

Priority Date 11/30/2021

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Wesana Health Inc. Confirmation No.: 7127  
Serial No.: 18/254,705 Group No.:  
Filing or 371(c) Date: May 26, 2023 Examiner:  
Entitled: Compositions and Methods for Treating Neurological Conditions

**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. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)
2. Int'l Pat. App. Pub. No. WO/2021/101926 "Tryptamine compositions for enhancing neurite outgrowth" (Published May 27, 2021)

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

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**1. A method for reducing a symptom of traumatic brain injury or post-concussion syndrome in a subject, the method comprising:**  
**(i) administering to the subject at least one loading dose comprising between about 5 mg and 30 mg psilocybin, inclusive; and**  
**(ii) subsequently administering to the subject at least one maintenance dose comprising between about 0.25 mg to about 0.3 mg psilocybin, inclusive, wherein the subject has been suspected or diagnosed as having traumatic brain injury or post-concussion syndrome.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

**From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."**

**From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."**

**From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."**

**From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."**

**From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."**

**2. The method of claim 1, wherein the symptom of traumatic brain injury or post-concussion syndrome comprises anxiety, depression, suicide ideation, stress, post-traumatic stress disorder, post-traumatic headache, progressive headache, feelings of dizziness, nausea, vomiting,**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

**From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."**

**From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a**

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noise sensitivity, being easily upset by loud noise, sleep disturbance, fatigue or tiring more easily, irritability, insomnia, nervousness, frustration or impatience, forgetfulness or poor memory, poor concentration, taking longer to think, blurred vision, light sensitivity, double vision, restlessness, insomnia, ringing in the ears, blurry vision, decrease in taste and/or smell, and various combinations thereof.

week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.”

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**3. The method of any of claims 1-2, wherein the at least one maintenance dose further comprises between about 100 mg and about 600 mg CBD, inclusive.**

**4. The method of any of claims 1-3, wherein the symptom of traumatic brain injury or post-concussion syndrome comprises anxiety and/or depression.**

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1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.”

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From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From **[199]**: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From **[7]**: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**5. The method of any of claims 1-4, wherein the loading dose comprises about 10 mg psilocybin**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

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From **[199]**: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From **[7]**: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**6. The method of any of claims 1-5, wherein the loading dose**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

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**comprises about 25 mg psilocybin.**

**From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."**

**From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."**

**From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."**

**From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."**

**From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."**

**From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."**

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**7. The method of any of claims 1-6, wherein the loading dose comprises about 30 mg psilocybin.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

**From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."**

**From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."**

**From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."**

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From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**8. The method of any of claims 1-7, wherein the psilocybin of the loading dose and/or the maintenance dose comprises synthetic psilocybin.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**9. The method of any of claims 1-8, wherein the psilocybin of the loading dose comprises synthetic psilocybin.**

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**10. The method of any of claims 1-9, wherein the psilocybin of the maintenance dose comprises synthetic psilocybin.**

**11. The method of any of claims 1-10, wherein the synthetic psilocybin is crystalline psilocybin.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

From [0236]: "The methods and formulations described herein include the use of N-oxides (if appropriate), crystalline forms..."

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**12. The method of any of claims 1-11, wherein the synthetic psilocybin is amorphous psilocybin.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of

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**from about 0.1 mg to about 50 mg** (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

From [0236]: "The methods and formulations described herein include the use of N-oxides (if appropriate), crystalline forms..."

From [141]: "In some instances, the pharmaceutical formulation includes multiparticulate formulations. In some instances, the pharmaceutical formulation includes nanoparticle formulations... In some cases, nanoparticles comprise solid lipid nanoparticles, polymeric nanoparticles..."

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**13. The method of any of claims 1-12, wherein the psilocybin is isolated from the mushroom Psilocybe cubensis.**

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**14. The method of any of claims 3-13, wherein the CBD comprises synthetic CBD.**

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**15. The method of any of claims 3-14, wherein the CBD**

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**comprises full-spectrum CBD.**

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**16. The method of any of claims 1-15, wherein the at least one maintenance dose further comprises a composition comprising at least one, at least two, at least three, at least four, at least five, or at least six mushrooms.**

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**17. The method of any of claims 1-16, wherein the mushroom composition comprising at least one, at least two, at least three, at least four, at least five, or at least six dried mushrooms comprises between about 0.01 g and about 0.5 g of the mushroom composition.**

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**18. The method of any of claims 16-17, wherein the mushroom composition comprises *Hericium erinaceus* and *Ganoderma lingzhi*.**

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**19. The method of any of claims 16-18, wherein the mushroom composition comprises *Laricifomes officinalis*, *Inonotus obliquus*, *Cordyceps* sp., *Hericium erinaceus*, *Ganoderma***

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**lingzhi, Trametes  
versicolor.**

**20. The method of any of claims 1-19, wherein the loading dose is administered prior to an initial maintenance dose by at least seven days.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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**21. The method of any of claims 1-20, wherein two or more loading doses are administered over a 6 month time period.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

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From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From **Claim 35**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered for at least 1 month, 2 months, 3 months, 4 months, 5 months, 6 months..."

