

**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): July 13, 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 shares, €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 July 13, 2021, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at [www.atai.life](http://www.atai.life). A copy of its current corporate slide presentation is attached to this Current Report on 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	<a href="#">Corporate Slide Presentation of ATAI Life Sciences N.V. dated July 2021</a>
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: July 13, 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 anticipated or implied in the forward-looking

statements. We caution you therefore against relying on these forward-looking statements, and we qualify all of our forward-looking statements by these cautionary statements.

The forward-looking statements included in this presentation are made only as of the date hereof. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved 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 any obligation to update any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations, except as may be required by law. You should read this presentation with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Unless otherwise indicated, information contained in this presentation concerning our industry, competitive position and the markets in which we operate is based on information from independent industry and research 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 assumptions made by us upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, projections, assumptions and estimates of the future performance of the industry in which we operate and our future performance are

necessarily subject to uncertainty and may differ materially from those expressed and by us. Industry publications, and the information they contain may not be reliable, but that the accuracy is not guaranteed. Forecasts and other sources are subject to the same uncertainties as forward-looking statements in this

This presentation contains information that has not been treated with compounds or product candidates in the context solely intended to be illustrative of potential beneficial results of such compounds in clinical stages of development that have not been approved by the FDA or any other

Any trademarks included herein are used for reference purposes only and do not constitute an endorsement of the products or services


# We are a founder-led team aiming to develop differentiated treatments for patients suffering from mental health disorders



**Christian Angermayer**  
Founder

**PEIRON**  
INVESTMENT GROUP

**Alynlam**  
PHARMACEUTICALS



**Florian Brand**  
Co-Founder & CEO

**ROCKETINTERNET**

**springlane**



**Lars Wilde**  
Co-Founder

**COMPASSION**  
Navigating Mental Health Pathways

**springlane**



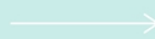
**Greg Weaver**  
CFO

**ELO**  
Eloxx Pharmaceuticals

**Sirna**  
Therapeutics



The atai team has collectively led



13

NDA through regulatory approval



50

# 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, **innovations remain limited**, with only 7 new neuropsychiatric drugs approved since 2015.
- 2 As a response to lack of innovation, atai focuses on **compounds with prior clinical evidence**, including psychedelics whose therapeutic potential has become evident in recent academic studies and which have benefited from recent regulatory momentum.
- 3 Since 2018 we have aggressively grown our platform to **6 psychedelic, 5 non-psychedelic drug** development programs and **6 enabling technologies**, focusing on differentiated and potentially disease-modifying mental health treatments.
- 4 Our **platform approach**: Decentralized drug development process, leveraging the atai team and our enabling technologies such as digital therapeutics to aim for improved safety, efficacy and probability of clinical success across our pipeline.
- 5 Increased investor appetite as the **IPO of COMPASS Pathways** and the **Otsuka partnership** with our subsidiary Perception Neurosciences demonstrate our ability to capture value.
- 6 With a team of more than 50 highly experienced professionals at atai, an additional 150 FTEs / consultants across our companies and a cash position as of March 31, 2021 of approx. \$449M<sup>(1)</sup>, we are **well positioned to achieve our upcoming anticipated value inflection** points.

(1) After giving effect to our Series D and IPO financings.



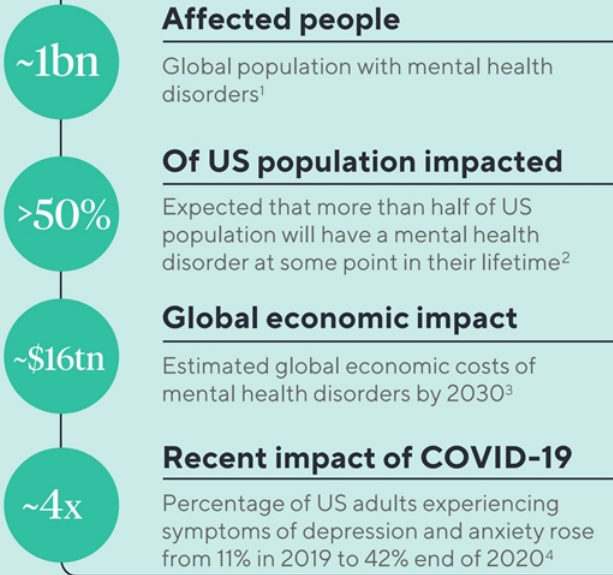
## Founded in 2018

As a response to the **significant unmet need** and **innovation** in the mental health treatment landscape as the **emergence of therapies that previously been overlooked or underused**, including psychedelic compounds and digital therapeutics.

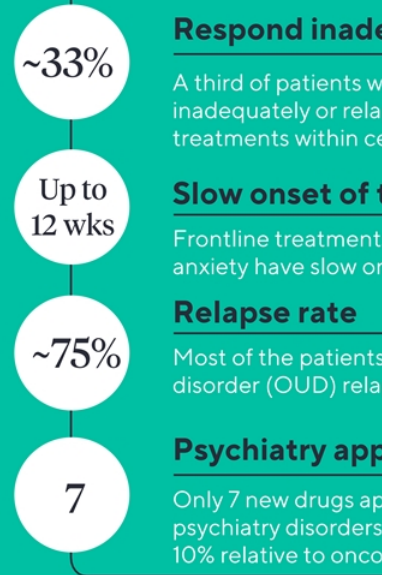


# Although mental health has become one of the largest global healthcare challenges, there has been little innovation for patients<sup>7</sup>

## SIGNIFICANT BURDEN



## URGENT NEED FOR INNOVATION



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 Recovery-Remission From Serious Mental Illness", Psychiatry Online (2019).  
6. Tew et al., "Impact of prior treatment exposure on response to antidepressant treatment in late life depression", Journal of Affective Disorders (2019).  
7. Sinha, "New Findings on Biological Factors Predicting Addiction Relapse Vulnerability" (2011).  
8. EvaluatePharma (as of 19.03.2021). New drugs include new molecular entities or new active ingredients.

