

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): August 11, 2021

ATAI LIFE SCIENCES N.V.
(Exact name of registrant as specified in its charter)

The Netherlands
(State or other jurisdiction of
incorporation or organization)

001-40493
(Commission
File Number)

Not Applicable
(I.R.S. Employer
Identification No.)

**c/o Mindspace
Krausenstraße 9-10
10117 Berlin, Germany**
(Address of principal executive offices) (Zip Code)

+49 89 2153 9035
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, €0.10 par value per share	ATAI	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

ATAI Life Sciences N.V. (the "Company") from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. On August 11, 2021, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at www.atai.life. A copy of its current corporate slide presentation is attached to this Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

The information contained in Item 7.01 of this Form 8-K (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following Exhibit 99.1 relating to Item 7.01 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Slide Presentation of ATAI Life Sciences N.V. dated August 2021
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ATAI LIFE SCIENCES N.V.

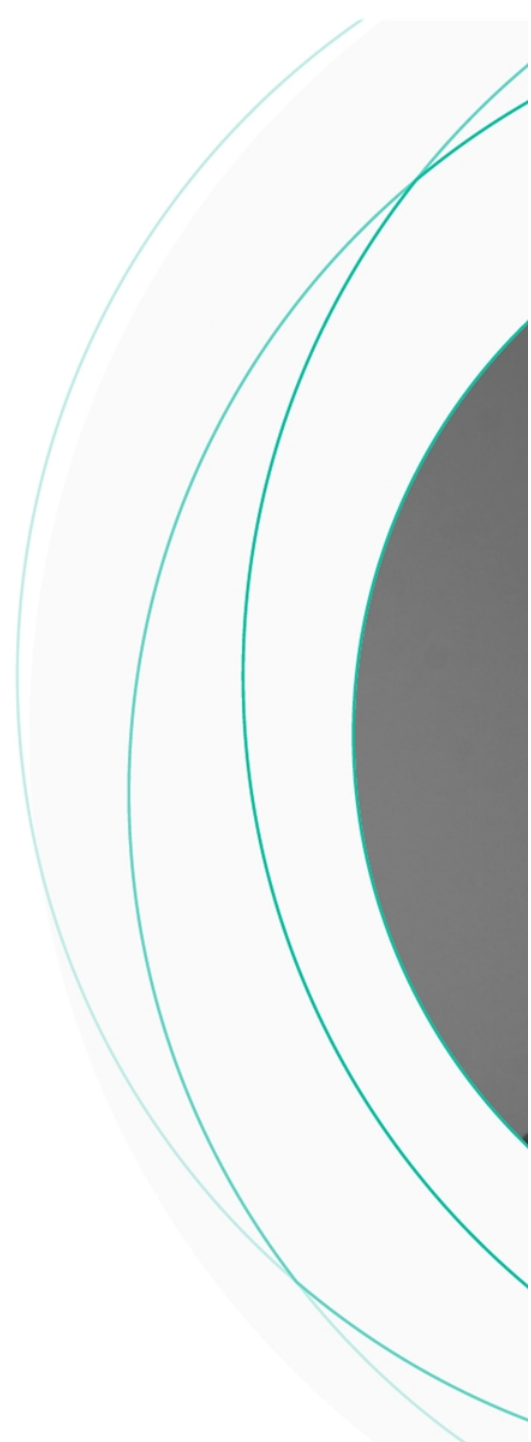
Date: August 11, 2021

By: /s/ Florian Brand
Florian Brand
Chief Executive Officer



Healing mental health disorders so that everyone everywhere can live a more fulfilled life.

Company Overview_____



Disclaimer

This presentation may include forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, industry dynamics, business strategy and plans and our objectives for future operations, are forward-looking statements. These statements represent our opinions, expectations, beliefs, intentions, estimates or strategies regarding the future, which may not be realized. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “targets,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions that are intended to identify forward-looking statements. Forward-looking statements are based largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short term and long-term business operations and objectives and financial needs. These forward-looking statements involve known and unknown risks, uncertainties, changes in circumstances that are difficult to predict and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statement. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and

circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those currently expected or implied in the forward-looking statements. We caution you against relying on these forward-looking statements, and we disclaim any liability for forward-looking statements by these cautionary statements.

The forward-looking statements included in this presentation are as of the date hereof. Although we believe that the expectations expressed in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or other circumstances reflected in the forward-looking statements will be realized or occur. Moreover, neither we nor our advisors nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Neither we nor our advisors undertake to update any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or our expectations, except as may be required by law. You should read this presentation with the understanding that our actual future activity, performance and events and circumstances may differ from what we expect.

Unless otherwise indicated, information contained in this presentation concerning our industry, competitive position and the market we operate in is based on information from independent industry organizations, other third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and other third-party sources, as well as data from our internal research, and are based on

We are a founder-led team **aiming to develop diff**
for patients suffering from **mental health disorders**



Christian Angermayer
Founder & Chairman



Florian Brand
Co-Founder & CEO



Lars Wilde
Co-Founder



Greg Weaver
CFO



The atai team has collectively led



13

NDA
regula

Executive Summary and Key Investment Highlights

1

Mental health disorders have become **one of largest global health burdens**, exacerbated by the COVID-19 pandemic. Despite the unmet patient need, **innovation remains limited**, with only 7 new neuropsychiatric drugs approved since 2010.

2

As a response to lack of innovation, atai focuses on **compounds with promising preclinical evidence**, including psychedelics whose therapeutic potential has become clear from recent academic studies and which have benefited from recent regulatory changes.

3

Our platform consists of **11 drug development programs and 6 enabling technologies**, focusing on differentiated and potentially **disease-modifying mental health treatments**. We intend to continue to grow our platform through acquisitions and in-house development.

4

Our **platform approach**: Decentralized drug development process, leveraging a cross-functional team and our enabling technologies such as digital therapeutics to aim for improved safety, efficacy and probability of clinical success across our pipeline.

5
























Validation of atai's operating model: IPO of COMPASS Pathways and our partnership with Perception (**first drug development partnership between a biopharmaceutical company and a psychedelic company developing psychedelics**).

6

Our **pipeline is rich in R&D catalysts over the next 18 months**, and we have more than 200 highly experienced FTEs / consultants across our platform, and a **cash position of approx. \$449M¹**.

(1) ~\$104M cash & cash equivalents as of March 31, 2021 with ~\$345M subsequently received in connection with the closing of Series D and IPO

Meaningful R&D catalysts over the next 18 months news flow, excluding potential for additional bus

	Recent Milestones	Anticipated
2021	 Recognify started Phase 2a study in CIAS with RL-007	 PCN-101
	 Perception closed licensing deal with Otsuka for Japan	 RL-007
	 atai entered strategic partnership with IntelGenx	 PCN-101
	 DemeRx received approval to start DMX-1002 Phase 1/2 in UK	 RL-007
	 atai announced successful closing of Series D, raising \$157m	 GRX-595
	 Perception announced positive Phase 1 results with PCN-101	 DMX-1002
	 Empath partnered with Bionomics on PTSD drug development	 NN-100
	 atai acquired majority stake in Recognify to develop RL-007 for CIAS	 DMX-1002
	 Launch of Revixia Life Sciences to develop RLS-01	 GRX-595
	 COMPASS successfully IPO-ed on NASDAQ	 NN-100
	 atai launched EmpathBio to develop EMP-01 for PTSD	 KUR-101
	 atai launched Introspect to develop Digital Therapeutics	

Legend 

Notes: FSI = First subject in, SQ = Subcutaneous, IV = Intravenous, BA = Bioavailability



Founded in

As a response to the s
innovation in the mer
well as the **emergenc**
have been overlooke
psychedelic compound

Although mental health has become one of the **largest** challenges, there has been **little innovation** for patients.

SIGNIFICANT BURDEN

~1bn

Affected people

Global population with mental health disorders¹

>50%

Of US population impacted

Expected that more than half of US population will have a mental health disorder at some point in their lifetime²

~\$16tn

Global economic impact

Estimated global economic costs of mental health disorders by 2030³

~4x

Recent impact of COVID-19

Percentage of US adults experiencing symptoms of depression and anxiety rose from 11% in 2019 to 42% end of 2020⁴

1. Ritchie, "Global mental health: five key insights which emerge from the data", Our World In Data (2018).
2. Kapil, "5 Surprising Mental Health Statistics", National Council for Behavioral Health (2019).
3. Patel et al., "The Lancet Commission on global mental health and sustainable development", The Lancet (2018).
4. Abbott, "COVID's mental-health toll: how scientists are tracking a surge in depression, Nature (2021)

5. Salzer, "National Estimates of Mental Health Disparities", National Council for Behavioral Health (2019).
6. Tew et al., "Impact of prior treatment on outcomes in a randomized controlled trial of a digital mental health intervention", BMC Psychiatry (2021).
7. Sinha, "New Findings on Biologics for Depression", EvaluatePharma (as of 19.03.2021).
8. EvaluatePharma (as of 19.03.2021).

A resurgence in psychedelic therapies is emerging modifying drug candidates progress with regulator



LSD synthesized by Dr. Albert Hofmann at Sandoz research labs¹



CHARLES UNIVERSITY

Dr. Stan Grof uses LSD to treat heroin addiction in Prague³



Psychedelic therapy developed by Dr. Abram Hoffer and Dr. Humphry Osmond, efficacious in treating alcoholics²

Drug Control Amendments forbid the manufacture and sale of psychedelic drugs (scheduling)⁴

“America’s public enemy number one is drug abuse.”
 PRESIDENT NIXON, 1971

————— Early research suggested efficacy in mental health —————>

Note: LSD = Lysergic acid diethylamide; TRD = Treatment-resistant depression; MDD = Major depressive disorder; PTSD = Post-traumatic stress disorder.