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**22. The method of any of claims 1-21, wherein the maintenance dose is administered every day.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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**23. The method of any of claims 1-22, wherein the maintenance dose is not administered every day.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of

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**from about 0.1 mg to about 50 mg** (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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**24. The method of any of claims 1-23, wherein the maintenance dose is administered according to a predetermined schedule.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of **from about 0.1 mg to about 50 mg** (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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**25. The method of any of claims 1-24, wherein the maintenance dose is administered for five out of every seven days.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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**26. The method of any of claims 1-25, wherein the maintenance dose is formulated in a single dosage form**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

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<b>27. The method of any of claims 1-26, wherein the maintenance dose is formulated in multiple dosage forms.</b>	<p>From <b>Claim 38</b>: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."</p> <p>From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."</p> <p>From [209]: "In some instances, the desired dose is conveniently presented in a single dose or as divided doses..."</p> <p>1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)</p> <p>From <b>Claim 3</b>: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."</p> <p>From <b>Claim 30</b>: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."</p> <p>From <b>Claim 36</b>: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."</p> <p>From <b>Claim 38</b>: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."</p> <p>From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."</p> <p>From [209]: "In some instances, the desired dose is conveniently presented in a single dose or as divided doses..."</p>
<b>28. A composition for treatment of traumatic brain injury or post-concussion syndrome, the composition comprising:</b>	<p>2. Int'l Pat. App. Pub. No. WO/2021/101926 "Tryptamine compositions for enhancing neurite outgrowth" (Published May 27, 2021)</p> <p>From <b>Description</b>: Another embodiment described herein is a method of treating or preventing serotonin (5- hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism</p>

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**psilocybin, and optionally a dried mushroom blend, wherein the dried mushroom blend comprises at least two mushrooms selected from the group consisting of Laricifomes officinalis, Inonotus obliquus, Cordyceps militaris, Hericium erinaceus, Ganoderma lingzhi, and Trametes versicolor.**

spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount of a composition comprising one or more tryptamines or in pure form** or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomers thereof, **or extracts or isolates from psilocybin containing mushrooms**

**From Description: In another aspect, the composition is effective to treat, alleviate, prevent or ameliorate psychiatric and mood disorders comprising** serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, depression, anxiety, major depressive disorder, treatment resistant depression, persistent depression, manic depression or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder, seasonal depressions, situational depression, panic disorder, obsessive compulsive disorder, post-traumatic stress disorder, attention deficit/hyperactivity disorder, sleep disorders, eating disorders, schizophrenia, personality disorders, substance abuse disorders (drug abuse, addiction, alcoholism); neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, **concussion...**

**From Description: In another aspect, the composition further comprises one or more extracts or pure chemicals from other fungi comprising one or more of, Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium, Hypsizyugus, Inonotus, Isaria, Panaeolus, Phellinus, Piptoporus, Pleurotus, Polyporus or Trametes**

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**29. The composition of claim 28, further comprising mushrooms belonging to a genus selected from the group consisting of: Agaricus, Schizophyllum, Wolfiporia, Fomes, Pleurotus, Phellinus, Grifola, and Lentinula.**

2. Int'l Pat. App. Pub. No. WO/2021/101926 "Tryptamine compositions for enhancing neurite outgrowth" (Published May 27, 2021)

**From Description: Another embodiment described herein is a method of treating or preventing serotonin (5- hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases,** congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount of a composition comprising one or more tryptamines or in pure form** or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomers thereof, **or extracts or isolates from psilocybin containing mushrooms**

**From Description: In another aspect, the composition is effective to treat, alleviate, prevent or ameliorate psychiatric and mood disorders comprising** serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, depression, anxiety, major depressive disorder, treatment resistant depression, persistent depression, manic depression or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder,

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seasonal depressions, situational depression, panic disorder, obsessive compulsive disorder, post-traumatic stress disorder, attention deficit/hyperactivity disorder, sleep disorders, eating disorders, schizophrenia, personality disorders, substance abuse disorders (drug abuse, addiction, alcoholism); neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, **concussion...**

From **Description: In another aspect, the composition further comprises one or more extracts or pure chemicals from other fungi comprising one or more of**, Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, **Grifola**, Hericium, Hypsizygyus, Inonotus, Isaria, Panaeolus, Phellinus, Piptoporus, **Pleurotus**, Polyporus or Trametes

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**30. The composition of claim 28, wherein the psilocybin and optionally the dried mushroom blend are formulated together or separately.**

2. Int'l Pat. App. Pub. No. WO/2021/101926 "Tryptamine compositions for enhancing neurite outgrowth" (Published May 27, 2021)

From **Description: Another embodiment described herein is a method of treating or preventing serotonin (5- hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a composition comprising one or more tryptamines or in pure form** or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomers thereof, **or extracts or isolates from psilocybin containing mushrooms**

