IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Confirmation No.: 7901
Serial No.: 18/851,294 Group No.:
Filing or 371(c) Date: September 26, 2024 Examiner:
Entitled: 5-METHOXY-N,N-DIMETHYLTRYPTAMINE FOR THE TREATMENT OF ANXIETY

THIRD-PARTY PRE-ISSUANCE SUBMISSION

Examiner:

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

1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022)
2. 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
3. BARKIN (2014) "The Psychometric Properties of the Barkin Index of Maternal Functioning" *Journal of Obstetric, Gynecologic & Neonatal Nursing*. 43(6): 792–802.
4. TREVETHAN (2022) "The Barkin Index of Maternal Functioning: an evaluation and foundations for a new parental functioning scale" *Health Services and Outcomes Research Methodology*. 22: 416–434
5. 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
6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022)
7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671

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

U.S.S.N. 18/851,294 Pending Claims	References
1. 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof for use in treating a patient suffering from anxiety, wherein the 5-MeO-DMT is administered via the intravenous, intramuscular or subcutaneous route.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, **anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
2. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the anxiety the patient is suffering from is a subthreshold anxiety.	
3. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1 or claim 2, wherein the patient has a comorbidity of anxiety and a further diagnosed disorder.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…"

	From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
4. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from a mental or nervous system disorder.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including post partum depression, major depressive disorder and treatment-resistant depression), **headache disorder** (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
5. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 4,	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022)

wherein the patient also suffering from a mental or nervous system disorder suffers from a treatment resistant form of the disorder.	From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and **treatment-resistant depression),** headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
6. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from a disorder characterized by depressive episodes.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression (including post partum depression, major depressive disorder and treatment-resistant depression),** headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can**

	be administered orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
7. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 6, wherein the patient also suffering from a disorder characterized by depressive episodes suffers from a treatment resistant form of the disorder.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and **treatment-resistant depression),** headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
8. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from major depressive disorder (MDD).	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, **major depressive disorder** and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."

	From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
9. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 8, wherein the patient also suffering from MDD suffers from a treatment resistant form of the disorder.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, **major depressive disorder and treatment-resistant depression**), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
10. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from postpartum depression (PPD).	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, **major depressive disorder** and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…"

	From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
11. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 10, wherein the patient also suffering from PPD suffers from a treatment resistant form of the disorder.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, **major depressive disorder** and **treatment-resistant depression**), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
12. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 10 or	2. 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

11, wherein the patient suffers in addition from compromised maternal functioning.	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)."
13. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 12, wherein the patient has a Barkin Index of Maternal Functioning (BIMF) score of 80 or below, such as 65 or below.	3. BARKIN (2014) "The Psychometric Properties of the Barkin Index of Maternal Functioning" *Journal of Obstetric, Gynecologic & Neonatal Nursing*. 43(6): 792–802. From **page** 5 "Participant Characteristics The characteristics of the study sample are displayed in Table 1. The majority of the sample was White (68%), unmarried (56%), and utilizing public health insurance (53%). On average, the mothers were age 28.2 years and infants were age 6.2 weeks. The average (SD) SIGH-ADS-29 score was 22 (6.3), which is indicative of **depression of moderate severity. On average, women had a BIMF average (SD) total score of 79.6** (16.2)." From **page 1** "**Conclusions: The BIMF** may be administered in its 18-item version, as two separate subscales, or in its original 20-item format. **A clinical threshold should be developed to facilitate accurate identification of mothers who are struggling with functioning during the postpartum period**." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post partum depression,** major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."

14. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 12 or 13, wherein the treatment improves maternal functioning.	4. TREVETHAN (2022) "The Barkin Index of Maternal Functioning: an evaluation and foundations for a new parental functioning scale" *Health Services and Outcomes Research Methodology*. 22: 416–434 From **page 420** "From thematic analysis of focus-group transcripts, Barkin et al. (2010) proposed the existence of seven domains that they attempted to ensure were subsequently represented when they created the **BIMF**. They labeled these domains self-care, infant care, **mother–child interaction, psychological well-being of the mother**, social support, management, and adjustment." 3. 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**."
15. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 14, wherein the improvement in maternal functioning is reflected by an improvement of the BIMF total score by 10% or more, preferably by 20% or more.	5. CHAMGURDANI (2019) "The effect of counseling with a skills training approach on maternal functioning: a randomized controlled clinical trial" *BMC Women's Health*. 20:51 From **page 3** "In studies in which the IFSAC was used, **maternal functional status was found to be associated with maternal depression** and low self-efficacy **in the postpartum period** [18], high levels of anxiety in women after childbirth [30], impaired infant development [15] and lactation difficulties [16]…**The BIMF is a more recently developed and patient-centered measure of postpartum functioning** [14]." From **page 6** "Post-intervention, the mean total score (SD) of the BIMF in the counseling group was 95.8 (11.8) and in the control group it was 70.3 (4.5). Based on the ANCOVA test, and after adjusting for the baseline score,

	the mean score of the **BIMF was significantly higher in the counseling group than in the control group (Mean Difference (MD): 22.9**; 95% CI: 18.2 to 27.6; $p < 0.001$). In summary, there was no significant difference between the two groups related to the seven BIMF domains before the intervention ($p > 0.05$). However, the post intervention scores of all BIMF domains including self-care (MD: 3.8; 95% CI: 2.8 to 4.8), infant care (MD: 2.0; 95% CI: 1.4 to 2.6), **mother-child interaction (MD: 4.8**; 95% CI: 3.9 to 5.7), psychological wellbeing (MD: 8.4; 95% CI: 6.8 to 9.9), social support (MD: 4.0; 95% CI: 3.1 to 4.8), management (MD: 6.8; 95% CI: 5.1 to 8.4), and adjustment (MD: 3.2; 95% CI: 2.4 to 3.9) were significantly higher in the intervention group compared to the control group ($P < 0.001$)"
16. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 14 or 15, wherein the improvement in maternal functioning, is reflected by at least an improvement in the BIMF total score 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.	
17. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 14 or 15, wherein the improvement in maternal functioning, as reflected by at least an improvement in the BIMF total score, occurs not later than about 6 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof and wherein the	