# A resurgence in psychedelic therapies is emerging as promising disease modifying drug candidates progress with regulatory momentum



LSD synthesized by Dr. Albert Hofmann at Sandoz research labs<sup>1</sup>



Dr. Stan Grof uses LSD to treat heroin addiction in Prague<sup>3</sup>



Psilocybin shows sustained decreases in depression and anxiety in cancer patients<sup>5</sup>



FDA design for tr

1938

1953

1960s

1965

2016

2017

2019

“America’s public enemy number one is drug abuse.”

PRESIDENT NIXON, 1971

Psychedelic therapy developed by Dr. Abram Hoffer and Dr. Humphry Osmond, efficacious in treating alcoholics<sup>2</sup>

Drug Control Amendments forbid the manufacture and sale of psychedelic drugs (scheduling)<sup>4</sup>



FDA Breakthrough designation for MDMA Assisted Psychotherapy and announcement of Phase 3 in PTSD<sup>6</sup>

Early research suggested efficacy in mental health

Novel results and regulatory support underscore therapeutic value

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 produces substantial and sustained decreases in depression and anxiety in cancer patients" (2016)
- MAPS, announcement breakthrough designation Phase 3 (2017)
- COMPASS, COMPASS Pathways Receives FDA Breakthrough Therapy Designation for Psilocybin (2019)
- FDA, FDA Approves New Nasal Spray (2019)

# Patient reports: In a study, more than half of the patients ranked psilocybin therapy among the top five most meaningful experiences of their lives

"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."<sup>2</sup>



Male, 25  
Ibogaine

"It sort of relieved a lot of stress, a lot of negative thoughts within my body... opened my eyes to see where my stress and conflict is coming from... It is hard to explain but... it just brought a lot of grief up that I had inside me, it brought it out and I got rid of a lot of grief."<sup>3</sup>



Male, 55  
Psilocybin

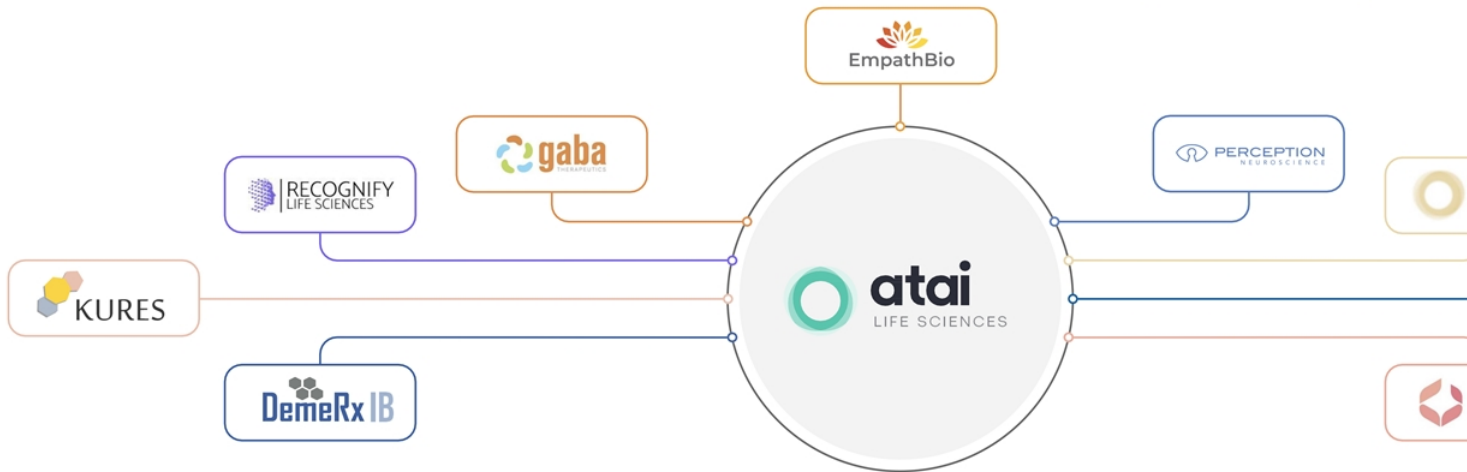
"I felt like, just new reborn person. I not felt that for a long time. I felt about myself



Female,  
Ayahuasca

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 process that leverages a diverse team and enabling technologies to aim for improved probability of clinical 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**

