #	73309805	FILING DATE	09/26/2024
CUSTOMER #	–	FIRST NAMED INVENTOR	
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 5

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	44 KB
Concise-description-generated.pdf		2	Concise Description of Relevance	25 KB
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
Claims_Chart.pdf		102	-	838 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-102)	102	Concise Description of Relevance	755 KB
2_Abel.pdf		10	-	648 KB
2_Abel-NPL.pdf	(1-10)	10	Non Patent Literature	636 KB

Digest

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CARD / 1643	**E2025AND21465233**	**NASTASSJA MATUS**

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
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3_Gerbasi-NPL.pdf	(1-9)	9	Non Patent Literature	262 KB

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PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 1643	**E2025AND36496113**	**NASTASSJA MATUS**

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
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