IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Arnold; Craig Michael et al	Confirmation No.: 1014
Serial No.:	17/624,377	Group No.:
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Entitled: METERED DOSING COMPOSITIONS AND METHODS OF USE OF PSYCHEDELIC COMPOUNDS

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. 2017/0157343 "Methods, Devices, and Systems for Pulmonary Delivery of Active Agents" (Published June 8, 2017)
2. Studies in Natural Product Chemistry Chapter 5 – Bioactive Alkaloids of Hallucinogenic Mushrooms (online). Volume 46, Pages 133-168, 2015 (retrieved on 21 December 2022). Retrieved from the Internet: <URL: https://www.sciencedirect.com/science/article/abs/pii/B9780444634627000051#:~:text=The%20main%20alkaloids%20tryptamine%2Findolamine,the%20psilocybin%20and%20norbaeocystin%20(Fig>
3. CA Pat. App. Pub. No. 3127854 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)
4. U.S. Pat. App. Pub. No. 2005/0288375 "Method and Composition for Treating Neurodegenerative Disorders" (Published December 29, 2005)
5. Int'l Pat. App. Pub. No. WO/2020/212952 "Treatment of Depression and Other Various Disorders with Psilocybin" (Published October 22, 2020)
6. U.S. Pat. App. Pub. No. 2019/0225612 "5-HT2C Receptor Agonists and Compositions and Methods of Use" (Published July 25, 2019)
7. Int'l Pat. App. Pub. No. WO/2004/041272 "Use of Serotonin Receptor Antagonists for the Treatment of Sleep Apnea" (Published May 21, 2004)
8. U.S. Pat. App. Pub. No. 2020/0147038 "Assessing and Treating Psychedelic-Responsive Subjects" (Published May 14, 2020)
9. U.S. Pat. App. Pub. No. 2021/0196697 "Combination Therapies for Treating Bipolar Disorder and ADHD, and Methods for Using the Same" (Published October 24, 2018)
10. Bob (2007) "Peaceful on a Hill: DMT & MAOI." Retrieved December 14, 2022. <URL: https://web.archive.org/web/20070607032408/https://erowid.org/experiences/exp.php?ID=42150>
11. U.S. Pat. App. Pub. No. 2011/0111029 "Composition for Transdermal Delivery of Cationic Active Agents" (Published May 12, 2011)
12. Int'l Pat. App. Pub. No. WO/2020/181194 "Compositions and Methods of Use Comprising Substances with Neural Plasticity Actions Administered at Non-Psychedelic/Psychotomimetic Dosages and Formulations (Published September 10, 2020)
13. Nowak (2016) "Identification and determination of ergot alkaloids in Morning Glory cultivars" Anal Bioanal Chem. 408:3093-3102.

14. Badig-Taika (2018) “Phytochemical characterization of Tabernanthe iboga root bark and its effects on dysfunctional metabolism and cognitive performance in high-fat-fed C57BL/6J Mice” J Food Bioact. 3:111-123
15. U.S. Pat. App. Pub. No. 2015/0258112 “Methods and Compositions for Treating Depression Using Ibogaine” (Published September 17, 2015)
16. Psychedelic Times (2016) “Drug Addicts aren’t the Only Ones Recovering: Iboga also Found to Cure Depression, Anxiety, and PTSD” Retrieved December 15, 2022. <URL: https://web.archive.org/web/20160220083153/https://psychedelictimes.com/learn-more-iboga/>
17. US. Pat. App. Pub. No. 2005/0288375 “Method and Composition for Treating Neurodegenerative Disorders” (Published December 29, 2005)
18. Int’l Pat. App. Pub. No. WO/2021/216489 “Methods for Treating Mild Brain Injury, Post Traumatic Stress Disorder and Mild Traumatic Brain Injury” (Published October 28, 2021)
19. Int’l Pat. App. Pub. No. WO/2020/169850 “5-Methoxy-N-N-Dimethyltryptamine (5-MeO-DMT) for Treating Depression” (Published August 27, 2020)

1. A metered dosing formulation comprising: An amount between 3 micrograms to 1.3 g of one or more psychedelic compounds from a class of mushroom-related compounds with any one or more of a preservative, a buffer, a chloride salt, a polymer, a carbohydrate, a solvent, a terpene, a surfactant, a liquified gas, a solvent, and combinations thereof.	1. US20170157343 From **claim 1** “A method of delivering to a pulmonary tract of a subject at least one pharmacologically active agent, the method comprising: vaporizing a first **metered amount of at least one pharmacologically active agent**; delivering said first metered amount to the subject from an inhaler device; wherein a controller associated with said inhaler device is preprogrammed with at least one predetermined effect to be induced in the subject by said at least one pharmacologically active agent.” From **paragraph [450**] “Optionally or additionally, the active pharmaceutically active agent is selected from the group comprising: tetrahydrocannabinol (THC), salvinorin A, benzoylmethylecgonine, dimethyltryptamine, **psilocybin**” From **paragraph [485]** “In some embodiments, the active agent is a **terpenoid**, alkaloid or cannabinoid. For example, in some embodiments, the active agent is a diterpenoid such as, but not limited to salvinorin A from *salvia*. In other embodiments, the active agent is an alkaloid such as, but not limited to, benzoylmethylecgonine from the coca plant, or the active agent is a **tryptamine such as psylocibin from mushrooms**. In alternative embodiments the active substance is dimethyltryptamine (DMT) from a variety of plants. In further embodiments,

	the active substance is nicotine from tobacco. In further embodiments, the active substance is a **terpenoid,** e.g., limonene, α-pinene, β-myrcene, linalool, β-caryophyllene, caryophyllene, nerolidol or phytol, present in various plant forms."
2. Formulation of claim 1, wherein said psychedelic compound is selected from said group of mushroom-related compounds comprising psilocybin (O-phosphoryl-4-hydroxy-N,N-dimethyltryptamine, 4-PO-Psilocin, or 4-PO—HO-DMT), psilocin (4-HO-DMT, 4-hydroxy DMT, psilocine, psilocyn, psilotsin), baeocystin, norbaeocystin, salts and isomers thereof, and combinations thereof.	1. US20170157343 From **paragraph [0041]** "According to some embodiments, the plant includes**... *Psilocybe spp.*** …" From **paragraph [450**] "Optionally or additionally, the active pharmaceutically active agent is selected from the group comprising: tetrahydrocannabinol (THC), salvinorin A, benzoylmethylecgonine, dimethyltryptamine, **psilocybin**" From **paragraph [485]** "In some embodiments, the active agent is a terpenoid, alkaloid or cannabinoid. For example, in some embodiments, the active agent is a diterpenoid such as, but not limited to salvinorin A from *salvia*. In other embodiments, the active agent is an alkaloid such as, but not limited to, benzoylmethylecgonine from the coca plant, or the active agent is a **tryptamine such as psylocibin from mushrooms**. In alternative embodiments the active substance is dimethyltryptamine (DMT) from a variety of plants. In further embodiments, the active substance is nicotine from tobacco. In further embodiments, the active substance is a terpenoid, e.g., limonene, α-pinene, β-myrcene, linalool, β-caryophyllene, caryophyllene, nerolidol or phytol, present in various plant forms." 2. Studies in Natural Products Chemistry Chapter 5 From **abstract** "…Hallucinogenic compounds have been chemically identified in mushrooms belonging to various genera, e.g., … *Psilocybe* ... Two of simple indole alkaloids: **psilocin** (3-[2 (dimethylamino)ethyl]-4-indolol) and **psilocybin** ([3-(2-dimethylaminoethyl)-1*H*-indol-4-yl] dihydrogen phosphate) are present in most psychedelic mushrooms. … [there] are also other analogs of psilocybin: **baeocystin,**

	norbaeocystin, bufotenin, and aeruginascin that are found in hallucinogenic mushrooms."
3. Formulation of claim 1, wherein said mushroom-related compounds include synthetic forms or their synthetic analogues thereof.	1. US20170157343 From **paragraph [0271] "**Alternatively, the substance is an organic material which contains, or consists of, for example, one or more natural plant materials, or a **synthetic material"** From **paragraph [0274]** "The agent may be of natural origin **or synthetic**."
4. Formulation of claim 1, wherein said formulation comprises a device or formulation that is capable of administering a metered dose between 3 micrograms to 1.3 g of psilocybin (0-phosphoryl-4-hydroxy-N,N-dimethyltryptamine, 4-PO-Psilocin, or 4-PO—HO-DMT), psilocin (4-HO-DMT, 4-hydroxy DMT, psilocine, psilocyn, psilotsin), baeocystin, norbaeocystin, salts and isomers, and combinations thereof.	1. US20170157343 From **paragraph [0016] "**According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering to a subject at least one pharmacologically active agent being in a plant material, the method comprising pulmonary delivering the agent to the subject using a **metered dose** inhaler device configured to vaporize at least one pre-determined vaporized amount of the agent upon controllably heating the plant material, wherein the at least one pre-determined vaporized amount of the agent is selected so as to achieve at least one pre-determined pharmacokinetic (PK) effect and/or at least one pre-determined pharmacodynamic (PD) effect induced by the agent in the subject." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg, from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween."
5. Formulation of claim 1, wherein said formulation further comprises a ratio of at least 0.004 part terpene to 1 part psychedelic compound to less than a ratio of 10 parts terpene to 1 part psychedelic compound.	1. US20170157343 From **paragraph [0079]** According to some embodiments, at least one of the first pharmacologically active agent and the second pharmacologically active agent includes Δ9-tetrahydrocannabinol (THC), cannabidiol (CBD), cannabigerols (CBG), cannabichromenes (CBC), cannabinol (CBN), cannabinodiol (CBDL),