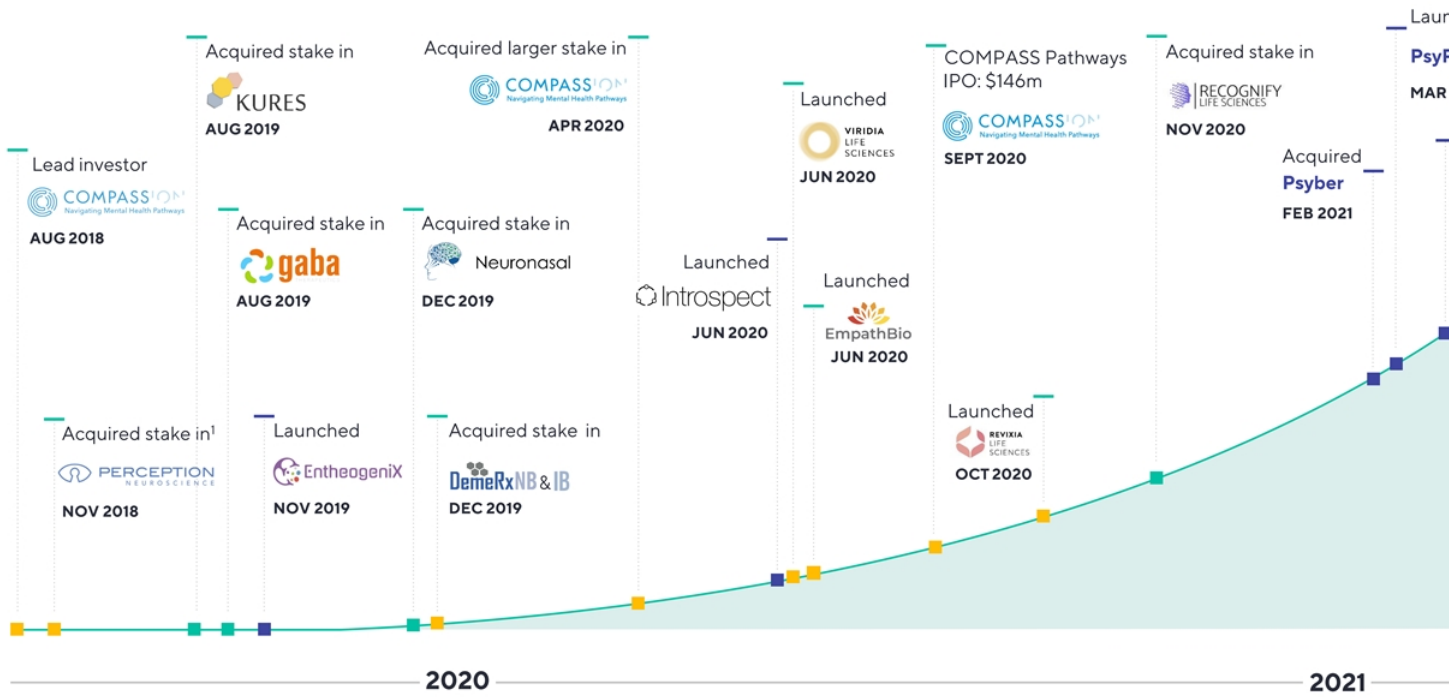
- Disciplined selection criteria (including prior evidence in humans)
- Impactful capital allocation to acquired and incubated companies
- Strategic value capturing and high degree of optionality

COMPASSION Navigating Mental Health Pathways Otsuka

**Enabling Technologies**

- AI
- Int


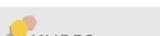



# Rapid Growth via incubations and acquisitions: 6 psychedelic programs, 5 non-psychedelic programs and 6 enabling tec






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 nonpsychedelic at effective doses.

# Development program overview: Our company ownership, lead compounds, lead indications and stage of development

## OUR PROGRAMS

Company	Lead Compound	Lead Indication	Type	Ownership % <sup>1</sup>	Preclinical	Phase 1	Phase 2
 PERCEPTION NEUROSCIENCE	PCN-101 / R-ketamine	TRD	VIE	50.1% <sup>2</sup>	<div style="width: 100%;"></div>		
 RECOGNIFY LIFE SCIENCES	RL-007 / Compound <sup>3</sup>	CIAS	VIE	51.9%	<div style="width: 100%;"></div>		
 DemeRx IB	DMX-1002 / Ibogaine	OUD	VIE	59.5%	<div style="width: 80%;"></div>		
 Neuronasal	NN-101 / N-acetylcysteine	mTBI	VIE	56.5% <sup>4</sup>	<div style="width: 80%;"></div>		
 KURES	KUR-101 / Deuterated mitragynine	OUD	VIE	54.1% <sup>5</sup>	<div style="width: 60%;"></div>		
 EmpathBio	EMP-01 / MDMA derivative	PTSD	Wholly Owned	100%	<div style="width: 100%;"></div>		
 REVIXIA LIFE SCIENCES	RLS-01 / Salvinorin A	TRD	Wholly Owned	100%	<div style="width: 100%;"></div>		
 VIRIDIA LIFE SCIENCES	VLS-01 / DMT	TRD	Wholly Owned	100%	<div style="width: 100%;"></div>		

## ENTITIES LIMITED TO EQUITY INTEREST

 COMPASS ONE Navigating Mental Health Pathways	Developing COMP360 therapy, with psychological support from specially trained therapists, for TRD. Phase 2b trial is ongoing.	19.4% <sup>6</sup>
 gaba THERAPEUTICS	Developing deuterated etifoxine HCl oral dosage form (GRX-917) as potential therapy for GAD. Phase 1 trial initiated.	53.8% <sup>7</sup>
 DemeRx NB	Developing DMX-1001, a formulation of noribogaine, as a potential at-home maintenance therapy for OUD. Preclinical stage.	6.3% <sup>8</sup>

Note: TRD = Treatment-resistant depression; CIAS = Cognitive impairment associated with schizophrenia; OUD = Opioid use disorder; GAD = Generalized anxiety disorder; mTBI = Mild traumatic brain injury; DMT = N,N-dimethyltryptamine; MDMA = 3,4-methylenedioxymethamphetamine; 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 30<sup>th</sup>, 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 not give effect to the obligation to acquire further shares upon the increase the ownership to up to 67.9%.

(6) As of June 30, 2021, we held a 19.4% ownership interest in COMPASS.

(7) GABA ownership does not give effect to the obligation to acquire further shares upon the increase the ownership to up to 54.2%.

(8) DemeRx NB ownership does not give effect to option to acquire further shares upon the increase the ownership to up to 57.1%.