- Hofmann, MAPS (1996)
- Dyck, "Hitting Highs at Rock Bottom: LSD Treatment for Alcoholism" (2006)
- Williams, "Human Psychedelic Research: A Historical and Sociological Analysis" (1999)
- FDA, Drug Law History (2018)
- Griffiths et al., "Psilocybin pr
- MAPS, announcement brea
- COMPASS, COMPASS Pat (2018)
- FDA, FDA Approves New N

Patient reports: In a study, more than half of the p therapy among the top five most meaningful expe

“When I had a craving, something in my head quickly thought about the good part, the taste, the feeling, the high, right? But if I think of the drug now... I quickly think about the downside. It changed the perception I have regarding the drug.”²



Male, 25
Ibogaine

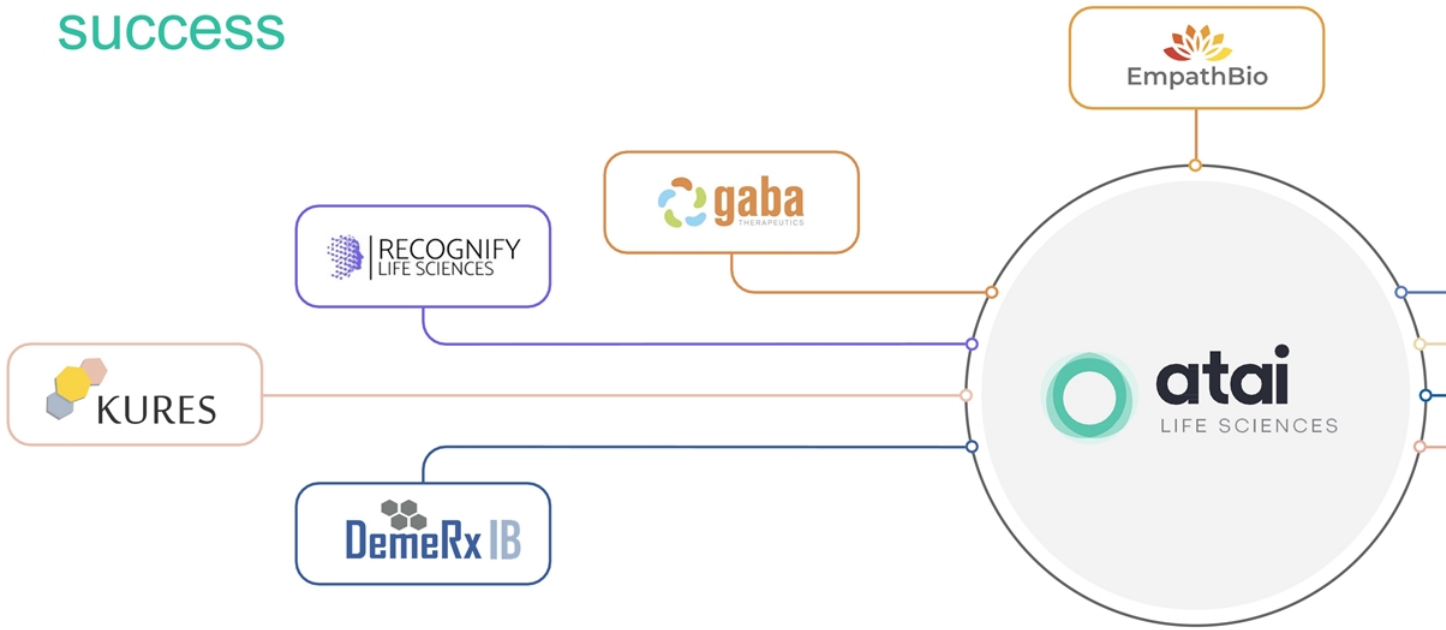
“It sort of relieved a lot of stress, a lot of negative thoughts within my body... opened my eyes to see wh my stress and conflict is coming from... It is hard to explain but... it just brough lot of grief up that I had ins me, it brought it out and I g rid of a lot of grief.”³



Male, 55
Psilocybin

1. Griffiths et al., “Psilocybin can occasion mystical-type experiences having substantial and sustained personal meaning and spiritual significance” (2006)
2. Schenberg et al., “Treating drug dependence with the aid of ibogaine: A qualitative study” (2017)
3. Watts et al., “Patients’ Accounts of Increased ‘Connectedness’ and ‘Acceptance’ After Psilocybin for Treatment-Resistant Depression” (2017)
4. Argento et al., “Exploring ayahuasca-assisted therapy for addiction: A qualitative analysis of preliminary findings among an Indigenous community in Canada” (2019)

The atai platform: Decentralized drug development team and enabling technologies to aim for improved success



People

- Small teams with entrepreneurial autonomy develop our compounds
- Operational involvement of interdisciplinary atai team
- Access to experienced group of strategic advisors and KOLs

bridgebio ROIVANT SCIENCES

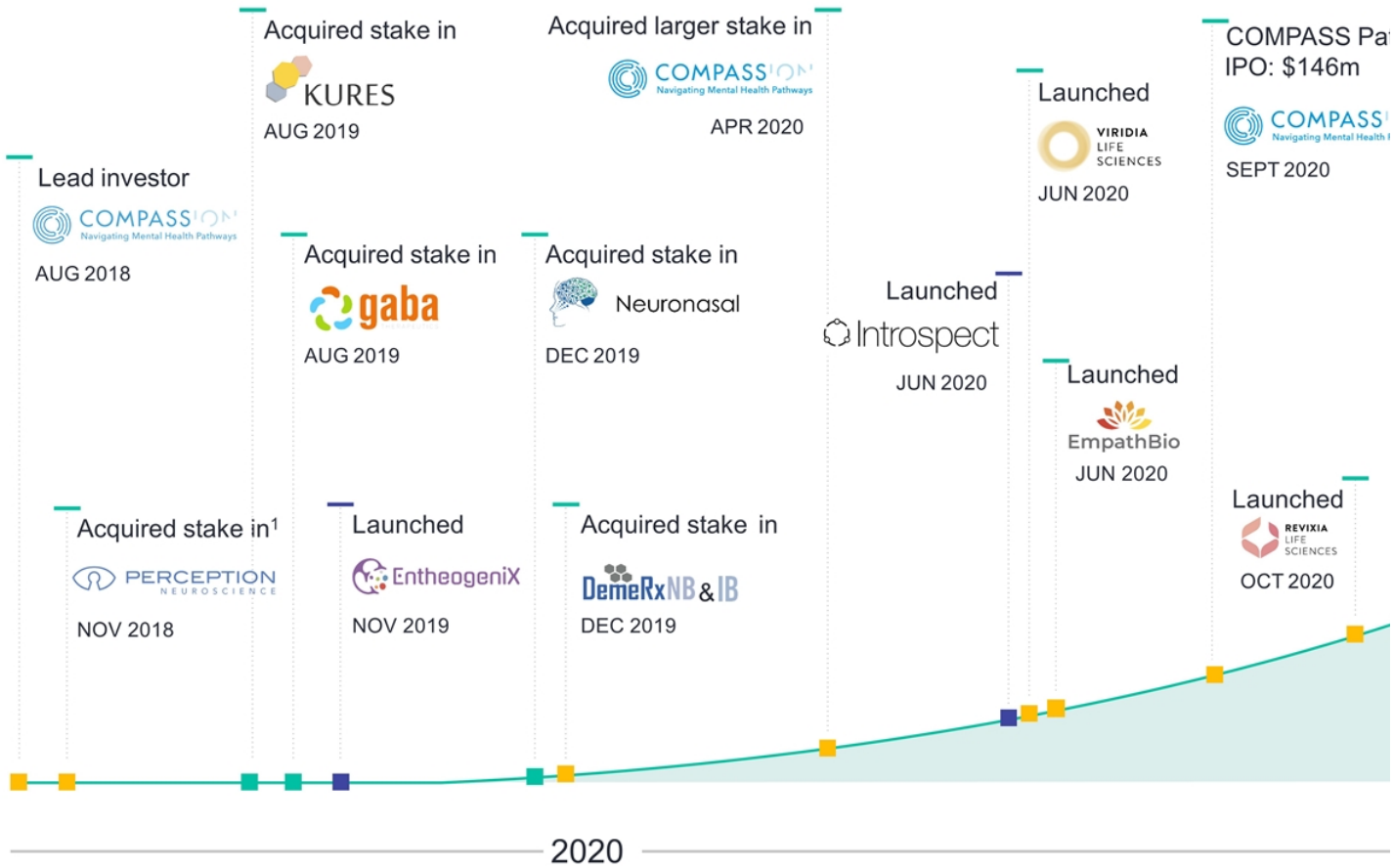
Process

- Disciplined selection criteria (including prior evidence in)
- Impactful capital allocation acquired and incubated cor
- Strategic value capturing a high degree of optionality

COMPASSION Navigating Mental Health Pathways

Rapid Growth via incubations and acquisitions:










6 psychedelic programs, 5 non-psychedelic program





1. Ketamine and S-ketamine are psychedelic/dissociative at therapeutic doses, while R-ketamine (the enantiomer that Perception Neuroscience is developing) is assumed to be nonpsyche

Development program overview: Our company on lead indications and stage of development

OUR PROGRAMS

Company	Lead Compound	Lead Indication	Type	Ownership % ¹
 PERCEPTION NEUROSCIENCE	PCN-101 / R-ketamine	TRD	VIE	50.1% ²
 RECOGNIFY LIFE SCIENCES	RL-007 / Compound ³	CIAS	VIE	51.9%
 DemeRx IB	DMX-1002 / Ibogaine	ODD	VIE	59.5%
 Neuronasal	NN-101 / N-acetylcysteine	mTBI	VIE	56.5% ⁴
 KURES	KUR-101 / Deuterated mitragynine	ODD	VIE	54.1% ⁵
 gaba THERAPEUTICS	GRX-917 / Deuterated etifoxine	GAD	Majority Owned Equity Interest ⁶	53.8% ⁶
 EmpathBio	EMP-01 / MDMA derivative	PTSD	Wholly Owned	100%
 REVIXIA LIFE SCIENCES	RLS-01 / Salvinorin A	TRD	Wholly Owned	100%
 VIRIDIA LIFE SCIENCES	VLS-01 / DMT	TRD	Wholly Owned	100%

ENTITIES LIMITED TO EQUITY INTEREST

 COMPASS PSYCHOPHARMACEUTICALS Navigating Mental Health Pathways	Developing COMP360 therapy, with psychological support from specially trained therapists, for TRD. Phase 2b trial is ongoing.			19.4% ⁷
 DemeRx NB	Developing DMX-1001, a formulation of noribogaine, as a potential at-home maintenance therapy for ODD. Preclinical stage.			6.3% ⁸

Note: TRD = Treatment-resistant depression; CIAS = Cognitive impairment associated with schizophrenia; ODD = Opioid use disorder; GAD = Generalized anxiety disorder; mTBI = Mild Traumatic Brain Injury; PTSD = Post-traumatic stress disorder; VIE = Variable interest entity.

(1) Unless otherwise indicated herein, ownership percentage based on ownership of securities with voting rights as of May 30th, 2021.