	cannabicyclol (CBL), cannabielsoin (CBE), cannabidivarin (CBDV), tetrahydrocannabivarin (THCV) and cannabitriol (CBT) The system, according to some of any of the embodiments of the present disclosure, provides the ability to use the MDI for delivering more than one pharmaceutically active agents (from one or more substances) **at any ratio** or pre-determined vaporized amounts so as to exhibit a pre-selected PD profile (e.g., maintaining an individual patient within the therapeutic window calculated per the patient). In some embodiments, different doses are selectively administered according to a regimen so as to prevent adverse effects while still alleviating symptoms.
6. Formulation of claim 1, wherein said formulation is for oral inhalation as delivered by a dry powder inhaler, thermal vaporizer (such as but not limited to an electronic cigarette), air jet nebulizer, vibrating mesh nebulizer, vaporizer, or pressurized metered dose inhaler	1. US20170157343 From **paragraph [0016] "**According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering to a subject at least one pharmacologically active agent being in a plant material, the method comprising pulmonary delivering the agent to the subject using a **metered dose inhaler device** configured to vaporize at least one pre-determined vaporized amount of the agent upon controllably heating the plant material, wherein the at least one pre-determined vaporized amount of the agent is selected so as to achieve at least one pre-determined pharmacokinetic (PK) effect and/or at least one pre-determined pharmacodynamic (PD) effect induced by the agent in the subject." 3. CA312785 From **Claim 1** "A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof " From **Description Page 9**

	5HT$_2$ RECEPTORS **[39]** In general, 5HT$_2$ receptors are characterized by having lower affinity for serotonin (and other indole alkylamines), and are linked to the G_q/phospholipase C pathway of signal transduction. In various instances, such receptors mediate a variety of physiological and behavioral functions via three distinct subtypes: 5HT$_{2A}$, 5HT$_{2B}$ and 5HT$_{2C}$. **Receptor** / **Physiological / behavioral function** 5HT$_{2A}$ Addiction, Anxiety, Appetite, Cognition, Imagination, Learning, Memory, Mood, Perception, Sexual Behavior, Sleep, Thermoregulation, Vasoconstriction 5HT$_{2B}$ Anxiety, Appetite, Cardiovascular Function, GI Motility, Sleep, Vasoconstriction 5HT$_{2C}$ Addiction, Anxiety, Appetite, GI Motility, Locomotion, Mood, Penile Erection, Sexual Behavior, Sleep, Thermoregulation, Vasoconstriction **Receptor** / **Uses of drugs that act on this receptor** 5HT$_{2A}$ Antipsychotics , Psychedelics, Noradrenergic and Specific Serotonergic Antidepressants (NaSSAs), Sleeping aids 5HT$_{2B}$ Migraines 5HT$_{2C}$ Antidepressant, Orexigenic, Anorectic, Antipsychotic **Receptor** / **Drugs acting on receptor** 5HT$_{2A}$ Agonists Bufotenin, Ergonovine, Lisuride, LSD, Mescaline, Myristicin, Psilocin, Psilocybin, DMT, DOM, PNU-22394, TFMPP, 25I-NBOMe, 2C-B, 5-MeO-DMT, BZP Antagonists 9 From **Claim 13**. "The method of any one of the preceding claims, wherein the 5HT receptor agonist is **psilocybin** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof." From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an oral formulation, a buccal formulation, a nasal formulation, or an **inhalation formulation**." From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and **atomized vapor."**
7. Formulation of claim 1, wherein said formulation is for nasal inhalation as delivered by nasal spray device containing one or more of water, liquified gas, solvent or thickening agent.	3. CA312785 From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an oral formulation, a buccal formulation, a **nasal** formulation, or an inhalation formulation." From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a **spray**, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor."

8. Formulation of claim 1, wherein said formulation is for oral administration as delivered by a sublingual film, orally disintegrating tablet, tablet, capsule, lozenge, troche, chewing gum or tincture.	3. CA312785 From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an **oral formulation**, a buccal formulation, a nasal formulation, or an inhalation formulation."
9. Formulation of claim 1, wherein said formulation is for topical administration as delivered by a transdermal patch, topical lotion, or topical spray.	5. WO2020212952 From **Claim 78 "**The method of any one of claims 59-77, wherein the psilocybin is administered by one of the following routes: oral, intravenous, intramuscular, parenteral, topical, inhalation, rectal, transmucosal, intranasal, buccal, vaginal, intrathecal, intraocular, **transdermal,** in utero, intralymphatic, or by direct tissue or organ injection." 3. CA312785 From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve**, solution, suspension, tincture, **patch**, and atomized vapor."
10. A method of use of said metered dosing formulation of claim 1, comprising a single unit dose or an application of a series of single doses until desired effect is reached.	1. US20170157343 From **Paragraph [0319]** "In the context of some embodiments of the present disclosure, the term "treatment" refers to any one of a **single pulmonary administration** of an agent at a given dose; **a fixed and limited series of pulmonary administrations** of an agent, given at the same or different doses at the same or different dose intervals (regimen); a chronic treatment which is administered as the limited series, but without a planned termination of the treatment"
11. A method for treating or mitigating a neurological, physiological, or mental health condition comprising an amount of said formulation from claim 1 applied to a subject thereof.	5. WO2020212952 From **Claim 111**. "A method of treating a subject in need thereof, the method comprising administering to the subject **a therapeutically-effective dose of psilocybin**, wherein the subject has at least one of the following **diseases, disorders, or conditions**: Disruptive Mood Dysregulation Disorder, Major Depressive Disorder (MDD), Treatment Resistant Depression, Persistent Depressive Disorder (Dysthymia), Premenstrual Dysphoric Disorder,

	Substance/Medication-Induced Depressive Disorder, Post-Partum depression, or Depressive Disorder due to Another Medical Condition, Separation Anxiety Disorder, Selective Mutism, Specific Phobia, Social Anxiety Disorder (Social Phobia), Panic Disorder, Panic Attack, Agoraphobia, Generalized Anxiety Disorder, Substance-Medication-Induced Anxiety Disorder, Anxiety Disorder Due to Another Medical Condition, Somatic Symptom Disorder, Illness Anxiety Disorder (hypochondriac), Conversion Disorder (Functional Neurological Symptom Disorder), Factitious Disorder, Post-Traumatic Stress Disorder (PTSD), Adjustment Disorders, Acute Distress Disorder, Obsessive-Compulsive Disorder, Body Dysmorphic Disorder, Hoarding Disorder, Trichotillomania (Hair-Pulling) Disorder, Excoriation (Skin-Picking) Disorder, Substance/Medication-Induced Obsessive-Compulsive and Related Disorder, Obsessive-Compulsive and Related Disorder due to Another Medical Condition, Substance-Related Disorders, Alcohol-Related Disorders, Cannabis-Related Disorders, Hallucinogen-Related Disorders, Inhalant-Related Disorders, Cocaine-Related Disorders, Opioid-Related Disorders, Sedative-, Hypnotic-, or Anxiolytic-Related Disorders, Stimulant-Related Disorders, Tobacco-Related Disorders, Non-Substance-Related Disorders (Gambling or Gaming Disorder), Migraines, Cluster Headaches such as Chronic Cluster Headaches, Cyclical Vomiting, Tension-Type Headache, Dysphasia, Pica, Anorexia Nervosa, Bulimia Nervosa, Binge-Eating Disorder, Oppositional Defiant Disorder, Intermittent Explosive Disorder, Conduct Disorder, Antisocial Personality Disorder, Psychopathy, Pyromania, or Kleptomania." From **Claim 112** "A method of treating a subject in need thereof, the method comprising administering to the subject a **therapeutically-effective dose of psilocybin**, wherein the subject has at least one of the following **diseases, disorders, or conditions:** Neurocognitive Disorders due to Alzheimer's, Lewy Bodies, Traumatic Brain Injury, Prion Disease, HIV Infection, Parkinson's, or Huntington's; concussion; chronic traumatic encephalopathy (CTE); Language Disorder, Speech Sound Disorder (Phonological Disorder); Childhood-

	Onset Fluency Disorder (Stuttering); Social (Pragmatic) Communication Disorder; Tourette's Disorder; Persistent (Chronic) Motor or Vocal Tic Disorder; Amnestic Disorder Due to Known Physiological Condition; Transient Cerebral Ischemic Attack, Cerebral Infarction, Cerebral Bleeding, Progressive Supranuclear Ophthalmoplegia, or Retrograde Amnesia."
12. A method for treating or improving neurological or mental health condition comprising an amount of said formulation of claim 1 applied to a subject thereof, wherein said neurological or mental health condition comprises: anxiety, post-traumatic stress disorder, attention deficit disorders, depression, memory loss, dementia, cognitive dysfunction, hearing loss, vision loss, neurologic pain, insomnia, erectile dysfunction, physiological pain or discomfort, or combinations thereof.	5. WO2020212952 From **Claim 30.** The method of claim 29, wherein the neurological disease is **dementia**, Alzheimer's Disease, or Parkinson's Disease. From **Claim 111** "A method of treating a subject in need thereof, the method comprising administering to the subject **a therapeutically-effective dose of psilocybin**, wherein the subject has at least one of the following diseases, disorders, or conditions: **Major Depressive Disorder (MDD), Treatment Resistant Depression, Persistent Depressive Disorder (Dysthymia), Premenstrual Dysphoric Disorder, Substance/Medication-Induced Depressive Disorder, Post-Partum depression, or Depressive Disorder due to Another Medical Condition, … Social Anxiety Disorder (Social Phobia),… Generalized Anxiety Disorder, Substance-Medication-Induced Anxiety Disorder, Anxiety Disorder Due to Another Medical Condition, … Post-Traumatic Stress Disorder (PTSD) …**" From **Claim 114 "**A method of treating a subject in need thereof, the method comprising administering to the subject **a therapeutically-effective dose of psilocybin**, wherein the subject has at least one of the following diseases, disorders, or conditions: **Attention-Deficit/Hyperactivity Disorder, Other Specified Attention-Deficit/Hyperactivity Disorder; or Unspecified Attention-Deficit/Hyperactivity Disorder.**" From **Claim 118** "A method of treating a subject in need thereof, the method comprising administering to the subject **a therapeutically-effective dose of psilocybin**, wherein the subject has at least one of the following diseases, disorders, or conditions: **Insomnia Disorder**,

