### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: NEONMIND BIOSCIENCES INC Confirmation No.:

Serial No.: 17/782,582 Group No.:

Filing or 371(c) Date: 03 December 2020 Examiner:

Entitled: USE OF PSILOCIN, PSILOCYBIN OR ANALOGS THEREOF IN WEIGHT LOSS,

TREATMENT OF OBESITY AND COMPULSIVE EATING DISORDER

### 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:

- Priority Doc. of Patent Doc. No. WO/2020/212951 "METHODS FOR TREATING ANXIETY DISORDERS, HEADACHE DISORDERS, AND EATING DISORDERS WITH PSILOCYBIN" (Filing date: 29 August 2019)
- 2. Int'l Pat. Doc. No. WO/2018/195455 "ASSESSING AND TREATING PSYCHEDELIC-RESPONSIVE SUBJECTS" (Publication date: 25 October 2018)
- Priority Doc. of Patent Doc. No. WO/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Filing date: 30 January 2019)
- 4. U.S. Pat. Doc. No. US/2018/0221396 "Compositions and methods comprising a psilocybin derivative" (Publication date: 09 August 2018)
- 5. Priority Doc. of Patent Doc. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Filing date: 19 November 2019)
- 6. BIGWOOD (1982) "Variation of psilocybin and psilocin levels with repeated flushes (harvests) of mature sporocarps of *Psilocybe cubensis* (earle) singer" Journal of Ethnopharmacology. 5(3):287-291.

- 7. PUBCHEM (2006) "4-Hydroxy-N-methyl-N-isopropyltryptamine" URL: <a href="https://pubchem.ncbi.nlm.nih.gov/compound/4-Hydroxy-N-methyl-N-isopropyltryptamine">https://pubchem.ncbi.nlm.nih.gov/compound/4-Hydroxy-N-methyl-N-isopropyltryptamine</a>
- 8. PUBCHEM (2007) "4-Hydroxy-N-methyl-N-ethyltryptamine" URL: https://pubchem.ncbi.nlm.nih.gov/compound/4-Hydroxy-N-methyl-N-ethyltryptamine

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.

U.S.S.N. 17/782,582	References
Pending Claims	Retricted
1. A method of	From the application of interest 17/782,582 paragraph [0005] "Many diet
treating compulsive	disorders exist, including binge eating disorder, also called compulsive
eating disorder, or of	eating disorder, where an individual will eat even when uncomfortably full
aiding in or causing	or not hungry, often eating much faster than normal with a loss of control
weight loss, or of	over how much or what is eaten."
treating obesity, or of	
treating a	
complication	1. Priority Patent Doc. No. of WO/2020/212951 "METHODS FOR
associated with	TREATING ANXIETY DISORDERS, HEADACHE DISORDERS, AND
obesity, or of altering	EATING DISORDERS WITH PSILOCYBIN" (Filing date: 29 August
a diet, in an individual	2019)
in need thereof,	
comprising	From paragraph [0159] "In some embodiments, a method of treating a
administering an	<b>patient</b> in need thereof comprising administering to the patient a
effective amount of a	therapeutically-effective dose of psilocybin, wherein the patient suffers
compound comprising	from Pica, Anorexia Nervosa, Bulimia Nervosa, or Binge-Eating
psilocin, psilocybin, or	disorder."
an analog thereof.	
	2. Int'l Pat. Doc. No. WO/2018/195455 "ASSESSING AND TREATING
	PSYCHEDELIC-RESPONSIVE SUBJECTS" (Publication date: 25 October
	2018)
	From claim 1 "A method of improving mental or physical well-being of a subject, the method comprising: (i) providing a subject, wherein based on a score of one or more predictors in the subject, the subject has been identified as likely to have a positive therapeutic response to a psychedelic agent; and (ii) following step (i), administering to the subject the psychedelic agent."
	From claim 3 "The method of claim 1 or 2, wherein the subject is obese, and the method comprises promoting weight loss in the subject."
	From <b>claim 53</b> "The method of any one of claims 1 -52, wherein the <b>psychedelic agent</b> is selected from lysergic acid diethylamide, <b>psilocybin</b> , and pharmaceutically acceptable salts thereof."
2. (canceled)	
3. (canceled)	
4. (canceled)	
5. A method of	2. Int'l Pat. Doc. No. WO/2018/195455 "ASSESSING AND TREATING
reducing food	PSYCHEDELIC-RESPONSIVE SUBJECTS" (Publication date: 25 October
cravings, improving	2018)
quality of diet,	
quanty of thet,	