improvement in maternal functioning, as reflected by at least an improvement in the BIMF total score, persists until at least 14 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof; more preferably until at least 28 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof.	
18. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from persistent depressive disorder.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and **treatment-resistant depression),** headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
19. 5-MeO-DMT or a pharmaceutically acceptable salt thereof	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022)

for use as in claim 18, wherein the patient also suffering from persistent depressive disorder suffers from a treatment resistant form of the disorder.	From **[0027]** "The condition or disease being treated can include, **but is not limited to, anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and **treatment-resistant depression),** headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
20. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from seasonal affective disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, **seasonal affective disorder**, dysthymia, anxiety and phobia disorders, **generalized anxiety disorder**, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
21. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 20, wherein the patient also suffering from seasonal affective disorder suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), **treatment-resistant depression (TRD)**, atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, **seasonal affective disorder**, dysthymia, anxiety and phobia disorders, **generalized anxiety disorder**, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
22. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from bipolar disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, **anxiety**, pain, such as chronic pain, schizophrenia, ADHD, **bipolar disorder**, OCD, binge eating disorder, and PTSD." From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),** mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA), racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) administration. In some

	embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."
23. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 22, wherein the patient is also suffering from bipolar II disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, **anxiety**, pain, such as chronic pain, schizophrenia, ADHD, **bipolar disorder**, OCD, binge eating disorder, and PTSD." From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),** mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA), racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12-4 SUBSTITUTE SHEET (RULE 26) administration. In some embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."
24. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 22, wherein the patient is also suffering from bipolar I disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, **anxiety**, pain, such as chronic pain, schizophrenia, ADHD, **bipolar disorder**, OCD, binge eating disorder, and PTSD."

	From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),** mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA), racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12-4 SUBSTITUTE SHEET (RULE 26) administration. In some embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."
25. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 22 to 24, wherein the patient suffers from a current major depressive episode.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, **anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, **major depressive disorder** and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."

	From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
26. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 22 to 25, wherein the patient also suffering from bipolar disorder suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, **depression**, **anxiety**, pain, such as chronic pain, schizophrenia, ADHD, **bipolar disorder**, OCD, binge eating disorder, and PTSD." From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), **treatment-resistant depression (TRD)**, atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." From **claim 41** "The pharmaceutical composition of claim 40, wherein the oxytocin-releasing agent is any of a melanocortin (MC) receptor agonist, a melanocyte stimulating hormone, a-melanocortin, a-melanotropin, melanotan II (MT-11), bremelanotide, a 5-HT1A agonist, a -HT2A agonist, or a 5-HT2c agonist, 6-(2-Aminopropy1)-2,3-dihydrobenzofuran (6-APDB), 6-(2-aminopropyl)benzofuran (6-APB), (4-fluoro-N-(2-{4-[(2S)-2-(hydroxyrnethyl)-2,3-dihydro-1,4-benzodioxin-5-ylThiperazin-1-y1}ethyl)benzamide (flesinoxan), 5-(3-R(2S)-1,4-benzodioxan-2-ylmethyl)amino]propoxy)-1,3-benzodioxole, (osemozotan), buspirone, gepirone, befiradol, eptapirone, 8-0H-DPAT, tandospirone, serotonin, ergine, ergotamine, lysergic acid, lysergic acid diethylamide (LSD), psilocybin, 4-hydroxy-dimethyltryptamine, N,N-di methyltryptamine (DMT), CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) **5-methoxy-dimethyltryptamine (5-MeO-DMT),** mescaline, an entactogen, 4-bromo-2,5-dimethoxyphenethylamine, 3,4-methylenedioxyamphetamine (MDA), methyl enedioxyethylamphetamine (MDEA), 3 -m ethoxy-4,5-m ethyl enedioxyamphetamine (MMDA),

	racemic 3,4-methylenedioxymethamphetamine, tenamfetamine, lorcaserin, or an analog, derivative, prodrug, or salt thereof." From **[0013]** "In some embodiments, the pharmaceutical composition is suitable for oral, mucosal, rectal, **subcutaneous, intravenous, intramuscular**, intranasal, inhaled, or transdermal CA 03221280 2023- 12- 4 SUBSTITUTE SHEET (RULE 26) administration. In some embodiments, the pharmaceutical compositions is suitable for oral administration and is formulated as a tablet or a capsule."
27. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient is suffering from an anxiety disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, **generalized anxiety disorder**, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
28. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 27, wherein the patient suffering from an anxiety disorder suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), **treatment-resistant depression (TRD)**, atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, **generalized anxiety disorder**, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."

29. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient is suffering from separation anxiety disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) 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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, **separation anxiety disorder**, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
30. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 29, wherein the patient suffering from separation anxiety disorder suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) 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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, **separation anxiety disorder**, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
31. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient is suffering from agoraphobia.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, **agoraphobia**, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."

32. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 31, wherein the patient suffering from agoraphobia suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), **treatment-resistant depression (TRD)**, atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, **agoraphobia**, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
33. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient is	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from

suffering from generalised anxiety disorder (GAD).	the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, **generalized anxiety disorder**, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
34. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 33, wherein the patient suffering from GAD suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), **treatment-resistant depression (TRD)**, atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and

	phobia disorders, **generalized anxiety disorder**, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
35. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient is suffering from social anxiety disorder (SAD).	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..."

	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."
36. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 35, wherein the patient suffering from SAD suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
37. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient is suffering from panic disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, **panic disorder**, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
38. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 37, wherein the patient suffering from panic disorder suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, **panic disorder**, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
39. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient is suffering from phobia.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and **phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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."
40. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 39, wherein the patient suffering from phobia suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and **phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ..." 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.”
41. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1, wherein the patient is suffering from substance/medication induced anxiety disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 “Enantiomeric entactogen compositions and methods of their use” (Published December 08, 2022) From **[0036]** “In some embodiments, the disorder is a mental health disorder. In some embodiments, the mental health disorder is selected from the group consisting of: depression, major depressive disorder (MDD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, ...” 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.”
42. 5-MeO-DMT or a pharmaceutically	