(2) Perception does not give effect to the shares of common stock issuable upon the conversion of outstanding convertible notes held by atai which may increase the ownership.

(3) RL-007 compound is (2R, 3S)-2-amino-3-hydroxy-3-pyridin-4-yl-1-pyrrolidin-1-yl-propan-1-one(L)-(+)-tartrate salt.

(4) Neuronasal ownership does not give effect to the obligation to acquire further shares upon the achievement of specified development milestones which may increase the ownership to up to 64.5%.

(5) Kures ownership does increase the ownership to 54.1%⁵.
(6) Operational involvement may increase the ownership to 53.8%⁶.
(7) As of June 30, 2021, ownership is 19.4%⁷.
(8) DemeRx NB ownership increase the ownership to 6.3%⁸.

SUMMARY



OWNERSHIP 19.4%

PRODUCT Oral Psilocybin (COMP360)

PHARMA-COLOGY 5-HT2A-R agonist

PRODUCT FEATURES Rapid onset, potential for sustained efficacy after single dose

INDICATIONS Primary: Treatment Resistant Depression
Potential: Major Depressive Disorder, Anorexia, Autism, Bipolar Disorder, Chronic Cluster Headache, Body Dysmorphic Disorder

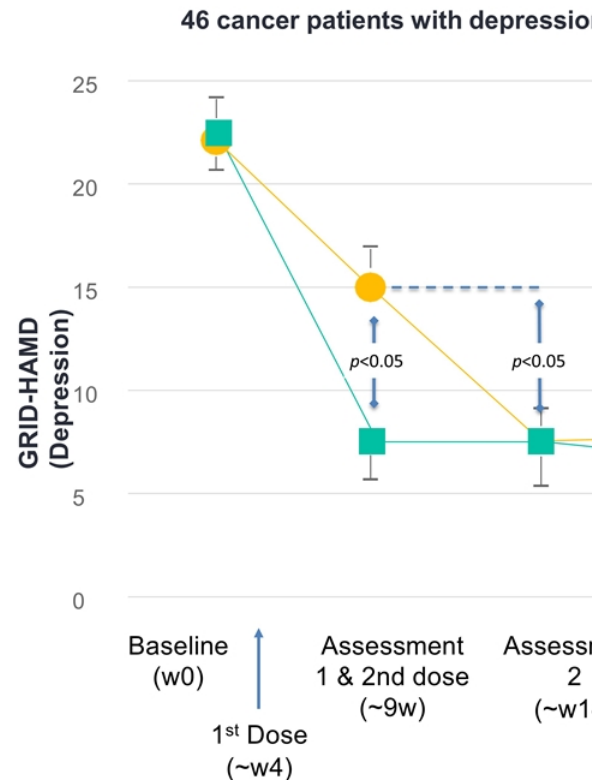
CURRENT STATUS COMP360 Phase 1 trial completed and results publicly available, Phase 2b trial results expected end of 2021

INTELLECTUAL PROPERTY Proprietary formulation of synthetic psilocybin, COMP360

HIGHLIGHT Psilocybin demonstrated efficacy in reducing depressive symptoms in humans in an academic, third-party study

Early clinical signals leads to rapid and sustained reduction in depressive symptoms

PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY)



Note: GRID-HAMD = GRID Hamilton Depression Rating Scale; COMP360 therapy, COMP360 is administered in conjunction with psychological support. 1. Griffiths et al., "Psilocybin produces substantial and sustained decreases in depressive symptoms in humans in an academic, third-party study"

SUMMARY



OWNERSHIP 50.1%

PRODUCT Subcutaneous R-ketamine (PCN-101)

PHARMA-COLOGY Glutamatergic modulator

PRODUCT FEATURES Rapid-acting, nonpsychedelic antidepressant with potential for at home use

INDICATIONS Primary: Treatment Resistant Depression
Potential: Substance Use Disorder

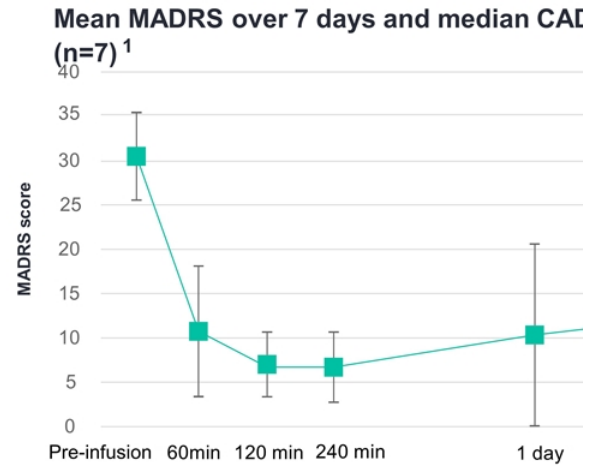
CURRENT STATUS Phase 1 trial showed safety and tolerability of R-ketamine at doses of up to 150mg, Phase 2 trial initiation anticipated in mid '21

INTELLECTUAL PROPERTY Issued methods of use of R-ketamine for treatment of depressive symptoms

HIGHLIGHT Third party study: Single IV dose (0.5 mg/kg) of R-ketamine led to a rapid and sustained decrease in MADRS in patients with TRD; dissociation was nearly absent¹

We aim to develop P antidepressant with p

PRIOR EVIDENCE IN HUMANS (THIRD PARTY S



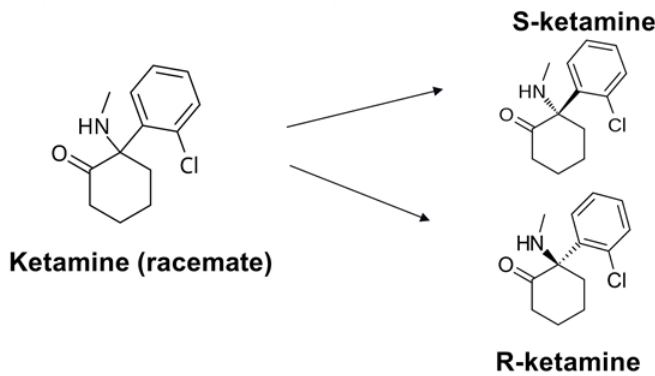
PLANNED PCN-101 PHASE 2 TRIAL: Randomize (n=93)



Note: MADRS = Montgomery-Asberg Depression Rate Scale, CADSS = C
1. Leal et al., "Intravenous arketamine for treatment-resistant depression"

Deep-dive R-ketamine vs. S-ketamine: Higher-potency antidepressant effect and lower potential for abuse

Profile of R- vs. S-ketamine



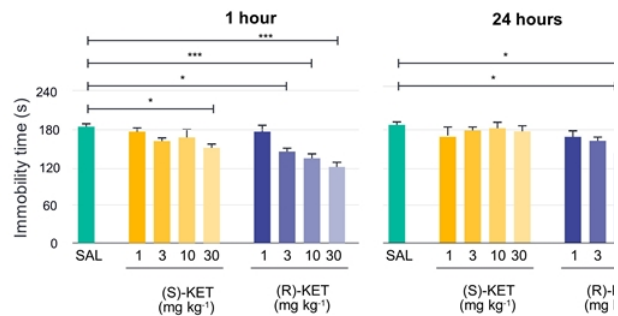
R-ketamine lacks the psychotomimetic and abuse potential of S-ketamine at therapeutic doses in preclinical models.

Like S-ketamine, R-ketamine's mechanism involves increased neuroplasticity through glutamatergic modulation, with potency differences putatively arising from:

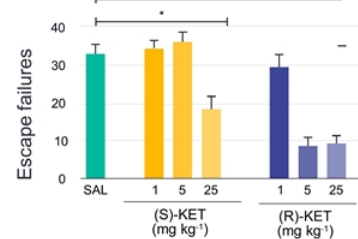
- Different active metabolite profiles
- Different pre- and post-synaptic sites of action
- Involvement of different intracellular pathways (mTORC1 vs. ERK)

Superior and more durable

Forced swim test¹ (third party study)



Learned helplessness test



R-ketamine outperformed and outlasted S-ketamine in mice; confirmed in multiple other animal models in different

Note: mTORC1 = Mechanistic target of rapamycin complex 1, ERK = Extracellular signal-regulated kinases.

Sources: Wei et al., "A historical review of antidepressant effects of ketamine and its enantiomers" (2020); Chang et al., "Comparison of antidepressant and side effects in mice after intranasal" (2019);

1. Zanos et al., "NDMAR inhibition-independent antidepressant actions of ketamine metabolites" (2016);

2. Yang et al., "R-ketamine: a rapid-onset and sustained antidepressant without psychotomimetic side effects" (2015).

SUMMARY



OWNERSHIP 100%

PRODUCT Dimethyltryptamine (DMT) in a buccal transmucosal film (VLS-01). DMT is the active psychedelic moiety in Ayahuasca

PHARMA-COLOGY 5-HT_{2A-R} agonist

PRODUCT FEATURES Rapid onset, sustained efficacy after single dose, short duration of psychedelic effect (~30 to 45 minutes)

INDICATIONS Primary: Treatment Resistant Depression
Potential: Eating Disorders, Substance Use Disorders

CURRENT STATUS Pre-clinical: Formulation work and safety testing in progress; Phase I clinical trial anticipated to initiate in mid-'22

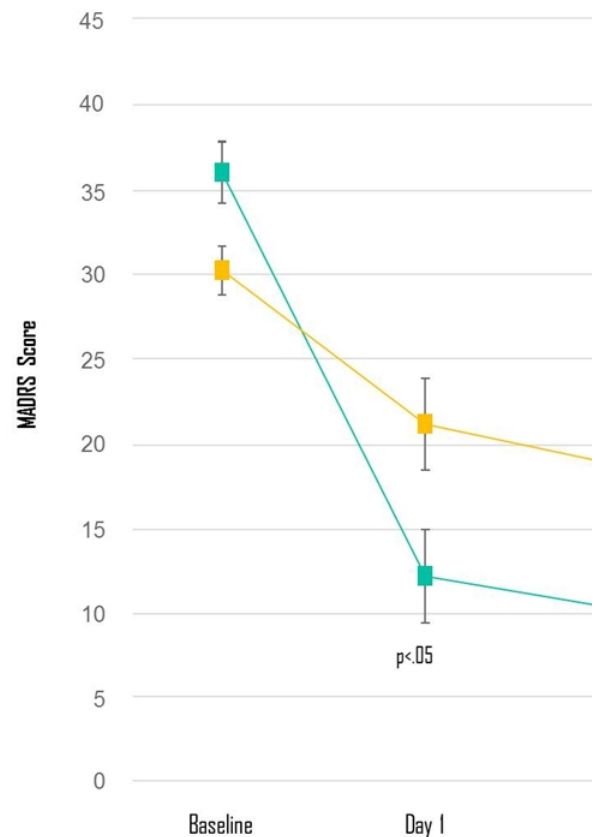
INTELLECTUAL PROPERTY Filed provisional on formulations of DMT