	Hypersomnolence Disorder, Narcolepsy, or Primary Central Sleep Apnea." From **Claim 120** "A method of treating a subject in need thereof, the method comprising administering to the subject a therapeutically-effective dose of psilocybin, wherein the subject has at least one of the following diseases, disorders, or conditions: age-related **hearing loss** or tinnitus.**"** From **Claim 122** "A method of treating a subject in need thereof, the method comprising administering to the subject a **therapeutically-effective dose of psilocybin**, wherein the subject suffers from **pain**." From **Claim 124 "**A method of treating a subject, the method comprising administering to the subject a **therapeutically-effective dose of psilocybin,** wherein after administration the subject exhibits an improvement in **cognition**." From **Claim 125 "**The method of embodiment 124 wherein the improvement in cognition is an improvement in attention**, episodic memory, working memory, spatial memory**, social cognition, executive function, and/or cognitive flexibility." 6. US20190225612 From **Paragraph [0001] "**Compounds of the present invention and pharmaceutical compositions thereof are directed to methods useful in the treatment of a 5-HT.sub.2C receptor-mediated disorder, such as … **erectile dysfunction** … " From **Paragraph [0895] "**In some embodiments, the drug is selected from amphetamine, a substituted amphetamine, a benzodiazepine, an atypical benzodiazepine receptor ligand, marijuana, cocaine, dextromethorphan, GHB, LSD, ketamine, a monoamine reuptake inhibitor, nicotine, an opiate, PCP, a substituted phenethylamine, **psilocybin**, and an anabolic steroid."
13. A metered dosing formulation comprising:	1. US20170157343

An amount between 720 mcg to 8.4 g of one or more psychedelic compounds from a class of mescaline-related compounds with any one or more of a preservative, a buffer, a chloride salt, a polymer, a carbohydrate, a solvent, a terpene, a surfactant, a liquified gas, a solvent, and combinations thereof.	From **claim 1** "A method of delivering to a pulmonary tract of a subject at least one pharmacologically active agent, the method comprising: vaporizing a first **metered amount of at least one pharmacologically active agent**; delivering said first metered amount to the subject from an inhaler device; wherein a controller associated with said inhaler device is preprogrammed with at least one predetermined effect to be induced in the subject by said at least one pharmacologically active agent." From **Paragraph [0485] "**In further embodiments, the active substance is a **terpenoid,** e.g., limonene, α-pinene, β-myrcene, linalool, β-caryophyllene, caryophyllene, nerolidol or phytol, present in various plant forms." From **Paragraphs [0857]-[0861]** "The following are some examples for plants that can be used as a source for vaporizable active agent(s) according to embodiments of the present disclosure, for having medicinal as well has psychoactive properties…. Peyote (Lophophora williamsii cactaceae) contains some 30-40 different potent alkaloids, with **mescaline** being the most active hallucinogen in the group."
14. Formulation of claim 13, wherein said mescaline-related compounds comprises mescaline (3,4,5-trimethoxyphenethylamine) or salts and isomers thereof (such as mescaline hydrochloride or mescaline fumarate); extracts of peyote (*Lophophora williamsii*), San Pedro (*Echinopsis pachanoi*), and Peruvian torch (*Echinopsis/Trichocereus peruviana*) cactus; and combinations thereof.	1. US20170157343 From **Paragraphs [0857]-[0861]** "The following are some examples for plants that can be used as a source for vaporizable active agent(s) according to embodiments of the present disclosure, for having medicinal as well has psychoactive properties…. **Peyote** (**Lophophora williamsii** cactaceae) contains some 30-40 different potent alkaloids, with **mescaline** being the most active hallucinogen in the group."
15. Formulation of claim 13. wherein said mescaline-related compounds include synthetic forms or their synthetic analogues thereof.	1. US20170157343 From **paragraph [0271] "**Alternatively, the substance is an organic material which contains, or consists of, for example, one or more natural plant materials, or a **synthetic material"** From **paragraph [0274]** "The agent may be of natural origin **or synthetic**."
16. Formulation of claim 13, wherein said formulation comprises a dose between 3 micrograms to 1.3 g of mescaline (3,4,5-	1. US20170157343

trimethoxyphenethylamine) or salts and isomers thereof (such as mescaline hydrochloride or mescaline fumarate); extracts of peyote (*Lophophora williamsii*), San Pedro (*Echinopsis pachanoi*), and Peruvian torch (*Echinopsis/Trichocereus peruviana*) cactus; and combinations thereof.	From **paragraph [0125] "** According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering at least one **pharmacologically active agent** to a patient (also referred to herein interchangeably as user of subject), the method comprising pulmonary delivering the agent to the patient from a **metered dose** inhaler device configured to release at least one **pre-determined** vaporized amount of the agent upon controllably heating a solid form of a substance comprising the agent, wherein the at least one pre-determined vaporized amount of the agent is selected so as to exhibit at least one pre-selected pharmacokinetic profile and/or at least one pre-selected pharmacodynamic profile of the agent in the patient." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg, from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween."
17. Formulation of claim 13, wherein said formulation further comprises a ratio of at least 0.004 part terpene to 1 part psychedelic compound to less than a ratio of 10 parts terpene to 1 part psychedelic compound.	1. US20170157343 From **paragraph [0079]** According to some embodiments, at least one of the first pharmacologically active agent and the second pharmacologically active agent includes Δ9-tetrahydrocannabinol (THC), cannabidiol (CBD), cannabigerols (CBG), cannabichromenes (CBC), cannabinol (CBN), cannabinodiol (CBDL), cannabicyclol (CBL), cannabielsoin (CBE), cannabidivarin (CBDV), tetrahydrocannabivarin (THCV) and cannabitriol (CBT) The system, according to some of any of the embodiments of the present disclosure, provides the ability to use the MDI for delivering more than one pharmaceutically active agents (from one or more substances) **at any ratio** or pre-determined vaporized amounts so as to exhibit a pre-selected PD profile (e.g., maintaining an individual patient within the therapeutic window calculated per the patient). In some embodiments,

	different doses are selectively administered according to a regimen so as to prevent adverse effects while still alleviating symptoms.
18. Formulation of claim 13, wherein said formulation is for oral inhalation as delivered by a dry powder inhaler, thermal vaporizer (such as but not limited to an electronic cigarette), air jet nebulizer, vibrating mesh nebulizer, vaporizer, or pressurized metered dose inhaler	1. US20170157343 From **paragraph [0016] "**According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering to a subject at least one pharmacologically active agent being in a plant material, the method comprising pulmonary delivering the agent to the subject using a **metered dose inhaler device** configured to vaporize at least one pre-determined vaporized amount of the agent upon controllably heating the plant material, wherein the at least one pre-determined vaporized amount of the agent is selected so as to achieve at least one pre-determined pharmacokinetic (PK) effect and/or at least one pre-determined pharmacodynamic (PD) effect induced by the agent in the subject." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg, from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween." 3. CA312785 From **Claim 1** "A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof " From **Description Page 9**

	$5HT_2$ RECEPTORS **[39]** In general, $5HT_2$ receptors are characterized by having lower affinity for serotonin (and other indole alkylamines), and are linked to the G_q/phospholipase C pathway of signal transduction. In various instances, such receptors mediate a variety of physiological and behavioral functions via three distinct subtypes: $5HT_{2A}$, $5HT_{2B}$ and $5HT_{2C}$. **Receptor** / **Physiological / behavioral function** $5HT_{2A}$ Addiction, Anxiety, Appetite, Cognition, Imagination, Learning, Memory, Mood, Perception, Sexual Behavior, Sleep, Thermoregulation, Vasoconstriction $5HT_{2B}$ Anxiety, Appetite, Cardiovascular Function, GI Motility, Sleep, Vasoconstriction $5HT_{2C}$ Addiction, Anxiety, Appetite, GI Motility, Locomotion, Mood, Penile Erection, Sexual Behavior, Sleep, Thermoregulation, Vasoconstriction **Receptor** / **Uses of drugs that act on this receptor** $5HT_{2A}$ Antipsychotics , Psychedelics, Noradrenergic and Specific Serotonergic Antidepressants (NaSSAs), Sleeping aids $5HT_{2B}$ Migraines $5HT_{2C}$ Antidepressant, Orexigenic, Anorectic, Antipsychotic **Receptor** / **Drugs acting on receptor** $5HT_{2A}$ Agonists Bufotenin, Ergonovine, Lisuride, LSD, Mescaline, Myristicin, Psilocin, Psilocybin, DMT, DOM, PNU-22394, TFMPP, 25I-NBOMe, 2C-B, 5-MeO-DMT, BZP Antagonists 9 From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an oral formulation, a buccal formulation, a nasal formulation, or an **inhalation formulation**." From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and **atomized vapor."**
19. Formulation of claim 13, wherein said formulation is for nasal inhalation as delivered by nasal spray device containing one or more of water, liquified gas, solvent or thickening agent.	3. CA312785 From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an oral formulation, a buccal formulation, a **nasal** formulation, or an inhalation formulation." From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a **spray**, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor."
20. Formulation of claim 13, wherein said formulation is for oral administration as delivered by a sublingual film, tablet, capsule, lozenge, troche, chewing gum or tincture	3. CA312785 From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an **oral formulation**, a buccal