acceptable salt thereof for use as in claim 41, wherein the patient suffering from substance/medication induced anxiety disorder suffers from a treatment resistant form of the disorder.	
43. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from somatic symptom disorder.	
44. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 43, wherein the patient also suffering from somatic symptom disorder suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0252]** ""Mental health disorder" or "psychiatric disorder" refers to a disease condition in a mammal, and preferably in a human, that generally involves negative changes in emotion, mood, thinking, and/or behavior. For example, mental health disorders include those characterized by the DSM-5, the Merck Manual, e.g., anxiety and depressive disorders, or other such diagnostic resources known to those of skill. Examples of mental health disorders include anxiety and stressor related disorders, dissociative disorders, eating disorders, mood disorders, e.g., depressive disorders, obsessive-compulsive and related disorders, personality disorders, schizophrenia and related disorders, sexuality, gender dysphoria, and paraphilias, **somatic symptom and related disorders**, suicidal behavior and self-injury, and substance-related disorders, which includes substance-induced and substance use disorders." 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."
45. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from an obsessive compulsive or related disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, **obsessive compulsive**, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
46. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 45, wherein the obsessive compulsive or related disorder is obsessive compulsive disorder (OCD).	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, **obsessive compulsive**, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
47. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 45 or 46, wherein the patient suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, **obsessive compulsive**, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
48. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from body dysmorphic disorder (BDD).	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, **body dysmorphic syndromes**, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
49. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 48, wherein the patient also suffering from BDD suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, **body dysmorphic syndromes**, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
50. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from post-traumatic stress disorder (PTSD).	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, **post-traumatic stress disorder**, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders."

	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."
51. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 50, wherein the patient also suffering from PTSD suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0036]** "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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, **post-traumatic stress disorder**, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders,

	attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
52. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from a pain disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…A "comorbidity" present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, anxiety, **pain, such as chronic pain**, schizophrenia, ADHD, bipolar disorder, OCD, binge eating disorder, and PTSD..." 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."
53. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 52, wherein the patient is also suffering from chronic pain.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…A "comorbidity" present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, anxiety, **pain, such as chronic pain**, schizophrenia, ADHD, bipolar disorder, OCD, binge eating disorder, and PTSD..." 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."
54. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 52 or 53, wherein the patient suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…A "comorbidity" present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, anxiety, **pain, such as chronic pain**, schizophrenia, ADHD, bipolar disorder, OCD, binge eating disorder, and PTSD..." 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."
55. 5-MeO-DMT or a pharmaceutically acceptable salt thereof	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022)

for use as in claims 1 to 3, wherein the patient is also suffering from fibromyalgia.	From **[0248]** "…A "comorbidity" present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, anxiety, **pain, such as chronic pain**, schizophrenia, ADHD, bipolar disorder, OCD, binge eating disorder, and PTSD..." 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."
56. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from migraine.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and **migraine headache**), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including

	gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as dementia, Alzheimer's Disease, Parkinson's Disease), autism spectrum disorder, eating disorders, or neurological disorders (such as stroke). From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
57. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from a mental and behavioural disorder due to psychoactive substance use.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0250]** "The terms "subject," "patient," and "individual" are used interchangeably herein, and refer to any mammal although preferably a human. As used herein, the terms "subject," "patient," and "individual" includes one who has a mental health disorder, a **substance use disorder**, or a condition related to the same for which similar treatment may be efficacious." 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."
58. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 57, wherein the mental and behavioural disorder due to psychoactive substance use the patient is also suffering from is substance use disorder (SUD).	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0250]** "The terms "subject," "patient," and "individual" are used interchangeably herein, and refer to any mammal although preferably a human. As used herein, the terms "subject," "patient," and "individual" includes one who has a mental health disorder, a **substance use disorder**, or a condition related to the same for which similar treatment may be efficacious." 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."

59. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 57 or 58, wherein the patient suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0250]** "The terms "subject," "patient," and "individual" are used interchangeably herein, and refer to any mammal although preferably a human. As used herein, the terms "subject," "patient," and "individual" includes one who has a mental health disorder, a **substance use disorder**, or a condition related to the same for which similar treatment may be efficacious." 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."
60. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from a psychotic disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0028]** "In some embodiments, the method treats a stress disorder, acute stress disorder, brief **psychotic disorder** with marked stressor(s), delirium, mild cognitive impairment (MCI), dementia, psychosis, psychotic major depression, autism, and psychological distress related to life-threatening illness or death in the subject.

	From **[0250]** “The terms "subject," "patient," and "individual" are used interchangeably herein, and refer to any mammal although preferably a human. As used herein, the terms "subject," "patient," and "individual" includes one who has a mental health disorder, a **substance use disorder**, or a condition related to the same for which similar treatment may be efficacious.” 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.”
61. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 60, wherein the patient also suffering from a psychotic disorder suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 “Enantiomeric entactogen compositions and methods of their use” (Published December 08, 2022) From **[0028]** “In some embodiments, the method treats a stress disorder, acute stress disorder, brief **psychotic disorder** with marked stressor(s), delirium, mild cognitive impairment (MCI), dementia, psychosis, psychotic major depression, autism, and psychological distress related to life-threatening illness or death in the subject. From **[0250]** “The terms "subject," "patient," and "individual" are used interchangeably herein, and refer to any mammal although preferably a human. As used herein, the terms "subject," "patient," and "individual" includes one who has a mental health disorder, a

	substance use disorder, or a condition related to the same for which similar treatment may be efficacious." 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."
62. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from schizophrenia.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) 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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders,

	including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, **schizoid and schizotypal personality disorders**, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
63. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 62, wherein the patient also suffering from schizophrenia suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) 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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control

	disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, **schizoid and schizotypal personality disorders**, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
64. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from Parkinson's disease.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal,

	methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as dementia, Alzheimer's Disease, **Parkinson's Disease**), autism spectrum disorder, eating disorders, or neurological disorders (such as stroke). From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
65. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from dementia.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as **dementia**, Alzheimer's Disease, Parkinson's Disease), autism spectrum disorder, eating disorders, or neurological disorders (such as stroke). From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie

	(DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
66. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from Alzheimer's dementia.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as dementia, **Alzheimer's Disease**, Parkinson's Disease), autism spectrum disorder, eating disorders, or neurological disorders (such as stroke). From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"

67. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from Parkinson's disease dementia.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as **dementia**, Alzheimer's Disease, **Parkinson's Disease**), autism spectrum disorder, eating disorders, or neurological disorders (such as stroke). From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
68. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from dementia with Lewy Bodies.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including

	alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, **neurodegenerative disorders** (such as dementia, Alzheimer's Disease, Parkinson's Disease), autism spectrum disorder, eating disorders, or neurological disorders (such as stroke). From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
69. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from vascular dementia.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as **dementia**, Alzheimer's Disease, Parkinson's Disease), autism spectrum disorder, eating disorders, or neurological disorders (such as stroke). From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-

	dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
70. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from fronto-temporal dementia.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as **dementia**, Alzheimer's Disease, Parkinson's Disease), autism spectrum disorder, eating disorders, or neurological disorders (such as stroke). From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"

71. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from an eating disorder.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as dementia, Alzheimer's Disease, Parkinson's Disease), autism spectrum disorder, **eating disorders**, or neurological disorders (such as stroke)." From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
72. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 71, wherein the patient also suffering from an eating disorder suffers from a treatment resistant form of the disorder.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From [**0027**] "The condition or disease being treated can include, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache), obsessive compulsive disorder (OCD), personality disorders (including conduct disorder), stress disorders (including adjustment disorders and post-traumatic stress disorder), drug disorders (including

	alcohol dependence or withdrawal, nicotine dependence or withdrawal, opioid dependence or withdrawal, cocaine dependence or withdrawal, methamphetamine dependence or withdrawal), other addictions (including gambling disorder, eating disorder, and body dysmorphic disorder), pain, neurodegenerative disorders (such as dementia, Alzheimer's Disease, Parkinson's Disease), autism spectrum disorder, **eating disorders**, or neurological disorders (such as stroke)." From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, **subcutaneously** or parenterally including **intravenous**, **intramuscular**, and intranasal administration…"
73. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from attention deficit hyperactivity disorder (ADHD).	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, anxiety, pain, such as chronic pain, schizophrenia, **ADHD**, bipolar disorder, OCD, binge eating disorder, and PTSD." 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."
74. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 73, wherein the patient also suffering from ADHD suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…present may include such other psychiatric disorders (depending on the primary diagnosis) such as antisocial personality disorder, borderline personality disorder, depression, anxiety, pain, such as chronic pain, schizophrenia, **ADHD**, bipolar disorder, OCD, binge eating disorder, and PTSD." 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."
75. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from a personality disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0248]** "…present may include such other psychiatric disorders (depending on the primary diagnosis) such as **antisocial personality disorder, borderline personality disorder**, depression, anxiety, pain, such as chronic pain, schizophrenia, ADHD, bipolar disorder, OCD, binge eating disorder, and PTSD." 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."
76. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 75, wherein the personality disorder the patient is also suffering from is	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) 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

schizotypal personality disorder.	medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, **schizoid and schizotypal personality disorders**, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
77. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 75 or 76, wherein the patient suffers from a treatment	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) 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

resistant form of the disorder.	(1V1DD), treatment-resistant depression (TRD), atypical depression, postpartum depression, catatonic depression, a depressive disorder due to a medical condition, premenstrual dysphoric disorder, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, **schizoid and schizotypal personality disorders**, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
78. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022)

3, wherein the patient is also suffering from a borderline personality disorder (BPD).	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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, **personality disorders**, including antisocial, avoidant, **borderline**, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."

79. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 78, wherein the patient also suffering from an BPD suffers from a treatment resistant form of the disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) 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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, **personality disorders**, including antisocial, avoidant, **borderline**, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
80. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from chronic fatigue syndrome.	
81. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from autism spectrum disorder.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) 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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, **autism**, social anxiety in autistic subject, and dissociative disorders." 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."
82. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient suffers from a traumatic brain injury and also from the anxiety.	
83. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient suffers from a HIV infection and also from the anxiety.	
84. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient suffers from a post COVID condition and also from the anxiety.	
85. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 84, wherein the treatment reduces or eliminates the anxiety.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0108]** "In some embodiments, improvements in **"physiological or psychological effects"** include any one or more of a reduction in nausea and vomiting, an improved pharmacokinetic profile, a reduction in subjective body load during the therapeutic window, an improvement in the subjective valence of the experience, an improvement in feelings of positive affect, an increase in the therapeutic window, an improvement in behavioral integration, **a**

	reduction of anxiety, a reduction in addictive liability or abuse potential, a reduction in neurotoxicity, a reduction in hyperthermia or hypothermia, and a reduction in stimulation." 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, seasonal affective disorder, dysthymia, anxiety and phobia disorders, **generalized anxiety disorder**, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
86. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 85, wherein the reduction or elimination of the anxiety is observed about 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof; 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.	
87. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 85, wherein the reduction or elimination of the anxiety occurs not later than about 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof and wherein the reduction or elimination of the anxiety persists until at least 6 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof; 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.	
88. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 4 to 26 and 43 to 87, wherein the treatment leads to an improvement in the diagnosed disorder in a patient also suffering from anxiety.	
89. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 88, wherein the improvement in the diagnosed disorder in a patient also suffering from anxiety, as reflected by a reduction in the Clinical Global Impression-Severity (CGI-S) score, is observed about 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof; 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.	6. 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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control

	disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
90. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 88, wherein the improvement in the diagnosed disorder in a patient also suffering from anxiety, as reflected by a reduction in the Clinical Global Impression-Severity (CGI-S) score, occurs	6. 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**

not later than about 2 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof and wherein the improvement in the diagnosed disorder in a patient also suffering from anxiety, as reflected by a reduction in the Clinical Global Impression-Severity (CGIS) score, persists until at least 6 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof; 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.	**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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
91. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 3, wherein the patient is also suffering from a sleep disturbance.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0041]** "In some embodiments, the mental health disorder is PTSD. In some embodiments, one or more symptoms of PTSD are reduced and/or a PTSD diagnosis is reversed, as determined by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). In some embodiments, the one or more symptoms of PTSD include any of flashbacks, nightmares, distressing and intense memories, distress or physical reactions after being exposed to triggers, blaming self or others for the trauma, decreased interest in things that were once enjoyable, negative feelings about self and the world, inability to remember the trauma clearly, difficulty feeling positive, feelings of isolation, negative affect, difficulty feeling positive, avoidance, aggression or irritability, hypervigilance and hyper-awareness, difficulty concentrating, difficulty sleeping, heightened startle response, engaging in self- destmctive, or risky behavior, **difficulty sleeping or staying asleep**, or suicidal ideation." 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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
92. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 91, wherein the sleep disturbance is insomnia.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0041]** "In some embodiments, the mental health disorder is PTSD. In some embodiments, one or more symptoms of PTSD are reduced and/or a PTSD diagnosis is reversed, as determined by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). In some embodiments, the one or more symptoms of PTSD include any of flashbacks, nightmares, distressing and intense memories, distress or physical reactions after being exposed to triggers, blaming self or others for the trauma, decreased interest in things that were once enjoyable, negative feelings about self and the world, inability to remember the trauma clearly, difficulty feeling positive, feelings of isolation, negative affect, difficulty feeling positive, avoidance, aggression or irritability, hypervigilance and hyper-awareness, difficulty concentrating, difficulty sleeping, heightened startle response, engaging in self- destmctive, or risky behavior, **difficulty sleeping or staying asleep**, or suicidal ideation." 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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
93. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 91 or 92, wherein the patient suffers from a treatment	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0041]** "In some embodiments, the mental health disorder is PTSD. In some embodiments, one or more symptoms of PTSD are reduced and/or a PTSD diagnosis is reversed, as determined by the Clinician-Administered