HIGHLIGHT VLS-01 is designed to have an improved duration of psychedelic effect while improving tolerability

VLS-01 may increase reducing patient and

PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY)

Double-blind, randomized placebo-controlled trial with Ayahu



Note: MADRS: Montgomery-Asberg Depression Rating Scale.
1. Palhano-Fontes et al. "Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant

SUMMARY



OWNERSHIP 100%

PRODUCT

RLS-01 is a buccal formulation of Salvinorin A (SalA), a naturally occurring psychedelic compound derived from the *Salvia divinorum* plant

PHARMA-COLOGY

Non-orally bioavailable, non-nitrogenous agonist of the kappa-opioid receptor (KOR), no interaction with serotonergic mechanisms

PRODUCT FEATURES

Rapid-acting hallucinogenic compound, no wash-out of SSRIs required

INDICATIONS

Primary: Treatment Resistant Depression
Potential: Substance Use Disorder, Pain

CURRENT STATUS

Phase 1 clinical trial anticipated to initiate in H2 '22

INTELLECTUAL PROPERTY

Filed provisional on formulation of SalA

HIGHLIGHT

Hallucinogenic experiences demonstrated by all six significantly elevated HRS clusters on an active dose, and no significant adverse events (third party study).¹

Salvinorin A's subjective to be similar to class

















PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY)

Participant ratings on Hallucinogen Rating Scale

Cluster	Placebo	Active
Affect	0.75 (0.47)	1.50 (0.47)
Cognition	0.37 (0.41)	1.61 (0.41)
Intensity	0.38 ² (0.76)	3.00 ² (0.76)
Perception	0.33 (0.36)	1.71 (0.36)
Somaesthesia	0.31 (0.33)	1.27 (0.33)
Volition	0.94 (0.53)	1.85 (0.53)

Note: Data are mean ratings with one standard deviation shown in parentheses
1. Addy, "Acute and post-acute behavioral and psychological effects of salvinorin A"
2. Median used instead of mean for nonparametric data

Depression positioning and landscape: atai's programs differentiated from one another and from competitors

	TRD treatments being developed by atai companies				Marketed therapies
	Compass	Perception	Viridia	Revixia	J&J
Company					
Compound	COMP360	R-ketamine	DMT	Salvinorin A	S-ketamine
Potential for at home use					
Potential for sustained efficacy					
Rapid onset of treatment effect ¹					
Mechanism of Action	5-HT2A-R agonist	Glutamatergic modulator	5-HT2A-R agonist	KOR agonist	NMDA-R antagonist

Note: 5HT2A-R = Serotonin 2A receptor, KOR = kappa-opioid receptor, NMDA-R = N-methyl-D-aspartate receptor, NET = Norepinephrine transporter, SERT = Serotonin Transporter, 5-HT2A-R agonist = 5-HT2A receptor agonist, 5-HT2A-R antagonist = 5-HT2A receptor antagonist, SSRI = Selective Serotonin Reuptake Inhibitor, SNRI = Selective serotonin-norepinephrine reuptake Inhibitor, 5-MeO-DMT = 5-methoxy-N,N-dimethyltryptamine, model of psilocybin therapy, COMP360 is administered in conjunction with psychological support from specially trained therapists.
 Sources: GlobalData, Evaluate Pharma (both as of 2021), Uthaug, M. V. et al. Prospective examination of synthetic 5-methoxy-N,N-dimethyltryptamine inhalation: effects on salivary cortisol and heart rate variability. *Journal of Clinical Psychopharmacology*. 2021;41(1):1-10.
 1. Rapid onset of treatment effect versus standard of care.

SUMMARY



OWNERSHIP 59.5%²

PRODUCT

Ibogaine HCl capsules (DMX-1002), ibogaine is a naturally occurring psychedelic compound isolated from a West African shrub, iboga

PHARMA-COLOGY

Opioid mediated, cholinergic, glutamatergic and monoaminergic receptor modulator

PRODUCT FEATURES

A single dose of ibogaine may precipitate a rapid withdrawal and long-term abstinence in OUD patients

INDICATIONS

Primary: Opioid Use Disorder
Potential: Substance Use Disorder, Post-Traumatic Stress Disorder, Traumatic Brain Injury

CURRENT STATUS

Phase 1/2 trial to initiate in mid '21

INTELLECTUAL PROPERTY

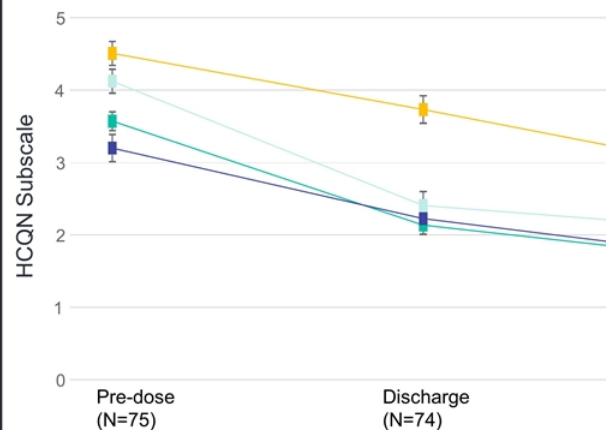
Pending method of treatment claims for OUD for ibogaine, issued method of treatment claims for OUD patients on methadone for noribogaine³

HIGHLIGHT

Potential sustained reduction in opioid craving with DMX-1002 single administration

A single-dose of ibogaine results in significant reductions in opioid craving in OUD patients

PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDIES)



ONGOING PHASE 1/2 TRIAL

Stage 1: Maximum Tolerated Dose

TREATMENT (MULTIPLE DOSES)

Subject cohort:
Recreational opioid users
(up to 30 subjects)

SAFETY/P

Objective
Dose finding

Note: HCQN = Heroin Craving Questionnaire, PTSD = Post-traumatic stress disorder
1. Mash et al., "Ibogaine Detoxification Transitions Opioid and Cocaine Abuse"
2. Refers to ownership in DemeRx IB. DemeRx NB ownership is 6.3%, which is not included in this summary.
3. Noribogaine Intellectual property resides in DemeRx NB

SUMMARY



OWNERSHIP 51.9%

PRODUCT (2R, 3S)-2-amino-3-hydroxy-3-pyridin-4-yl-1-pyrrolidin-1-yl-propan-1-one(L)-(+)-tartrate salt oral capsules (RL-007)

PHARMA-COLOGY Cholinergic, glutamatergic and GABA-B receptor modulator

PRODUCT FEATURES No drug-related serious adverse events in over 500 study subject exposures, pro-cognitive effects demonstrated in two Phase 1 and one Phase 2 trials

INDICATIONS Primary: Cognitive Impairment Associated with Schizophrenia
Potential: Autism, Alzheimer's dementia

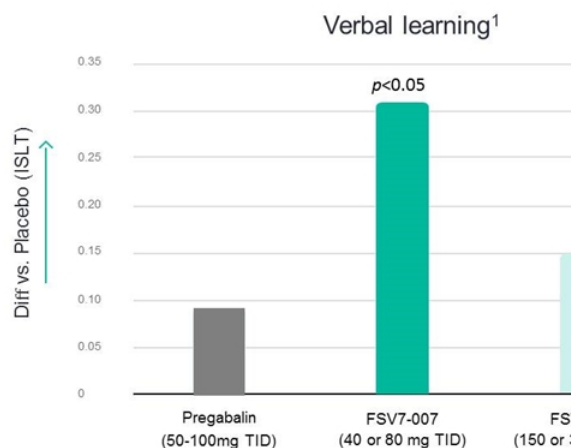
CURRENT STATUS Phase 2a trial initiated in H1'21

INTELLECTUAL PROPERTY Issued composition of matter patent

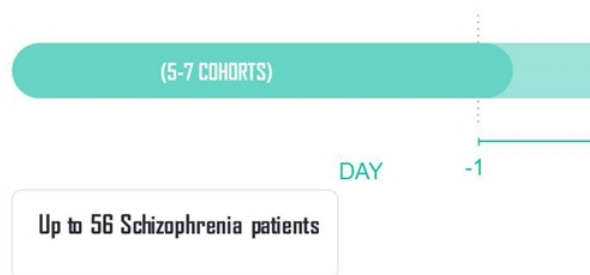
HIGHLIGHT Previous Phase 2 showed pro-cognitive potential of RL-007 in 180 patients with diabetic peripheral neuropathic pain

RL-007 has previous human clinical studies

PRIOR EVIDENCE IN HUMANS



ONGOING PHASE 2 TRIAL: Single-arm, single-blind dose-ranging clinic



Note: CIAS = Cognitive impairment associated with schizophrenia; RL-007 is (2R, 3S)-2-amino-3-hydroxy-3-pyridin-4-yl-1-pyrrolidin-1-yl-propan-1-one(L)-(+)-tartrate salt oral capsules.
1. Verbal learning was assessed by the "International Shopping List Task" (ISLT)
2. Verbal delayed recall was assessed by ISLT with a delayed recall, as a parameter for short-term memo

SUMMARY



OWNERSHIP 53.8%

PRODUCT Deuterated etifoxine HCl oral dosage form (GRX-917)

PHARMA-COLOGY Etifoxine facilitates endogenous production of neurosteroids like allopregnanolone through agonist activity at the mitochondrial translocator protein (TSPO)

PRODUCT FEATURES GRX-917 is designed to have rapid onset activity of anxiolytic activity like benzodiazepines but without the sedating, addicting, or cognitive impairing properties

INDICATIONS Primary: Generalized Anxiety Disorder
Potential: Social Anxiety Disorder, Postpartum Depression

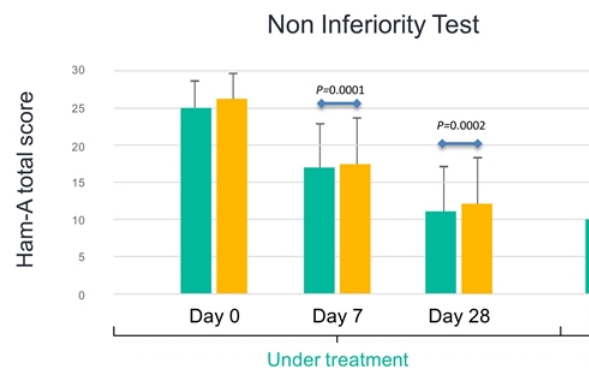
CURRENT STATUS Phase 1 trial initiated in H1'21