# 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

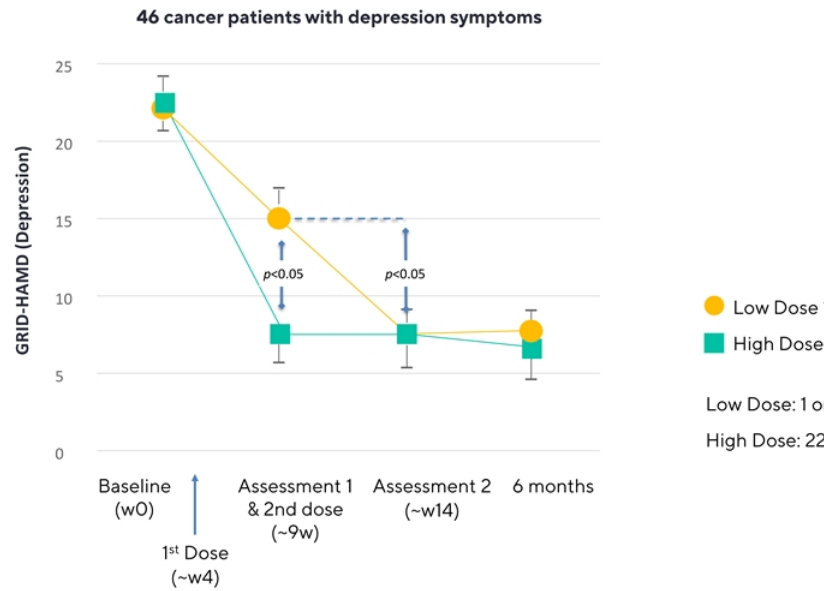
CURRENT STATUS COMP360 Phase 1 trial completed and results publicly available, Phase 2b trial results expected end of 2021

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 have shown psiloc leads to rapid and sustained reduction in symptoms

## PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY<sup>1</sup>)



Note: GRID-HAMD = GRID Hamilton Depression Rating Scale; COMP360 = a proprietary high-purity, polymorphic crystalline formulation of psilocybin. COMP360 is administered in conjunction with psychological support from specially trained therapists.

1. Griffiths et al., "Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer." *Journal of Clinical Psychopharmacology*, 2016.

# 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

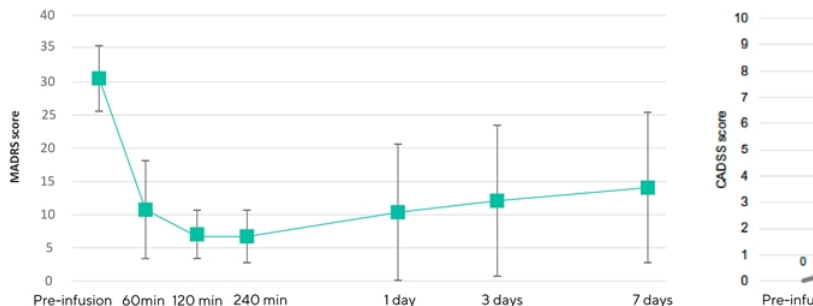
INTELLECTUAL PROPERTY Issued methods of use of R-ketamine for treatment of depressive symptoms

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 absent<sup>1</sup>

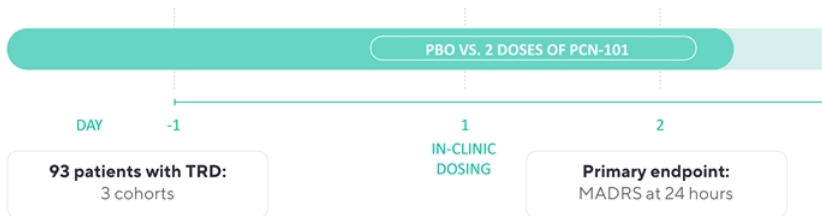
# We aim to develop PCN-101 as a rapid acting antidepressant with potential for at-home use

## PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY<sup>1</sup>)

Mean MADRS over 7 days and median CADSS scores of TRD patients after single IV dose (0.5mg)



## PLANNED PCN-101 PHASE 2 TRIAL: Randomized, double blind, placebo-controlled (n=93)

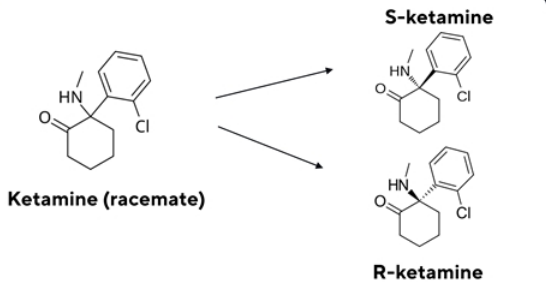


Note: MADRS = Montgomery-Asberg Depression Rate Scale, CADSS = Clinician-administered dissociative states scale, IV = Intravenous, PE 1. Leal et al, "Intravenous arketamine for treatment-resistant depression: open-label pilot study" (2020)



# Deep-dive R-ketamine vs. S-ketamine: Higher-potency, longer lasting antidepressant effect and lower potential for abuse in preclinical model

## Profile of R- vs. S-ketamine



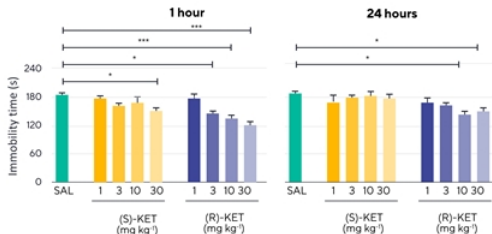
R-ketamine lacks the psychomimetic and abuse potential of S-ketamine at therapeutic doses in preclinical models.