resistant form of the disorder.	PTSD Scale for DSM-5 (CAPS-5). In some embodiments, the one or more symptoms of PTSD include any of flashbacks, nightmares, distressing and intense memories, distress or physical reactions after being exposed to triggers, blaming self or others for the trauma, decreased interest in things that were once enjoyable, negative feelings about self and the world, inability to remember the trauma clearly, difficulty feeling positive, feelings of isolation, negative affect, difficulty feeling positive, avoidance, aggression or irritability, hypervigilance and hyper-awareness, difficulty concentrating, difficulty sleeping, heightened startle response, engaging in self- destmctive, or risky behavior, **difficulty sleeping or staying asleep**, or suicidal ideation." 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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
94. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 91 to 93, wherein the sleep disturbance occurs in a patient also suffering from anxiety and also from a mental or nervous system disorder, such as disorders characterized by depressive episodes for example, Major Depressive Disorder (MDD), Postpartum Depression (PPD), Persistent Depressive Disorder, Seasonal Affective Disorder and Bipolar Disorder (BD), such as Bipolar I Dis-order and Bipolar II Disorder; Anxiety Disorder, for example Separation Anxiety Disorder, Agoraphobia, Generalised Anxiety Disorder (GAD), Social Anxiety Disorder (SAD), Panic Disorder, Phobias, and Substance/Medication Induced Anxiety Disorder; Somatic Symptom Disorder; Obsessive Compulsive	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0041]** "In some embodiments, the mental health disorder is **PTSD**. In some embodiments, one or more symptoms of PTSD are reduced and/or a PTSD diagnosis is reversed, as determined by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). In some embodiments, the one or more symptoms of PTSD include any of flashbacks, nightmares, distressing and intense memories, distress or physical reactions after being exposed to triggers, blaming self or others for the trauma, decreased interest in things that were once enjoyable, negative feelings about self and the world, inability to remember the trauma clearly, difficulty feeling positive, feelings of isolation, negative affect, difficulty feeling positive, avoidance, aggression or irritability, hypervigilance and hyper-awareness, difficulty concentrating, difficulty sleeping, heightened startle response, engaging in self- destmctive, or risky behavior, **difficulty sleeping or staying asleep**, or suicidal ideation." 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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders."

and Related Disorders, for example, Obsessive Compulsive Disorder (OCD) and Body Dysmorphic Disorder (BDD); Post-Traumatic Stress Disorder (PTSD); Pain Disorders, for 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; Parkinson's Disease; Dementia, for example Alzheimer's Dementia (AD), Parkinson's Disease Dementia (PDD), Dementia with Lewy Bodies, Vascular Dementia, Fronto-Temporal Dementias; Eating Disorders; Attention Deficit Hyperactivity Disorder (ADHD); Personality Disorders, for example Schizotypal Personality Disorder and Borderline Personality Disorder; Autism Spectrum Disorder; Chronic Fatigue Syndrome; or a medical health condition leading to an associated mental or nervous system condition, for example anxiety due to Traumatic Brain Injury (TBI), HIV infection, or post COVID condition.	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."

95. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 94, wherein the treatment leads to an improvement in anxiety and sleep disturbance and furthermore to an improvement in the associated mental or the nervous system disorder or the medical health condition leading to an associated mental or nervous system condition.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0108]** "In some embodiments, improvements in "physiological or psychological effects" include any one or more of a reduction in nausea and vomiting, an improved pharmacokinetic profile, a reduction in subjective body load during the therapeutic window, an improvement in the subjective valence of the experience, **an improvement in feelings of positive affect**, an increase in the therapeutic window, **an improvement in behavioral integration**, **a reduction of anxiety**, a reduction in addictive liability or abuse potential, a reduction in neurotoxicity, a reduction in hyperthermia or hypothermia, and a reduction in stimulation." From **[0041]** "In some embodiments, the mental health disorder is **PTSD**. In some embodiments, one or more symptoms of PTSD are reduced and/or a PTSD diagnosis is reversed, as determined by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). In some embodiments, the one or more symptoms of PTSD include any of flashbacks, nightmares, distressing and intense memories, distress or physical reactions after being exposed to triggers, blaming self or others for the trauma, decreased interest in things that were once enjoyable, negative feelings about self and the world, inability to remember the trauma clearly, difficulty feeling positive, feelings of isolation, negative affect, difficulty feeling positive, avoidance, aggression or irritability, hypervigilance and hyper-awareness, difficulty concentrating, difficulty sleeping, heightened startle response, engaging in self- destmctive, or risky behavior, **difficulty sleeping or staying asleep**, or suicidal ideation." 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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders."