INTELLECTUAL PROPERTY Issued composition of matter on deuterated etifoxine (GRX-917) and corresponding methods of use

HIGHLIGHT GRX-917 is aimed to be an improved version of Etifoxine, which already showed promising results

GRX-917 has the potential for rapid-onset efficacy

PRIOR EVIDENCE IN HUMANS (THIRD PARTY SOURCES)



ONGOING PHASE 1 TRIAL

Part 1: Single Ascending Dose

TREATMENT

SAFETY/PK

Up to 40 healthy subjects:
Up to 5 cohorts

PD Endpoint
qEEG

Note: HAM-A = Hamilton Anxiety Rating Scale, SD = standard deviation, qEEG
1. Nguyen et al., "Efficacy of etifoxine compared to lorazepam monotherapy"
2. Cottin et al., "Safety profile of etifoxine: A French pharmacovigilance survey"

SUMMARY



Neuronasal

OWNERSHIP 56.5%

PRODUCT Intranasal N-acetylcysteine (NN-101)

PHARMA-COLOGY N-acetylcysteine (NAC) stimulates glutathione production thus reducing oxidative damage

PRODUCT FEATURES Direct-to-brain intranasal administration showed to increase concentrations in the brain and reduce side effects associated with very high doses of oral or IV NAC

INDICATIONS Primary: mild Traumatic Brain Injury
Potential: Parkinson's Disease

CURRENT STATUS Pilot study completed in H2'20,
Phase 1 trial anticipated to initiate in mid '21

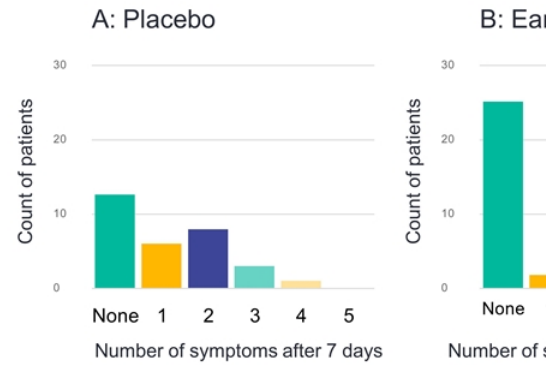
INTELLECTUAL PROPERTY Pending patent on methods of use of NAC for treating post-concussion syndrome

HIGHLIGHT Improved brain-penetration of NN-101 and NAC effect in early mTBI

NN-101 has the potential for a novel pharmacological treatment

PRIOR EVIDENCE IN HUMANS (THIRD PARTY SOURCES)

Treatment of 81 mTBI patients with NAC (24h post-injury) showed a 2x higher probability of symptom resolution by ~2x (OR = 2.0)



PLANNED PHASE 1 TRIAL: Single-site, 4-part clinical trial

RANDOMIZED OPEN LABEL

FORMULATION COORDINATION

Subject cohort:
Healthy volunteers

Identifier

Note: HAM-A = Hamilton Anxiety Rating Scale.
1. Hoffer et al., "Amelioration of acute sequelae of blast induced mild traumatic brain injury by N-acetylcysteine."



SUMMARY

OWNERSHIP 100%

PRODUCT

EMP-01 is an oral formulation of an MDMA derivative being developed for the treatment of PTSD

PHARMA-COLOGY

A monoamine releaser and reuptake inhibitor with prominent effects on serotonin (5-HT)

PRODUCT FEATURES

An entactogen; a compound class that increases feelings of empathy and closeness--with a potentially improved cardiovascular profile compared to MDMA

INDICATIONS

Primary: Post-traumatic Stress Disorder
Potential: General Anxiety Disorder

CURRENT STATUS

Phase 1 trial anticipated to initiate in mid '22

INTELLECTUAL PROPERTY

Filed provisional on formulation, combination approach

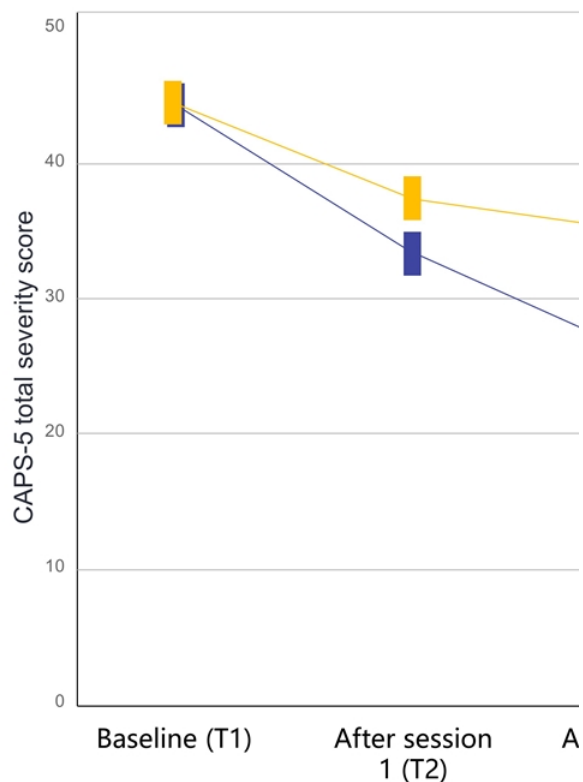
HIGHLIGHT

EMP-01 is aimed to be an improved version of MDMA to treat PTSD symptoms, through an improved cardiovascular profile and potential digital therapeutic support

MDMA-assisted psych PTSD symptoms in 9

PRIOR EVIDENCE IN HUMANS (THIRD PARTY)

MDMA-assisted therapy significantly re (n=90)

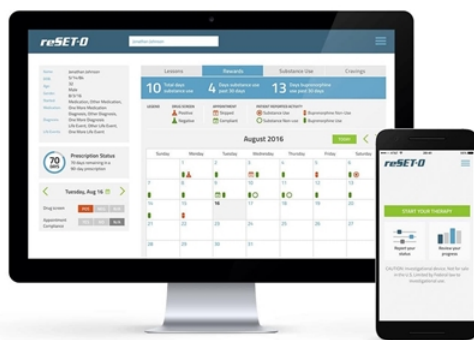


Note: Change in CAPS-V total severity score from T1 to T4 (P < 0.0001, d outcome. Primary analysis was completed using least square means from Mitchell et al., "MDMA-assisted therapy for severe PTSD: a randomized, c

Deep dive Introspect: Powerful digital therapeutics across the pipeline with goal to improve treatment

Pear Tx created a precedent

reSET-O © from Pear Therapeutics is the first prescription digital therapeutic that obtained FDA approval for treatment of patients with OUD (2018)



Positive regulatory sentiment

FDA is supporting and stimulating Digital Health initiatives¹:



1. FDA, "Digital Health Innovation Action Plan" (2018)

Financial Position

Issuer (ticker)

ATAI Life Sciences N.V. (NASDAQ: ATAI)

Market capitalization

~\$2.7B⁽¹⁾

Outstanding shares

154.8M

Cash & cash equivalents

- ~\$104M cash & cash equivalents as of March 31, 2021
- ~\$345M subsequently received in connection with the closing of Series D and IPO
- atai is well financed to fund planned operations through 2023

 PEIRON®
INVESTMENT GROUP

 NOVATOR

 CATALIO
CAPITAL MANAGEMENT

 THIEL

 GALAXY
INVESTMENT PARTNERS, LLC

 WOODLINE
PARTNERS

 FUTURE
VENTURES

 SUBVERSIVE
CAPITAL

 FALCON EDGE CAPITAL

 MOORE CAPITAL MANAGEMENT, LP

 puravida
INVESTMENTS

(1) As of July 20, 2021



Investor Contact:

Greg Weaver

Chief Financial Officer

Email: greg.weaver@atai.life



Appendix

ATAI PLATFORM

INDICATION DEEP DIVES

- Overview
- Depression
- CIAS
- SUD
- Anxiety
- mTBI
- MoA

The atai approach:
We are leveraging a
platform approach to
to aim for improved
**probability of clinical
success**



Process

Our process is designed to aim for effective program development and value capturing



Disciplined New Program Selection

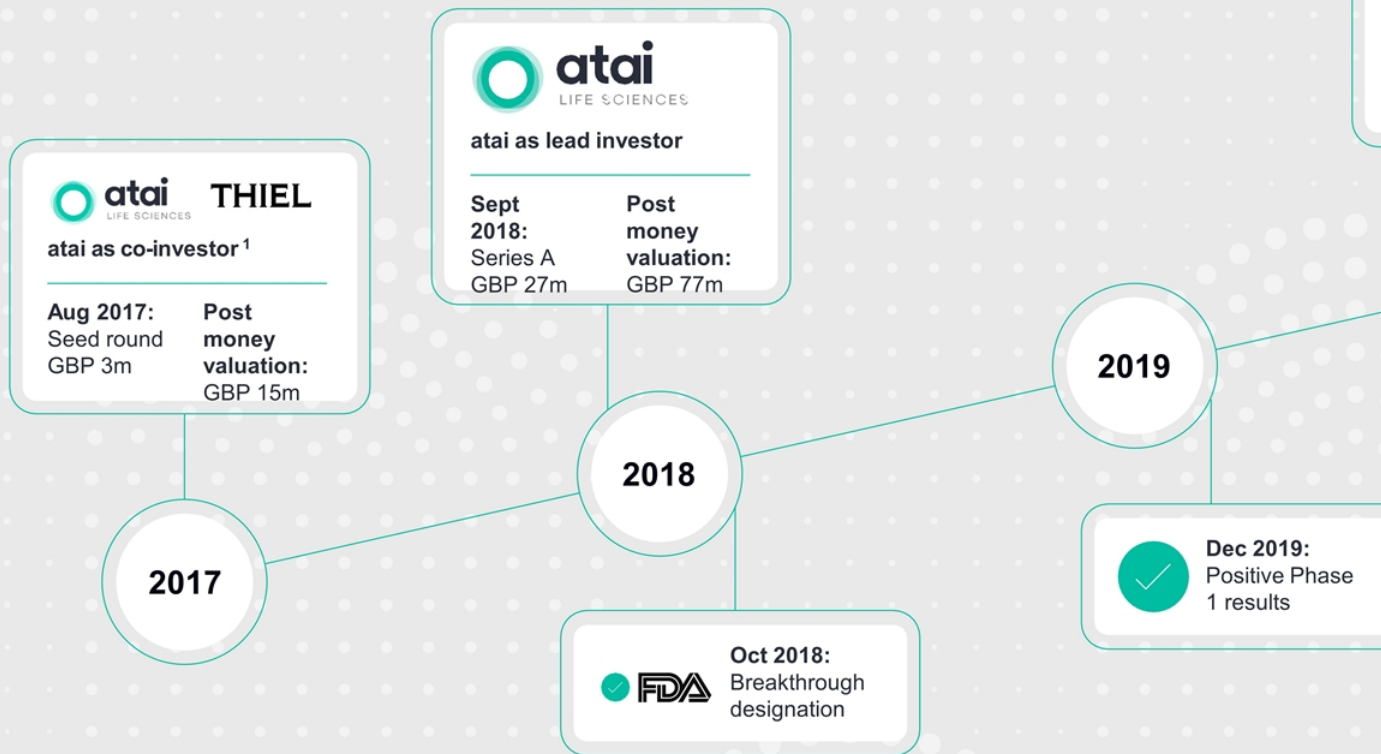
- ✔ Prior evidence in humans to increase probability of success
- ✔ Differentiated treatment effect to address unmet patient needs
- ✔ Significant commercial potential and complementary to drug candidates already in pipeline



