

## Intellectual Property Landscape Assessment

The following is an Intellectual Property landscape analysis for psilocybin applied in the treatment of depression prepared by Porta Sophia for \_\_\_\_[entity name]\_\_\_\_. The entity \_\_[has / does not have]\_\_ a provisional application filed at the USPTO (document number \_\_\_\_ ) with a priority date of \_\_[date]\_\_. The proposed invention describes **the use of 0.5 mg to 50 mg of synthetic, >95% pure psilocybin or a pharmaceutically acceptable salt thereof as a single-dose, orally administered monotherapy for treatment resistant depression or a clinical symptom thereof.**

Searches were conducted through international and domestic patent databases using the search terms “psilocybin” and “depression” in patent claims. 271 results were returned and what follows is an analysis of claims described in existing documents that have priority dates that predate the abovementioned priority document [document number \_\_\_\_]. The search was completed on September 15, 2023.

This document is split into three parts:

- 1) Granted, active U.S. patents
- 2) Pending U.S. patent applications and additional patent documents relevant to the proposed invention
- 3) Non-patent references pertinent to the described technology that exists in the public domain

Also included in this package are all priority documents of patent applications listed in above section 2.

# 1. Granted, Active Patents

The following table documents all active patents relevant to the portion of the IP landscape the proposed invention seeks to occupy.

The “relevant claims” column contains text highlighted in **green** if it is directly relevant to and in the scope of the proposed invention, and **red** if it qualifies the claim and lends credibility to its inapplicability to the presently proposed invention.

Patent Number	Legal Status	Family Members	Title	Assignee	Relevant claims	International national stage applications filed? (Y/N)	Relevant litigation (Y/N)	Relevance (Y/N)
US10519175	Active	<u>U.S. Patents</u> 10947257, 10954259, 11149044, 11180517, 11447510, 11505564, 11629159  <u>U.S. Applications</u> 17/990,979, 18/135,265	Preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use	Compass Pathfinder Limited	1. A method of <b>treating drug resistant depression comprising orally administering to a subject</b> in need thereof a therapeutically effective amount of an oral dosage form, wherein, the oral dosage form comprises: <b>crystalline psilocybin in the form Polymorph A characterized by peaks in an XRPD diffractogram at 11.5, 12.0, 14.5, 17.5, and 19.7°2θ±0.1°2θ</b> , wherein the <b>crystalline psilocybin has a chemical purity of greater than 97%</b> by HPLC, and no single impurity of greater than 1%; and silicified microcrystalline cellulose.  2. The method of <b>claim 1</b> , wherein <b>the oral dosage form comprises 1 mg to 40 mg of crystalline psilocybin in the form Polymorph A</b> .  3. The method of <b>claim 2</b> , wherein <b>the oral dosage form comprises 5 mg of crystalline psilocybin in the form Polymorph A</b> .  4. The method of <b>claim 2</b> , wherein <b>the oral dosage form comprises 10 mg of crystalline psilocybin in the form Polymorph A</b> .  5. The method of <b>claim 2</b> , wherein <b>the oral dosage form comprises 25 mg of crystalline psilocybin in the form Polymorph A</b> .	Y	N	N
US10947257	Active	<u>U.S. Patents</u> 10519175,	Preparation of psilocybin, different	Compass Pathfinder Limited	1. An oral dosage form comprising: a <b>therapeutically effective amount of crystalline psilocybin in the form Polymorph A characterized by peaks in an</b>	Y	Y (PGR - unsuccessful)	N

		10954259, 11149044, 11180517, 11447510, 11505564, 11629159  <u>U.S. Applications</u> 18/135,265	polymorphic forms, intermediates, formulations and their use		<b>XRPD diffractogram at 11.5, 12.0, 14.5, 17.5, and 19.7°2θ±0.1°2θ</b> , wherein <b>the crystalline psilocybin has a chemical purity of greater than 97%</b> by HPLC, and no single impurity of greater than 1%; and silicified microcrystalline cellulose.  2. The <b>oral dosage form of claim 1</b> comprising about <b>1 mg to 40 mg of crystalline psilocybin in the form Polymorph A</b> .  3. The <b>oral dosage form of claim 2</b> comprising about <b>5 mg of crystalline psilocybin in the form Polymorph A</b> .  4. The <b>oral dosage form of claim 2</b> comprising about <b>10 mg of crystalline psilocybin in the form Polymorph A</b> .  5. The <b>oral dosage form of claim 2</b> comprising about <b>25 mg of crystalline psilocybin in the form Polymorph A</b> .  21. A <b>method of treating major depressive disorder</b> comprising <b>orally administering to a subject in need thereof the oral dosage form of claim 1</b> .		challenge to patentability)	
US10954259	Active	<u>U.S. Patents</u> 10519175, 10947257, 11149044, 11180517, 11447510, 11505564, 11629159  <u>U.S. Applications</u> 18/135,265	Preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use	Compass Pathfinder Limited	16. A <b>method of treating major depressive disorder</b> , the method comprising: <b>administering a therapeutically effective amount of crystalline Polymorph A of psilocybin</b> to a patient in need thereof, wherein the <b>Polymorph A is characterized by X-ray powder diffraction (XRPD) peaks at 11.5±0.1, 12.0±0.1, 14.5±0.1, 17.5±0.1 and 19.7±0.1 °2θ</b> , and wherein <b>the psilocybin has a chemical purity of greater than 97%</b> and no single impurity of greater than 1% as determined by HPLC analysis.  17. The method of <b>claim 16</b> , wherein about <b>5 mg of the crystalline Polymorph A of psilocybin is administered</b> .  18. The method of <b>claim 16</b> , wherein about <b>10 mg of the crystalline Polymorph A of psilocybin is administered</b> .  19. The method of <b>claim 16</b> , wherein about <b>25 mg of the crystalline Polymorph A of psilocybin is administered</b> .  20. The method of <b>claim 16</b> , wherein the <b>crystalline Polymorph A of psilocybin is orally administered</b> .	Y	Y (PGR - unsuccessful challenge to patentability)	N
US11149044	Active	<u>U.S. Patents</u> 10519175, 10947257, 10954259, 11180517,	Preparation of psilocybin, different polymorphic forms,	Compass Pathfinder Limited	15. A <b>method of treating major depressive disorder</b> , the method comprising: <b>administering a therapeutically effective amount of crystalline Hydrate A of psilocybin</b> to a patient in need thereof,	Y	N	N

		11447510, 11505564, 11629159  <u>U.S. Applications</u> 18/135,265	intermediates, formulations and their use		<p>wherein the <b>crystalline Hydrate A is characterized by X-ray powder diffraction (XRPD) peaks at 8.9±0.1, 13.8±0.1, 19.4±0.1, 23.1±0.1 and 23.5±0.1°2θ</b>, and wherein <b>the psilocybin has a chemical purity of greater than 97%</b> and no single impurity of greater than 1% as determined by HPLC analysis.</p> <p>16. The method of <b>claim 15</b>, wherein about <b>5 mg of the crystalline Hydrate A of psilocybin is administered</b>.</p> <p>17. The method of <b>claim 15</b>, wherein about <b>10 mg of the crystalline Hydrate A of psilocybin is administered</b>.</p> <p>18. The method of <b>claim 15</b>, wherein about <b>25 mg of the crystalline Hydrate A of psilocybin is administered</b>.</p> <p>19. The method of <b>claim 15</b>, wherein the crystalline Hydrate A of <b>psilocybin is orally administered</b>.</p>			
US11180517	Active	<u>U.S. Patents</u> 10519175, 10947257, 10954259, 11149044, 11447510, 11505564, 11629159  <u>U.S. Applications</u> 18/135,265	Preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use	Compass Pathfinder Limited	<p>13. A <b>method of treating treatment resistant depression</b>, the method comprising <b>administering a therapeutically effective amount of psilocybin to a patient in need</b> thereof, wherein <b>the psilocybin comprises a crystalline Polymorph A of psilocybin characterized by X-ray powder diffraction (XRPD) peaks at 11.5±0.1, 12.0±0.1, 14.5±0.1, 17.5±0.1 and 19.7±0.1°2θ</b>, and wherein the <b>psilocybin has a chemical purity of greater than 97%</b> as determined by HPLC analysis.</p> <p>14. The method of <b>claim 13</b>, wherein <b>about 1 mg to about 40 mg of psilocybin is administered</b>.</p> <p>15. The method of <b>claim 13</b>, wherein <b>about 10 mg to about 30 mg of psilocybin is administered</b>.</p> <p>16. The method of <b>claim 13</b>, wherein <b>about 1 mg of psilocybin is administered</b>.</p> <p>17. The method of <b>claim 13</b>, wherein <b>about 5 mg of psilocybin is administered</b>.</p> <p>18. The method of <b>claim 13</b>, wherein <b>about 10 mg of psilocybin is administered</b>.</p> <p>19. The method of <b>claim 13</b>, wherein <b>about 25 mg of psilocybin is administered</b>.</p> <p>20. The method of <b>claim 13</b>, wherein <b>the psilocybin is orally administered</b>.</p>	Y	N	N