From **Description: In another aspect, the composition is effective to treat, alleviate, prevent or ameliorate psychiatric and mood disorders comprising serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, depression, anxiety, major depressive disorder, treatment resistant depression, persistent depression, manic depression or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder, seasonal depressions, situational depression, panic disorder, obsessive compulsive disorder, post-traumatic stress disorder, attention deficit/hyperactivity disorder, sleep disorders, eating disorders, schizophrenia, personality disorders, substance abuse disorders (drug abuse, addiction, alcoholism); neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, **concussion...****

From **Description: In another aspect, the composition further comprises one or more extracts or pure chemicals from other fungi comprising one or more of**, Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, **Grifola**, Hericium, Hypsizygyus, Inonotus, Isaria, Panaeolus, Phellinus, Piptoporus, **Pleurotus**, Polyporus or Trametes

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**31. The composition of claim 28, wherein the composition further comprises a cannabinoid, niacin, piperine, turmeric, and/or an omega fatty acid.**

2. Int'l Pat. App. Pub. No. WO/2021/101926 "Tryptamine compositions for enhancing neurite outgrowth" (Published May 27, 2021)

From **Description: Another embodiment described herein is a method of treating or preventing serotonin (5- hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a composition comprising one or more tryptamines or in pure form or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomers thereof, or extracts or isolates from psilocybin containing mushrooms**

From **Description: In another aspect, the composition further comprises one or more cannabinoids in pure form...**

From **Description: In another aspect, the composition is effective to treat, alleviate, prevent or ameliorate psychiatric and mood disorders comprising serotonin (5-hydroxytryptamine, 5-HT) receptor disorders, depression, anxiety, major depressive disorder, treatment resistant depression, persistent depression, manic depression or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder, seasonal depressions, situational depression, panic disorder, obsessive compulsive disorder, post-traumatic stress disorder, attention deficit/hyperactivity disorder, sleep disorders, eating disorders, schizophrenia, personality disorders, substance abuse disorders (drug abuse, addiction, alcoholism); neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, **concussion...****

From **Description: In another aspect, the composition further comprises one or more extracts or pure chemicals from other fungi comprising one or more of, Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, **Grifola**, Hericium, Hypsizygyus, Inonotus, Isaria, Panaeolus, Phellinus, Piptoporus, **Pleurotus**, Polyporus or Trametes**

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**32. The composition of claim 28, wherein the composition further comprises a serotonin reuptake inhibitor (SSRI), folic acid, St. John's Wart, dried Codiaeum variegatum, Codiaeum variegatum**

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extract, fish oil, flax seed oil, or combinations thereof.

**33. A method for reducing a symptom of traumatic brain injury or post-concussion syndrome in a subject, the method comprising: (i) administering to the subject one or more loading dose(s) of at least about 1 mg psilocybin; and (ii) subsequently administering to the subject one or more maintenance dose(s) comprising psilocybin and a dried mushroom blend, wherein the dried mushroom blend comprises at least two mushrooms selected from the group consisting of Laricifomes officinalis, Inonotus obliquus, Cordyceps militaris, Hericium erinaceus, Ganoderma lingzhi, and Trametes versicolor, wherein the maintenance dose comprises less than about 1 mg psilocybin, and wherein the subject has had a traumatic brain injury or has post-concussion syndrome.**

2. Int'l Pat. App. Pub. No. WO/2021/101926 "Tryptamine compositions for enhancing neurite outgrowth" (Published May 27, 2021)

From **Description**: "Another embodiment described herein is a method of treating or preventing serotonin (5- hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount of a composition comprising one or more tryptamines or in pure form** or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomers thereof, **or extracts or isolates from psilocybin containing mushrooms...**"

From **Description**: "The composition may be administered in one or more doses, one or more times per day... In one aspect, **the compositions described herein are effective to at least partially treat, alleviate, prevent or ameliorate... neuronal injuries** or physical neurodegeneration (e.g., **physical injury, head trauma, spinal cord trauma, concussion...**"

From **Description**: "In another aspect, **the composition further comprises one or more extracts** or pure chemicals **from other fungi comprising one or more of**, Antrodia, Beauveria, Copelandia, **Cordyceps**, Fomitopsis, **Ganoderma**, Grifola, **Hericium...**"

From **Description**: " In another aspect, **the composition comprises 0.001 mg to 0.01 mg, 0.01 mg to 0.1 mg, 0.01 mg to 1 mg, 0.1 mg to 5 mg, 0.1 mg to 1 mg, 0.5 mg to 1 mg, 0.5 mg to 5 mg, 0.25 mg to 1 mg, 0.2 mg to 2 mg, or 0.2 mg to 5 mg of one or more tryptamines or an amount of a plant or mushroom extract or plant or mushroom to provide an equivalent dose.**"

**34. The method of claim 33, wherein the psilocybin is purified**

2. Int'l Pat. App. Pub. No. WO/2021/101926 "Tryptamine compositions for enhancing neurite outgrowth" (Published May 27, 2021)

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and/or synthetic  
psilocybin.