Capital Allocation and Decentralized Operations

- ✔ Small teams with entrepreneurial autonomy develop our drugs
- ✔ Access to milestone-based fund shared services and enabling teams
- ✔ Economies of scope and cross-fertilization across our development programs

Case study: COMPASS Pathways creates a precision medicine company: From foundation in 2017 to public company



1. atai co-founder, Christian Angermayer (though his family office, Apeiron) was initial investor into Compass which shareholding was contributed to atai upon atai's incorporation
 2. Market Cap as of July 20, 2021

Our People: Over 50 atai professionals with strong track records support the CEOs of our companies with the executive



Ryan Barrett
GC & Lead of
Corporate Development



Greg Bates
VP, Regulatory Affairs



Roman Dahl
VP, Operations &
Innovation



Majed Fawaz
VP, CMC



Anne Johnson
VP, Global Controller



David Keene
VP, Digital Therapeutics



Georgina Kilfoil, PMP
VP, Clinical Operations



Glenn Short
VP, Early Development



Vicki Klutzaritz
Sr Director, Development
Operations



Sanjeev Kumar
Sr Director, Technical
Accounting



Edmund Neuhaus, PhD
Senior Director,
Psychology



Carrie Bowe
Director, Neuroscience



Sarah McEwen, PhD
Director, Clinical Science



Galyna Pidpruzhnykova, PhD
Director, Innovation Strategy



Anna Richardson
Chief of Staff, Director
Stakeholder Engagement



Nicki Shah
Director, Technology



Michael Auerbach
Supervisory Board



Jason Camm
Supervisory Board



Andrea Heslin Smiley
Supervisory Board



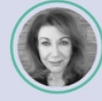
Amir Kalali,
Supervisory Board



Terence A. Kelly, PhD
CEO Perception
Neuroscience



Ian Massey
CEO GABA Therapeutics



Deborah Mash, PhD
CEO DemeRx




Tom Bradshaw
CEO Neuro



Our enabling technologies are designed to efficient drug discovery and improved treatment outcomes

Digital Therapeutics

 Introspect

- ✓ Wholly owned digital therapeutics platform dedicated to providing more comprehensive, personalized care management with potential to secure stronger IP protection

Psyber

- ✓ Utilizes digital combination tools to empower atai's programs, such as remote monitoring and remote counseling

AI Enabled Drug Discovery

 EntheogeniX

- ✓ Joint venture with Cyclica, with atai currently owning 80%
- ✓ AI-enabled computational biophysics platform designed to optimize and accelerate drug discovery
- ✓ Potential to be a product engine for atai supporting the next generation of novel programs

We are initially focused on **mental health disorder** **patient need** and **significant ma**



~300m

Patients with **Depression** (global)¹

~33% of patients are resistant to front line treatments



~40m

Patients with **Anxiety Disorders** (US)²

Current treatments have slow onset (4- 12 weeks) or side effects including sedation



~18m

Patients with **Cognitive Impairment Associated with Schizophrenia** (global)³

No pharmacological treatments approved for CIAS

1. World Health Organization (2020)

2. Anxiety and Depression Association of America (2020)

3. Using CSCI Criterion; Reichenberg et al., "Neuropsychological Function and Dysfunction in Schizophrenia and Psychotic Affective Disorders" (2009)

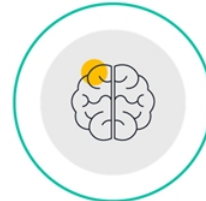
4. SAMSHA - National Survey on Drug Use and Health (2017)

5. Georges et al, "Traumatic Bra

Robust Ability to Block Strategy: IP, regulat create framework for excluding would-be com



Robust Specialty
Pharma IP Strategy



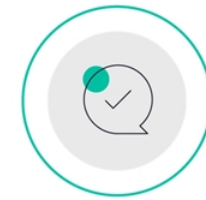
Drug & Digital Com
Therapeutics
Exclusivity
Strategy



Differential
De-scheduling



Strategic Restrictive
Covenants

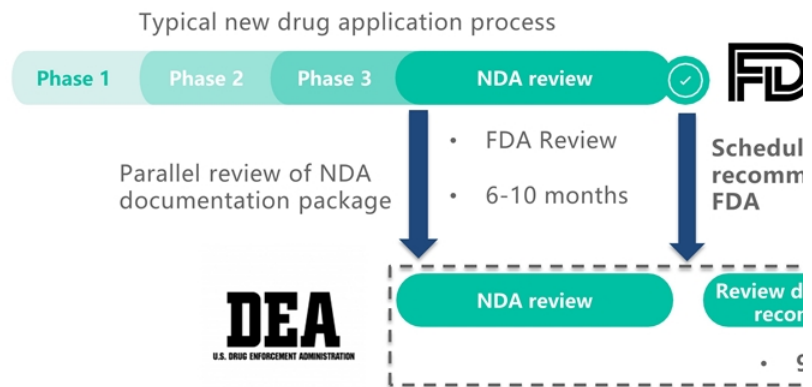


Leading IP and
Regulatory
Advisors

FDA evaluates NDAs and shares information on down-scheduling of the parent drug

Additional **DEA** process for schedule 1 process, takes approx. 4 months

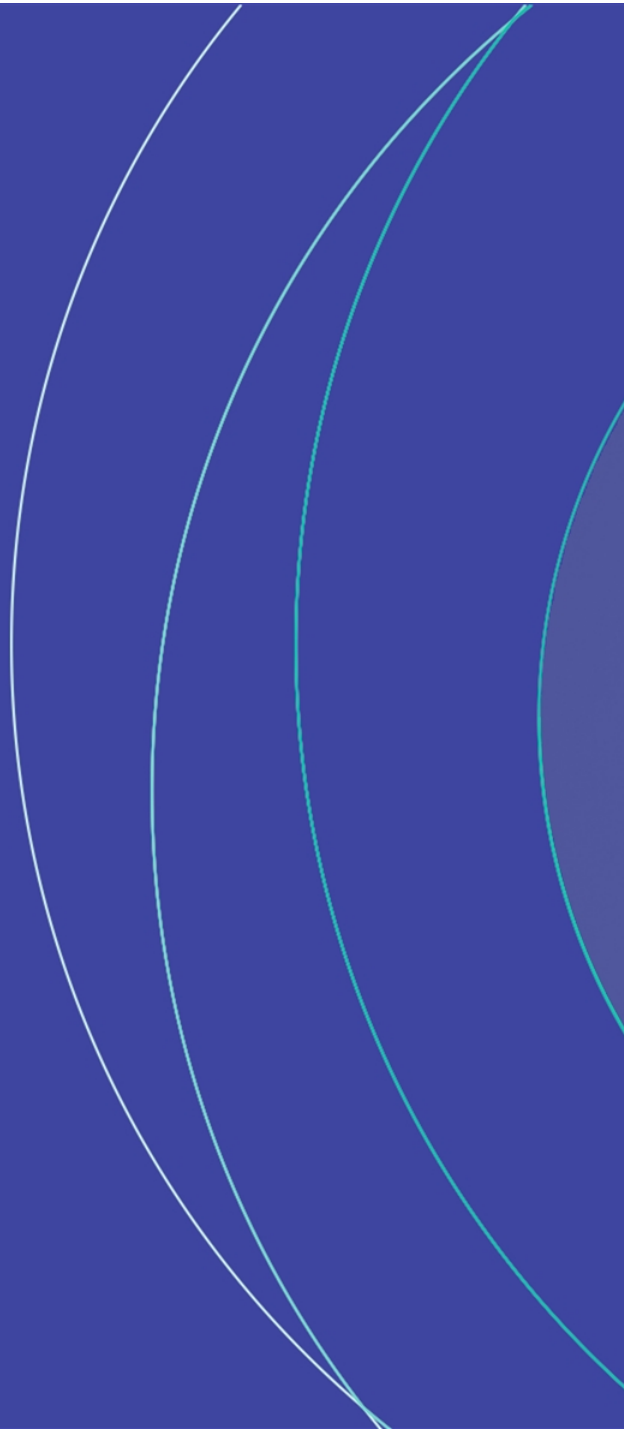
Successful precedents include GHB and THC



Brand name	Xyrem	Mar
Compound	Sodium oxybate (sodium salt of GHB*)	THC
Indication	Narcolepsy	Che
Launch	2002	198

Source: FDA website
* GHB = γ -hydroxybutyric acid

Depression



Depression

Opportunity Overview

Treatment resistant depression (TRD) is diagnosed after two failed courses of antidepressants.



Treatment options for TRD



Antidepressants

Augmentation therapy¹ S-

Ketamine

Somatic therapy²

High-intensity psychological interventions



~300m

Global sufferers of depression³



2

Approved drugs for (Spravato, Symbyo)

1. Includes mood stabilizers, atypical antipsychotics, and esketamine.

2. Includes rTMS (repetitive transcranial magnetic stimulation), tDCS (transcranial direct current stimulation), ECT (electroconvulsive therapy), and DBS (deep-brain stimulation).