US11447510	Active	<u>U.S. Patents</u> 10519175, 10947257, 10954259, 11149044, 11180517, 11505564, 11629159  <u>U.S. Applications</u> 17/990,979, 18/135,265	Preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use	Compass Pathfinder Limited	14. A <b>method of treating treatment resistant depression</b> , the method comprising <b>administering a therapeutically effective amount of psilocybin to a patient in need thereof</b> , wherein <b>the psilocybin comprises a crystalline Hydrate A of psilocybin characterized by X-ray powder diffraction (XRPD) peaks at 8.9±0.1, 13.8±0.1, 19.4±0.1, 23.1±0.1 and 23.5±0.1°2θ</b> , and wherein <b>the psilocybin has a chemical purity of greater than 97%</b> and no single impurity of greater than 1% as determined by HPLC analysis.  15. The method of <b>claim 14</b> , wherein <b>about 1 mg to about 40 mg of psilocybin is administered</b> .  16. The method of <b>claim 14</b> , wherein <b>about 10 mg to about 30 mg of psilocybin is administered</b> .  17. The method of <b>claim 14</b> , wherein <b>about 1 mg of psilocybin is administered</b> .  18. The method of <b>claim 14</b> , wherein <b>about 5 mg of psilocybin is administered</b> .  19. The method of <b>claim 14</b> , wherein <b>about 10 mg of psilocybin is administered</b> .  20. The method of <b>claim 14</b> , wherein <b>about 25 mg of psilocybin is administered</b> .  21. The method of <b>claim 14</b> , wherein <b>the psilocybin is orally administered</b> .	Y	N	N
US11505564	Active	<u>U.S. Patents</u> 10519175, 10947257, 10954259, 11149044, 11180517, 11447510, 11629159  <u>U.S. Applications</u> 17/990,979, 18/135,265	Preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use	Compass Pathfinder Limited	N/A	Y	N	N
US10729706	Active	<u>U.S. Applications</u> 17/880,134  <u>WIPO Applications</u> PCT/NL2018/050037	Psilocybin and/or psilocin in combination with	Procare Beheer B.V.	1. A <b>method for preventing or treating a psychological disorder in a patient, comprising: administrating psilocybin and/or psilocin in combination with at least one cannabinoid and/or at least one terpene, wherein the at least one cannabinoid and/or at least one terpene is</b>	Y	N	N

			cannabinoids and/or terpenes		<p><b>administered separately, sequentially or simultaneously to the psilocybin and/or psilocin.</b></p> <p>2. The <b>method of claim 1, wherein the psychological disorder is chosen from depression, psychotic disorder, schizophrenia, schizophreniform disorder (acute schizophrenic episode); schizoaffective disorder; bipolar I disorder (mania, manic disorder, manic-depressive psychosis); bipolar II disorder; major depressive disorder with psychotic feature (psychotic depression); delusional disorders (paranoia); Shared Psychotic Disorder (Shared paranoia disorder); Brief Psychotic disorder (Other and Unspecified Reactive Psychosis); Psychotic disorder not otherwise specified (Unspecified Psychosis); paranoid personality disorder; schizoid personality disorder; schizotypal personality disorder, anxiety disorder, panic disorder, panic attacks, agoraphobia, attention deficit syndrome, premenstrual dysphoric disorder (PMDD), and premenstrual syndrome (PMS).</b></p>			
US11471450	Active	<p><u>U.S. Patents</u> 11590120</p> <p><u>U.S. Applications</u> 16/211,281 15/494,503 17/942,763</p> <p><u>Priority documents</u> 62/365,982 (02/23/2016)</p>	Psilocybin compositions	Turtle Bear Holdings LLC	<p>1. A <b>composition comprising: 0.1 mg to 10 mg of psilocybin or psilocin; an extract of <i>Herichium erinaceus</i> comprising 50 mg to 200 mg of erinacines or hericenones; and 199 mg of one or more medicinal mushroom species of <i>Inonotus mycelia</i>, fruitbodies, mycelial extracts, fruitbody extracts, or combinations thereof.</b></p> <p>6. A <b>composition comprising: 0.1 to 10 mg of psilocybin or psilocin; an extract of <i>Herichium erinaceus</i> comprising 50 mg to 200 mg of erinacines or hericenones; 199 mg of one or more medicinal mushroom species of <i>Inonotus mycelia</i>, fruitbodies, mycelial extracts, fruitbody extracts or combinations thereof, and niacin.</b></p>	N	N	N
US11590120	Active	<p><u>U.S. Patents</u> 11471450 11701348</p> <p><u>U.S. Applications</u> 15/494,503 17/669,845 18/354,403 16/992,631 16/951,012 17/308,869 18/114,381 17/942,763 17/480,789</p> <p><u>Priority documents</u></p>	Psilocybin compositions	Turtle Bear Holdings LLC	<p>1. A <b>pharmaceutical formulation comprising of: 0.1 mg to 10 mg of psilocybin or psilocin; and an extract of <i>Herichium erinaceus</i> comprising 0.1 mg to 200 mg of erinacines or hericenones.</b></p> <p>6. A <b>pharmaceutical formulation comprising of: 0.1 mg to 10 mg of psilocybin or psilocin; an extract of <i>Herichium erinaceus</i> comprising 0.1 mg to 200 mg of erinacines or hericenones; and 1 mg to 50 mg of niacin.</b></p> <p>10. A <b>pharmaceutical formulation comprising of: 0.1 mg to 10 mg psilocybin or psilocin; and 1 mg to 50 mg of niacin.</b></p> <p>15. A <b>pharmaceutical dosage comprising a tablet, capsule, elixir, or suspension comprising of: 0.1 mg to 10 mg psilocybin or psilocin; an extract of <i>Herichium erinaceus</i></b></p>	N	N	N

		62/365,982 (02/23/2016)			comprising 0.1 mg to 200 mg of erinacines or hericenones; and 1 mg to 50 mg of niacin.			
US11701348	Active	<u>U.S. Patents</u> 11590120  <u>U.S. Applications</u> 18/354,403 16/211,281 15/494,503  <u>Priority documents</u> 62/365,982 (02/23/2016)	Psilocybin compositions	Turtle Bear Holdings LLC	<p>1. A method for reducing symptoms of depression in a subject in need thereof comprising: administering a dosage form comprising: 0.1 mg to 10 mg of psilocybin or psilocin; an extract of <i>Herichium erinaceus</i> comprising 0.1 mg to 200 mg of erinacines or hericenones; and 1 mg to 50 mg of niacin; sufficient to reduce the symptoms of depression in the subject</p> <p>2. The method of <b>claim 1</b>, wherein the dosage form comprises 0.1 mg to 0.6 mg; 0.6 mg to 0.9 mg; 0.9 mg to 10 mg; or 1 mg to 10 mg of psilocybin or psilocin.</p> <p>6. The method of <b>claim 1</b>, wherein the dosage form is a capsule.</p> <p>8. A method for reducing symptoms of depression in a subject in need thereof comprising: administering a dosage form comprising: 0.1 mg to 10 mg of psilocybin or psilocin; and an extract of <i>Herichium erinaceus</i> comprising 0.1 mg to 200 mg of erinacines or hericenones; sufficient to reduce the symptoms of depression in the subject.</p> <p>10. The method of <b>claim 8</b>, wherein the dosage form comprises 0.1 mg to 0.6 mg; 0.6 mg to 0.9 mg; 0.9 mg to 10 mg; or 1 mg to 10 mg of psilocybin or psilocin.</p> <p>14. The method of <b>claim 8</b>, wherein the dosage form is a capsule.</p> <p>16. A method for reducing symptoms of depression in a subject in need thereof comprising: administering a dosage form comprising: 0.1 mg to 10 mg of psilocybin or psilocin; 1 mg to 50 mg of niacin; sufficient to reduce the symptoms of depression in the subject.</p> <p>18. The method of <b>claim 16</b>, wherein the dosage form comprises 0.1 mg to 0.6 mg; 0.6 mg to 0.9 mg; 0.9 mg to 10 mg; or 1 mg to 10 mg of psilocybin or psilocin.</p> <p>22. The method of <b>claim 16</b>, wherein the dosage form is a capsule.</p>	N	N	N

## 2. Additional Patent Documents

The following table documents relevant patent documents (active applications, expired patents, etc.) that are relevant to the portion of the IP landscape the proposed invention seeks to occupy.

The “published patent doc #” column is color coded according to Porta Sophia’s opinion regarding the likelihood of the specific document’s claims being granted patent rights as those claims are described at the point this landscape analysis was generated. **Red** denotes that it is unlikely that the claims will be granted in their current state, **yellow** indicates that there is some chance that some claims may be granted as they stand, and **green** indicates that it is likely that the claims will be granted in their current form.

The “relevant claims” column contains text highlighted in **green** if it is directly relevant to and in the scope of the proposed invention, and **red** if it qualifies the claim and lends credibility to its inapplicability to the presently proposed invention.