From **Description**: “Another embodiment described herein is a method of treating or preventing serotonin (5- hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount of a composition comprising one or more tryptamines or in pure form** or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomers thereof, **or extracts or isolates from psilocybin containing mushrooms...**”

From **Description**: “The composition may be administered in one or more doses, one or more times per day... In one aspect, the compositions described herein are effective to at least partially treat, alleviate, prevent or ameliorate... neuronal injuries or physical neurodegeneration (e.g., physical injury, head trauma, spinal cord trauma, concussion...)”

From **Description**: “In another aspect, the composition further comprises one or more extracts or pure chemicals from other fungi comprising one or more of, Antrodia, Beauveria, Copelandia, Cordyceps, Fomitopsis, Ganoderma, Grifola, Hericium...”

From **Description**: “ In another aspect, the composition comprises 0.001 mg to 0.01 mg, 0.01 mg to 0.1 mg, 0.01 mg to 1 mg, 0.1 mg to 5 mg, 0.1 mg to 1 mg, 0.5 mg to 1 mg, 0.5 mg to 5 mg, 0.25 mg to 1 mg, 0.2 mg to 2 mg, or 0.2 mg to 5 mg of one or more tryptamines or an amount of a plant or mushroom extract or plant or mushroom to provide an equivalent dose.”

From **Description**: “The tryptamine may be a natural product extracted from or isolated from a natural source, such as a Psilocybe mushroom, or synthesized synthetically. Exemplary tryptamines include psilocybin...”

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**35. The method of claim 33, wherein the loading dose comprises about 1 mg to about 50 mg of purified and/or synthetic psilocybin.**

2. Int’l Pat. App. Pub. No. WO/2021/101926 “Tryptamine compositions for enhancing neurite outgrowth” (Published May 27, 2021)

From **Description**: “Another embodiment described herein is a method of treating or preventing serotonin (5- hydroxytryptamine, 5-HT) receptor disorders, neuronal injuries, neurodegeneration, neurological diseases, congenital or organic cognitive impairment, learning disabilities, autism spectrum disorder, psychiatric and mood disorders, cognitive enhancement, physical or motor neuron enhancement, or general improvement of mental health in a subject in need thereof, **the method comprising administering to the subject a therapeutically effective amount of a composition comprising one or more tryptamines or in**

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**pure form** or pharmaceutically acceptable salts, hydrates, solvates, prodrugs, stereoisomers, or tautomers thereof, **or extracts or isolates from psilocybin containing mushrooms...**”

From **Description**: “The **composition may be administered in one or more doses, one or more times per day...** In one aspect, **the compositions described herein are effective to at least partially treat, alleviate, prevent or ameliorate... neuronal injuries** or physical neurodegeneration (e.g., **physical injury, head trauma, spinal cord trauma, concussion...**”

From **Description**: “In another aspect, **the composition further comprises one or more extracts** or pure chemicals **from other fungi comprising one or more of**, Antrodia, Beauveria, Copelandia, **Cordyceps**, Fomitopsis, **Ganoderma**, Grifola, **Heridium...**”

From **Description**: “In another aspect, **the composition comprises 0.001 mg to 0.01 mg, 0.01 mg to 0.1 mg, 0.01 mg to 1 mg, 0.1 mg to 5 mg, 0.1 mg to 1 mg, 0.5 mg to 1 mg, 0.5 mg to 5 mg, 0.25 mg to 1 mg, 0.2 mg to 2 mg, or 0.2 mg to 5 mg of one or more tryptamines...**”

From **Description**: “The **tryptamine may be a natural product** extracted from or isolated **from a natural source, such as a Psilocybe mushroom, or synthesized synthetically**. Exemplary tryptamines include **psilocybin...**”

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**36. The method of claim 33, further comprising administering to the subject a subsequent loading dose, wherein the subsequent loading dose comprises from about 1 mg to about 50 mg psilocybin.**

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**37. The method of claim 36, wherein the subsequent loading dose is separated from the most recently administered loading dose by at least about 1 month.**

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**38. The method of claim 33, wherein the maintenance dose is**

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**administered about daily.**

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**39. The method of claim 33, wherein the maintenance dose is administered for about 3-5 consecutive days followed by no administration for about 1-3 consecutive days.**

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**40. The method of claim 33, wherein the maintenance dose is administered daily followed by no administration for 2 consecutive days.**

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**41. The method of claim 33, wherein the maintenance dose further comprises turmeric and piperine.**

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**42. The method of claim 33, wherein the maintenance dose further comprises cannabidiol.**

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**43. The method of claim 33, wherein the maintenance dose comprises from about 0.05 to about 1 mg psilocybin.**

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**44. The method of claim 33, wherein the maintenance dose comprises from about 5 mg to about 100 mg cannabidiol.**