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

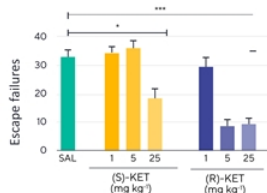
- Different active metabolite profiles
- Different pre- and post-synaptic sites of action
- Involvement of different intracellular pathways (mTORC1 vs. ERK)

## Superior and more durable

### Forced swim test<sup>1</sup> (third party study)



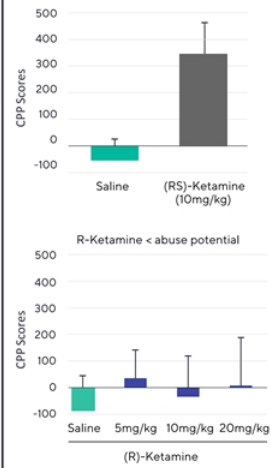
### Learned helplessness test



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

## Lower potential for abuse

### Conditioned place preference (third party study)



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 administration of (R,S)-ketamine, (R)-ketamine, and (S)-ketamine" (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 psychomimetic 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-HT2A-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 1 clinical trial anticipated to initiate in early '22

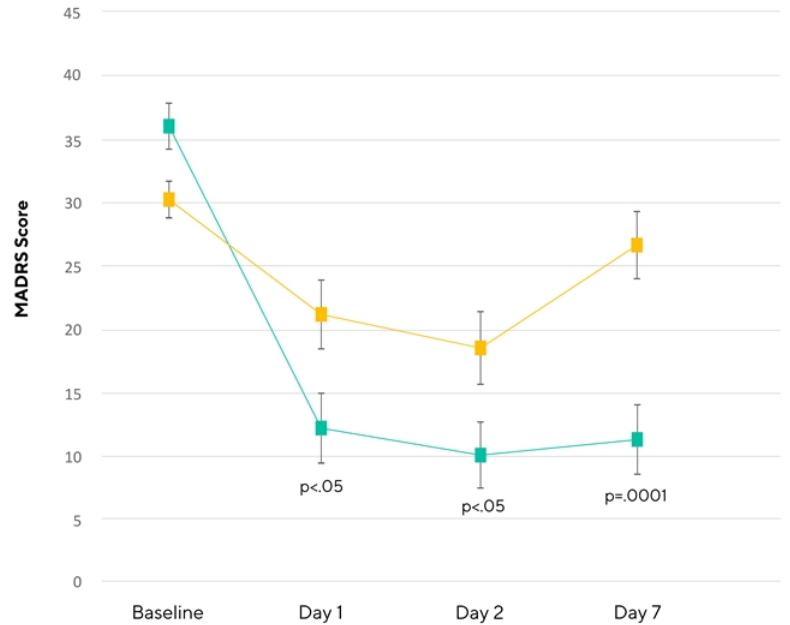
INTELLECTUAL PROPERTY Filed provisional on formulations of DMT

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

## VLS-01 may increase patient accessibility and clinic time commitment

### PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY<sup>1</sup>)

Double-blind, randomized placebo-controlled trial with Ayahuasca in 29 patients with



Note: MADRS: Montgomery-Asberg Depression Rate Scale.

1. Palhano-Fontes et al. "Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression", Psychol Med (2019)

# 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 mid '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).<sup>1</sup>

## Salvinorin A's subjective effects were comparable to classical psychedelics

### PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY<sup>1</sup>)

#### Participant ratings on Hallucinogen Rating Scale (HRS) completed 1h after drug administration

Cluster	Placebo	Active	P value	
Affect	0.75 (0.47)	1.50 (0.58)	<0.001*	Study showed ability to distinguish between placebo and active S. divinorum. All six Hallucinogen clusters were significantly elevated on the active S. divinorum.
Cognition	0.37 (0.41)	1.61 (0.81)	<0.001*	
Intensity	0.38 <sup>2</sup> (0.76)	3.00 <sup>2</sup> (0.77)	<0.001*	
Perception	0.33 (0.36)	1.71 (0.73)	<0.001*	No significant adverse events reported by the participants.
Somaesthesia	0.31 (0.33)	1.27 (0.54)	<0.001*	
Volition	0.94 (0.53)	1.85 (0.46)	<0.001*	Five patients reported significant changes in relationships with loved ones.

Note: Data are mean ratings with one standard deviation shown in parentheses (\*P < 0.05).  
1. Addy, "Acute and post-acute behavioral and psychological effects of salvinorin A in humans" (2011)  
2. Median used instead of mean for nonparametric data

# Depression positioning and landscape: atai's programs are designed to be differentiated from one another and from competitors

	TRD treatments being developed by atai companies				Marketed therapies		Phase II and III c	
	Compass	Perception	Viridia	Revixia	J&J	e.g. Lilly, Pfizer	Various	GH Resea
Company	COMPASS DMT Navigating Mental Health Pathways	PERCEPTION NEUROSCIENCE	VIRIDIA LIFE SCIENCES	REVIXIA LIFE SCIENCES	Johnson & Johnson	Lilly Pfizer	NOVARTIS NeuroRx Johnson & Johnson AXSOME	GH Resea
Compound	COMP360	R-ketamine	DMT	Salvinorin A	S-ketamine	SSRI/SNRI	MIJ-821, NRX-102, JNJ-5515, AXS-05	5-MeO-D
Potential for at home use								
Potential for sustained efficacy							tbd	
Rapid onset of treatment effect <sup>1</sup>							tbd	
Mechanism of Action	5-HT2A-R agonist	Glutamatergic modulator	5-HT2A-R agonist	KOR agonist	NMDA-R antagonist	SERT / NET blockade	NMDA-R / mGluR2 antagonists	5-HT1A-5-HT2 agonis

Note: 5HT2A-R = Serotonin 2A receptor, KOR = kappa-opioid receptor, NMDA-R = N-methyl-D-aspartate receptor, NET = Norepinephrine transporter, SERT = Serotonin Transporter, mGluR2 = Metabotropic glutamate receptor 2, GABA = Gamma-Aminobutyric acid, 5-MeO-DMT = 5-methoxy-N,N-dimethyltryptamine, SSRI = Selective Serotonin Reuptake Inhibitor, SNRI = Selective serotonin-norepinephrine reuptake Inhibitor, COMP360 = a proprietary high-purity, polymorphic crystalline 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 IL-6, cortisol levels, affect, and non-judgment. Psychopharmacology. 2021; 394: 1-11.  
1. Rapid onset of treatment effect versus standard of care.