Published Patent Doc #	Legal Status	Family Members	Title	Assignee	Relevant claims	International national stage applications filed? (Y/N)	Relevance (Y/N)	Third party intervention filed (Y/N)
US20210251976	Pending	<u>U.S. Patents</u> 11590120  <u>U.S. Applications</u> 16/951,012 16/211,281 15/494,503  <u>Priority documents:</u> U.S. 62/937,536 (11/19/2019) U.S. 63/007,482 (04/09/2020) U.S. 62/365,982 (07/23/2016)	TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH	Turtle Bear Holdings LLC	1. A method of <b>treating or improving a mental health disorder in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of a composition comprising from about 1 mg to about 10 mg of one or more of psilocybin, psilocin, esters, or salts thereof; or an equivalent amount of a psilocybin containing mushroom;</b> and one or more pharmaceutically acceptable excipients.  2. The <b>method of claim 1, wherein the mental health disorder is a psychiatric and mood disorder comprising depression, anxiety, major depressive disorder, treatment resistant depression, persistent depression, manic depression</b> or bipolar disorder, depressive psychosis, perinatal depression, premenstrual dysphoric disorder, seasonal depression, situational depression,	N	Y	N



					panic disorder, post-traumatic stress disorder, or a combination thereof.			
US2023000885	Pending	<p>U.S. Applications 17/634,729</p> <p>WIPO applications: PCT/US2020/04614 9</p> <p>Priority documents: U.S. 62/886,090 (13 August 2019)</p>	Methods of Treating Psychological and Brain Disorders	University of Maryland, Baltimore	<p>25. <b>A method for treating depression</b> or symptoms thereof in a subject in need thereof, <b>comprising:</b></p> <p>(a) <b>administering to the subject a serotonin receptor 2A antagonist; and</b></p> <p>(b) <b>administering to the subject a serotonin agonist selected from psilocybin</b>, psilocin, LSD and lisurgide; wherein the serotonin agonist is administered separately, sequentially or simultaneously with the serotonin receptor 2A antagonist.</p> <p>30. The <b>method of claim 25</b>, wherein the <b>serotonin agonist is psilocybin</b> or psilocin.</p> <p>31. The <b>method of claim 30</b>, wherein the <b>serotonin agonist is psilocybin</b>.</p> <p>39. The <b>method of claim 25</b>, wherein the <b>depression is</b> major depression, psychotic depression, <b>treatment-resistant depression (TRD)</b>, or postpartum depression.</p>	Y	N	Y
US20230023092	Pending	<p>WIPO applications: PTC/IB2020/05368 8</p> <p>Priority documents: U.S. 62/946,159 (12/10/2019) U.S. 62/893,611 (08/29/2019) U.S.62/893,110 (08/28/2019) U.S. 62/835,485 (04/17/2019) U.S. 62/835,484 (04/17/2019) U.S. 62/835,482 (104/17/2019) U.S. 62/835,481 (04/17/2019) U.S. 62/835,480 (04/17/2019) U.S. 62/835,479 (04/17/2019) U.S. 62/835,478</p>	TREATMENT OF DEPRESSION AND OTHER VARIOUS DISORDERS WITH PSILOCYBIN	Compass Pathfinder Limited	<p>1. <b>A method of treating depression in a subject in need thereof, the method comprising administering an effective amount of crystalline psilocybin to the subject</b>, wherein the <b>crystalline psilocybin is characterized by XRPD peaks at 11.5±0.1, 12.0±0.1, 14.5±0.1, 17.5±0.1 and 19.7±0.1°</b> <b>20</b>, wherein the <b>crystalline psilocybin has a chemical purity of greater than 97%</b> as determined by HPLC analysis, and wherein the subject has bipolar disorder, or a depressive disorder due to a medical condition.</p> <p>8. The method of <b>claim 1</b>, wherein <b>at least one sign or symptom of depression</b> selected from depressed mood, diminished interest in activities, weight loss or gain, decrease or increase in appetite, insomnia or hypersomnia, psychomotor agitation or retardation, fatigue or loss of energy, feelings of worthlessness or excessive or inappropriate guilt, diminished ability to concentrate or indecisiveness, or suicidal ideation or behavior <b>is reduced</b>.</p>	Y	N	N

		(04/17/2019) U.S. 62/835,477 (04/17/2019) U.S. 62/835,476 (04/17/2019) U.S. 62/835,474 (04/17/2019) U.S. 62/835,472 (04/17/2019) U.S. 62/835,465 (04/17/2019) U.S. 62/835,464 (04/17/2019) U.S. 62/835,460 (04/17/2019) U.S. 62/835,458 (04/17/2019) U.S. 62/835,450 (04/17/2019) U.S. 62/835,449 (104/17/2019)			56. The method of <b>claim 1</b> , wherein the <b>crystalline psilocybin is administered in an oral dosage form.</b>  60. The method of <b>claim 1</b> , wherein the effective <b>amount of crystalline psilocybin is in the range of about 0.1 mg to about 100 mg.</b>  61. The method of <b>claim 60</b> , wherein the effective <b>amount of crystalline psilocybin is about 1 mg.</b>  62. The method of <b>claim 60</b> , wherein the effective <b>amount of crystalline psilocybin is about 10 mg.</b>  63. The method of <b>claim 60</b> , wherein the effective <b>amount of crystalline psilocybin is about 25 mg.</b>			
US20230151036	Pending	<u>WIPO applications:</u> PCT/US2022/07975 2  <u>Priority documents:</u> U.S. 63/278,943 (11/12/2021) U.S. 63/279,005 (11/12/2021) U.S. 63/280,294 (11/17/2021) U.S. 63/280,300 (11/17/2021) U.S. 63/285,050 (12/01/2021) U.S. 63/300,957 (01/19/2022) U.S. 63/300,961 (01/19/2022) U.S. 63/305,642 (02/01/2022) U.S. 63/305,643 (02/01/2022) U.S. 63/310,984 (02/16/2022) U.S. 63/310,987 (02/16/2022) U.S. 63/311,878	PSILOCYBIN AND O-ACETYLPSILOCIN, SALTS AND SOLID STATE FORMS THEREOF	Terran Biosciences Inc.	<b>1. A crystalline form of psilocybin.HCl (Form A) that is characterized as having: an X-ray powder diffraction (XRPD) diffractogram with characteristic peaks at 6.1±0.2° 2-Theta, 9.9±0.2° 2-Theta, and 14.3±0.2° 2-Theta</b> , optionally further comprising peaks at 18.0±0.2° 2-Theta and 19.8±0.2° 2-Theta, as measured with Cu Ka radiation, or an XRPD diffractogram with characteristic peaks at 6.0±0.2° 2-Theta, 9.9±0.2° 2-Theta, and 14.6±0.2° 2-Theta, optionally with further characteristic peaks at 18.0±0.2° 2-Theta and 19.7±0.2° 2-Theta, as measured with Cu Ka radiation, or an XRPD diffractogram with characteristic peaks at 6.1±0.2° 2-Theta, 9.9±0.2° 2-Theta, and 14.3±0.2° 2-Theta, optionally further comprising peaks at 16.9±0.2° 2-Theta and 18.1±0.2° 2-Theta, as measured with Cu Ka radiation.  <b>5. A crystalline form of psilocybin.HCl (Form A) that is characterized as having: an X-ray powder diffraction (XRPD) diffractogram with characteristic peaks at 6.1±0.2° 2-Theta, 9.9±0.2° 2-Theta, and 14.3±0.2° 2-Theta</b> , optionally further	N	N	N