	formulation, a nasal formulation, or an inhalation formulation."
21. Formulation of claim 13, wherein said formulation is for topical administration as delivered by a transdermal patch, topical lotion, or topical spray.	7. WO2004041272 From **Summary** "Routes of administration for the foregoing methods may be by any systemic means including oral, intraperitoneal, subcutaneous, intravenous, intramuscular, **transdermal**, or by other routes of administration." From **Summary** "Exemplary serotonin receptor antagonists include, but are not limited to… **mescaline** …" 3. CA312785 From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve**, solution, suspension, tincture, **patch**, and atomized vapor."
22. A method of use of said metered dosing formulation of claim 13, comprising a single unit dose or an application of a series of single doses until desired effect is reached.	1. US20170157343 From **Paragraph [0319]** "In the context of some embodiments of the present disclosure, the term "treatment" refers to any one of a **single pulmonary administration** of an agent at a given dose; **a fixed and limited series of pulmonary administrations** of an agent, given at the same or different doses at the same or different dose intervals (regimen); a chronic treatment which is administered as the limited series, but without a planned termination of the treatment"
23. A method for treating or mitigating a neurological, physiological or mental health condition comprising an amount of said formulation from claim 13 applied to a subject thereof.	8. US20200147038 From **Paragraph [0017]** "In some embodiments, the psychedelic agent is selected … **3,4,5-trimethoxyphenethylamine (mescaline)**… or a pharmaceutical acceptable salt thereof" From **Claim 1 "**A method of improving **mental or physical well-being** of a subject, the method comprising: (i) providing a subject, wherein based on a score of one or more predictors in the subject, the subject has been identified as likely to have a positive therapeutic response to a psychedelic agent; and (ii) following step (i), administering to the subject the psychedelic agent.

	From Claim 4 "The method of claim 1, wherein the method is **for treating a condition** in a subject, improving the mood of a subject, or enhancing the performance of a subject." From Claim 5 "The method of claim 4, wherein the condition is a **psychological disorder**."
24. A method for treating or improving neurological or mental health condition comprising an amount of said formulation of claim 13 applied to a subject thereof, wherein said neurological or mental health condition comprises: anxiety, post-traumatic stress disorder, attention deficit disorders, depression, memory loss, insomnia, erectile dysfunction, dementia, cognitive dysfunction, hearing loss, vision loss, neurologic pain, physiological pain or discomfort, or combinations thereof.	8. US20200147038 From **Claim 2** "The method of claim 1, wherein the method is for treating stress in the subject, treating **anxiety** in the subject, treating addiction in the subject, treating **depression** in the subject, or treating a compulsive behavior in the subject." From **Claim 38** "The method of any one of claims 5- 37, wherein the psychological disorder is selected from the group consisting of a **depressive disorder**, an **anxiety disorder**, an addiction, or a compulsive behavior disorder." From **Claim 41** "The method of claim 39 or 40, wherein the depressive disorder is associated with one or more prodromal symptoms selected from the group consisting of … **initial insomnia, middle insomnia** …" From **Claim 43** "The method of claim 42, wherein said **anxiety disorder** is end of life anxiety, generalized anxiety disorder, panic disorder, social anxiety, **post-traumatic stress disorder**, acute stress disorder, obsessive compulsive disorder, or a social phobia." From **Claim 49** "The method of claim 48, wherein the somatic symptom comprises **chronic pain**, anxiety disproportionate to severity of physical complaints, **pain disorder**, body dysmorphia, conversion, hysteria, **neurological conditions** without identifiable cause, or psychosomatic illness." 9. US20210196697 From **Claim 1** "A method of determining an optimal combination drug treatment therapy for a patient with **attention deficit hyperactivity disorder** (ADHD)"

	From **Claim 17 "**The method of claim 1, wherein the agent that alters K+ channel activity is ethanol, amphetamine, ephedrine, cocaine, caffeine, nicotine, methylphenidate, lithium, δ-9-tetrahydrocannibinol, phencyclidine, lysergic acid diethylamide (LSD), **mescaline**, or combinations thereof."
25. A metered dosing formulation comprising: An amount between 75 mcg to 830 mg of one or more psychedelic compounds from a class of DMT-related compounds with any one or more of a preservative, a buffer, a chloride salt, a polymer, a carbohydrate, a solvent, a terpene, a surfactant, a liquified gas, a solvent, and combinations thereof.	1. US20170157343 From **claim 1** "A method of delivering to a pulmonary tract of a subject at least one pharmacologically active agent, the method comprising: vaporizing a first **metered amount of at least one pharmacologically active agent**; delivering said first metered amount to the subject from an inhaler device; wherein a controller associated with said inhaler device is preprogrammed with at least one predetermined effect to be induced in the subject by said at least one pharmacologically active agent." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg, from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween." From **Paragraph [0485]** "In some embodiments, the active agent is a **terpenoid**, alkaloid or cannabinoid. For example, in some embodiments, the active agent is a diterpenoid such as, but not limited to salvinorin A from *salvia*. In other embodiments, the active agent is an alkaloid such as, but not limited to, benzoylmethylecgonine from the coca plant, or the active agent is a tryptamine such as psylocibin from mushrooms. In alternative embodiments the active substance is **dimethyltryptamine (DMT)** from a variety of plants. In further embodiments, the active substance is nicotine from tobacco. In further embodiments, the active substance is a **terpenoid,** e.g., limonene, α-pinene, β-myrcene, linalool, β-caryophyllene, caryophyllene, nerolidol or phytol, present in various plant forms."

26. Formulation of claim 25, wherein said psychedelic compound is selected from the group comprising N,N-dimethyltryptamine, N,N-DMT, extracts of DMT-related compounds, and combinations thereof.	1. US20170157343 From **Paragraph [0485] "**In alternative embodiments the active substance is **dimethyltryptamine (DMT)** from a variety of plants."
27. The formulation of claim 25, further comprising a monoamine oxidase inhibitor (MAOI).	10. Peaceful on a Hill – DMT & MAOI "My friend had been extracting **DMT** from this root for a few weeks now, and one day he calls me up and says, 'its ready.' So he comes over and weighs out 100 mg, and puts it in a capsule. We had to take what he called, **MAOI**, something about it helps the dmt not get broken down in the stomach, I don't know. **So we take the maoi and 30 minutes later, down goes the dmt**."
28. Formulation of claim 25, wherein said DMT-related compounds includes synthetic forms or their synthetic analogues thereof.	1. US20170157343 From **paragraph [0271] "**Alternatively, the substance is an organic material which contains, or consists of, for example, one or more natural plant materials, or a **synthetic material"** From **paragraph [0274]** "The agent may be of natural origin **or synthetic**."
29. Formulation of claim 25, wherein said formulation comprises a dose between 3 micrograms to 1.3 g of N,N-dimethyltryptamine, N,N-DMT, extracts of DMT-related compounds, and combinations thereof.	1. US20170157343 From **paragraph [0125] "** According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering at least one **pharmacologically active agent** to a patient (also referred to herein interchangeably as user of subject), the method comprising pulmonary delivering the agent to the patient from a **metered dose** inhaler device configured to release at least one **pre-determined** vaporized amount of the agent upon controllably heating a solid form of a substance comprising the agent, wherein the at least one pre-determined vaporized amount of the agent is selected so as to exhibit at least one pre-selected pharmacokinetic profile and/or at least one pre-selected pharmacodynamic profile of the agent in the patient." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg,

	from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween.”
30. Formulation of claim 25, wherein said formulation further comprises a ratio of at least 0.004 part terpene to 1 part psychedelic compound to less than a ratio of 10 parts terpene to 1 part psychedelic compound.	1. US20170157343 From **paragraph [0079]** According to some embodiments, at least one of the first pharmacologically active agent and the second pharmacologically active agent includes Δ9-tetrahydrocannabinol (THC), cannabidiol (CBD), cannabigerols (CBG), cannabichromenes (CBC), cannabinol (CBN), cannabinodiol (CBDL), cannabicyclol (CBL), cannabielsoin (CBE), cannabidivarin (CBDV), tetrahydrocannabivarin (THCV) and cannabitriol (CBT) The system, according to some of any of the embodiments of the present disclosure, provides the ability to use the MDI for delivering more than one pharmaceutically active agents (from one or more substances) **at any ratio** or pre-determined vaporized amounts so as to exhibit a pre-selected PD profile (e.g., maintaining an individual patient within the therapeutic window calculated per the patient). In some embodiments, different doses are selectively administered according to a regimen so as to prevent adverse effects while still alleviating symptoms.
31. Formulation of claim 25, wherein said formulation is for oral inhalation as delivered by a dry powder inhaler, thermal vaporizer (such as but not limited to an electronic cigarette), air jet nebulizer, vibrating mesh nebulizer, vaporizer, or pressurized metered dose inhaler	1. US20170157343 From **paragraph [0016] “**According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering to a subject at least one pharmacologically active agent being in a plant material, the method comprising pulmonary delivering the agent to the subject using a **metered dose inhaler device** configured to vaporize at least one pre-determined vaporized amount of the agent upon controllably heating the plant material, wherein the at least one pre-determined vaporized amount of the agent is selected so as to achieve at least one pre-determined pharmacokinetic (PK) effect and/or at least one pre-determined pharmacodynamic (PD) effect induced by the agent in the subject.” 3. CA312785