3. World Health Organization (2020)

4. Hasler et al., Acute psychol (2004)

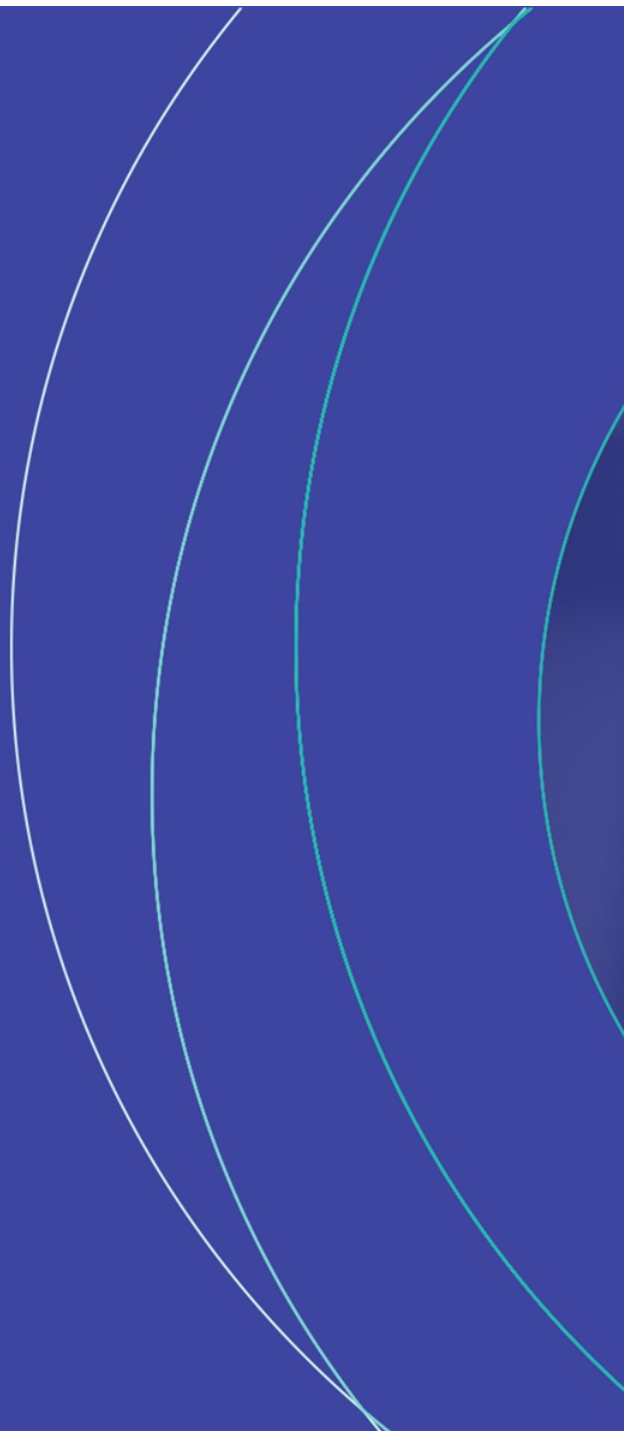
5. Pandarakalam, 2018; Sussm

6. Evaluate Pharma (as of 19.03)

atai is targeting depression via multiple co

	Company	COMPASSION [™] Navigating Mental Health Pathways	VIRIDIA LIFE SCIENCES
	Compound	COMP360	DMT
Population / Drug class	Indication	TRD	TRD
	MoA Target / Drug Class	5-HT2A-R agonist	5-HT2A-R agonist
Convenience / Use	Potential for at home use	⊗	⊗
	Potential for concomitant use with SSRIs	⊗	⊗
	In-clinic duration	6-8 hours	~2 hours
Commercial	Distribution channels	New clinics infrastructure	S-ketamine/ psilocybin clinics

Cognitive Impairment Associated with Schizophrenia



Cognitive Impairment Associated with Schizophrenia (CIAS)

Opportunity Overview

Schizophrenia is a chronic, psychiatric disorder characterized by a heterogeneous combination of symptoms, including psychosis, social withdrawal, flat emotional affect and cognitive impairment. Nearly all schizophrenia patients are affected by CIAS, limiting both social and non-social cognitive functions.



To date, there are no pharmacological treatments approved for CIAS



~21m

Global sufferers of schizophrenia ¹



~\$155bn-

Estimated annual US economic burden due to schizophrenia⁴

1. Charlson et al., "Global Epidemiology and Burden of Schizophrenia: Findings From the Global Burden of Disease Study" (2016)

2. Using CSCI Criterion; Reichenberg et al., "Neuropsychological Function and Dysfunction in Schizophrenia and Psychotic Affective Disorders" (2009)

3. Laursen, Nordentoft & Mørtzen

4. Cloutier et al., "The Economic Burden of Schizophrenia" (2009)

5. EvaluatePharma (as of 19.03.2019)

PIPELINE SUMMARY




9 Clinical Stage Therapies in Development for CIAS

12 Pre-Clinical Stage Therapies in Development

17 Different Mechanisms of Action

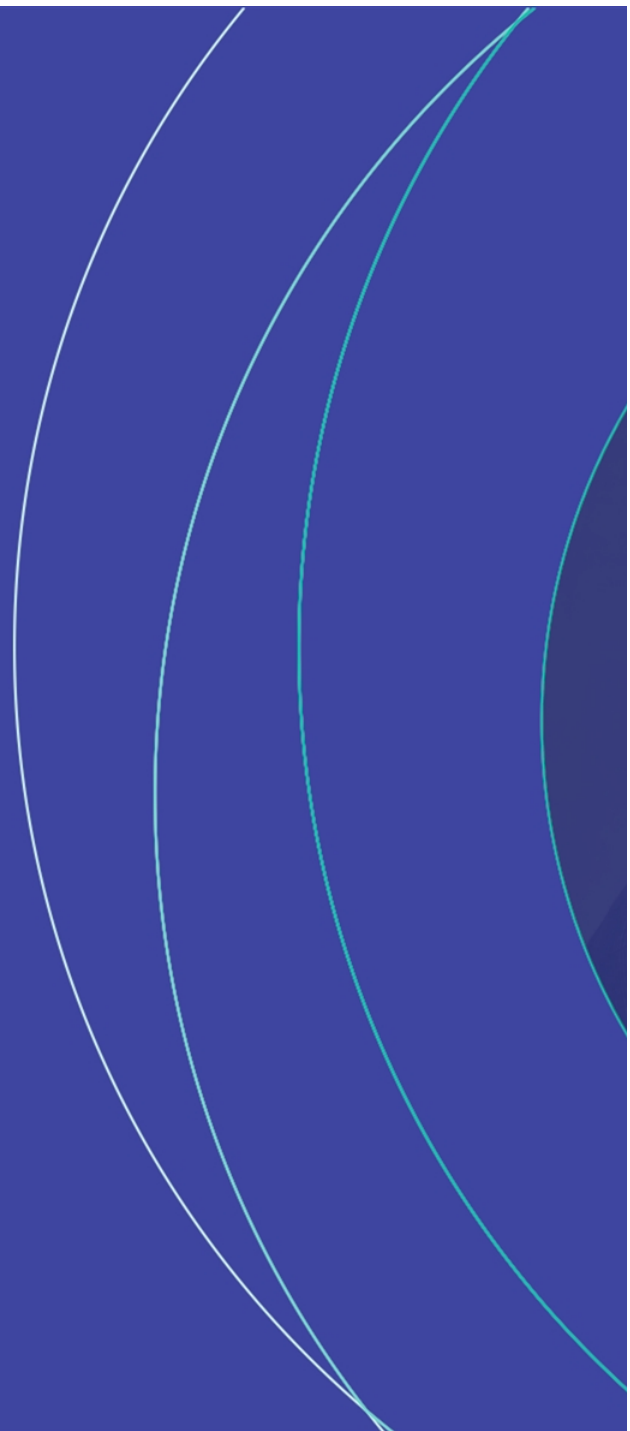
RL-007 is well positioned, cor signal of pro-cognitive effects

Overview of Leading Clinical Stage Competitors for Cognitive Impairment

			
Therapy	RL-007	BI-425809	PF-03463275
Primary Indication	CIAS	CIAS	CIAS
MoA	GABA / nicotinic modulator	GlyT1 inhibitor	GlyT1 inhibitor
Current Phase	II	II	II
Notes	Previously assessed in over 500 subjects for other indications with no serious adverse events observed	Completed Phase II with positive results; recruiting for Ph III	Ongoing Phase

Note: GABA = Gamma aminobutyric acid; TAAR1 = trace amine-associated receptor; GlyT1 = Glycine Transporter 1; M4 = muscarinic acetylcholine receptor 4; PAM = positive allosteric modulator
Sources: GlobalData, Evaluate Pharma (both as of 2021)

Substance Use Disorder



Substance Use Disorder (SUD)

Opportunity Overview

Substance use disorders are highly prevalent disorders characterized by an inability to control the use of a legal or illegal drug, medication or other psychoactive compound

Treatment options for Opioid Use Disorder (OUD)



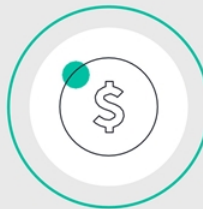
Synthetic opioid receptor agonists (methadone and buprenorphine)

Opioid antagonists (naltrexone and naloxone)



~20m

US sufferers of SUD in 2017¹



\$787b

Societal cost associated with OUD in US

1. SAMSHA - National Survey on Drug Use and Health (2017)
2. Wilson et al., "Drug and opioid-involved overdose deaths – United States, 2017-2018" (2020)

3. Murphy, "The cost of opioid u
4. Sinha, "New Findings on Bioc

SUMMARY

DMX-1002 could potentially become a paradigm-shifting therapy for Opioid Use Disorder

Current standard of care for OUD is medication therapy, requiring opioid substitutes that carry significant side effects