		<p>(02/18/2022) U.S. 63/315,901 (03/02/2022) U.S. 63/316,952 (03/04/2022) U.S. 63/319,746 (03/14/2022) U.S. 63/321,593 (03/18/2022) U.S. 63/324,878 (03/29/2022) U.S. 63/326,364 (04/01/2022) U.S. 63/326,421 (04/01/2022) U.S. 63/326,522 (04/01/2022) U.S. 63/326,713 (04/01/2022) U.S. 63/357,378 (06/30/2022) U.S. 63/357,512 (06/30/2022)</p>			<p>comprising peaks at <math>18.0 \pm 0.2^\circ</math> 2-Theta and <math>19.8 \pm 0.2^\circ</math> 2-Theta, as measured with Cu K<math>\alpha</math> radiation, or an XRPD diffractogram with characteristic peaks at <math>6.0 \pm 0.2^\circ</math> 2-Theta, <math>9.9 \pm 0.2^\circ</math> 2-Theta, and <math>14.6 \pm 0.2^\circ</math> 2-Theta, optionally with further characteristic peaks at <math>18.0 \pm 0.2^\circ</math> 2-Theta and <math>19.7 \pm 0.2^\circ</math> 2-Theta, as measured with Cu K<math>\alpha</math> radiation, or an XRPD diffractogram with characteristic peaks at <math>6.1 \pm 0.2^\circ</math> 2-Theta, <math>9.9 \pm 0.2^\circ</math> 2-Theta, and <math>14.3 \pm 0.2^\circ</math> 2-Theta, optionally further comprising peaks at <math>16.9 \pm 0.2^\circ</math> 2-Theta and <math>18.1 \pm 0.2^\circ</math> 2-Theta, as measured with Cu K<math>\alpha</math> radiation; and a differential scanning calorimetry (DSC) thermogram with an endotherm at about <math>189.3^\circ</math> C. when measured at a heating rate of <math>10^\circ</math> C./min, or a thermogravimetric analysis (TGA) spectrum showing a 0.2% loss up to <math>130^\circ</math> C., and a 1.3% loss from <math>130^\circ</math> C. to <math>195^\circ</math> C., or both.</p> <p>9. A <b>crystalline form of psilocybin.HCl</b> that is <b>characterized as having unit cell parameters substantially equal to the following at 100 K:</b> <b>crystal system, space group Monoclinic, P21/n data collection temperature (K) 150 a (<math>\text{\AA}</math>) 8.4691 (4) b (<math>\text{\AA}</math>) 29.5481 (14) c (<math>\text{\AA}</math>) 11.5761 (5) <math>\beta</math> (<math>^\circ</math>) 102.6579 (14) volume (<math>\text{\AA}^3</math>) 2826.5 (2) Z 4.</b></p> <p>10. A <b>crystalline form of psilocybin.HCl</b> that is a <b>co-crystal of psilocybin and hydrochloric acid with an overall stoichiometry of two moles of psilocybin to one mole of hydrochloric acid and is characterized as having unit cell parameters substantially equal to the following at 100 K:</b> <b>crystal system, space group Monoclinic, P21/n data collection temperature (K) 150 a (<math>\text{\AA}</math>) 8.4691 (4) b (<math>\text{\AA}</math>) 29.5481 (14) c (<math>\text{\AA}</math>) 11.5761 (5) <math>\beta</math> (<math>^\circ</math>) 102.6579 (14) volume (<math>\text{\AA}^3</math>) 2826.5 (2) Z 4.</b></p> <p>12. A <b>method of treating a neurological disorder, a psychiatric disorder, or both in a human subject comprising administering</b></p>			
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				<p>to the human subject in need thereof an amount of the crystalline form of psilocybin.HCl according to claim 1 that is equivalent to about 10 mg to about 50 mg of psilocybin, wherein the neurological disorder, psychiatric disorder, or both comprises depression, addiction, substance use disorder, anxiety, post-traumatic stress disorder, suicidal ideation, bipolar disorder, schizophrenia, stroke, traumatic brain injury, or a combination thereof.</p> <p>17. A method of treating a neurological disorder, a psychiatric disorder, or both in a human subject comprising administering to the human subject in need thereof an amount of the crystalline form of psilocybin.HCl according to claim 5 that is equivalent to about 10 mg to about 50 mg of psilocybin, wherein the neurological disorder, psychiatric disorder, or both comprises depression, addiction, substance use disorder, anxiety, post-traumatic stress disorder, suicidal ideation, bipolar disorder, schizophrenia, stroke, traumatic brain injury, or a combination thereof.</p> <p>18. The method of claim 17, wherein the neurological disorder, psychiatric disorder, or both comprises treatment resistant depression.</p> <p>20. The method of claim 17, wherein the method comprises orally administering to the human subject in need thereof an amount of the crystalline form of psilocybin.HCl according to claim 5 that is equivalent to about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, or about 50 mg of psilocybin.</p> <p>22. A method of treating a neurological disorder, a psychiatric disorder, or both in a human subject comprising administering to the human subject in need thereof an amount of the crystalline form of psilocybin.HCl according to claim 9 that is equivalent to about 10 mg to about 50 mg of psilocybin, wherein the neurological</p>			
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					<p><b>disorder, psychiatric disorder, or both comprises depression</b>, addiction, substance use disorder, anxiety, post-traumatic stress disorder, suicidal ideation, bipolar disorder, schizophrenia, stroke, traumatic brain injury, or a combination thereof.</p> <p>23. The <b>method of claim 22</b>, wherein the <b>neurological disorder, psychiatric disorder, or both comprises treatment resistant depression</b>.</p> <p>25. The <b>method of claim 22</b>, wherein the method comprises <b>orally administering to the human subject in need thereof an amount of the crystalline form of psilocybin.HCl according to claim 9</b> that is equivalent to about <b>10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, or about 50 mg of psilocybin</b>.</p> <p>26. A pharmaceutical composition, comprising the <b>crystalline form of psilocybin.HCl</b> according to claim 10, and a pharmaceutically acceptable excipient.</p> <p>27. A method of <b>treating a neurological disorder, a psychiatric disorder, or both in a human subject comprising administering to the human subject in need thereof an amount of the crystalline form of psilocybin.HCl according to claim 10</b> that is equivalent to about <b>10 mg to about 50 mg of psilocybin</b>, wherein the <b>neurological disorder, psychiatric disorder, or both comprises depression</b>, addiction, substance use disorder, anxiety, post-traumatic stress disorder, suicidal ideation, bipolar disorder, schizophrenia, stroke, traumatic brain injury, or a combination thereof.</p> <p>28. The <b>method of claim 27, wherein the neurological disorder, psychiatric disorder, or both comprises treatment resistant depression</b>.</p>			
US20220169668	Pending	WIPO applications: PCT/IB2020/05368 4	METHODS OF TREATING NEUROCOGNITIVE	Compass Pathfinder Limited	1. A method for treating one or more neurocognitive disorders in a subject in need thereof, the method comprising <b>administering</b>	Y	N	N

	<p><u>Priority documents:</u>  U.S. 62/946,159  (12/10/2019)  U.S. 62/893,611  (08/29/2019)  U.S. 62/893,110  (08/28/2019)  U.S. 62/835,485  (04/17/2019)  U.S. 62/835,484  (04/17/2019)  U.S. 62/835,482  (04/17/2019)  U.S. 62/835,481  (04/17/2019)  U.S. 62/835,480  (04/17/2019)  U.S. 62/835,479  (04/17/2019)  U.S. 62/835,478  (04/17/2019)  U.S. 62/835,477  (04/17/2019)  U.S. 62/835,476  (04/17/2019)  U.S. 62/835,474  (04/17/2019)  U.S. 62/835,472  (04/17/2019)  U.S. 62/835,465  (04/17/2019)  U.S. 62/835,464  (04/17/2019)  U.S. 62/835,460  (04/17/2019)  U.S. 62/835,458  (04/17/2019)  U.S. 62/835,450  (04/17/2019)  U.S. 62/835,449  (04/17/2019)</p>	<p>DISORDERS,  CHRONIC PAIN  AND REDUCING  INFLAMMATION</p>	<p><b>to the subject a therapeutically effective amount of psilocybin</b> or an active metabolite thereof.</p> <p>5. The method of any one of claims 1- 4, wherein the subject has at least one <b>comorbidity</b>, and wherein administration of psilocybin ameliorates the comorbidity.</p> <p>6. The method of claim 5, wherein the <b>comorbidity is</b> hypertension, connective tissue disease, <b>depression</b>, diabetes, or chronic pulmonary disease.</p> <p>7. A method for treating a Parkinsonian syndrome or symptom thereof in a subject in need thereof, <b>the method comprising administering to the subject a therapeutically effective amount of psilocybin</b> or an active metabolite thereof.</p> <p>10. The method of claim 7 or 8, <b>wherein the subject has a neuropsychiatric disturbance, and wherein the neuropsychiatric disturbance is</b> dementia, <b>depression</b>, psychosis, apathy, anxiety, or hallucinations, or combinations thereof.</p> <p><b>13.</b> A method for treating attention-deficit hyperactivity (ADHD) disorder in a subject in need thereof, <b>the method comprising administering to the subject a therapeutically effective amount of psilocybin</b> or an active metabolite thereof.</p> <p>15. The method of <b>claim 13</b> or 14, <b>wherein subject has a comorbidity.</b></p> <p>16. The method of <b>claim 15</b>, wherein <b>the comorbidity is selected from</b> oppositional defiant disorder, learning difficulties, <b>depression</b>, anxiety, bipolar disorder, substance use disorders, autism spectrum disorders, personality disorder, obsessive compulsive disorder, or combinations thereof.</p> <p>40. A method of treating chronic pain in a subject in need thereof, <b>the method comprising administering to the subject a</b></p>			
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				<p>therapeutically effective amount of psilocybin or an active metabolite thereof.</p> <p>42. The method of claim 40, wherein administering the psilocybin also ameliorates one or more conditions comorbid with the chronic pain.</p> <p>43. The method of claim 42, wherein the condition comorbid with the chronic pain is a mood disorder.</p> <p>44. The method of claim 43, wherein the mood disorder is depression.</p> <p>47. A method of reducing inflammation in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof.</p> <p>54. The method of any one of claims 47- 52, wherein reducing inflammation in the subject treats or prevents a mood disorder in the subject.</p> <p>55. The method of claim 54, wherein the mood disorder is depression.</p> <p>66. A method for treating a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof; wherein the subject is recovering from a stroke</p> <p>69. The method of any one of claims 63- 68, wherein the subject has depression.</p> <p>70. The method of claim 69, wherein the administration of psilocybin alleviates depression in the subject.</p> <p>71. A method for treating amyotrophic lateral sclerosis (ALS) a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of psilocybin or an active metabolite thereof.</p>			
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					<p>74. The method of any one of <b>claims 71- 73</b>, wherein <b>the subject has depression</b>.</p> <p>75. The method of <b>claim 74</b>, wherein <b>the administration of psilocybin alleviates depression in the subject</b>.</p>			
US2023000883	Pending	<p><u>U.S. Patents</u> 11564935 11738035</p> <p><u>U.S. applications</u> 18/210,526</p> <p><u>WIPO applications</u> PCT/IB2020/05368 7</p> <p><u>Priority documents</u> U.S. 62/946,159 (12/10/2019) U.S. 62/893,611 (08/28/2019) U.S. 62/893,110 (08/28/2019) U.S. 62/835,485 (04/17/2019) U.S. 62/835,482 (04/17/2019) U.S. 62/835,481 (04/17/2019) U.S. 62/835,484 (04/17/2019) U.S. 62/835,480 (04/17/2019) U.S. 62/835,479 (04/17/2019) U.S. 62/835,478 (04/17/2019) U.S. 62/835,477 (04/17/2019) U.S. 62/835,476 (04/16/2019) U.S. 62/835,474 (04/17/2019) U.S. 62/835,472 (04/17/2019) U.S. 62/835,465 (04/17/2019)</p>	Methods for treating anxiety disorders, headache disorders, and eating disorders with psilocybin	Compass Pathfinder Limited	<p>1. <b>A method of treating an anxiety disorder in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of crystalline psilocybin</b>, wherein the <b>crystalline psilocybin is characterized by XRPD peaks at 11.5±0.1, 12.0±0.1, 14.5±0.1, 17.5±0.1 and 19.7±0.1°2θ, and wherein the crystalline psilocybin has a chemical purity of greater than 97% as determined by HPLC analysis.</b></p> <p>8. The method of <b>claim 1</b>, wherein the <b>subject has one or more conditions comorbid with an anxiety disorder</b>.</p> <p>9. The method of <b>claim 8</b>, wherein the <b>one or more conditions comorbid with an anxiety disorder is a mood disorder, major depressive disorder, bipolar disorder, schizophrenia, an eating disorder, attention deficit/hyperactivity disorder, epilepsy, cardiovascular disease, migraine, a headache disorder, irritable bowel syndrome, dementia, Alzheimer's disease, Parkinson's disease, or combinations thereof</b>.</p> <p>11. <b>A method of preventing or treating a cluster headache in a subject in need thereof, the method comprising administering to the subject a therapeutically effect amount of crystalline psilocybin</b>, wherein the <b>crystalline psilocybin is characterized by XRPD peaks at 11.5±0.1, 12.0±0.1, 14.5±0.1, 17.5±0.1 and 19.7±0.1°2θ, and wherein the crystalline psilocybin has a chemical purity of greater than 97% as determined by HPLC analysis.</b></p> <p>13. The method of <b>claim 11</b>, wherein the <b>subject has one or more diseases, disorders, or conditions comorbid with a cluster headache</b>.</p>	Y	N	N