	From **Claim 1** "A method of managing a neurological condition or one or more symptoms thereof in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising: a) a therapeutically effective amount of one or more **5HT receptor agonist** or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof " From **Description Page 9** **$5HT_2$ RECEPTORS** **[39]** In general, $5HT_2$ receptors are characterized by having lower affinity for serotonin (and other indole alkylamines), and are linked to the G_q/phospholipase C pathway of signal transduction. In various instances, such receptors mediate a variety of physiological and behavioral functions via three distinct subtypes: $5HT_{2A}$, $5HT_{2B}$ and $5HT_{2C}$. **Receptor** / **Physiological / behavioral function** $5HT_{2A}$: Addiction, Anxiety, Appetite, Cognition, Imagination, Learning, Memory, Mood, Perception, Sexual Behavior, Sleep, Thermoregulation, Vasoconstriction $5HT_{2B}$: Anxiety, Appetite, Cardiovascular Function, GI Motility, Sleep, Vasoconstriction $5HT_{2C}$: Addiction, Anxiety, Appetite, GI Motility, Locomotion, Mood, Penile Erection, Sexual Behavior, Sleep, Thermoregulation, Vasoconstriction **Receptor** / **Uses of drugs that act on this receptor** $5HT_{2A}$: Antipsychotics , Psychedelics, Noradrenergic and Specific Serotonergic Antidepressants (NaSSAs), Sleeping aids $5HT_{2B}$: Migraines $5HT_{2C}$: Antidepressant, Orexigenic, Anorectic, Antipsychotic **Receptor** / **Drugs acting on receptor** $5HT_{2A}$: Agonists Bufotenin, Ergonovine, Lisuride, LSD, Mescaline, Myristicin, Psilocin, Psilocybin, DMT, DOM, PNU-22394, TFMPP, 25I-NBOMe, 2C-B, 5-MeO-DMT, BZP Antagonists 9 From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an oral formulation, a buccal formulation, a nasal formulation, or an **inhalation formulation**." From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and **atomized vapor."**
32. Formulation of claim 25, wherein said formulation is for nasal inhalation as delivered by nasal spray device containing one or more of water, liquified gas, solvent or thickening agent.	3. CA312785 From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an oral formulation, a buccal formulation, a **nasal** formulation, or an inhalation formulation."

	From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a **spray**, aerosol, mist, nebulae, ointment, cream, gel, paste, salve, solution, suspension, tincture, patch, and atomized vapor."
33. Formulation of claim 25, wherein said formulation is for oral administration as delivered by a sublingual film, tablet, capsule, lozenge, troche, chewing gum or tincture	3. CA312785 From **Claim 16** "The method of any one of the preceding claims, wherein the pharmaceutical composition is an **oral formulation**, a buccal formulation, a nasal formulation, or an inhalation formulation."
34. Formulation of claim 25, wherein said formulation is for topical administration as delivered by a transdermal patch, topical lotion, or topical spray.	3. CA312785 From **Claim 17** "The method of any one of the preceding claims, wherein the pharmaceutical composition is in a form selected from a spray, aerosol, mist, nebulae, **ointment, cream, gel, paste, salve**, solution, suspension, tincture, **patch**, and atomized vapor." 11. US20110111029 From **Claim 1 "**A self-adhesive **transdermal patch** composition for iontophoretic transdermal delivery of at least one cationic active agent or a salt thereof" From **Claim 9** "The self-adhesive transdermal patch composition according to claim 1, wherein said cationic indole compounds comprise **N-dimethyltryptamine** and psilocin, and pharmacologically acceptable salts of said cationic indole compounds."
35. A method of use of said metered dosing formulation of claim 25, comprising a single unit dose or an application of a series of single doses until desired effect is reached.	1. US20170157343 From **Paragraph [0319]** "In the context of some embodiments of the present disclosure, the term "treatment" refers to any one of a **single pulmonary administration** of an agent at a given dose; **a fixed and limited series of pulmonary administrations** of an agent, given at the same or different doses at the same or different dose intervals (regimen); a chronic treatment which is administered as the limited series, but without a planned termination of the treatment"
36. A method for treating or mitigating a neurological, physiological or mental health condition comprising an amount of said	12. WO2020181194 From **Claim 1** "A compound comprising a structural analogue to psilocin, norpsilocin,

formulation from claim 25 applied to a subject thereof.	psilocybin, baeocystin, norbaeocystin or **N,N-dimethyltryptamine**, according to formula I" From **Claim 5 "**A method **for preventing or treating diseases and conditions** or improving functions in patients or subjects, the method comprising: administration of a compound of any of claims 1-4 at doses, dosages, posology, or formulations devoid of clinically meaningful psychedelic or psychotomimetic actions or effects"
37. A method for treating or improving neurological or mental health condition comprising an amount of said formulation of claim 25 applied to a subject thereof, wherein said neurological or mental health condition comprises: anxiety, post-traumatic stress disorder, attention deficit disorders, depression, memory loss, insomnia, erectile dysfunction, dementia, cognitive dysfunction, hearing loss, vision loss, neurologic pain, physiological pain or discomfort, or combinations thereof.	12. WO2020181194 From **Claim 31 "**The method of claims 5 or 16, wherein the method includes the treatment of vision impairment and **visual loss** including macular degeneration and retinopathies." From **Claim 32 "**The method of claims 5 or 16, wherein the method includes the treatment of neurological diseases, including neurodevelopmental diseases and neurodegenerative diseases that may benefit from modulation of neural plasticity, including: Neurological diseases and their symptoms and signs that may respond to neuroplastogen drugs and SMSNs include: **Alzheimer's disease; presenile dementia; senile dementia; vascular dementia; Lewy body dementia; cognitive impairment**, including mild cognitive impairment associated with aging and with chronic disease and its treatment, including chemotherapy, immunotherapy and radiotherapy,Parkinson's disease and Parkinsonian related disorders including but not limited **to Parkinson dementia …** Symptoms or manifestations of nervous system disorders that may be treated or prevented by neuroplastogen substances and drugs include a decline, impairment, or abnormality in cognitive abilities including executive function, attention, cognitive speed, **memory** … **disturbed sleep pattern … hearing** and balance… " From **Claim 33** " The method of claims 5 or 16, wherein the method includes the treatment of psychiatric diseases as defined by DMS5 and ICD11 that may benefit from modulation of neural plasticity, including Schizophrenia spectrum and other psychotic disorders, Bipolar

	and related disorders, **Depressive disorders**, **Anxiety disorders**, Obsessive-compulsive and related disorders, Trauma- and **stressor-related disorders**, Dissociative disorders, Somatic symptom and related disorders, Feeding and eating disorders, Elimination disorders, **Sleep-wake disorders**, **Sexual dysfunctions**, Gender dysphoria, Disruptive, impulse-control, and conduct disorders, Substance-related and addictive disorders, Neurocognitive disorders, Personality disorders, Paraphilic disorders."
38. A metered dosing formulation comprising: An amount between 150 mcg to 5 g of one or more psychedelic compounds from a class of LSA- and Ibogaine-related compounds with any one or more of a preservative, a buffer, a chloride salt, a polymer, a carbohydrate, a solvent, a terpene, a surfactant, a liquified gas, a solvent, and combinations thereof.	1. US20170157343 From **claim 1** "A method of delivering to a pulmonary tract of a subject at least one pharmacologically active agent, the method comprising: vaporizing a first **metered amount of at least one pharmacologically active agent**; delivering said first metered amount to the subject from an inhaler device; wherein a controller associated with said inhaler device is preprogrammed with at least one predetermined effect to be induced in the subject by said at least one pharmacologically active agent." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg, from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween." From **Paragraph [0041]** According to some embodiments, the plant includes … ***Tabernanthe iboga*** … ***Ipomoea violacea*** *…"* From **Paragraph [0485] "**In further embodiments, the active substance is a **terpenoid,** e.g., limonene, α-pinene, β-myrcene, linalool, β-caryophyllene, caryophyllene, nerolidol or phytol, present in various plant forms." 13. Nowak et al 2015 Identification and determination of ergot alkaloids in Morning Glory cultivars