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**45. The method of claim 33, wherein the dried mushroom blend comprises: from about 1 wt % to about 60 wt % by dry**

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**weight of *Inonotus obliquus*,  
from about 0.3 wt %  
to about 8 wt % by  
dry weight of  
*Agaricus subrufescens*,  
from about 3 wt % to  
about 60 wt % by dry  
weight of *Laricifomes officinalis*,  
from about 3 wt % to  
about 60 wt % by dry  
weight of *Trametes versicolor*,  
from about 3 wt % to  
about 60 wt % by dry  
weight of *Ganoderma lingzhi*,  
from about 0.3 wt %  
to about 8 wt % by  
dry weight of  
*Schizophyllum commune*,  
from about 3 wt % to  
about 60 wt % by dry  
weight of *Hericium erinaceus*,  
from about 0.3 wt %  
to about 8 wt % by  
dry weight of  
*Wolfiporia extensa*,  
from about 3 wt % to  
about 60 wt % by dry  
weight of *Cordyceps militaris*,  
from about 0.3 wt %  
to about 8 wt % by  
dry weight of *Fomes fomentarius*,  
from about 0.3 wt %  
to about 8 wt % by  
dry weight of  
*Pleurotus ostreatus*,  
from about 0.3 wt %  
to about 8 wt % by**

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**dry weight of  
Phellinus linteus,  
from about 0.3 wt %  
to about 8 wt % by  
dry weight of Grifola  
frondosa, and  
from about 0.3 wt %  
to about 8 wt % by  
dry weight of  
Lentinula edodes.**

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**46. The method of  
claim 42, wherein the  
wherein the  
psilocybin, the  
cannabidiol, and/or  
the dried mushroom  
blend are formulated  
together or separately.**

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**47. The method of  
claim 46, wherein the  
psilocybin, the  
cannabidiol, and/or  
the dried mushroom  
blend are  
administered  
concurrently or  
substantially  
concurrently.**

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**48. The method of  
claim 46, wherein the  
psilocybin, the  
cannabidiol, and/or  
the dried mushroom  
blend are  
administered within  
hours or days of one  
another.**

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**49. The method of  
claim 33, wherein the  
maintenance dose  
further comprises  
niacin, piperine,  
turmeric, and/or  
omega fatty acid.**

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**50. The method of  
claim 33, wherein the  
maintenance dose**

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**further comprises an agent selected from the group consisting of a serotonin reuptake inhibitor (SSRI), folic acid, St. John's Wart, dried Codiaenum variegatum, Codiaenum variegatum extract, fish oil, and flax seed oil.**

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**51. The method of claim 33, wherein the subject has post-concussion syndrome.**

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**52. The method of claim 33, wherein the subject has had a traumatic brain injury.**

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**53. The method of claim 33, wherein the maintenance dose and/or loading dose comprises the mushroom Psilocybe cubensis.**

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**54. A method for reducing a symptom of traumatic brain injury or post-concussion syndrome in a subject, the method comprising: (i) administering to the subject at least one loading dose comprising between about 5 mg and about 30 mg psilocybin, inclusive; and (ii) subsequently administering to the subject at least one maintenance dose comprising between**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

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about 1 mg to about 600 mg of a neurotransmitter activity modulator, and wherein the subject has been suspected or diagnosed as having traumatic brain injury or post-concussion syndrome.

**55. The method of claim 54, wherein the symptom of traumatic brain injury or post-concussion syndrome comprises anxiety, depression, suicide ideation, stress, post-traumatic stress disorder, post-traumatic headache, progressive headache, feelings of dizziness, nausea, vomiting, noise sensitivity, being easily upset by loud noise, sleep disturbance, fatigue or tiring more easily, irritability, insomnia, nervousness, frustration or impatience, forgetfulness or poor memory, poor concentration, taking longer to think, blurred vision, light sensitivity, double vision, restlessness, insomnia, ringing in the ears, blurry vision, decrease in taste and/or smell, and various combinations thereof.**

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**56. The method of any of claims 54-55, wherein the symptom of traumatic brain injury or post-concussion syndrome comprises anxiety and/or depression.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**57. The method of any of claims 54-56, wherein the loading dose comprises about 5 mg to about 15 mg psilocybin.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

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From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From **[199]**: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From **[7]**: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**58. The method of any of claims 54-57 wherein the loading dose comprises about 8 mg to about 12 mg psilocybin.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From **[199]**: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From **[7]**: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**59. The method of any of claims 54-58, wherein the loading**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

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**dose comprises about 25 mg psilocybin.**

**From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."**

**From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."**

**From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."**

**From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."**

**From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."**

**From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."**

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**60. The method of any of claims 54-59, wherein the loading dose comprises about 30 mg psilocybin.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

**From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."**

**From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."**

**From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."**

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From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**61. The method of any of claims 54-60, wherein the at least one maintenance dose further comprises between about 0.25 mg and about 0.3 mg psilocybin.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

From [7]: "In certain embodiments, compositions provided herein are useful in or used in the treatment depression, anxiety..."