		<p>U.S. 62/835,464 (04/17/2019) U.S. 62/835,460 (04/17/2019) U.S. 62/835,458 (04/17/2019) U.S. 62/835,450 (04/17/2019) U.S. 62/835,449 (04/17/2019)</p>		<p>14. The method of <b>claim 13</b>, wherein the one or more diseases, disorders, or conditions comorbid with a cluster headache is sleep apnea, <b>depression</b>, anxiety, aggressive behavior, suicidal ideation, or bipolar disorder.</p> <p>16. A method of preventing or treating a <b>migraine</b> in a subject in need thereof, the method comprising administering to the subject a therapeutically effect amount of crystalline psilocybin, wherein the crystalline psilocybin is characterized by XRPD peaks at <b>11.5±0.1, 12.0±0.1, 14.5±0.1, 17.5±0.1 and 19.7±0.1°2θ</b>, and wherein the crystalline psilocybin has a chemical purity of greater than 97% as determined by HPLC analysis.</p> <p>19. The method of <b>claim 16</b>, wherein the subject has one or more diseases, disorders, or conditions comorbid with a migraine.</p> <p>20. The method of <b>claim 19</b>, wherein the one or more diseases, disorders, or conditions comorbid with a migraine is stroke, vascular brain lesions, coronary heart disease, patent foramen ovale, hypertension, <b>depression</b>, anxiety, bipolar disorder, panic disorder, suicide, restless leg syndrome, epilepsy, inflammatory bowel disease, or asthma.</p> <p>22. A method for treating an eating disorder in a subject in need thereof, the method comprising administering to the subject a therapeutically effective amount of crystalline psilocybin, wherein the crystalline psilocybin is characterized by XRPD peaks at <b>11.5±0.1, 12.0±0.1, 14.5±0.1, 17.5±0.1 and 19.7±0.1°2θ</b>, and wherein the crystalline psilocybin has a chemical purity of greater than 97% as determined by HPLC analysis.</p> <p>27. The method of <b>claim 22</b>, wherein the subject has one or more conditions comorbid with an eating disorder.</p> <p>28. The method of <b>claim 27</b>, wherein the one or more conditions comorbid with an eating</p>			
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					<p>disorder is obesity, one or more conditions related to obesity, or both.</p> <p>31. The method of <b>claim 27</b>, wherein the one or more conditions comorbid with an eating disorder is a psychiatric disorder selected from the group consisting of schizophrenia, schizoaffective disorder, bipolar disorder, <b>major depressive disorder</b>, anxiety disorder, obsessive compulsive disorder, post-traumatic stress disorder, attention deficit hyperactivity disorder, autism, alcohol use disorder, drug use disorder, and suicide attempt.</p>			
US20230233584	Pending	<p><u>WIPO applications</u> PCT/IB2021/000488</p> <p><u>Priority documents</u> U.S. 63/058,386 (07/29/2020)</p>	EXTENDED RELEASE 5-HT RECEPTOR AGONISTS FOR NEUROLOGICAL CONDITIONS	Diamond Therapeutics Inc.	<p>40. A method for improving symptoms of a <b>cognitive or neuropsychiatric disorder</b>, in an individual in need thereof, <b>comprising</b>:</p> <p>a. <b>administering to the individual a therapeutically effective amount of psilocybin</b> or psilocin, or a pharmaceutically acceptable salt thereof, and</p> <p>b. maintaining a plasma concentration of an active form of psilocybin or psilocin (i) at or above a minimum therapeutically effective threshold in the individual and (ii) below a hallucinogenic threshold in the individual for more than or equal to two hours.</p> <p>46. The method of <b>claim 40</b>, wherein the <b>cognitive or neuropsychiatric disorder is an anxiety, attention, or depression disorder</b>.</p> <p>47. The method of <b>claim 46</b>, wherein the <b>depression disorder is major depressive disorder</b>.</p> <p>59. The method of <b>claim 40</b>, wherein the <b>therapeutically effective amount of psilocybin</b> or psilocin, or a pharmaceutically acceptable salt thereof <b>is administered orally</b>.</p>	Y	Y	N
US20220273680	Pending	<p><u>U.S. applications</u> 17/940,950</p> <p><u>WIPO applications</u> PCT/US2020/046149</p> <p><u>Priority documents</u> U.S. 62/886,090 (08/13/2019)</p>	Methods of Treating Psychological and Brain Disorders	University of Maryland, Baltimore	<p>1. A <b>method for preventing or treating a psychological disorder, comprising the step of: administering a serotonin agonist in combination with a serotonin receptor 2A antagonist</b>, wherein said agonist is administered separately, sequentially or simultaneously with said antagonist.</p> <p>2. The method of <b>claim 1</b>, wherein said <b>serotonin agonist is psilocybin</b>, psilocin,</p>	Y	N	N

				<p>baecocystin, norbaecocystin, lisurgide, LSD, dimethyltryptamine, carboxamindotryptamine, ibogaine, 3,4-methylenedioxy-methamphetamine (MDMA) or a compound that promotes a release of serotonin or a combination thereof.</p> <p>11. The method of <b>claim 1, wherein the psychological disorder is depression,</b> psychotic disorder, schizophrenia, schizophreniform disorder (acute schizophrenic episode), schizoaffective disorder; bipolar I disorder (mania, manic disorder, manic-depressive psychosis), bipolar II disorder, <b>major depressive disorder with psychotic feature (psychotic depression),</b> delusional disorders (paranoia), shared Psychotic Disorder (shared paranoia disorder), Brief Psychotic disorder (other and unspecified Reactive Psychosis), psychotic disorder not otherwise specified (unspecified psychosis), paranoid personality disorder, schizoid personality disorder, schizotypal personality disorder, anxiety disorder, panic disorder, panic attacks, agoraphobia, attention deficit syndrome, premenstrual dysphoric disorder, premenstrual syndrome, ADHD, ADD, anorexia nervosa, antisocial personality disorder, autism, addiction, avoidant personality disorder, bipolar disorder, bulimia nervosa, borderline personality disorder, catatone schizophrenia, chronic motor or vocal tic disorder, conversion disorder, cyclothymia, dependent personality disorder, delier, dementia, depersonalization disorder, depression, Dhat syndrome, dissociative amnesia, dissociative fugue, dissociative identity disorder, dissociative disorder, dissociative disorder, not otherwise specified, dysthymic disorder, Da Costa's syndrome, ephobophilia, exhibitionism, generalized anxiety disorder, grandiose delusions, hypochondria, hoarding disorder, intermittent explosive disorder, jealousy, kleptomania, Kluver-Bucy syndrome, maternity psychosis, mental retardation, monomania, Munchhausen syndrome, misophony, narcissistic personality disorder, obsessive-compulsive disorder, oniomania, organic personality disorder, phobia, paranoid personality disorder,</p>			