	From **Pages 3093-3094** "The highest concentration of **LSA** can be found in seeds of Rivea corymbosa, **Ipomoea violacea**, and Argyreia nervosa (Hawaiian Baby Woodrose) species, the latter being a popular legal high." 14. Badig-Taika et al 2018 Phytochemical characterization of Tabernanthe iboga root bark and its effects on dysfunctional metabolism and cognitive performance in high-fat-fed C57BL/6J Mice From **Abstract** "Preparations of the root bark of ***Tabernanthe iboga*** have long been used in Central and West African traditional medicine to combat fatigue, as a neuro-stimulant in rituals, and for treatment of diabetes. The principal alkaloid of T. iboga, **ibogaine**, has attracted attention in many countries around the world for providing relief for opioid craving in drug addicts."
39. Formulation of claim 38, wherein said psychedelic compound is selected from the group comprising an amount of D-lysergic acid amide (LSA), also-known as Ergine and d-lysergamide or salts and isomers thereof; extracts of plants or seeds of the convolvulaceae or morning glory family; Ibogaine; extracts of plants of the Apocynacea family, such as *Tabernanthe iboga* (or "iboga") *Voacanga african*, or combinations thereof.	1. US20170157343 From **Paragraph [0041]** According to some embodiments, the plant includes … ***Tabernanthe iboga*** … ***Voacanga Africana*** …" From **Paragraph [0864] "**Other plants comprising active agent(s) with known psychoactive properties include, without limitation: … **Convolvulaceae (morning-glory)"**
40. Formulation of claim 38, wherein said LSA-related compounds or Ibogaine-related compounds includes synthetic forms or their synthetic analogues thereof.	1. US20170157343 From **paragraph [0271] "**Alternatively, the substance is an organic material which contains, or consists of, for example, one or more natural plant materials, or a **synthetic material"** From **paragraph [0274]** "The agent may be of natural origin **or synthetic**."
41. Formulation of claim 38, wherein said formulation comprises a dose between 3 micrograms to 1.3 g of D-lysergic acid amide (LSA), also-known as Ergine and d-lysergamide or salts and isomers thereof; extracts of plants or seeds of the convolvulaceae or morning glory family; Ibogaine; extracts of plants of the	1. US20170157343 From **paragraph [0125] "** According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering at least one **pharmacologically active agent** to a patient (also

Apocynacea family, such as *Tabernanthe iboga* (or "iboga") *Voacanga african*, or combinations thereof.	referred to herein interchangeably as user of subject), the method comprising pulmonary delivering the agent to the patient from a **metered dose** inhaler device configured to release at least one **pre-determined** vaporized amount of the agent upon controllably heating a solid form of a substance comprising the agent, wherein the at least one pre-determined vaporized amount of the agent is selected so as to exhibit at least one pre-selected pharmacokinetic profile and/or at least one pre-selected pharmacodynamic profile of the agent in the patient." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg, from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween."
42. Formulation of claim 38, wherein said formulation further comprises a ratio of at least 0.004 part terpene to 1 part psychedelic compound to less than a ratio of 10 parts terpene to 1 part psychedelic compound.	1. US20170157343 From **paragraph [0079]** According to some embodiments, at least one of the first pharmacologically active agent and the second pharmacologically active agent includes Δ9-tetrahydrocannabinol (THC), cannabidiol (CBD), cannabigerols (CBG), cannabichromenes (CBC), cannabinol (CBN), cannabinodiol (CBDL), cannabicyclol (CBL), cannabielsoin (CBE), cannabidivarin (CBDV), tetrahydrocannabivarin (THCV) and cannabitriol (CBT) The system, according to some of any of the embodiments of the present disclosure, provides the ability to use the MDI for delivering more than one pharmaceutically active agents (from one or more substances) **at any ratio** or pre-determined vaporized amounts so as to exhibit a pre-selected PD profile (e.g., maintaining an individual patient within the therapeutic window calculated per the patient). In some embodiments, different doses are selectively administered according to a regimen so as to prevent adverse effects while still alleviating symptoms.
43. Formulation of claim 38, wherein said formulation is for oral inhalation as delivered by a	1. US20170157343

dry powder inhaler, thermal vaporizer (such as but not limited to an electronic cigarette), air jet nebulizer, vibrating mesh nebulizer, vaporizer, or pressurized metered dose inhaler	From **paragraph [0016] "**According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering to a subject at least one pharmacologically active agent being in a plant material, the method comprising pulmonary delivering the agent to the subject using a **metered dose inhaler device** configured to vaporize at least one pre-determined vaporized amount of the agent upon controllably heating the plant material, wherein the at least one pre-determined vaporized amount of the agent is selected so as to achieve at least one pre-determined pharmacokinetic (PK) effect and/or at least one pre-determined pharmacodynamic (PD) effect induced by the agent in the subject."
44. Formulation of claim 38, wherein said formulation is for nasal inhalation as delivered by nasal spray device containing one or more of water, liquified gas, solvent or thickening agent.	15. US20150258112 From **Claim 1** "A method for treating depression disorder in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof" From **Paragraph [0022}** "Any route of administration, such as topical, subcutaneous, peritoneal, intraarterial, inhalation, vaginal, rectal, **nasal,** introduction into the cerebrospinal fluid, or instillation into body compartments can be used.
45. Formulation of claim 38, wherein said formulation is for oral administration as delivered by a sublingual film, tablet, capsule, lozenge, troche, chewing gum or tincture	15. US20150258112 From **Claim 1** "A method for treating depression disorder in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof" From **Paragraph [0023] "**Administration may be via transdermal patch, **gum, lozenge, sublingual tablet,** intranasal, intrapulmonary, oral administration, or any other mode of administration."
46. Formulation of claim 38, wherein said formulation is for topical administration as delivered by a transdermal patch, topical lotion, or topical spray.	15. US20150258112 From **Claim 1** "A method for treating depression disorder in a patient in need thereof, comprising administering to the patient a therapeutically

	effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof" From **Paragraph [0022]** "Any route of administration, such as **topical,** subcutaneous, peritoneal, intraarterial, inhalation, vaginal, rectal, nasal**,** introduction into the cerebrospinal fluid, or instillation into body compartments can be used." From **Paragraph [0023] "**Administration may be via **transdermal patch**, gum, lozenge, sublingual tablet, intranasal, intrapulmonary, oral administration, or any other mode of administration."
47. A method of use of said metered dosing formulation of claim 38, comprising a single unit dose or an application of a series of single doses until desired effect is reached.	1. US20170157343 From **Paragraph [0319]** "In the context of some embodiments of the present disclosure, the term "treatment" refers to any one of a **single pulmonary administration** of an agent at a given dose; **a fixed and limited series of pulmonary administrations** of an agent, given at the same or different doses at the same or different dose intervals (regimen); a chronic treatment which is administered as the limited series, but without a planned termination of the treatment"
48. A method for treating or mitigating a neurological, physiological or mental health condition comprising an amount of said formulation from claim 38 applied to a subject thereof.	15. US20150258112 From **Paragraph [0094]** "'Therapeutically effective amount' refers to an amount of a drug or an agent that, when administered to a patient **suffering from a condition**, will have the intended therapeutic effect, e.g., alleviation, amelioration, palliation or elimination of one or more manifestations of the **condition** in the patient. " 12. WO2020181194 From **Claim 4** "A compound comprising a structural analogue to **ibogaine**, according to formula IV" From **Claim 5 "**A method **for preventing or treating diseases and conditions** or improving functions in patients or subjects, the method comprising: administration of a compound of any of claims 1-4 at doses, dosages, posology, or formulations devoid of clinically meaningful

	psychedelic or psychotomimetic actions or effects"
49. A method for treating or improving neurological or mental health condition comprising an amount of said formulation of claim 38 applied to a subject thereof, wherein said neurological or mental health condition comprises: anxiety, post-traumatic stress disorder, attention deficit disorders, depression, memory loss, insomnia, erectile dysfunction, dementia, cognitive dysfunction, hearing loss, vision loss, neurologic pain, physiological pain or discomfort, or combinations thereof.	15. US20150258112 From **Claim 1** "A method for treating **depression disorder** in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof" 16. https://web.archive.org/web/20160220083153/https://psychedelictimes.com/learn-more-iboga/ From **Treating Mood Disorders with Iboga** "While most patients undergo **ibogaine** therapy as a way to recover from serious drug addiction, this type of treatment can also trigger recoveries from many other psychological issues including depression, anxiety, and trauma. The drug's deeply personal and illuminating nature also allows patients to let go of different types of patterns not related to drug use that may be equally difficult for them to break. This is especially life changing for victims of **chronic depression, anxiety disorders,** and **post-traumatic stress disorder (PTSD),** which often cause such intense emotional stress that recovery seems impossible." 4. US20050288375 From **Paragraph [0002] "**The invention is useful for treating and preventing neurodegenerative disorders such as Alzheimer's disease, **dementia,** and mild cognitive impairment. From **Claim 3** "The composition of claim 2 wherein said NMDA antagonist is selected from the group consisting of memantine, adamantane, amantadine, an adamantane derivative, dextromethorphan, dextrorphan, dizocilpine, **ibogaine**, ketamine, remacemide, and phencyclidine. From **Claim 31 "**The method of claims 5 or 16, wherein the method includes the treatment of

	vision impairment and **visual loss** including macular degeneration and retinopathies." From **Claim 32 "**The method of claims 5 or 16, wherein the method includes the treatment of neurological diseases, including neurodevelopmental diseases and neurodegenerative diseases that may benefit from modulation of neural plasticity, including: Neurological diseases and their symptoms and signs that may respond to neuroplastogen drugs and SMSNs include: **Alzheimer's disease; presenile dementia; senile dementia; vascular dementia; Lewy body dementia; cognitive impairment**, including mild cognitive impairment associated with aging and with chronic disease and its treatment, including chemotherapy, immunotherapy and radiotherapy,Parkinson's disease and Parkinsonian related disorders including but not limited **to Parkinson dementia …** Symptoms or manifestations of nervous system disorders that may be treated or prevented by neuroplastogen substances and drugs include a decline, impairment, or abnormality in cognitive abilities including executive function, attention, cognitive speed, **memory** … **disturbed sleep pattern … hearing** and balance… " From **Claim 33** " The method of claims 5 or 16, wherein the method includes the treatment of psychiatric diseases as defined by DMS5 and ICD11 that may benefit from modulation of neural plasticity, including Schizophrenia spectrum and other psychotic disorders, Bipolar and related disorders, **Depressive disorders**, **Anxiety disorders**, Obsessive-compulsive and related disorders, Trauma- and **stressor-related disorders**, Dissociative disorders, Somatic symptom and related disorders, Feeding and eating disorders, Elimination disorders, **Sleep-wake disorders**, **Sexual dysfunctions**, Gender dysphoria, Disruptive, impulse-control, and conduct disorders, Substance-related and addictive disorders, Neurocognitive disorders, Personality disorders, Paraphilic disorders."
50. A metered dosing formulation comprising: An amount between 10 mcg to 500 mg of one or more psychedelic compounds from a class of psychedelic synthetics or their synthetic analogues	1. US20170157343 From **paragraph [0271] "**Alternatively, the substance is an organic material which contains,