# SUMMARY



OWNERSHIP 59.5%<sup>2</sup>

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

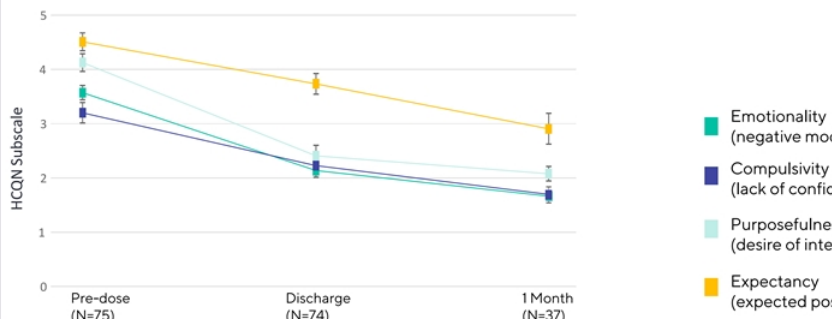
CURRENT STATUS Phase 1/2 trial to initiate in mid '21

INTELLECTUAL PROPERTY Pending method of treatment claims for OUD for ibogaine, issued method of treatment claims for OUD patients on methadone for noribogaine<sup>3</sup>

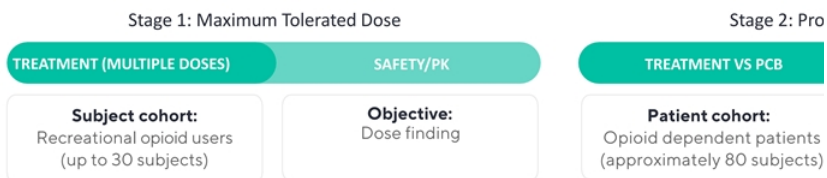
HIGHLIGHT Potential sustained reduction in opioid craving with DMX-1002 single administration

# A single-dose of ibogaine showed sustained reduction in opioid cravings in 75 opioid-dependent patients

## PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY<sup>1</sup>)



## ONGOING PHASE 1/2 TRIAL



Note: HCQN = Heroin Craving Questionnaire, PTSD = Post-traumatic stress disorder, OUD = Opioid use disorder, PCB = Placebo, PK = Pharmacokinetics  
 1. Mash et al., "Ibogaine Detoxification Transitions Opioid and Cocaine Abusers Between Dependence and Abstinence: Clinical Observations and Implications for Treatment"  
 2. Refers to ownership in DemeRx IB. DemeRx NB ownership is 6.3%, which does not give effect to option to acquire further shares which may be exercised in the future.  
 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

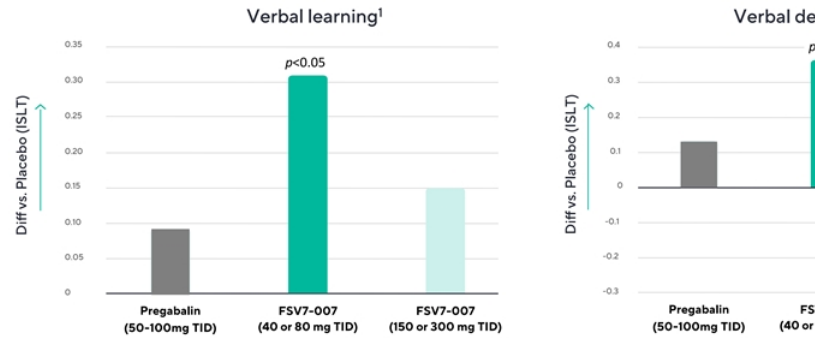
CURRENT STATUS Phase 2a trial initiated in H1'21

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 previously shown pro-cognitive human clinical studies

## PRIOR EVIDENCE IN HUMANS



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



Note: CIAS = Cognitive impairment associated with schizophrenia; RL-007 is (2R, 3S)-2-amino-3-hydroxy-3-pyridin-4-yl-1-pyrrolidin-1-yl-propa  
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 memory

# 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

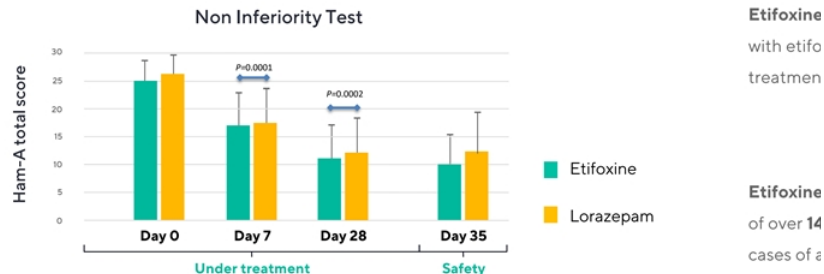
CURRENT STATUS Phase 1 trial initiated in H1'21

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 benzodia onset efficacy with improved safety and

## PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY<sup>1</sup>)



## ONGOING PHASE 1 TRIAL



Note: HAM-A = Hamilton Anxiety Rating Scale, SD = standard deviation, qEEG = Quantitative electroencephalography, PK = Pharmacokinetics.  
 1. Nguyen et al., "Efficacy of etifoxine compared to lorazepam monotherapy" (2006)  
 2. Cottin et al., "Safety profile of etifoxine: A French pharmacovigilance survey" (2016)