increasing
metabolism,
decreasing food intake
in an individual in
need or desire thereof,
or aiding a healthy
individual to maintain
a healthy weight,
comprising
administering an
effective amount of a
compound comprising
psilocin, psilocybin, or
an analog thereof.

From claim 1 "A method of improving mental or physical well-being of a subject, the method comprising: (i) providing a subject, wherein based on a score of one or more predictors in the subject, the subject has been identified as likely to have a positive therapeutic response to a psychedelic agent; and (ii) following step (i), administering to the subject the psychedelic agent."

From **claim 53** "The method of any one of claims 1 -52, wherein the **psychedelic agent** is selected from lysergic acid diethylamide, **psilocybin**, and pharmaceutically acceptable salts thereof."

From claim 3 "The method of claim 1 or 2, wherein the subject is obese, and the method comprises promoting weight loss in the subject."

From page 3 paragraph 7 "In some embodiments of any of the preceding aspects, the psychological disorder is selected from the group consisting of a depressive disorder, an anxiety disorder, an addiction, or a compulsive behavior disorder. In some instances, the psychological disorder is a depressive disorder (e.g., major depression, melancholic depression, atypical depression, or dysthymia). The depressive disorder may be associated with one or more prodromal symptoms selected from the group consisting of depressed mood, decreased appetite, weight loss, increased appetite, weight gain, initial insomnia, middle insomnia, early waking, hypersomnia, decreased energy, decreased interest or pleasure, self-blame, decreased concentration, indecision, suicidality, psychomotor agitation, psychomotor retardation, crying more frequently, inability to cry, hopelessness, worrying/brooding, decreased self-esteem, irritability, dependency, self-pity, somatic complaints, decreased effectiveness, helplessness, and decreased initiation of voluntary responses, any of which may be treated using any of the preceding methods described herein. The psychological disorder may be an anxiety disorder (e.g., end of life anxiety, generalized anxiety disorder, panic disorder, social anxiety, post-traumatic stress disorder, acute stress disorder, obsessive compulsive disorder, or a social phobia). The psychological disorder may be an addiction (substance abuse or an eating disorder). The psychological disorder may be a compulsive disorder (e.g., a primary impulse-control disorder or an obsessive-compulsive disorder)."

### 6. (canceled)

7. The method of claim 1 or 5 wherein the compound is contained within a dried mushroom powder of the genus Psilocybe.

4. U.S. Pat. Doc. No. US/2018/0221396 "Compositions and methods comprising a psilocybin derivative" (Publication date: 09 August 2018)

From paragraph [0019] "Disclosed herein are new methods and compositions comprising a psilocybin derivative. In one embodiment, the compositions disclosed herein comprise one or more psilocybin derivatives chosen from the following: [3-(2-Dimethylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, 4-hydroxy-N,N-