				<p>paranoid delusions, passive-aggressive personality, pathological gambling, pathological lying, personality disorder not otherwise defined, pervasive developmental disorder, pica, pain disorder, post encephalitic syndrome, postpartum depression, posttraumatic stress disorder, psychosis, psychotic disorder due to substance use, pyromania, querulant delusions, ruminational disorder, schizophrenia, schizoaffective disorder, schizoid personality disorder, schizotypal personality disorder, separation anxiety, social phobia, somatisation disorder, somatic delusion, somatoform disorder, syndrome of Capgras, syndrome of Cotard, syndrome of Ganser, syndrome of Gilles de la Tourette, selective mutism, theatrical personality disorder, trichotillomania, or undifferentiated somatoform disorder.</p> <p>12. A <b>method for preventing or treating a psychological disorder, comprising the step of: administering an agonist of serotonin receptors in combination with a serotonin receptor 2A antagonist</b>, wherein said agonist is administered separately, sequentially or simultaneously with said antagonist.</p> <p>13. The method of <b>claim 12, wherein said agonist of serotonin receptors is an agonist of serotonin receptor 1B, serotonin receptor 4, serotonin receptor 6, or serotonin receptor 7.</b></p> <p>18. The method of <b>claim 13, wherein said serotonin agonist is a derivative of psilocybin</b> or psilocin.</p> <p>24. The method of <b>claim 12, wherein the psychological disorder is depression,</b> psychotic disorder, schizophrenia, schizophreniform disorder (acute schizophrenic episode), schizoaffective disorder; bipolar I disorder (mania, manic disorder, manic-depressive psychosis), bipolar II disorder, <b>major depressive disorder with psychotic feature (psychotic depression),</b> delusional disorders (paranoia), shared Psychotic Disorder (shared paranoia disorder), Brief Psychotic disorder (other and</p>			
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				<p>unspecified Reactive Psychosis), psychotic disorder not otherwise specified (unspecified psychosis), paranoid personality disorder, schizoid personality disorder, schizotypal personality disorder, anxiety disorder, panic disorder, panic attacks, agoraphobia, attention deficit syndrome, premenstrual dysphoric disorder, premenstrual syndrome, ADHD, ADD, anorexia nervosa, antisocial personality disorder, autism, addiction, avoidant personality disorder, bipolar disorder, bulimia nervosa, borderline personality disorder, catatone schizophrenia, chronic motor or vocal tic disorder, conversion disorder, cyclothymia, dependent personality disorder, delier, dementia, depersonalization disorder, depression, Dhat syndrome, dissociative amnesia, dissociative fugue, dissociative identity disorder, dissociative disorder, dissociative disorder, not otherwise specified, dysthymic disorder, Da Costa's syndrome, ephobophilia, exhibitionism, generalized anxiety disorder, grandiose delusions, hypochondria, hoarding disorder, intermittent explosive disorder, jealousy, kleptomania, Kluver-Bucy syndrome, maternity psychosis, mental retardation, monomania, Munchhausen syndrome, misophony, narcissistic personality disorder, obsessive-compulsive disorder, oniomania, organic personality disorder, phobia, paranoid personality disorder, paranoid delusions, passive-aggressive personality, pathological gambling, pathological lying, personality disorder not otherwise defined, pervasive developmental disorder, pica, pain disorder, post encephalitic syndrome, postpartum depression, posttraumatic stress disorder, psychosis, psychotic disorder due to substance use, pyromania, querulant delusions, ruminational disorder, schizophrenia, schizoaffective disorder, schizoid personality disorder, schizotypal personality disorder, separation anxiety, social phobia, somatisation disorder, somatic delusion, somatoform disorder, syndrome of Capgras, syndrome of Cotard, syndrome of Ganser, syndrome of Gilles de la Tourette, selective mutism, theatrical personality disorder, trichotillomania, or undifferentiated somatoform disorder.</p>			
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US20220323378	Pending	<u>Priority documents</u> U.S. 63/170,486 (04/03/2021) U.S. 63/173,795 (04/12/2021) U.S. 63/177,601 (04/21/2021) U.S. 63/245,592 (09/17/2021) U.S. 63/247,773 (09/23/2021) U.S. 63/277,998 (11/10/2021)	Pharmaceutical Compositions and Methods for Treating Mental Health Disorders and Promoting Neural Plasticity	Shawn Joseph	<p>1. A <b>composition comprising a serotonergic psychedelic compound and a ketamine compound</b> in synergistically effective amounts <b>for treating a patient suffering from a brain condition or disorder and/or promoting neural plasticity in a patient in need thereof.</b></p> <p>2. The composition of <b>claim 1, wherein the serotonergic psychedelic compound is selected from the group consisting of psilocybin, psilocin, a psilocybin derivative, tryptamine, phenethylamine, lysergamide, and one or more combinations thereof.</b></p> <p>3. The composition of <b>claim 1, wherein the psychedelic compound is selected from the group consisting of psilocybin, psilocin, and a psilocybin derivative.</b></p> <p>6. A composition according to <b>claim 1, wherein the brain condition or disorder is depression.</b></p> <p>7. A <b>method of treating a patient suffering from a brain condition or disorder and/or promoting neural plasticity in a patient in need thereof comprising administering to the patient a composition according to claim 1.</b></p> <p>12. The method of <b>claim 7, wherein the brain condition or disorder comprises a major depressive disorder.</b></p>	N	N	Y
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US20220016104	Pending	<u>U.S. Patents</u> 11590120  <u>U.S. applications</u> 16/211,281 15/494,503  <u>Priority documents</u> U.S. 62/365,982 (07/23/2016)	COMPOSITIONS AND METHODS FOR TREATING DEPRESSION	Turtle Bear Holdings LLC	<p>1. A <b>method for reducing symptoms of depression</b> or anxiety in a subject in need thereof comprising: <b>administering a therapeutically effective amount of a composition comprising psilocybin</b> or psilocin sufficient to reduce the symptoms of depression or anxiety in the subject.</p> <p>4. The method of <b>claim 1, wherein the composition comprises 0.1 mg to 10 mg; 0.1 mg to 0.6 mg; 0.6 mg to 0.9 mg; 0.9 mg to 10 mg; or 1 mg to 10 mg of psilocybin</b> or psilocin <b>per 70 kg of the subject's body mass</b>.</p> <p>7. The method of <b>claim 1, wherein the composition is administered in a capsule</b>.</p> <p>11. A <b>method for reducing symptoms of depression</b> or anxiety in a subject in need thereof <b>comprising: administering a composition comprising 0.1 mg to 10 mg of psilocybin or psilocin per 70 kg of the subject's body mass</b> sufficient to reduce the symptoms of depression or anxiety in the subject.</p> <p>14. The method of <b>claim 11, wherein the composition comprises 0.1 mg to 10 mg; 0.1 mg to 0.6 mg; 0.6 mg to 0.9 mg; 0.9 mg to 10 mg; or 1 mg to 10 mg of psilocybin</b> or psilocin per 70 kg of the subject's body mass.</p> <p>17. The method of <b>claim 11, wherein the composition is administered in a capsule</b>.</p>	N	Y	Y
US20230218603	Pending	<u>U.S. Patents</u> 11590120  <u>U.S. applications</u> 16/211,281 15/494,503  <u>Priority documents</u> U.S. 62/365,982 (07/23/2016)	PSILOCYBIN COMPOSITIONS	Turtle Bear Holdings LLC	<p>1. A <b>method for reducing symptoms of depression in a subject in need thereof</b>, the method comprising: <b>administering a dosage form comprising: 0.1 to 10 mg of baeocystin, norbaeocystin, salts thereof, or combinations thereof; and 1 to 50 mg of niacin;</b> sufficient to reduce the symptoms of depression in the subject.</p> <p>2. The method of <b>claim 1</b>, wherein the <b>dosage form further comprises 0.1 to 10 mg of psilocybin</b>, psilocin, salts thereof, or combinations thereof.</p>	N	N	N

US20230059204	Pending	<u>Priority documents</u> U.S. 63/229,015 (08/03/2021) U.S. 63/324,288 (03/28/2022)	TRANSDERMAL MICRO-DOSING DELIVERY OF PHARMACEUTICAL AGENTS	Pike Therapeutics, Inc.	<p>1. A <b>transdermal and/or topical pharmaceutical composition comprising: at least one active agent selected from the group consisting of:</b></p> <p>about 0.1% to about 50% of an active agent selected from the group consisting of tetrahydrocannabinol (THC), cannabidiol (CBD), <b>psilocybin</b>, psilocin, lysergic acid diethylamine (LSD), and/or ibogaine, the free base thereof, salts thereof, isomers thereof, amorphous forms thereof, crystalline forms thereof, co-crystalline forms thereof, prodrugs thereof, analogs thereof, derivatives thereof, synthetic forms thereof, naturally derived forms thereof, active metabolites thereof, polymorph thereof, solid solution thereof, coated form thereof, and combinations thereof, further wherein the pharmaceutical composition comprises:</p> <p>about 10% to about 99.9% of an adhesive and/or polymer;</p> <p>optionally, about 0.1% to about 99% of a permeation enhancer;</p> <p>optionally, about 0.1% to about 99% of a solvent,</p> <p>wherein said pharmaceutical composition will have no or minimal hallucinogenic or psychoactive effect in a patient to whom the pharmaceutical composition is applied.</p> <p>3. The <b>pharmaceutical composition of claim 1</b>, wherein the pharmaceutical formulation provides a dose of active agent to a patient equal to or greater than, for example, about 0.001 ng/day, 0.01 ng/day, 0.025 ng/day, 0.05 ng/day, 0.1 ng/day, 0.25 ng/day, 0.5 ng/day, 1 ng/day, 10 ng/day, 25 ng/day, 50 ng/day, 100 ng/day, 250 ng/day, 500 ng/day, 1000 ng/day, 0.001 microgram/day, 0.01 microgram/day, 0.025 microgram/day, 0.050 microgram/day, 0.1 microgram/day, 0.25 microgram/day, <b>0.5 microgram/day, 1 microgram/day, 2.5 microgram/day, 5 microgram/day, 10 microgram/day, 25 microgram/day, 50 microgram/day</b>, 100 microgram/day, 250 microgram/day, 500 microgram/day, about 0.001 mg/day, 0.01 mg/day, 0.025 mg/day, 0.05 mg/day, 0.1 mg/day, 0.25 mg/day, 0.5 mg/day, 1 mg/day, 10 mg/day, or 25 mg/day.</p>	N	N	Y
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					33. The <b>pharmaceutical composition of claim 1 indicated for the treatment and/or prevention and/or control</b> of chronic pain, multiple sclerosis, <b>severe depression (treatment resistant)</b> , major depressive disorder, obsessive-compulsive disorder, post-traumatic stress disorder, quitting smoking, alcohol addiction, cocaine addiction, opioid addiction, anxiety (stress), adjustment disorder, prolonged grief disorder (PGD), adult ADHD, cluster headaches, and cancer related or other end-of-life psychological distress in a patient.			
WO2022261263	Published	<u>Patent family members:</u> No relevant national stage applications have been published for this family at the date of generation of this document  <u>Priority documents</u> U.S. 63/208,339 (06/08/2021) U.S. 63/298,493 (01/11/2022)	Methods of treating neuropsychiatric disorders	Gilgamesh Pharmaceuticals, Inc.	1. A <b>method of treating a neuropsychiatric disorder in a patient in need thereof, comprising administering to the patient an effective amount of an orexin receptor antagonist and further comprising administering to the patient an effective amount of a serotonin receptor agonist or an NMDA receptor antagonist.</b>  67. The method of any of <b>claims 1-49, wherein the serotonin receptor agonist is psilocybin.</b>  68. The method of any of <b>claims 1-49, wherein the psilocybin is administered orally at a dose of 1-40 mg.</b>  77. The method of <b>claim 67</b> , wherein the <b>psilocybin is administered as an oral dosage form, wherein, the oral dosage form comprises: crystalline psilocybin in the form Polymorph A characterized by peaks in an XRPD diffractogram at 11.5, 12.0, 14.5, 17.5, and 19.7°2Q±0.1°2Q, wherein the crystalline psilocybin has a chemical purity of greater than 97% by HPLC, and silicified microcrystalline cellulose.</b>  87. The method of any of <b>claims 1-86</b> , wherein the <b>neuropsychiatric disorder is a mood disorder.</b>  88. The method of <b>claim 87, wherein the mood disorder is depression.</b>	N	N/A	N