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**62. The method of any of claims 54-61, wherein the psilocybin of the loading dose comprises synthetic psilocybin.**

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**63. The method of any of claims 54-62, wherein the psilocybin of the maintenance dose comprises synthetic psilocybin.**

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**64. The method of any of claims 54-63, wherein the synthetic psilocybin is crystalline psilocybin.**

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**65. The method of any of claims 54-64, wherein the synthetic psilocybin is amorphous psilocybin.**

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**66. The method of any of claims 54-65, wherein the psilocybin is isolated from the mushroom *Psilocybe cubensis*.**

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**67. The method of any of claims 54-66, wherein the neurotransmitter activity modulator comprises one or more selected from the group consisting of a tricyclic antidepressant (TCA), a selective serotonergic reuptake inhibitor (SSRI), a serotonin-norepinephrine reuptake inhibitor (SNRI), and a norepinephrine reuptake inhibitor (NRI).**

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**68. The method of any of claims 54-67, wherein the neurotransmitter activity modulator**

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**comprises a tricyclic antidepressant (TCA).**

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**69. The method of any of claims 54-67, wherein the neurotransmitter activity modulator comprises an SSRI.**

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**70. The method of any of claims 54-67, wherein the neurotransmitter activity modulator comprises an SNRI.**

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**71. The method of any of claims 54-67, wherein the neurotransmitter activity modulator comprises an NRI.**

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**72. The method of any of claims 54-68, wherein the neurotransmitter activity modulator comprises imipramine.**

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**73. The method of any of claims 54-72, wherein the loading dose is administered prior to an initial maintenance dose by at least seven days.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

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From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From **[199]**: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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**74. The method of any of claims 54-73, wherein two or more loading doses are administered over a 6 month time period.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From **[199]**: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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**75. The method of any of claims 54-74, wherein the maintenance dose is administered every day.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a

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**week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.”**

**From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."**

**From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."**

**From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."**

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**76. The method of any of claims 54-75, wherein the maintenance dose is not administered every day.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

**From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."**

**From Claim 30: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month.”**

**From Claim 36: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."**

**From Claim 38: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."**

**From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."**

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**77. The method of any of claims 54-76, wherein the maintenance dose is administered according to a predetermined schedule.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

**From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of**

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**from about 0.1 mg to about 50 mg** (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From **Claim 30**: "The method of any one of the preceding claims, wherein the pharmaceutical composition is administered to a subject in need thereof once a day, every alternate day, three times a week, twice a week, once a week, every other week, two weeks per month, three weeks per month, once a month, twice a month or three times per month."

From **Claim 36**: "The method of any one of the preceding claims, wherein the neurological condition is a neurological disorder."

From **Claim 38**: "The method of any one of the preceding claims, wherein the symptoms of the neurological condition are physical, behavioral, emotional, mental or a combination thereof."

From [199]: "Further examples of the disorders, conditions and symptoms which may be managed or treated include... traumatic brain injury (TBI)...concussion..."

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**78. A method for reducing a symptom of traumatic brain injury or post-concussion syndrome in a subject, the method comprising:**

- (i) administering to the subject at least one maintenance dose comprising between about 0.25 mg and about 0.3 mg psilocybin, inclusive;**
- and**
- (ii) administering to the subject at least one maintenance dose comprising between about 1 mg to about 600 mg of CBD, inclusive, wherein the subject has been suspected or diagnosed as having traumatic brain**

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**injury or post-concussion syndrome.**

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**79. The method of claim 78, wherein the symptom of traumatic brain injury or post-concussion syndrome comprises anxiety, depression, suicide ideation, stress, post-traumatic stress disorder, post-traumatic headache, progressive headache, feelings of dizziness, nausea, vomiting, noise sensitivity, being easily upset by loud noise, sleep disturbance, fatigue or tiring more easily, irritability, insomnia, nervousness, frustration or impatience, forgetfulness or poor memory, poor concentration, taking longer to think, blurred vision, light sensitivity, double vision, restlessness, insomnia, ringing in the ears, blurry vision, decrease in taste and/or smell, and various combinations thereof.**

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**80. The method of any of claims 78-79, wherein the symptom of traumatic brain injury or post-concussion syndrome comprises anxiety or depression.**

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**81. The method of any of claims 78-80, wherein the symptom of traumatic brain injury or post-concussion syndrome comprises anxiety.**

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**82. The method of any of claims 78-81 wherein the symptom of traumatic brain injury or post-concussion syndrome comprises depression.**

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**83. The method of any of claims 78-82, wherein the maintenance dose is administered every day.**

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**84. The method of any of claims 78-83, wherein the maintenance dose is administered according to a predetermined schedule.**

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**85. The method of any of claims 78-84, wherein the loading dose comprises synthetic psilocybin.**