	<b>dimethyltryptamine</b> , [3-(2-methylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1H-indol-4-yl] dihydrogen phosphate, [3-(2-trimethylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N,N,N-trimethyltryptamine."
	From paragraph [0034] "In one embodiment, a dried powder is a solid collected from a plant (e.g., mushrooms) and pulverized into a powder, e.g., using a mortar and pestle."
	From paragraph [0387] "In one embodiment, an addiction is a dependence on an activity, e.g., gambling, eating, shopping, etc."
8. The method of claim 1 or 5 wherein the compound is a	4. U.S. Pat. Doc. No. US/2018/0221396 "Compositions and methods comprising a psilocybin derivative" (Publication date: 09 August 2018)
the compound is a purified psilocin or psilocybin in a pharmaceutically acceptable carrier.	From paragraph [0019] "Disclosed herein are new methods and compositions comprising a psilocybin derivative. In one embodiment, the compositions disclosed herein comprise one or more psilocybin derivatives chosen from the following: [3-(2-Dimethylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, 4-hydroxy-N,N-dimethyltryptamine, [3-(2-methylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1H-indol-4-yl] dihydrogen phosphate, [3-(2-trimethylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N,N-trimethyltryptamine."  From paragraph [0387] "In one embodiment, an addiction is a dependence on an activity, e.g., gambling, eating, shopping, etc."  From paragraph [0020] "In one embodiment, the compositions disclosed herein comprise one or more purified psilocybin derivatives chosen from: [3-(2-Dimethylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, 4-hydroxytryptamine, 4-hydroxy-N,N-dimethyltryptamine, [3-(2-methylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, 4-hydroxy-N-methyltryptamine, [3-(aminoethyl)-1H-indol-4-yl] dihydrogen phosphate, and 4-hydroxy-N,N,N-trimethyltryptamine."
	From paragraph [0081] "As used herein, the term "psilocybin derivative" refers to a compound having a core structure similar to the compound [3-(2-Dimethylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate, aka "psilocybin"."
9. The method of claim 8 wherein the purified psilocin or psilocybin is	1. Priority Patent Doc. No. of WO/2020/212951 "METHODS FOR TREATING ANXIETY DISORDERS, HEADACHE DISORDERS, AND EATING DISORDERS WITH PSILOCYBIN" (Filing date: 29 August 2019)

### manufactured synthetically.

From **paragraph** [0159] "In some embodiments, a method of treating a patient in need thereof comprising administering to the patient a **therapeutically-effective dose of psilocybin, wherein the patient suffers from** Pica, Anorexia Nervosa, Bulimia Nervosa, or **Binge-Eating disorder**."

From paragraph [0150] "The psilocybin manufactured prior to crystallization may be produced using any method: synthetic or biological, e.g. by fermentation or obtained by extraction from mushrooms."

From paragraph [0024] "Further provided herein, are pharmaceutical compositions wherein the 5HT receptor agonist is a 5HT2 receptor agonist...Further provided herein, are pharmaceutical compositions wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereon. Further provided herein, are pharmaceutical compositions wherein the 5HT receptor agonist is psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof."

From paragraph [0037] "In some instances, disorders in which the 5-HT2A receptor are involved include, but are not limited to schizophrenia, depression/suicide, anxiety, obsessive compulsive disorders (OCD), bipolar disorders, attention deficit hyperactivity disorder (ADHD), eating disorders such as anorexia nervosa, autism and autism spectrum disorders, Asperger's, neuropsychiatric diseases and disorders, sexual disorders such as erectile dysfunction, neurodegenerative diseases, inflammatory diseases, autoimmune diseases, metabolic diseases such as obesity and diabetes, central nervous system disorders, peripheral nervous system disorders, Alzheimer's disease, snoring, sleep apnea (obstructive sleep apnea, central sleep apnea), insomnia, sleep deprivation, restless legs syndrome, parasomnia, nightmares, night terrors, sleepwalking, hypersomnia (daytime sleepiness), narcolepsy and pain."

10. The method of claim 1 or 5 wherein the effective amount is 0.6 to 2.5 mg of psilocin, psilocybin, or analog thereof, per day.

1. Priority Patent Doc. No. of WO/2020/212951 "METHODS FOR TREATING ANXIETY DISORDERS, HEADACHE DISORDERS, AND EATING DISORDERS WITH PSILOCYBIN" (Filing date: 29 August 2019)

From paragraph [0159] "In some embodiments, a method of treating a patient in need thereof comprising administering to the patient a therapeutically-effective dose of psilocybin, wherein the patient suffers from Pica, Anorexia Nervosa, Bulimia Nervosa, or Binge-Eating disorder."

From paragraph [0133] "In some embodiments, psilocybin is administered to the patient at a dose of between about 0.1mg to 100mg, about 1mg to about 50mg, or about 5mg to 30mg."

## 11. The method of claim 7 wherein the effective amount is 50 to 500 mg of dried mushroom powder per day.

5. Priority Doc. of Patent Doc. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Filing date: 19 November 2019)

From **claim 17** "The composition of claim 1, wherein **the composition is effective to treat**, alleviate, prevent or ameliorate psychiatric and mood disorders, e.g.,...eating disorders..."