					89. The method of <b>claim 88, wherein the depression is selected from the group consisting of major depressive disorder, persistent depressive disorder, postpartum depression, premenstrual dysphoric disorder, seasonal affective disorder, psychotic depression, disruptive mood dysregulation disorder, substance/medication-induced depressive disorder, prolonged or pathological grief, and depressive disorder due to another medical condition.</b>			
WO2022195489	Published	<u>Patent family members:</u> No relevant national stage applications have been published for this family at the date of generation of this document  <u>Priority documents</u> U.S. 63/161,070 (3/15/2021)	IMPROVED METHODS FOR THE USE OF PSYCHEDELICS	Tryp Therapeutics, Inc.	1. A <b>method of treating a psychological disorder in a subject, the method comprising: administering to a subject having a psychological disorder an amount of a psychedelic</b> sufficient to induce a dissociative state in the subject less than 30 minutes after administration; and thereafter maintaining the mean plasma concentration of the psychedelic at a predetermined value to maintain the dissociative state during a therapeutic window; <b>wherein the psychedelic is psilocybin, psilocin, a co-crystal, a co-former, or a salt thereof, or a combination thereof.</b>  9. The method of any one of <b>claims 1-8, wherein the administration of the psychedelic is by intravenous administration.</b>  44. The method of any one of <b>claims 1, 6, 7, and 9-43, wherein the mean plasma concentration of the psychedelic is maintained at the predetermined value during the therapeutic window by administration of a maintenance dose of the psychedelic.</b>  45. The method of <b>claim 44, wherein the maintenance dose of the psychedelic is administered by continuous or intermittent administration of the psychedelic.</b>  48. The method of <b>claim 45, wherein the maintenance dose of the psychedelic is administered by intermittent administration of the psychedelic and the intermittent administration is via a subcutaneous, oral,</b>	N	N/A	Y

					<p>transdermal, intramuscular, intranasal, intranasal/pharyngeal, or buccal route.</p> <p>63. The method of any one of <b>claims 1-62</b>, wherein the <b>total amount of psychedelic that is administered to the subject is up to at or about 1.0 mg, 1.5 mg, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg or 20 mg per subject</b>, or a range defined by any of the foregoing.</p> <p>78. The method of any one of <b>claims 1-7 and 9-77</b>, wherein the <b>psychological disorder is selected from the group consisting of PTSD</b>, alcohol addition, drug addiction, <b>treatment resistant depression</b>, anxiety, end of life anxiety, an eating disorder, fibromyalgia, neuropathic pain, phantom limb pain, hypothalamic induced obesity, Prader-Willi syndrome, and binge-eating disorder.</p>			
WO2022212854	Published	<p><u>Patent family members:</u> No relevant national stage applications have been published for this family at the date of generation of this document</p> <p><u>Priority documents</u> U.S. 63/169,722 (04/01/2021) U.S. 63/274,308 (11/01/2021) U.S. 63/294,801 (12/29/2021) U.S. 63/308,206 (02/09/2022)</p>	Methods and compositions relating to psychedelics and serotonin receptor modulators	Terran Biosciences Inc., University of Maryland, Baltimore	<p>44. A <b>method of treating a disease or disorder in a subject in need thereof, the method comprising administering to the subject a composition comprising: a) a psychedelic; b) a serotonin receptor modulator;</b> and c) an excipient, wherein the serotonin receptor modulator is released at most about 3 hours prior to the release of the psychedelic.</p> <p>45. The method of <b>claim 44, wherein the disease or disorder is depression</b> or a disease or disorder related to depression.</p> <p>46. The method of <b>claim 44, wherein the depression is major depressive disorder, persistent depressive disorder, bipolar disorder, treatment resistant depression (TRD)</b>, postpartum depression, premenstrual dysphoric disorder, or seasonal affective disorder.</p> <p>57. The method of any one of <b>claims 44-47, wherein the psychedelic is psilocybin</b> or a pharmaceutically acceptable salt, solvate, metabolite, deuterated analogue, derivative, or prodrug thereof.</p>	N	N/A	N

					80. The method of any one of <b>claims 44-74, wherein the psychedelic is provided at a dose of about 10 mg</b> to about 100 mg.			
WO2023114529	Published	<p><u>Patent family members:</u> No relevant national stage applications have been published for this family at the date of generation of this document</p> <p><u>Priority documents</u> U.S. 63/291,333 (12/17/2021)</p>	PHARMACOACTIVE FORMULATIONS FOR DELIVERY OF PSYCHEDELIC COMPOUNDS	Bennes, Inc.	<p>1. A <b>lozenge for rapid delivery of a psychedelic compound through the oral mucosa</b>, the lozenge comprising: a water-insoluble polymer; and one or more psychedelic compounds.</p> <p>4. The <b>lozenge of claim 1, wherein the psychedelic compound is selected from a 5-HT2A agonist selected from LSD, psilocybin, DOI (±)-1-(2,5-dimethoxyphenyl)-2-aminopropane hydrochloride; (R)-DOI ((R)-1-(2,5-dimethoxy-4-iodophenyl)-2-aminopropane); LA-SS-Az (2'S,4'S)-(+)-9,10-Didehydro-6-methylergoline-8B-(trans-2,4-dimethyl-azetidide); 2C-BCB (4-Bromo-3,6-dimethoxybenzocyclobuten-1-yl) methylamine); ayahuasca; 3,4,5-trimethoxyphenethylamine (mescaline); 5-methoxy-N,N-dimethyltryptamine (5-meo-DMT) and ibogaine, and combinations thereof.</b></p> <p>8. The <b>lozenge of claim 1, wherein the psychedelic agent is used to treat at least one symptom selected from</b> of obsessive compulsive disorder (OCD), pain, chronic pain, anxiety disproportionate to severity of physical complaints, psychological disorder, <b>major depression</b>, melancholic depression, atypical depression, dysthymia, pain disorder, body dysmorphia, conversion, hysteria, neurological conditions without identifiable cause, psychosomatic illness, pain management in relation to existing physical condition, irritability, fibromyalgia, post-traumatic stress disorder (PTSD), cluster headaches, paranoia, psychosis, anxiety, panic attacks, flashbacks, smoking addiction, alcohol addiction, cocaine addiction, improving creativity, boosting physical energy level, attaining emotional balance, increasing performance on problems-solving tasks, treating anxiety, treating depression, treating addiction, or any combination thereof.</p> <p>20. A <b>method for making a lozenge according to claim 1, the method comprising:</b> (i) <b>preparing an admixture of</b></p>	N	N/A	N

					<p><b>0.10-200 mg of a desired psychedelic compound</b>, ethyl cellulose, and optionally, an essential oil and a sweetening agent; and (ii) setting the admixture at room temperature and ambient humidity until a soft, pliable, and tacky lozenge material is formed.</p>			
WO2022061196	Published	<p><u>Patent family members:</u> No national stage applications have been published for this family at the date of generation of this document</p> <p><u>Priority documents</u> U.S. 63/080,679 (09/18/2020)</p>	<p>NOVEL FORMULATIONS OF PSILOCYBIN AND PSILOCIN COMPOUNDS AS SEROTONIN AGONISTS IN COMBINATION WITH 3,4 METHYLENEDIOXY METHAMPHETAMINE (MDMA)</p>	Mydecine Innovations Group Inc	<p>124. A <b>method of treating a serotonin receptor related disease or condition, comprising the step of administering to a subject in need thereof, with a therapeutically effective amount of a tryptamine compound and an entactogen compound</b>, wherein said tryptamine compound and said entactogen compound modulate serotonin receptor activity in said subject, and wherein said serotonin receptor is activated to approximately the same level as the activation by said tryptamine compound without said entactogen.</p> <p>126. The method of any of <b>claims 124-125, wherein said tryptamine compound comprises psilocybin</b>, or psilocin.</p> <p>143. The method of <b>claim 124, wherein said subject comprises a human subject</b>.</p> <p>144. The method of <b>claim 143, wherein said human subject comprise a human subject suffering from, or at risk from suffering from serotonin receptor related disease or condition</b>.</p> <p>146. The method of any of <b>claims 144-145 wherein said serotonin receptor related disease or condition is selected from the group consisting of:</b> schizophrenia, addiction, <b>depression</b>, obsessive compulsive disorder (OCD), cluster headaches, dementia, Alzheimer's disease, paralysis, attention deficit-hyperactivity disorder (ADHD), eating disorders, post-traumatic stress disorder (PTSD), anxiety, and autism.</p> <p>154. The method of any of <b>claims 124-150, wherein the dose of psilocybin or psilocin compound is in a dosage range of 10pg to 1 g/kg or 10pg to 200 mg/kg body weight of the subject being treated</b>, per day.</p>	N	N/A	N