with any one or more of a preservative, a buffer, a chloride salt, a polymer, a carbohydrate, a solvent, a terpene, a surfactant, a liquified gas, a solvent, and combinations thereof.	or consists of, for example, one or more natural plant materials, or a **synthetic material"** From **paragraph [0274]** "The agent may be of natural origin **or synthetic**." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg, from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween." From **claim 1** "A method of delivering to a pulmonary tract of a subject at least one pharmacologically active agent, the method comprising: vaporizing a first **metered amount of at least one pharmacologically active agent**; delivering said first metered amount to the subject from an inhaler device; wherein a controller associated with said inhaler device is preprogrammed with at least one predetermined effect to be induced in the subject by said at least one pharmacologically active agent."
51. Formulation of claim 50, wherein said psychedelic compound is a synthetic or analog of naturally occurring psychedelic tryptamine, psilocybin, psilocin, baeocystin, norbaeocystin, or salts thereof, extracts of psilocybin mushrooms or synthetic forms thereof, mescaline, 3,4,5-trimethoxyphenethylamine, extracts of peyote or synthetic forms thereof, N,N-dimethyltryptamine, N,N-DMT, extracts of DMT-related compounds or synthetic forms thereof, LSA/Ergine, other plant or fungal derived psychedelic compounds including but not limited to ibogaine, or combinations thereof.	1. US20170157343 From **paragraph [0041]** "According to some embodiments, the plant includes**... *Psilocybe spp.*** …" From **paragraph [450**] "Optionally or additionally, the active pharmaceutically active agent is selected from the group comprising: tetrahydrocannabinol (THC), salvinorin A, benzoylmethylecgonine, dimethyltryptamine, **psilocybin**" From **paragraph [0271] "**Alternatively, the substance is an organic material which contains, or consists of, for example, one or more natural plant materials, or a **synthetic material"** From **paragraph [0274]** "The agent may be of natural origin **or synthetic**."

52. Formulation of claim 50, wherein said formulation comprises a dose between 3 micrograms to 1.3 g of a synthetic or analog of naturally occurring psychedelic tryptamine, psilocybin, psilocin, baeocystin, norbaeocystin, or salts thereof, extracts of psilocybin mushrooms or synthetic forms thereof, mescaline, 3,4,5-trimethoxyphenethylamine, extracts of peyote or synthetic forms thereof, N,N-dimethyltryptamine, N,N-DMT, extracts of DMT-related compounds or synthetic forms thereof, LSA/Ergine, other plant or fungal derived psychedelic compounds including but not limited to ibogaine, or combinations thereof.	1. US20170157343 From **paragraph [0016] "**According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering to a subject at least one pharmacologically active agent being in a plant material, the method comprising pulmonary delivering the agent to the subject using a **metered dose** inhaler device configured to vaporize at least one pre-determined vaporized amount of the agent upon controllably heating the plant material, wherein the at least one pre-determined vaporized amount of the agent is selected so as to achieve at least one pre-determined pharmacokinetic (PK) effect and/or at least one pre-determined pharmacodynamic (PD) effect induced by the agent in the subject." From **paragraph [502] "** In some embodiments, individual **pre-selected vaporized amounts (doses)** …, are released electronically … in amount increments of 0.1 mg, ranging from 0.1 to 6.0 mg, 0.3 to 1.7 mg, 0.1 to 2.0 mg, from 0.2 to 1.9 mg, from 0.2 to 1.8 mg, from 0.3 to 1.8 mg, from 0.3 to 1.6 mg, from 0.4 to 1.6 mg, from 0.5 to 2.0 mg, from 0.6 to 2.0 mg or from 0.3 to 0.9 mg, including any subranges and any intermediate values therebetween."
53. Formulation of claim 50, wherein said formulation further comprises a ratio of at least 0.004 part terpene to 1 part psychedelic compound to less than a ratio of 10 parts terpene to 1 part psychedelic compound.	1. US20170157343 From **paragraph [0079]** According to some embodiments, at least one of the first pharmacologically active agent and the second pharmacologically active agent includes Δ9-tetrahydrocannabinol (THC), cannabidiol (CBD), cannabigerols (CBG), cannabichromenes (CBC), cannabinol (CBN), cannabinodiol (CBDL), cannabicyclol (CBL), cannabielsoin (CBE), cannabidivarin (CBDV), tetrahydrocannabivarin (THCV) and cannabitriol (CBT) The system, according to some of any of the embodiments of the present disclosure, provides the ability to use the MDI for delivering more than one pharmaceutically active agents (from one or more substances) **at any ratio** or pre-determined vaporized amounts so as to exhibit a

	pre-selected PD profile (e.g., maintaining an individual patient within the therapeutic window calculated per the patient). In some embodiments, different doses are selectively administered according to a regimen so as to prevent adverse effects while still alleviating symptoms.
54. Formulation of claim 50, wherein said formulation is for oral inhalation as delivered by a dry powder inhaler, thermal vaporizer (such as but not limited to an electronic cigarette), air jet nebulizer, vibrating mesh nebulizer, vaporizer, or pressurized metered dose inhaler	1. US20170157343 From **paragraph [0125] "** According to an aspect of some embodiments of the present disclosure there is provided a method of pulmonary delivering at least one **pharmacologically active agent** to a patient (also referred to herein interchangeably as user of subject), the method comprising pulmonary delivering the agent to the patient from a **metered dose** inhaler device configured to release at least one **pre-determined** vaporized amount of the agent upon controllably heating a solid form of a substance comprising the agent, wherein the at least one pre-determined vaporized amount of the agent is selected so as to exhibit at least one pre-selected pharmacokinetic profile and/or at least one pre-selected pharmacodynamic profile of the agent in the patient."
55. Formulation of claim 50, wherein said formulation is for nasal inhalation as delivered by nasal spray device containing one or more of water, liquified gas, solvent or thickening agent.	15. US20150258112 From **Claim 1** "A method for treating depression disorder in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof" From **Paragraph [0022}** "Any route of administration, such as topical, subcutaneous, peritoneal, intraarterial, inhalation, vaginal, rectal, **nasal,** introduction into the cerebrospinal fluid, or instillation into body compartments can be used.
56. Formulation of claim 50, wherein said formulation is for oral administration as delivered by a sublingual film, tablet, capsule, lozenge, troche, chewing gum or tincture	15. US20150258112 From **Claim 1** "A method for treating depression disorder in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof"

	From **Paragraph [0023] "**Administration may be via transdermal patch, **gum, lozenge, sublingual tablet,** intranasal, intrapulmonary, oral administration, or any other mode of administration."
57. Formulation of claim 50, wherein said formulation is for topical administration as delivered by a transdermal patch, topical lotion, or topical spray.	15. US20150258112 From **Claim 1** "A method for treating depression disorder in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof" From **Paragraph [0022]** "Any route of administration, such as **topical,** subcutaneous, peritoneal, intraarterial, inhalation, vaginal, rectal, nasal**,** introduction into the cerebrospinal fluid, or instillation into body compartments can be used." From **Paragraph [0023] "**Administration may be via **transdermal patch**, gum, lozenge, sublingual tablet, intranasal, intrapulmonary, oral administration, or any other mode of administration."
58. A method of use of said metered dosing formulation of claim 50, comprising a single unit dose or an application of a series of single doses until desired effect is reached.	15. US20150258112 From **Claim 1** "A method for treating depression disorder in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof" From **Paragraph [0022]** "Any route of administration, such as **topical,** subcutaneous, peritoneal, intraarterial, inhalation, vaginal, rectal, nasal**,** introduction into the cerebrospinal fluid, or instillation into body compartments can be used." From **Paragraph [0023] "**Administration may be via **transdermal patch**, gum, lozenge, sublingual tablet, intranasal, intrapulmonary, oral administration, or any other mode of administration."
59. A method for treating or mitigating a neurological, physiological or mental health condition comprising an amount of said formulation from claim 50 applied to a subject thereof.	15. US20150258112 From **Paragraph [0094]** "'Therapeutically effective amount' refers to an amount of a drug or an agent that, when administered to a patient

	suffering from a condition, will have the intended therapeutic effect, e.g., alleviation, amelioration, palliation or elimination of one or more manifestations of the **condition** in the patient. " 12. WO2020181194 From **Claim 4** "A compound comprising a structural analogue to **ibogaine**, according to formula IV" From **Claim 5 "**A method **for preventing or treating diseases and conditions** or improving functions in patients or subjects, the method comprising: administration of a compound of any of claims 1-4 at doses, dosages, posology, or formulations devoid of clinically meaningful psychedelic or psychotomimetic actions or effects"
60. A method for treating or improving neurological or mental health condition comprising an amount of said formulation of claim 50 applied to a subject thereof, wherein said neurological or mental health condition comprises: anxiety, post-traumatic stress disorder, attention deficit disorders, depression, memory loss, insomnia, erectile dysfunction, dementia, cognitive dysfunction, hearing loss, vision loss, neurologic pain, physiological pain or discomfort, or combinations thereof.	15. US20150258112 From **Claim 1** "A method for treating **depression disorder** in a patient in need thereof, comprising administering to the patient a therapeutically effective amount of **ibogaine, ibogaine derivative**, or a pharmaceutically acceptable salt and/or solvate thereof" 16. https://web.archive.org/web/20160220083153/https://psychedelictimes.com/learn-more-iboga/ From **Treating Mood Disorders with Iboga** "While most patients undergo **ibogaine** therapy as a way to recover from serious drug addiction, this type of treatment can also trigger recoveries from many other psychological issues including depression, anxiety, and trauma. The drug's deeply personal and illuminating nature also allows patients to let go of different types of patterns not related to drug use that may be equally difficult for them to break. This is especially life changing for victims of **chronic depression, anxiety disorders,** and **post-traumatic stress disorder (PTSD),** which often cause such intense emotional stress that recovery seems impossible."