# 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

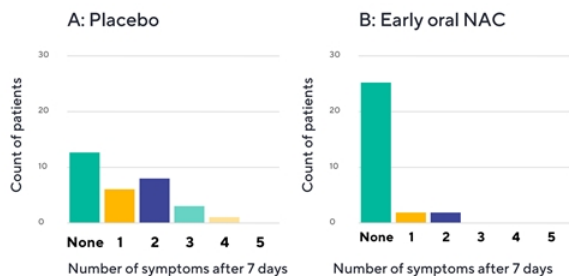
INTELLECTUAL PROPERTY Pending patent on methods of use of NAC for treating post-concussion syndrome

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

# NN-101 has the potential to become the pharmacological treatment for mTBI

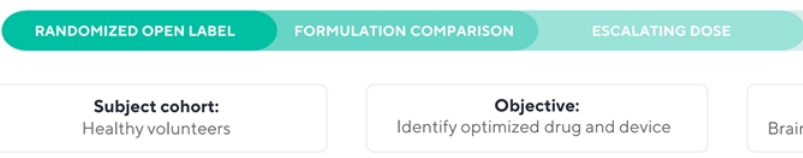
## PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY<sup>1</sup> AND NEURONASAL PILOT)

Treatment of 81 mTBI patients with NAC (24h post blast) increased probability of symptom resolution by ~2x (OR = 3.60,  $p = 0.0062$  overall)



NN-101 correlation response

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



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: a double-blind, placebo-controlled study." *Journal of Neurotrauma*, 2013.



# 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

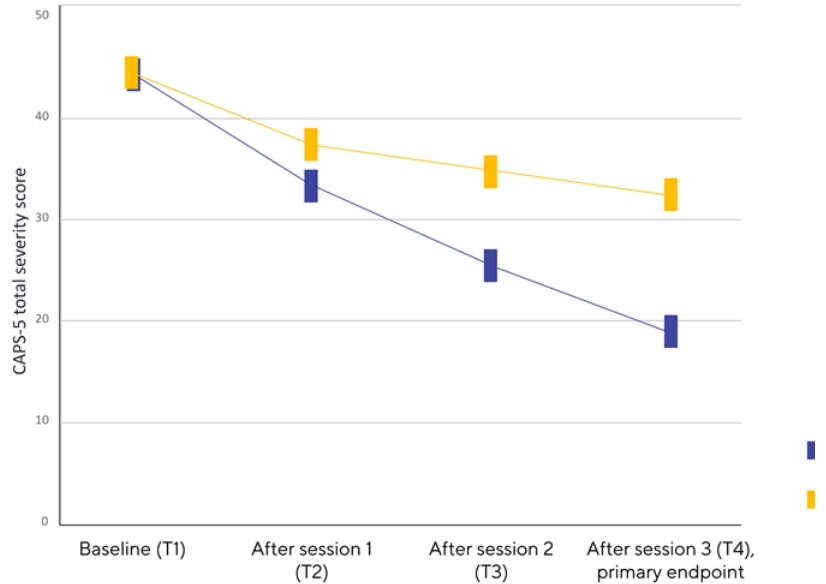
INTELLECTUAL PROPERTY Filed provisional on formulation, combination approach

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 psychotherapy significantly reduces PTSD symptoms in 90 severe PTSD patients

## PRIOR EVIDENCE IN HUMANS (THIRD PARTY STUDY<sup>1</sup>)

MDMA-assisted therapy significantly reduced CAPS-V scores in PTSD patients (primary endpoint)



Note: Change in CAPS-V total severity score from T1 to T4 ( $P < 0.0001$ ,  $d = 0.91$ ,  $n = 89$  (MDMA  $n = 46$ )), as a measure of the primary outcome. Primary analysis was completed using least square means from a mixed model repeated measure (MMRM) analysis model; ( $n=90$ ) Mitchell et al., "MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study" (2021)

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



## 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 initiatives!



## atai's oppo

Aimed at improved treatment outcomes

Regulatory exclusivity development of combination (i.e., digital app + drug)

Combination also provides opportunity for IP scope expansion



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

# Recent achievements and upcoming value inflection points

## Recent Milestones

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

## Anticipated Milestones next 1

- PCN-101 Phase 2a FSI
- DMX-1002 Phase 1/2 FSI
- PCN-101 (SQ vs. IV BA) results
- NN-101 Phase 1 FSI
- RL-007 Phase 2a results
- PCN-101 Phase 2a results
- DMX-1002 Phase 1 results
- GRX-917 Phase 1 results
- NN-101 Phase 1 results
- RL-007 Phase 2b FSI
- GRX-917 Phase 2 FSI
- KUR-
- EMP-
- VLS-
- Intro:
- Enth-
- Psyb-
- Innar

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

# Financial Position



**Issuer (ticker)** ATAI Life Sciences N.V. (NASDAQ: ATAI)

**Market capitalization** ~\$2.8B<sup>(1)</sup>

**Outstanding shares** 154.8M

**Cash & cash equivalents**

- ~\$449M cash & cash equivalents as of March 31, 2021<sup>(2)</sup>
- In the second quarter of 2021, atai successfully completed an IPO and raised total gross proceeds of ~\$258.8M (including the underwriters' allotment)
- atai is well financed to fund planned operations through 2023

**PEIRON**  
INVESTMENT GROUP

**NOVATOR**

**CATALIO**  
CAPITAL MANAGEMENT

**THIEL**

**GALAXY**  
HOLDINGS FINANCIAL LTD.

**WOODLINE**  
PARTNERS

**FUTURE**  
VENTURES

**SUBVERSIVE**  
CAPITAL

**FALCON EDGE CAPITAL**

**MOORE CAPITAL MANAGEMENT LP**

**puravida**  
INVESTMENTS

(1) As of June 9, 2021

(2) After giving effect to our Series D and IPO financings.