From page 26 paragraph 1 "One embodiment described herein is a composition comprising one or more tryptamines such as psilocybin (4-phosphoryloxy-N,N-dimethyltryptamine)..."

From page 30 paragraph 3 "In one embodiment, the pharmaceutical composition comprises a dose of about 1ng to 10mg of one of or more tryptamines or an amount of a mushroom (or plant) extract or mushroom (or plant) having the equivalent amount of tryptamine(s)."

From page 34 paragraph 3 "One or more dosage forms of the compositions described herein can be administered, for example, 1x, 2x, 3x, 4, 5x, or 6x or even more times per day."

6. BIGWOOD (1982) "Variation of psilocybin and psilocin levels with repeated flushes (harvests) of mature sporocarps of *Psilocybe cubensis* (earle) singer" Journal of Ethnopharmacology. 5(3):287-291.

### From page 289

### TABLE 1

The dry weight variation of psilocybin and psilocin levels in *Psilocybe cubensis* as a function of flush number (quantified by HPLC)

Flush No.	Miniculture No. 1		Miniculture No. 2		Miniculture No. 3		
	Psilocybin (mg/g)	Psilocin (mg/g)	Psilocybin (mg/g)	Psilocin (mg/g)	Psilocybin (mg/g)	Psilocin (mg/g)	
1	8.3	0.5	5.1	0	7.6	0	
2	6.5	1.5	7.3	0	6.2	0	
3	13.3	1.0	4.7	1.7	5.3	0.9	
4	4.8	2.6	3.7	2.9	3.2	1.8	
5	_	-	5.2	2.2	6.7	1.7	
6	6.8	0.5	_	_	<u> </u>	_	

## 12. The method of claim 1 or 5 wherein the complication associated with obesity is selected from the group consisting of sleep

3. Priority Doc. of Patent Doc. No. WO/2020/157569 "METHODS AND COMPOSITIONS COMPRISING A 5HT RECEPTOR AGONIST FOR THE TREATMENT OF PSYCHOLOGICAL, COGNITIVE, BEHAVIORAL, AND/OR MOOD DISORDERS" (Filing date: 30 January 2019)

apnea, abnormal regulation of blood glucose, diabetes mellitus, cardiovascular disease, high blood pressure, hypertension, multiple sclerosis, erectile dysfunction, urinary incontinence, chronic renal failure, asthma, and cancer.

From paragraph [0024] "Further provided herein, are pharmaceutical compositions wherein the 5HT receptor agonist is a 5HT2 receptor agonist...Further provided herein, are pharmaceutical compositions wherein the 5HT receptor agonist is psilocin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereon. Further provided herein, are pharmaceutical compositions wherein the 5HT receptor agonist is psilocybin or a pharmaceutically acceptable salt, solvate, metabolite, derivative, or prodrug thereof."

From paragraph [0037] "In some instances, disorders in which the 5-HT2A receptor are involved include, but are not limited to schizophrenia, depression/suicide, anxiety, obsessive compulsive disorders (OCD), bipolar disorders, attention deficit hyperactivity disorder (ADHD), eating disorders such as anorexia nervosa, autism and autism spectrum disorders, Asperger's, neuropsychiatric diseases and disorders, sexual disorders such as erectile dysfunction, neurodegenerative diseases, inflammatory diseases, autoimmune diseases, metabolic diseases such as obesity and diabetes, central nervous system disorders, peripheral nervous system disorders, Alzheimer's disease, snoring, sleep apnea (obstructive sleep apnea, central sleep apnea), insomnia, sleep deprivation, restless legs syndrome, parasomnia, nightmares, night terrors, sleepwalking, hypersomnia (daytime sleepiness), narcolepsy and pain."

### 13. The method of claim 1 or 5 wherein the administering is an oral administration.

1. Priority Patent Doc. No. of WO/2020/212951 "METHODS FOR TREATING ANXIETY DISORDERS, HEADACHE DISORDERS, AND EATING DISORDERS WITH PSILOCYBIN" (Filing date: 29 August 2019)

From paragraph [0159] "In some embodiments, a method of treating a patient in need thereof comprising administering to the patient a therapeutically-effective dose of psilocybin, wherein the patient suffers from Pica, Anorexia Nervosa, Bulimia Nervosa, or Binge-Eating disorder."