Current strategies for withdrawal support have high rates of relapse

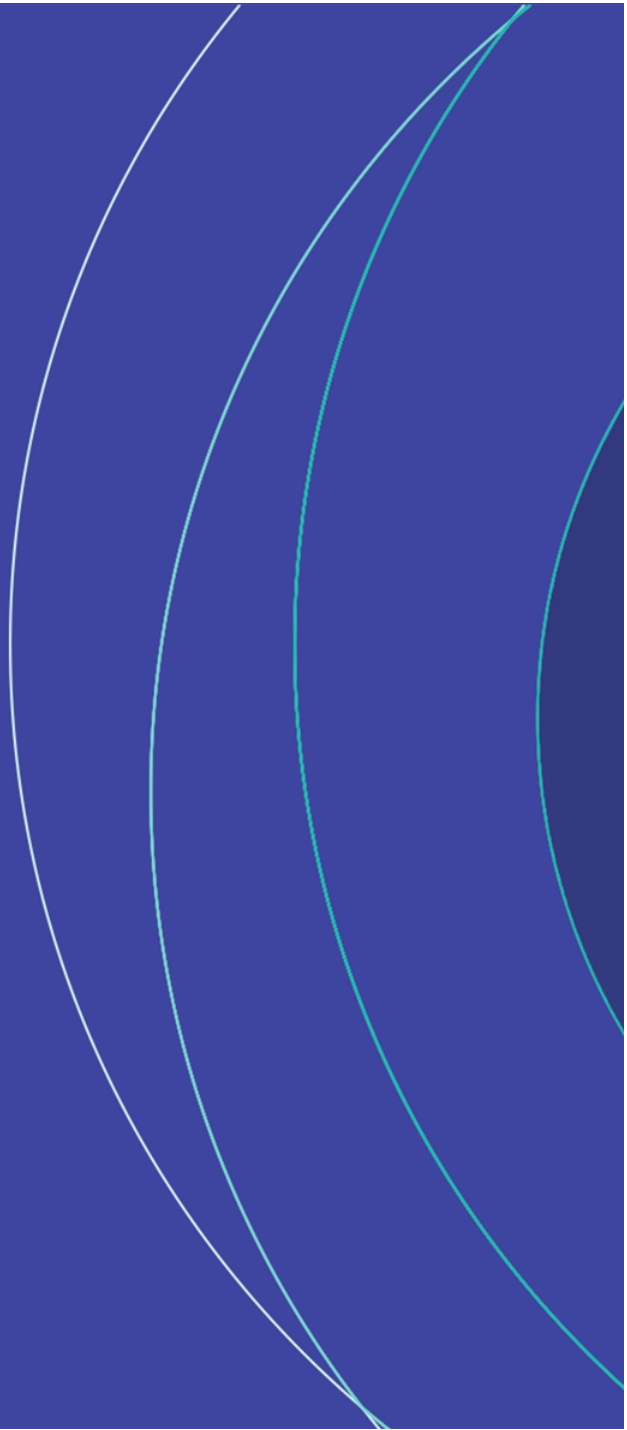
DMX-1002 has the potential to be a disease-modifying treatment for OUD,

	Therapy	Mechanism of Action
Disease Modification Single dose administered in monitored setting, providing both withdrawal support and oneiric experience with goal of complete remission	Ibogaine (DMX-1002) 	Mixed
Withdrawal Support² Therapies given for symptomatic management during supervised withdrawal (detoxification)	Clonidine <hr/> Lofexidine <hr/> Methadone <hr/> Buprenorphine <hr/> Naltrexone	Alpha-2 agonist <hr/> Alpha-2 agonist <hr/> Mu-agonist <hr/> Partial Mu-agonist <hr/> Mu-antagonist

Source: GlobalData, Evaluate Pharma (both as of 2021)

1. Current Standard of Care
2. Rarely used given high rates of relapse. Used primarily in institutional or penitentiary settings

Anxiety



Anxiety

Opportunity Overview

Anxiety disorders develop when feelings of apprehension and unease persist over an extended period and potentially worsen over time



Treatment options for anxiety disorders



Antidepressants (SSRIs)

Benzodiazepines

Psychotherapy



~40m

Anxiety disorder sufferers in the US¹



<50%

Less than half of patients with Anxiety disorder in the US receive treatment²

1. National Alliance on Mental Illness (2021)
2. Anxiety and Depression Association of America (2021)
3. DeVane et al., "Anxiety Disorders in the 21st Century: Status, Challenges, Opportunities, and Comorbidity With Depression", AJMC (2005)

SUMMARY



There is an unmet need in GAD for therapies with rapid onset, high efficacy, and minimal side effects

SSRI's are current standard of care for GAD but require 4-6 weeks for onset of effect and have several disadvantages¹:

1. SSRI/SNRI-specific inadequacy
2. Lack of tolerability
3. Patient nonadherence to medications that fail to relieve symptoms of anxiety quickly

Benzodiazepines are second-line treatment, offering fast and effective relief, but carrying significant risk of:

1. Sedation
2. Impaired cognition
3. Dependence/addiction

GRX-917 can fill unmet need (GAD) with rapid onset and f

Overview of Current Therapeutic Options for Generalized Anxiety Disorder

Class	Examples	Mechanism of action	Favo safety
Benzoxazine	deu-etifoxine (GRX-917) 	GABA _A Channel and TSPO Potentiation	
Selective Serotonin Reuptake Inhibitor (SSRI)	Escitalopram	SERT blockade	
Serotonin and Norepinephrine Reuptake Inhibitor (SNRI)	Venlafaxine	SERT AND NET blockade	
Benzodiazepines	Alprazolam	GABA _A Potentiation	
Tricyclic Antidepressant (TCA)	Imipramine	Mixed MoA	
Azapirones	Buspirone	partial 5-HT1A agonist	
Gabapentinoid	Pregablin	VDCC inhibition	

Note: GABA = Gamma aminobutyric acid, SERT = serotonin transporter, NET = serotonin transporter; MoA = mechanism of action

Source: GlobalData, Evaluate Pharma (both as of 19.03.2021)

1. DeMartini et al., "Generalized Anxiety Disorder" (2019)

Traumatic Brain Injury



Traumatic Brain Injury (TBI)

Opportunity Overview

Traumatic brain injury typically occurs when a sudden force impacts the head or body, resulting in damage and functional impairment of the brain. atai initially focuses on mild traumatic brain injuries.



To date, there are no pharmacological treatments approved for Traumatic Brain Injury



~1.7m

People sustain TBI each year in US¹



5.3m

Americans live with TBI related disabilities³

1. Georges et al., "Traumatic Brain Injury", NCBI (2020)

2. CDC, "Surveillance Report of Traumatic Brain Injury-related Emergency Department Visits, Hospitalizations, and Deaths" (2014)

3. Thurman et al., "Report to Cc

4. Hoffer et al., "Repositioning c

While **mental health is the initial focus**, adjacent indications may allow for **significant expansion**

Anti-inflammatory properties make psychedelics potentially interesting for a variety of therapeutic indications¹

Selected CNS indications of interest for psychedelic therapeutics

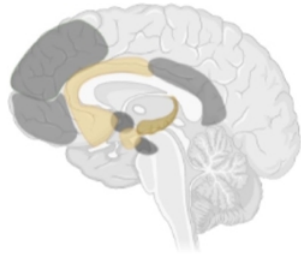
Indication	Estimated 2026 Market Size (\$BN)
Eating disorders	7.4*
Obsessive-Compulsive Disorder	3.7*
Attention Deficit Hyperactivity Disorder	3.3
Autism Spectrum Disorders	1.4*
Multiple Sclerosis	21.1
Ischemic/Hypoxic Brain Injury	20.0
Alzheimer's Disease	10.6
Migraine Headache	9.6
Parkinson's Disease	2.4
Amyotrophic lateral sclerosis	1.0
Cluster Headache	0.3
	80

* Company estimate based on worldwide incidence

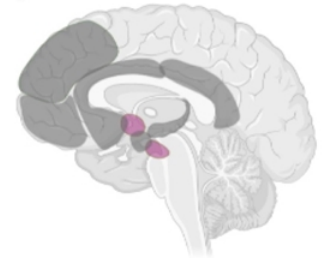
Source: EvaluatePharma for all indications with exception of Eating disorders, Autism spectrum disorders. Market size was calculated based on estimated worldwide incidence and current yearly average cost. 1. Flanagan & Nichols, "Psychedelics as anti-inflammatory agents" (2018). 2. Spriggs et al., "Positive effects of psilocybin on social behavior in a rat model of post-traumatic stress disorder" (2020). 3. Lea et al., "Perceived outcomes of psychedelic microdosing as self-managed treatment for anxiety and depression" (2020). 4. Leary et al., "The effects of psilocybin on social behavior in a rat model of post-traumatic stress disorder" (2020). 5. Leary et al., "The effects of psilocybin on social behavior in a rat model of post-traumatic stress disorder" (2020). 6. Szabo et al., "The Endogenous Hallucinogen and Trace Amine-Associated Receptor 1 Receptor Activation in Human Primary iPSC-Derived Cortical Neurons and Microglia-Like Cells" (2020). 7. Katchborian-Neto et al., "Neuroprotective potential of Ayahuasca in a mouse model of Alzheimer's Disease Dementia" (2020). 8. Katchborian-Neto et al., "Neuroprotective potential of Ayahuasca in a mouse model of Alzheimer's Disease Dementia" (2020). 9. Szabo et al., "Psychedelics as a novel approach to treating autoimmune conditions" (2020). 10. Szabo et al., "Exploratory Controlled Study of the Migraine-Suppressing Effects of Psilocybin" (2020).

atai aims to develop novel **disease-modifying** treatments for mental health by focusing on neuroplasticity

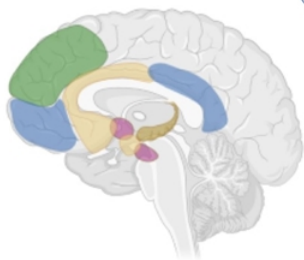
Standard of Care



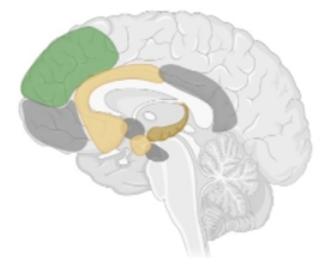
- 1 SSRIs localized to serotonergic pathways with slow onset, mainly ↓AN: reduced stress, emotional blunting.



- 2 Buprenorphine ↓RN Opioid receptor agonists for maintenance; drawbacks: respiratory depression and maintained dependency.



- 1 Pleiotropic re-set of DMN & AN. Increased neuroplasticity combined with psychedelic experience facilitates regaining control of CC and RN and “unlearning” negative behaviors.
- 2



- 3 Modulatory (+/-) effect on AN. Restoration of top-down control of emotion: from CC.

“Watching my best friend and business partner suffer, being let down by existing treatments, and finally finding comfort in psychedelic therapy was all the inspiration I needed to commit to this cause.”

Florian Brand | CEO | atai life sciences