WO2022115796	Published	<u>Priority Documents:</u> U.S. 63/119,529 (11/30/2020)	COMPOSITIONS AND METHODS FOR TREATING NEUROLOGICAL CONDITIONS	Wesana Health Inc.	<p>1. A method for reducing a symptom of traumatic brain injury or post-concussion syndrome in a subject, the method comprising:</p> <ul style="list-style-type: none"> <li>(i) administering to the subject at least one loading dose comprising between about 5 mg and 30 mg psilocybin, inclusive; and</li> <li>(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.</li> </ul> <p>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.</p> <p>5. The method of any of claims 1-4 wherein the loading dose comprises about 10 mg psilocybin.</p> <p>6. The method of any of claims 1-5, wherein the loading dose comprises about 25 mg psilocybin.</p> <p>7. The method of any of claims 1-6, wherein the loading dose comprises about 30 mg psilocybin.</p> <p>9. The method of any of claims 1-8, wherein the psilocybin of the loading dose comprises synthetic psilocybin.</p> <p>10. The method of any of claims 1-9, wherein the psilocybin of the maintenance dose comprises synthetic psilocybin.</p> <p>78. A method for reducing a symptom of traumatic brain injury or post-concussion syndrome in a subject, the method comprising:</p> <ul style="list-style-type: none"> <li>(i) administering to the subject at least one maintenance dose comprising between about 0.25 mg and about 0.3 mg psilocybin, inclusive; and</li> </ul>	Y	N/A	Y
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					<p><b>(ii) administering to the subject at least one maintenance dose comprising between about 1 mg to about 600 mg of CBD,</b> inclusive, wherein the subject has been suspected or diagnosed as having traumatic brain injury or post-concussion syndrome.</p> <p>79. The method of <b>claim 78, wherein the symptom of traumatic brain injury or postconcussion syndrome comprises</b> anxiety, <b>depression</b>, 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.</p> <p>80. The method of any of <b>claims 78-79, wherein the symptom of traumatic brain injury or post-concussion syndrome comprises</b> anxiety or <b>depression</b>.</p> <p>82. The method of any of <b>claims 78-81 wherein the symptom of traumatic brain injury or post-concussion syndrome comprises depression</b>.</p>			
WO2019073379	Published	<p><u>U.S. Patents</u> 10519175, 10947257, 10954259, 11149044, 11180517, 11447510, 11505564, 11629159</p> <p><u>U.S. Applications</u> 17/990,979, 18/135,265</p> <p><u>Priority Documents:</u></p>	Preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use	Compass Pathways Limited	<p>1. <b>Crystalline psilocybin in the form Polymorph A or Polymorph A', characterised by one or more of:</b></p> <p><b>a. peaks in an XRPD diffractogram at 11.5, 12.0 and 14.5 °2<math>\theta</math>±0.1°2<math>\theta</math>;</b></p> <p><b>b. peaks in an XRPD diffractogram at 11.5, 12.0 and 14.5 °2<math>\theta</math>±0.1°2<math>\theta</math>, further characterised by at least one further peak at 19.7, 20.4, 22.2, 24.3 or 25.7 °2<math>\theta</math>±0.1°2<math>\theta</math>;</b></p> <p><b>c. an XRPD diffractogram as substantially illustrated in Figure 7a or 7b; or d. an endothermic event in a DSC thermogram having an onset temperature of between 205 and 220°C substantially as illustrated in Figure 8a or 8b.</b></p>	Y	N/A	N

		G.B. 1716505.1 (10/09/2017) G.B. 1810588.2 (06/28/2018) G.B. 1816438.4 (10/09/2018)			<p>13. A <b>pharmaceutical formulation comprising crystalline psilocybin in the form Polymorph A or Polymorph A'</b> as claimed in any preceding claim.</p> <p>14. A pharmaceutical formulation as claimed in <b>claim 13</b> which is <b>an oral dosage form</b>.</p> <p>15. A pharmaceutical formulation as claimed in <b>claim 13 or 14</b> wherein the <b>crystalline psilocybin in the form Polymorph A or Polymorph A'</b> is present in an <b>amount providing a dose of from 0.01mg/kg to 1mg/kg</b>.</p> <p>21. <b>Crystalline psilocybin in the form Polymorph A or Polymorph A'</b> as claimed in <b>claims 1 to 11</b> for use in treating drug resistant depression.</p> <p>24. <b>Crystalline psilocybin in the form Polymorph A (12A)</b> for use in in treating drug resistant depression.</p> <p>25. A method of <b>treating drug resistant depression comprising administering to a subject in need thereof an effective dose of crystalline psilocybin in the form Polymorph A (12A)</b>.</p>			
WO2023114097	Published	<p><u>Patent family members:</u> No national stage applications have been published for this family at the date of generation of this document</p> <p><u>Priority Documents:</u> U.S. 63/288,938 (12/13/2021)</p>	PSILOCYBIN AND AN ADJUNCTIVE SEROTONIN REUPTAKE INHIBITOR FOR USE IN THE TREATMENT OF TREATMENT-RESISTANT DEPRESSION	Compass Pathfinder Limited	<p>1. A <b>method of treating treatment-resistant depression in a subject in need thereof, the method comprising administering an effective amount of psilocybin</b> or an active metabolite thereof to the subject <b>as an adjunctive to Selective Serotonin Reuptake Inhibitor (SSRI) therapy</b>.</p> <p>6. The method of any one of <b>claims 1-5</b>, wherein <b>about 25 mg of psilocybin or an active metabolite thereof is administered to the subject</b>.</p> <p>35. The method of any one of <b>claims 1-34</b>, wherein the <b>psilocybin is administered by one of the following routes: oral, intravenous, intramuscular, parenteral, topical, inhalation, rectal, transmucosal, intranasal, buccal, vaginal, intrathecal, intraocular,</b></p>	N	N/A	N



					<p>transdermal, in utero, intralymphatic, or by direct tissue or organ injection.</p> <p>36. The method of <b>claim 35, wherein the psilocybin is administered orally.</b></p> <p>45. The method of any one of <b>claims 1-44</b>, wherein the <b>psilocybin has a chemical purity of greater than 97%</b> as determined by HPLC analysis.</p>			
WO2023086252	Published	<p><u>Patent family members:</u> No national stage applications have been published for this family at the date of generation of this document</p> <p><u>Priority documents:</u> U.S. 63/284,973 (12/01/2021) U.S. 63/277,407 (11/09/2021)</p>	TREATMENT OF TREATMENT RESISTANT DEPRESSION WITH PSILOCYBIN	Compass Pathfinder Limited	<p>1. A method of treating <b>treatment-resistant depression with psilocybin</b> in a subject that did not respond to a first dose of psilocybin, comprising <b>administering a second dose of psilocybin about 3 weeks after administering the first dose of psilocybin.</b></p> <p>2. A method of <b>treating treatment-resistant depression in a subject in need thereof, comprising administering a first dose of psilocybin to the subject;</b> measuring the subject's depressive symptoms using a clinical depression evaluation after administering the first dose of psilocybin; identifying the subject as a non-responder to the first dose of psilocybin; <b>and administering a second dose of psilocybin to the subject 3 weeks after administering the first dose.</b></p> <p>26. A method of <b>treating treatment-resistant depression in a subject that responded to a first dose of psilocybin,</b> comprising <b>administering a second dose at least about 26 weeks after administering the first dose.</b></p> <p>29. The method of any one of <b>claims 26-28</b>, wherein the subject experiences a <b>reduction in symptoms of depression after administering the first dose of psilocybin.</b></p>	N	N/A	N
WO2023114097	Published	<p><u>Patent family members:</u> No national stage applications have been published for this family at the date of generation of this document</p>	PSILOCYBIN AND AN ADJUNCTIVE SEROTONIN REUPTAKE INHIBITOR FOR USE IN THE TREATMENT OF TREATMENT-RESISTANT DEPRESSION	Compass Pathfinder Limited	<p>1. A method of <b>treating treatment-resistant depression in a subject in need thereof, the method comprising administering an effective amount of psilocybin</b> or an active metabolite thereof to the subject <b>as an adjunctive to Selective Serotonin Reuptake Inhibitor (SSRI) therapy.</b></p> <p>6. The method of any one of <b>claims 1-5, wherein about 25 mg of psilocybin</b> or an</p>	N	N/A	N

		<p>Priority documents: U.S. 63/288,938 (12/13/2021)</p>		<p>active metabolite thereof is administered to the subject.</p> <p>7. The method of any one of <b>claim 1-6</b>, wherein <b>at least one sign or symptom of depression is reduced by the administration of psilocybin</b>.</p> <p>35. The method of any one of <b>claims 1-34</b>, wherein the <b>psilocybin is administered by one of the following routes: oral</b>, intravenous, intramuscular, parenteral, topical, inhalation, rectal, transmucosal, intranasal, buccal, vaginal, intrathecal, intraocular, transdermal, in utero, intralymphatic, or by direct tissue or organ injection.</p> <p>45. The method of any one of <b>claims 1-44</b>, wherein the <b>psilocybin has a chemical purity of greater than 97%</b> as determined by HPLC analysis.</p>			
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### 3. Prior Art References

#### Scientific publications

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### Clinical trials

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“The Safety and Efficacy of Psilocybin in Patients With Treatment-resistant Depression and Chronic Suicidal Ideation” ClinicalTrials.gov ID: NCT05220410 (Registered 01/21/2022)

“Pilot RECAP Study in Healthy Volunteers (RECAP)” ClinicalTrials.gov ID: NCT04842045 (Registered 04/09/2021)

“Psilocybin for Psychological and Existential Distress in Palliative Care” ClinicalTrials.gov ID: NCT04754061 (Registered 02/15/2021)

“Psilocybin Treatment of Major Depressive Disorder With Co-occurring Alcohol Use Disorder (PsiloMDDAUD)” ClinicalTrials.gov ID: NCT04620759. (Registered 11/03/2020)

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