	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."
96. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 85 to 95, wherein the treatment leads to an improvement in the sleep disturbance.	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0108]** "In some embodiments, improvements in "physiological or psychological effects" include any one or more of a reduction in nausea and vomiting, an improved pharmacokinetic profile, a reduction in subjective body load during the therapeutic window, an improvement in the subjective valence of the experience, **an improvement in feelings of positive affect**, an increase in the therapeutic window, **an improvement in behavioral integration**, a reduction of anxiety, a reduction in addictive liability or abuse potential, a reduction in neurotoxicity, a reduction in hyperthermia or hypothermia, and a reduction in stimulation." From **[0041]** "In some embodiments, the mental health disorder is **PTSD**. In some embodiments, one or more symptoms of PTSD are reduced and/or a PTSD diagnosis is reversed, as determined by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). In some embodiments, the one or more symptoms of PTSD include any of flashbacks, nightmares, distressing and

	intense memories, distress or physical reactions after being exposed to triggers, blaming self or others for the trauma, decreased interest in things that were once enjoyable, negative feelings about self and the world, inability to remember the trauma clearly, difficulty feeling positive, feelings of isolation, negative affect, difficulty feeling positive, avoidance, aggression or irritability, hypervigilance and hyper-awareness, difficulty concentrating, difficulty sleeping, heightened startle response, engaging in self- destmctive, or risky behavior, **difficulty sleeping or staying asleep**, or suicidal ideation." 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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
97. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 96, wherein the improvement in the sleep disturbance, as reflected by a reduction in the Clinical Global Impression-Severity (CGI-S) score, is observed 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.	
98. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 96, wherein the improvement in the sleep disturbance, as reflected by a reduction in the Clinical Global Impression-Severity (CGI-S) score, occurs not later than about 24 hours after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof	

and wherein the improvement in the sleep disturbance, as reflected by a reduction in the Clinical Global Impression-Severity (CGI-S) score, persists until at least 6 days after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof; 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.	
99. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 96, wherein the improvement in the sleep disturbance, as reflected by a reduction in the Clinical Global Impression-Severity (CGI-S) score, is observed on day 7 after the last administration of 5-MeO-DMT or a pharmaceutically acceptable salt thereof and preferably persists until at least 14 days, more preferably until at least 28 days.	
100. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 99, wherein the patient suffers from suicidal ideation and the	6. CA. Pat. App. Pub. No. CA3221280A1 "Enantiomeric entactogen compositions and methods of their use" (Published December 08, 2022) From **[0041]** "In some embodiments, the mental health disorder is PTSD. In some embodiments, one or more symptoms of PTSD are reduced and/or a PTSD diagnosis is reversed, as determined by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). In some embodiments, the one or more

treatment reduces or eliminates suicidal ideation.	symptoms of PTSD include any of flashbacks, nightmares, distressing and intense memories, distress or physical reactions after being exposed to triggers, blaming self or others for the trauma, decreased interest in things that were once enjoyable, negative feelings about self and the world, inability to remember the trauma clearly, difficulty feeling positive, feelings of isolation, negative affect, difficulty feeling positive, avoidance, aggression or irritability, hypervigilance and hyper-awareness, difficulty concentrating, difficulty sleeping, heightened startle response, engaging in self- destmctive, or risky behavior, difficulty sleeping or staying asleep, or **suicidal ideation**." From **[0108]** "In some embodiments, improvements in "physiological or psychological effects" include any one or more of a reduction in nausea and vomiting, an improved pharmacokinetic profile, a reduction in subjective body load during the therapeutic window, an improvement in the subjective valence of the experience, **an improvement in feelings of positive affect**, an increase in the therapeutic window, **an improvement in behavioral integration**, a reduction of anxiety, a reduction in addictive liability or abuse potential, a reduction in neurotoxicity, a reduction in hyperthermia or hypothermia, and a reduction in stimulation." 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, seasonal affective disorder, dysthymia, **anxiety and phobia disorders**, generalized anxiety disorder, agoraphobia, panic disorder, separation anxiety disorder, social anxiety disorder, post-traumatic stress disorder, adjustment disorders, feeding and eating disorders, including binge eating, bulimia, and anorexia nervosa, other binge behaviors, body dysmorphic syndromes, drug abuse or dependence disorders, disruptive behavior disorders, impulse control disorders, gaming disorders, gambling disorders, memory loss, dementia of aging, attention deficit hyperactivity disorder, personality disorders, including antisocial, avoidant, borderline, histrionic, narcissistic, obsessive compulsive, paranoid, schizoid and schizotypal personality disorders, attachment disorders, autism, social anxiety in autistic subject, and dissociative disorders." 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."
101. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 100, wherein the 5-MeO-DMT or salt thereof is administered at a dose or in a dosage regimen that causes the patient to experience a peak psychedelic experience.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, **6**, 12, and 18 **mg 5-MeO-DMT administered via inhalation as well as individualized dose escalation (IDE) of 5- MeO-DMT at doses ranging from 6 to 18 mg**. The overall aim of the study was to **determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, **because strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines**"
102. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 101, wherein a dosage of about 1 mg to about 10 mg 5-MeO-DMT is administered, or wherein equimolar amounts of the pharmaceutically	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, **6**, 12, and 18 **mg 5-MeO-DMT administered via inhalation as well as individualized dose escalation (IDE) of 5- MeO-DMT at doses ranging from 6 to 18 mg**. The overall aim of the study was to **determine the**

acceptable salt are administered instead of 5-MeO-DMT.	**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**"
103. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 101, wherein a dosage of about 2 mg; or of about 5 mg; or of about 8 mg is administered, or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, **6**, 12, and 18 **mg 5-MeO-DMT administered via inhalation as well as individualized dose escalation (IDE) of 5- MeO-DMT at doses ranging from 6 to 18 mg**. The overall aim of the study was to **determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, **because strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines**"
104. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 101, wherein a dosage of about 1 mg; or of about 2 mg; or of about 3 mg is administered, or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, 6, 12, and 18 **mg 5-MeO-DMT administered via inhalation as well as individualized dose escalation (IDE) of 5- MeO-DMT** at doses ranging from 6 to 18 mg. The overall aim of the study was to **determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, **because strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines**"
105. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 102, wherein the 5-MeO-DMT or salt thereof is administered in a first dosage amount for a first administration; and the	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 3** "The phase 1 study was comprised of two single-arm parts, where Part A was a single-ascending dose study and **Part B used an individualized dose escalation regimen (IDE)**... **In Part B, an IDE**

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.	**regimen of 6, 12, and 18 mg was applied, where at least one and up to three doses of 5-MeO-DMT** (as GH001) interspaced at 3 h were given on a single day. **The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously administered dose** and whether the previously administered dose was safe. **If no PE had been achieved, the next dose was administered, up to the maximum of three doses**, after consultation with and consent from the participant." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, **anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months."

106. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1 to 102 or 105, wherein the 5-MeO-DMT is administered in a dosage from about 1 mg to about 3 mg for a first administration, and then increased, unless the patient has already experienced a peak psychedelic experience, to a dosage from about 4 mg to about 6 mg for a second administration, and then increased, unless the patient has already experienced a peak psychedelic experience, to a dosage from about 7 mg to about 9 mg for a third administration, or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 3** "The phase 1 study was comprised of two single-arm parts, where Part A was a single-ascending dose study and **Part B used an individualized dose escalation regimen (IDE)**... **In Part B, an IDE regimen of 6, 12, and 18 mg was applied, where at least one and up to three doses of 5-MeO-DMT** (as GH001) interspaced at 3 h were given on a single day. **The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously administered dose** and whether the previously administered dose was safe. **If no PE had been achieved, the next dose was administered, up to the maximum of three doses**, after consultation with and consent from the participant." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, **anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin

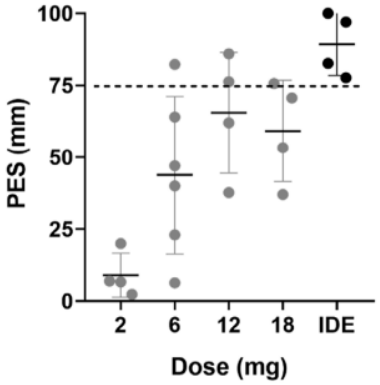
	can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months."
107. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 106, wherein the first dosage of 5-MeO-DMT is about 2 mg, the second dosage of 5-MeO-DMT is about 5 mg, and the third dosage of 5-MeO-DMT is about 8 mg; or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The study evaluated **single, ascending doses of 2**, **6**, 12, and 18 **mg 5-MeO-DMT administered via inhalation as well as individualized dose escalation (IDE) of 5- MeO-DMT at doses ranging from 6 to 18 mg**. The overall aim of the study was to **determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, **because strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines**"
108. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 1 to 102 or 105, wherein the 5-MeO-DMT is administered in a dosage from about 0.5 mg to about 1.5 mg for a first administration, and then increased, unless the patient has already experienced a peak psychedelic experience, to a dosage from about 1.5 mg to about 2.5 mg for a second administration, and then increased, unless the patient has already experienced a peak psychedelic experience,	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 3** "The phase 1 study was comprised of two single-arm parts, where Part A was a single-ascending dose study and **Part B used an individualized dose escalation regimen (IDE)**... **In Part B, an IDE regimen of 6, 12, and 18 mg was applied, where at least one and up to three doses of 5-MeO-DMT** (as GH001) interspaced at 3 h were given on a single day. **The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously administered dose** and whether the previously administered dose was safe. **If no PE had been achieved, the next dose was administered, up to the maximum of three doses**, after consultation with and consent from the participant." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022)

to a dosage from about 2.5 mg to about 3.5 mg for a third administration, or wherein equimolar amounts of the pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	From **[0027]** "**The condition or disease being treated can include**, but is not limited to, **anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months."
109. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 108, 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	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, **anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-**

pharmaceutically acceptable salt are administered instead of 5-MeO-DMT.	**dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months."
110. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 105 to 109, 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 1 to 2 hours.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 3** "The phase 1 study was comprised of two single-arm parts, where Part A was a single-ascending dose study and Part B used an individualized dose escalation regimen (IDE)... In Part B, an IDE regimen of 6, 12, and 18 mg was applied, **where at least one and up to three doses of 5-MeO-DMT** (as GH001) **interspaced at 3 h were given on a single day**. The decision to move on to the next dose was guided by an evaluation of whether the participant achieved a PE at the previously administered dose and whether the previously administered dose was safe. If no PE had been achieved, the next dose was administered, up to the maximum of three doses, after consultation with and consent from the participant." 1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0027]** "**The condition or disease being treated can include**, but is not limited to, anxiety disorders (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), **depression** (including **post**

	partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof." From **[0015]** "**The psychedelics in the present invention can be**, but are not limited to, ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, or homologues thereof. Preferably, the dose of the psychedelic is one that provides a meaningful effect. A dose of 1-1000 mg of ibogaine or noribogaine can be used. A dose of 0.01-1 mg (10-1000 μg) can be used of LSD. Psilocybin can be dosed at 5-50 mg, psilocin can be dosed at 1-100 mg, mescaline can be dosed at 50-800 mg, **5-MeO-DMT can be dosed at 1-20 mg**, DMT can be dosed at 20-100 mg, DOI can be dosed at 0.1-5 mg, and DOB can be dosed at 0.1-5 mg." From **[0021]** "**The doses can be single doses or multiple doses or a continuous dose over a period of several hours**, days, weeks, or months."
111. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 101 to 110, 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	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 7-8** "For example, in the present study, only **three individuals achieved a rating >60% across all subscores of the MEQ (i.e., MEQ rating >3), which is the MEQ threshold for a mystical experience (Barrett et al., 2015; Barsuglia et al., 2018).** …The MEQ, EDI and 5D-ASC scales capture many aspects of a psychedelic experience that seem not to be typical for the intense, short-lasting psychoactive effects of 5-MeO-DMT when used in the clinical setting, and those scores may be more appropriate in the spiritual or self-exploratory contexts of naturalistic use. For example, among visitors of a psychospiritual retreat program in Mexico (Barsuglia et al., 2018) who received 50 mg of toad venom containing 5-MeO-DMT, over 75% had "a complete mystical experience" (≥60% on all MEQ subscales)."