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**86. The method of claim 85, wherein the synthetic psilocybin is crystalline psilocybin.**

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**87. The method of claim 85, wherein the synthetic psilocybin is amorphous psilocybin.**

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**88. The method of any of claims 78-84, wherein the psilocybin is isolated from the mushroom *Psilocybe cubensis*.**

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**89. The method of any of claims 78-88, wherein the neurotransmitter activity modulator comprises one or more selected from the group consisting of a tricyclic antidepressant (TCA), a selective serotonergic reuptake inhibitor (SSRI), a serotonin-norepinephrine reuptake inhibitor (SNRI), and a norepinephrine reuptake inhibitor (NRI).**

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**90. The method of any of claims 78-89, wherein the neurotransmitter activity modulator comprises a tricyclic antidepressant (TCA).**

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**91. The method of any of claims 78-89, wherein the neurotransmitter activity modulator comprises an SSRI.**

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**92. The method of any of claims 78-89, wherein the neurotransmitter activity modulator comprises an SNRI.**

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**93. The method of any of claims 78-89, wherein the neurotransmitter activity modulator comprises an NRI.**

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**94. The method of any of claims 78-89,**

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wherein the neurotransmitter activity modulator comprises imipramine.

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**95. A composition comprising psilocybin and a neurotransmitter activity modulator from the group consisting of a tricyclic antidepressant, an SSRI, an SNRI, and an NRI.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From [52]: "In certain embodiments, a composition or formulation described herein comprises an antidepressant..."

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**96. The composition of claim 95, wherein the neurotransmitter activity modulator comprises a tricyclic antidepressant.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From [52]: "In certain embodiments, a composition or formulation described herein comprises an antidepressant..."

From [114]: "In some embodiments, a coating or layer (e.g. immediate release or controlled release coating or layer) comprises an antidepressant. In some embodiments, the antidepressant is selected from the group consisting of Abilify (aripiprazole), Adapin (doxepin), Anafranil (clomipramine), Aplenzin (bupropion), Asendin (amoxapine), Aventyl HCl (nortriptyline), Celexa (citalopram), Cymbalta (duloxetine), Desyrel (trazodone), Effexor XR (venlafaxine), Emsam (selegiline), Etrafon (perphenazine and amitriptyline)..."

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**97. The composition of claim 95, wherein the neurotransmitter activity modulator comprises imipramine.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of

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**from about 0.1 mg to about 50 mg** (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From [52]: **"In certain embodiments, a composition or formulation described herein comprises an antidepressant..."**

From [114]: **"In some embodiments, a coating or layer (e.g. immediate release or controlled release coating or layer) comprises an antidepressant. In some embodiments, the antidepressant is selected from the group consisting of Abilify (aripiprazole), Adapin (doxepin), Anafranil (clomipramine), Aplenzin (bupropion), Asendin (amoxapine), Aventyl HCl (nortriptyline), Celexa (citalopram), Cymbalta (duloxetine), Desyrel (trazodone), Effexor XR (venlafaxine), Emsam (selegiline), Etrafon (perphenazine and amitriptyline), Elavil (amitriptyline), Endep (amitriptyline), Fetzima (levomilnacipran), Khedezla (desvenlafaxine), Latuda (lurasidone), Lamictal (lamotrigine), Lexapro (escitalopram), Limbitrol (amitriptyline and chlordiazepoxide), Marplan (isocarboxazid), Nardil (phenelzine), Norpramin (desipramine), Oleptro (trazodone), Pamelor (nortriptyline), Parnate (tranylcypromine), Paxil (paroxetine), Pexeva (paroxetine), Prozac (fluoxetine), Pristiq (desvenlafaxine), Remeron (mirtazapine), Sarafem (fluoxetine), Seroquel XR (quetiapine), Serzone (nefazodone), Sinequan (doxepin), Surmontil (trimipramine), Symbyax (fluoxetine and the atypical antipsychotic drug olanzapine), **Tofranil (imipramine)...**"**

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**98. The composition of claim 95, wherein the neurotransmitter activity modulator comprises an SSRI.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of **from about 0.1 mg to about 50 mg** (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From [52]: **"In certain embodiments, a composition or formulation described herein comprises an antidepressant. Similarly, in some embodiments, a therapeutic method provided herein comprises the administration of an antidepressant, such as utilizing a formulation or composition described herein. In certain instances, antidepressants are classified into three families: monoamine oxidase inhibitors (MAOIs), tricyclics and selective serotonin reuptake inhibitors (SSRIs)."**

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**99. The composition of claim 95, wherein the neurotransmitter**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

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**activity modulator comprises an SNRI.**

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From [52]: "In certain embodiments, a composition or formulation described herein comprises an antidepressant..."

From [114]: "In some embodiments, a coating or layer (e.g. immediate release or controlled release coating or layer) comprises an antidepressant. In some embodiments, the antidepressant is selected from the group consisting of Abilify (aripiprazole), Adapin (doxepin), Anafranil (clomipramine), Aplenzin (bupropion), Asendin (amoxapine), Aventyl HCl (nortriptyline), Celexa (citalopram), Cymbalta (duloxetine), Desyrel (trazodone), **Effexor XR (venlafaxine)**..."