From paragraph [0137] "Exemplary modes for administration of psilocybin include oral..."

# 14. The method of claim 1 or 5 wherein the analog thereof is 4-SH-dimethyltryptamine, 1-methylpsilocin, 4-fluoro-N,N-dimethyltryptamine, O-acetylpsilocin, 4-hydroxy-N-methyl-N-

5. Priority Doc. of Patent Doc. No. WO/2021/101926 "TRYPTAMINE COMPOSITIONS FOR ENHANCING NEURITE OUTGROWTH" (Filing date: 19 November 2019)

From claim 1 "A composition comprising one or more tryptamines in pure form or extracts or isolates from psilocybin containing mushrooms, or combinations thereof combined with one or more erinacines or hericenones in pure form, extracts or isolates from *Hericium* mushroom species or combinations thereof."

isopropyltryptamine, or 4-hydroxy-Nmethyl-Nethyltryptamine. From **claim 17** "The composition of claim 1, wherein **the composition is effective to treat**, alleviate, prevent or ameliorate psychiatric and mood disorders, e.g.,...**eating disorders**..."

From page 30 paragraph 3 "In one embodiment, the pharmaceutical composition comprises a dose of about 1ng to 10mg of one of or more tryptamines or an amount of a mushroom (or plant) extract or mushroom (or plant) having the equivalent amount of tryptamine(s)."

From **page 38 paragraph 1** "In another embodiment, the tryptamine comprises...4-hydroxy-n-isopropyl-n-methyl-tryptamine (**4-HO-MiPT**)...N-ethyl-4-hydroxy-N-methyl-tryptamine (**4-HO-MET**)..."

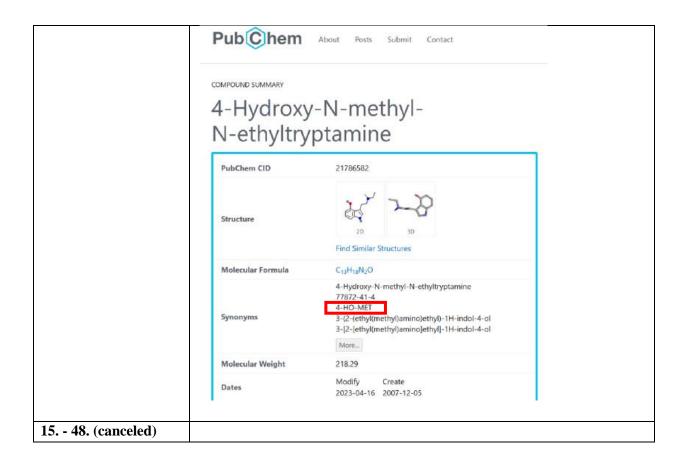
7. PUBCHEM (2006) "4-Hydroxy-N-methyl-N-isopropyltryptamine" <a href="https://pubchem.ncbi.nlm.nih.gov/compound/4-Hydroxy-N-methyl-N-isopropyltryptamine">https://pubchem.ncbi.nlm.nih.gov/compound/4-Hydroxy-N-methyl-N-isopropyltryptamine</a>



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COMPOUND SUMMARY

8. PUBCHEM (2007) "4-Hydroxy-N-methyl-N-ethyltryptamine" <a href="https://pubchem.ncbi.nlm.nih.gov/compound/4-Hydroxy-N-methyl-N-ethyltryptamine">https://pubchem.ncbi.nlm.nih.gov/compound/4-Hydroxy-N-methyl-N-ethyltryptamine</a>



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First Named Inventor/Applicant Name:	Penny White			
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2	Third-Party Submission Under 37 CFR 1.290	Third-party-preissuance- submission.pdf	dd8c242fca333919fcd546e90d5f05c1ab13 33d6		
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If a new application is being filed and the application includes the necessary components for a 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.

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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 is being filed and the international application is being filed and the international application.

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.