	4. US20050288375 From **Paragraph [0002] "**The invention is useful for treating and preventing neurodegenerative disorders such as Alzheimer's disease, **dementia,** and mild cognitive impairment. From **Claim 3** "The composition of claim 2 wherein said NMDA antagonist is selected from the group consisting of memantine, adamantane, amantadine, an adamantane derivative, dextromethorphan, dextrorphan, dizocilpine, **ibogaine**, ketamine, remacemide, and phencyclidine. From **Claim 31 "**The method of claims 5 or 16, wherein the method includes the treatment of vision impairment and **visual loss** including macular degeneration and retinopathies." From **Claim 32 "**The method of claims 5 or 16, wherein the method includes the treatment of neurological diseases, including neurodevelopmental diseases and neurodegenerative diseases that may benefit from modulation of neural plasticity, including: Neurological diseases and their symptoms and signs that may respond to neuroplastogen drugs and SMSNs include: **Alzheimer's disease; presenile dementia; senile dementia; vascular dementia; Lewy body dementia; cognitive impairment**, including mild cognitive impairment associated with aging and with chronic disease and its treatment, including chemotherapy, immunotherapy and radiotherapy,Parkinson's disease and Parkinsonian related disorders including but not limited **to Parkinson dementia …** Symptoms or manifestations of nervous system disorders that may be treated or prevented by neuroplastogen substances and drugs include a decline, impairment, or abnormality in cognitive abilities including executive function, attention, cognitive speed, **memory** … **disturbed sleep pattern … hearing** and balance… " From **Claim 33** " The method of claims 5 or 16, wherein the method includes the treatment of psychiatric diseases as defined by DMS5 and ICD11 that may benefit from modulation of neural plasticity, including Schizophrenia spectrum and other psychotic disorders, Bipolar and related disorders, **Depressive disorders**,

	Anxiety disorders, Obsessive-compulsive and related disorders, Trauma- and **stressor-related disorders**, Dissociative disorders, Somatic symptom and related disorders, Feeding and eating disorders, Elimination disorders, **Sleep-wake disorders**, **Sexual dysfunctions**, Gender dysphoria, Disruptive, impulse-control, and conduct disorders, Substance-related and addictive disorders, Neurocognitive disorders, Personality disorders, Paraphilic disorders."
61. A metered dose nasal spray comprising: a metered dosing formulation further comprising an amount of at least one or more psychedelic compound(s) said psychedelic compound selected from the group comprising mushroom-related compounds, mescaline-related compounds, DMT-related compounds, LSA-related compounds, Ibogaine-related compounds, or synthetic compounds or their synthetic analogs thereof; a solvent; anda nasal spray device to administer said formulation via the nasal passages.	18. WO/2021/216489 From **summary** "In one nonlimiting embodiment, the device is used to administer a psychedelic agent and/or NAC." From **Claim 14 "**The pharmaceutical composition of claim 12 formulated in a nasal spray."
62. The nasal spray from claim 61 further comprising of at least two of: a terpene; an emulsifying agent; a preservative; a thickening agent; a monoamine oxidase inhibitor; a solvent; a liquified gas; or combinations thereof.	18. WO/2021/216489 From **detailed description** "In one nonlimiting embodiment, an encapsulation technique is used to enclose various concentrations of the **psychedelic agent** and NAC in a relatively stable shell known as a capsule, allowing them to, for example, be taken orally. In one nonlimiting embodiment, the formulation of the present invention comprises a hard-shelled capsule containing dry, powdered ingredients, miniature pellets made by processes such as extrusion and spheronization or mini tablets. The hard-shelled capsules are typically made in two halves: a smaller-diameter body that is filled and then sealed using a larger-diameter cap. The capsule itself is typically made from aqueous solutions of gelling agents, such as animal protein (mainly gelatin) or plant polysaccharides or their derivatives (such as carrageenans and modified forms of starch and cellulose). **Other ingredients** can be added to the gelling agent solution including **plasticizers** such as glycerin or sorbitol to decrease the capsule's hardness, coloring agents, **preservatives**, disintegrants, lubricants and surface treatment.

63. The metered dose spray of claim 61, wherein said canister further comprises a metered dose valve that is configured to dispense between 25 and 200 microliters of formulation per actuation.	18. WO/2021/216489 From **Claim 5** "The method of claim 3 wherein the **psychedelic agent** and NAC in various concentrations are formulated as a solution or a suspension with one or more excipients in a nonpressurized dispenser or dispensers and delivered to a patient as a **nasal spray containing a metered dose** of each ingredient."
64. A formulation for metered dose inhalation comprising: an amount of at least one of psilocybin, psilocin, or extract of psilocybe mushrooms, wherein the amount of at least one of psilocybin, psilocin, or extract of psilocybe mushrooms is a dose between 3 micrograms and 5 mg; an amount of propellant suitable for metered dose inhalation application to a human subject, wherein the propellant comprises at least one HFA; a solvent.	18. WO/2021/216489 From **Claim 5** "The method of claim 3 wherein the **psychedelic agent** and NAC in various concentrations are formulated as a solution or a suspension with one or more excipients in a nonpressurized dispenser or dispensers and delivered to a patient as a **nasal spray containing a metered dose** of each ingredient." From **Detailed Description "**Doses and routes for administration for psychedelic agents will vary depending upon the psychedelic agent selected for administration. Selection may be based upon similar dosing regimens known in the art to be safe while exhibiting pharmacological activity. As nonlimiting examples, LSD has been administered in doses ranging from 20 to 800 micrograms; DMT has been administered in doses ranging from 10-60 milligrams both orally and via inhalation; dosages is 200-400 milligrams"
65. A formulation for metered dose inhalation comprising: an amount of at least one of mescaline (3,4,5-trimethoxyphenethylamine) or salts and isomers thereof (such as mescaline hydrochloride or mescaline fumarate); extracts of peyote (*Lophophora wilhamsii*), San Pedro (*Echinopsis pachanoi*), and Peruvian torch (*Echinopsis/Trichocereus peruviana*) cactus; and combinations thereof; an amount of propellant suitable for metered dose inhalation application to a human subject, wherein the propellant comprises at least one HFA; and a solvent and/or surfactant.	18. WO/2021/216489 From **Background "**Psychedelics are a subset of hallucinogenic drugs whose primary effect is to trigger non-ordinary states of consciousness (known as psychedelic experiences or "trips") via serotonin 2A receptor agonism. This causes specific psychological, visual and auditory changes, and often a substantially altered state of consciousness. Psychedelics with the largest scientific and cultural influence include **mescaline**, lysergic acid diethylamide (LSD,), psilocybin, and N,N-Dimethyltryptamine (DMT)."
66. A formulation for metered dose inhalation, said formulation comprising: an amount of N,N-dimethyltryptamine, N,N-DMT, extracts of DMT-related compounds, and combinations thereof. an amount of propellant suitable for metered dose inhalation application to a human subject, wherein	19. WO/2020/169850 From **Claim 18** "1**5-MeO-DMT** or a pharmaceutically acceptable salt thereof for use as in any of the prior claims, wherein the 5-MeO-

the propellant comprises at least one HFA; and a solvent and/or surfactant and/or MAOI.	DMT or a pharmaceutically acceptable salt thereof is administered via **inhalation**."

Electronic Acknowledgement Receipt

EFS ID:	47989169
Application Number:	17624377
International Application Number:	
Confirmation Number:	1014
Title of Invention:	METERED DOSING COMPOSITIONS AND METHODS OF USE OF PSYCHEDELIC COMPOUNDS
First Named Inventor/Applicant Name:	Craig Michael Arnold
Customer Number:	158723
Filer:	Taylor Kurtzweil
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Warnings:					
Information:					
2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance-submission.pdf	66236 e72f16b6dd895917d75d94facf3d51ed1ab7983a	no	3
Warnings:					
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3	Request for Notification of Non-compliant Third-Party Submission	Third-party-notification-request.pdf	23740 7316852786b3858f9b34d65f923b4a08912c61a7	no	1
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4	Concise Description of Relevance	20220304980_Claims_Chart_05112023.pdf	399843 81b46c421074a04e5a0c16a44272dd107839b704	no	38
Warnings:					
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5	Fee Worksheet (SB06)	fee-info.pdf	37593 6d2b0fae2d0d0897db99ba14cf6a6fad651a0a4a	no	2
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