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 2** "The overall aim of the study was **to determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, because **strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines** (Garcia-Romeu et al., 2014; Johnson et al., 2014; Bogenschutz et al., 2015; Griffiths et al., 2016; Ross et al., 2016; Roseman et al., 2018)." From **page 3** "**Subjective ratings included the** Peak Experience Scale (PES), duration of experience, the Ego Dissolution Inventory (EDI) (Nour et al., 2016), the **Mystical Experiences Questionnaire (MEQ)** (Studerus et al., 2010; Barrett et al., 2015), the Challenging Experiences Questionnaire (CEQ) (Barrett et al., 2016) and the 5-Dimensional Altered States of Consciousness Questionnaire (5D-ASC) (Studerus et al., 2010)." From **page 6** "Overall, **5-MeO-DMT elicited a substantial psychedelic experience as retrospectively assessed with all questionnaires**, except the CEQ. **All doses elicited significantly higher** PES and **MEQ ratings as compared to the lowest dose of 2 mg**. In total, eight participants reported a peak experience (i.e., PES rating ≥75%): one participant at the 6 mg dose, two participants at the 12 mg dose, one participant at the 18 mg dose, and **all four participants in the individualized dose escalation group**."
112. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claim 111, wherein the occurrence of a peak psychedelic experience is identified through achievement of a Peak Experience Scale (PES) Total Score of at least 75.	7. RECKWEG (2021) "A Phase 1, Dose-Ranging Study to Assess Safety and PsychoactiveEffects of a Vaporized 5-Methoxy-N,N-Dimethyltryptamine Formulation (GH001) in Healthy Volunteers" *Frontiers in Pharmacology*. 12: 760671 From **page 2** "The overall aim of the study was **to determine the dosing regimen of 5-MeO-DMT that would achieve a peak experience** in healthy volunteers. That aim is relevant for future dose selection in clinical populations, because **strong associations between psychedelic peak experiences and therapeutic effects have been reported for other tryptamines** (Garcia-Romeu et al., 2014; Johnson et al., 2014; Bogenschutz et al., 2015; Griffiths et al., 2016; Ross et al., 2016; Roseman et al., 2018)." From **page 3** "**Subjective ratings included the** Peak Experience Scale (PES), duration of experience, the Ego Dissolution Inventory (EDI) (Nour et al., 2016), the **Mystical Experiences Questionnaire (MEQ)** (Studerus et al., 2010; Barrett et al., 2015), the Challenging Experiences Questionnaire (CEQ) (Barrett et al., 2016) and the 5-Dimensional Altered States of Consciousness Questionnaire (5D-ASC) (Studerus et al., 2010)."

	From **page 6** "Overall, **5-MeO-DMT elicited a substantial psychedelic experience as retrospectively assessed with all questionnaires**, except the CEQ. **All doses elicited significantly higher** PES and **MEQ ratings as compared to the lowest dose of 2 mg**. In total, eight participants reported a peak experience (i.e., PES rating ≥75%): one participant at the 6 mg dose, two participants at the 12 mg dose, one participant at the 18 mg dose, and **all four participants in the individualized dose escalation group**." From **page 4-5** "n Part A, **one participant achieved a PE (i.e., PES rating ≥75%) in the 6 mg dose group**…**FIGURE 1 | Mean (SE) and individual retrospective ratings of the acute psychedelic experience (PES**, EDI, MEQ, CEQ) per dose level" 
113. 5-MeO-DMT or a pharmaceutically acceptable salt thereof for use as in claims 1 to 112, wherein the 5-MeO-DMT or a pharmaceutically acceptable salt thereof is administered via intravenous injection.	1. U.S. Pat. App. Pub. No. US/2022/0354862 "LIPOSOME DELIVERY OF PSYCHEDELICS" (Published November 10, 2022) From **[0020]** "In the method of the present invention, the compounds of the present invention can be administered in various ways. It should be noted that they can be administered as the compound and can be administered alone or as an active ingredient in combination with pharmaceutically acceptable carriers, diluents, adjuvants, and vehicles. **The compounds can be administered** orally, transcutaneously, subcutaneously or parenterally including **intravenous**, intramuscular, and intranasal administration…" From **[0027]** "**The condition or disease being treated can include**, but is not limited to, **anxiety disorders** (including anxiety in advanced stage illness e.g. cancer, as well as generalized anxiety disorder), depression (including post partum depression, major depressive disorder and treatment-resistant depression), headache disorder (including cluster headaches and migraine headache)…" From **claim 2** "The composition of claim 1, wherein said **psychedelic is chosen from the group consisting of** ibogaine, noribogaine, lysergic acid diethylamide (LSD), psilocybin, psilocin, mescaline, **5-methoxy-N,N-**

	dimethyltryptamine (5-MeO-DMT), dimethyltryptamine (DMT), 2,5-dimethoxy-4-iodoamphetamine (DOI), 2,5-dimethoxy-4-bromoamphetamie (DOB), salts thereof, solvates thereof, tartrates thereof, analogs thereof, and homologues thereof."

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P.O. Box 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/851,294	**12/02/2025 12:00:46 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	SISI LI
PATENT CENTER #	73400199	FILING DATE	09/26/2024
CUSTOMER #	–	FIRST NAMED INVENTOR	
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 10

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf		3	Third-Party Submission Under 37 CFR 1.290	62 KB
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
Concise-description-generated.pdf		2	Concise Description of Relevance	33 KB
Claims_Chart.pdf		93	-	809 KB
Claims_Chart-3P.RELEVANCE.pdf	(1-93)	93	Concise Description of Relevance	741 KB
2_WALKER.pdf		12	-	458 KB
2_WALKER-NPL.pdf	(1-12)	12	Non Patent Literature	370 KB

3_BARKIN.pdf		11	-	132 KB
3_BARKIN-NPL.pdf	(1-11)	11	Non Patent Literature	122 KB
4_TREVETHAN.pdf		19	-	2680 KB
4_TREVETHAN-NPL.pdf	(1-19)	19	Non Patent Literature	2667 KB
5_CHAMGURDANI.pdf		10	-	682 KB
5_CHAMGURDANI-NPL.pdf	(1-10)	10	Non Patent Literature	639 KB
6_CA3221280A1.pdf		128	-	6831 KB
6_CA3221280A1-FOR.pdf	(1-128)	128	Foreign Reference	6806 KB
7_RECKWEG.pdf		12	-	1175 KB
7_RECKWEG-NPL.pdf	(1-12)	12	Non Patent Literature	1158 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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Claims_Chart.pdf	EECDCC2146AB0BF961F3D4DA96A3448E81AD2E65D7309B5E4FDE8BEF905845E66E560CDFADB8A87815D430C3C96D8DAF6833AF3CFA63B4BBEC6C79F2C8C06FAA
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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/851,294	**12/02/2025 12:00:46 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	SISI LI
PATENT CENTER #	73400199	AUTHORIZED BY	-
CUSTOMER #	–	FILING DATE	09/26/2024
INTL. APPLICATION #	-	INTL. FILING DATE	-
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 0642	**E2025B2C01455339**	**SISI LI**

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

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