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**100. The composition of claim 95, wherein the neurotransmitter activity modulator comprises an NRI.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From [52]: "In certain embodiments, a composition or formulation described herein comprises an antidepressant..."

From [114]: "In some embodiments, a coating or layer (e.g. immediate release or controlled release coating or layer) comprises an antidepressant. In some embodiments, the antidepressant is selected from the group consisting of Abilify (aripiprazole), Adapin (doxepin), Anafranil (clomipramine), **Aplenzin (bupropion)**..."

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**101. The composition of any of claims 95-100, wherein the neurotransmitter activity modulator comprises about 1 mg to about 600 mg of the neurotransmitter activity modulator.**

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**102. The composition of claim 101, wherein the neurotransmitter**

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**activity modulator comprises about 1 mg to about 300 mg of the neurotransmitter activity modulator.**

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**103. The composition of claim 101, wherein the neurotransmitter activity modulator comprises about 1 mg to about 200 mg of the neurotransmitter activity modulator.**

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**104. The composition of claim 101, wherein the neurotransmitter activity modulator comprises about 1 mg to about 100 mg of the neurotransmitter activity modulator.**

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**105. The composition of claim 101, wherein the neurotransmitter activity modulator comprises about 1 mg to about 50 mg of the neurotransmitter activity modulator.**

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**106. The composition of claim 95, wherein the psilocybin comprises about 0.1 mg to about 0.5 mg.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

From Claim 3: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From [52]: "In certain embodiments, a composition or formulation described herein comprises an antidepressant..."

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**107. The composition of claim 95, wherein the psilocybin comprises about 0.25 mg to about 0.3 mg.**

1. Int'l Pat. App. Pub. No. WO/2020/157569 "Methods and Compositions Comprising a 5HT Receptor Agonist for the Treatment of Psychological, Cognitive, Behavioral, and/or Mood Disorders" (Published August 6, 2020)

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From **Claim 3**: "The method of any one of the preceding claims, wherein the 5HT receptor agonist or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof is present in an amount of from about 0.1 mg to about 50 mg (e.g. about 0.1 mg to about 10 mg, about 0.2 mg to about 5 mg, about 10 mg to about 50 mg, or the like)."

From [52]: "In certain embodiments, a composition or formulation described herein comprises an antidepressant..."

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**18/254,705**

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### Title of Invention

### Application Information

APPLICATION TYPE	PATENT #
CONFIRMATION #	FILED BY Jeremy Rolquin
PATENT CENTER # 66554860	FILING DATE 05/26/2023
CUSTOMER # -	FIRST NAMED INVENTOR
INTL. APPLICATION # -	INTL. FILING DATE -
CORRESPONDENCE ADDRESS	AUTHORIZED BY -

### Documents

**TOTAL DOCUMENTS: 7**

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf	2	Third-Party Submission Under 37 CFR 1.290	49 KB
Concise-description-generated.pdf	1	Concise Description of Relevance	26 KB
Third-party-notification-request.pdf	1	Request for Notification of Non-compliant Third-Party Submission	14 KB
3PS.pdf	42	-	455 KB
3PS-3P.RELEVANCE.pdf (1-42)	42	Concise Description of Relevance	313 KB

3PS-3P.RELEVANCE.pdf	(1-42)	42	Concise Description of Relevance	313 KB
WO2020157569A1-2.pdf		139	-	8074 KB
WO2020157569A1-2-FOR.pdf	(1-139)	139	Foreign Reference	8052 KB
WO2021101926-PAMPH-20210527-1116.pdf		120	-	6102 KB
WO2021101926-PAMPH-20210527-1116-FOR.pdf	(1-120)	120	Foreign Reference	6102 KB

## Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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WO2020157569A1-2-FOR.pdf	0A51323D572DD77BF40B4321782784BC1F162D1EC3A89C749 56AF41FA1FD934664B4F1431B1497A8D81AA81A27E3A6D3FC FB993BD3B0432F1D6F3A6F5CBA2211
WO2021101926-PAMPH- 20210527-1116.pdf	882632C88DF6851F01C4475BDD63F8FAC9BA79601275FF216B 378F1F5030A13315A91C6F47F1DD1287FDC7C7D2B42F471FE 156DA0BB0CD6FDEE9564640BBBCE2
WO2021101926-PAMPH- 20210527-1116-FOR.pdf	E0D49563A80B6679FCC94DBF0BD06AE8EB05FE75D64C2E3E D7227AEBA81D3AEBF0D095811596F0CBDA5C986E888A90499 CC80546D7550D874657C47A9F0A7D0A

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#### **New Applications Under 35 U.S.C. 111**

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

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

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

#### **New International Application Filed with the USPTO as a Receiving Office**

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