**Investor Contact:**

Greg Weaver

Chief Financial Officer

Email: [greg.weaver@atai.life](mailto:greg.weaver@atai.life)





# Appendix

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## 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



People

E

# The atai model: Rigorous process paired with the right people and enabling technologies as our approach to increase probability of success



## Process

- ✓ Disciplined selection criteria (including prior evidence in humans)
- ✓ Impactful capital allocation to acquired and incubated companies
- ✓ Strategic value capture and high degree of optionality



## People

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



## Enabling Technologies

- ✓ Digital Therapeutics
- ✓ Formulation
- ✓ AI-enabled



# Our process is designed to aim for effective program selection, drug 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 funding, shared services and enabling tech
- ✓ Economies of scope and cross-fertilization across our development programs

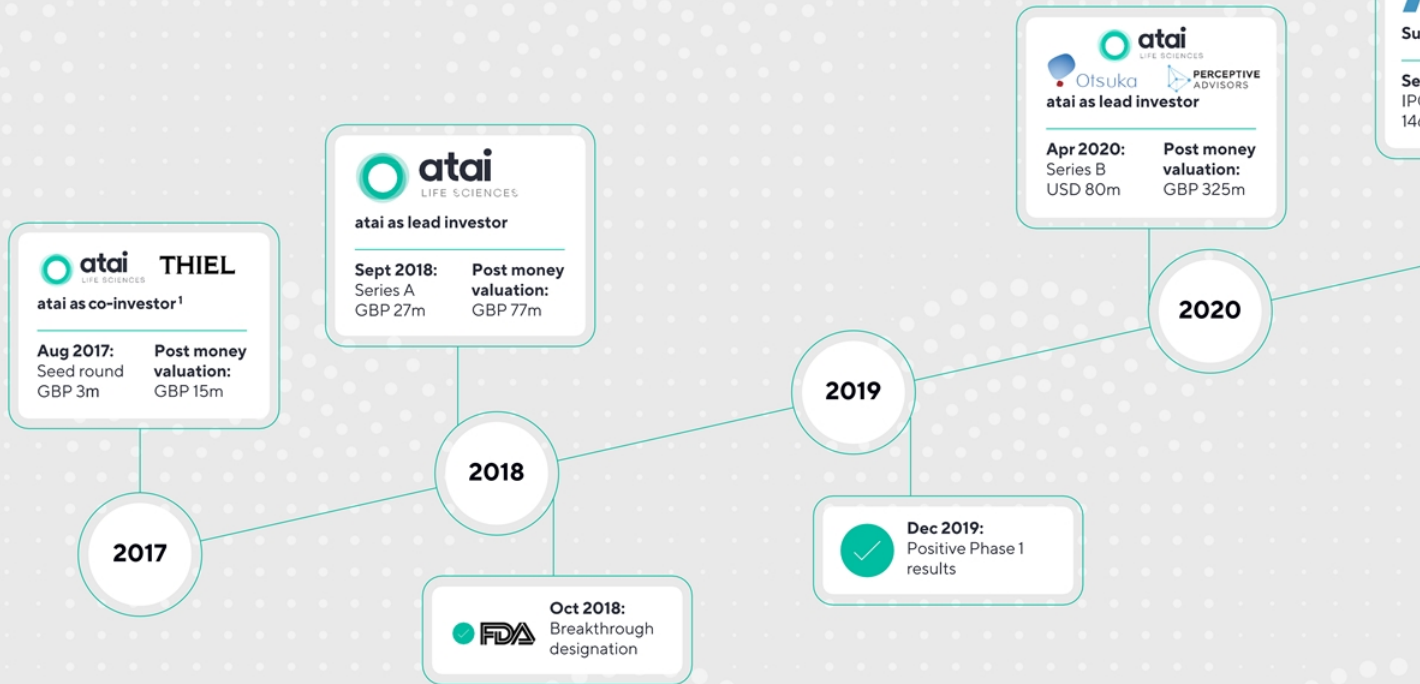


## Optior Strategic V

- ✓ Internal Dev
- ✓ Strategic Pa
- ✓ IPO 
























# Case study: COMPASS Pathways creates a precedent for atai's compa

## From foundation in 2017 to public company today



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 9, 2021

# Our People: 50 atai professionals with strong track record and a group of experts support the CEOs of our companies with the execution of our trial

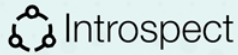
 <b>Greg Bates</b> VP, Regulatory Affairs	 <b>Carrie Bowen, PhD</b> Director, Neuroscience	 <b>Glenn Short, PhD</b> VP, Early Development	 <b>Anne Johnson</b> VP, Global Controller	 <b>Ryan Barrett</b> GC & Lead of Corporate Development
 <b>Georgina Kilfoil, PMP</b> VP, Clinical Operations	 <b>Majed Fawaz, PhD</b> VP, CMC	 <b>Roman Dahl</b> VP, Operations & Innovation	 <b>David Keene</b> VP, Digital Therapeutics	 <b>Danny Talati</b> Director, Business Development
 <b>Arvind Tewari</b> VP, Digital Strategy and Operations	 <b>Paul Simboli</b> Director, IP Counsel	 <b>Galyna Pidpruzhnykova, PhD</b> Director, Innovation Strategy	 <b>Sarah McEwen, PhD</b> Director, Clinical Science	 <b>Frank Stegert</b> VP, Operations and Investment
 <b>Alan Schatzberg, MD</b> Scientific Advisor COMPASS and GABA	 <b>John Krystal, MD</b> Scientific Advisor	 <b>Frank Sasinowski</b> Regulatory Advisor	 <b>Amir Kalali, MD</b> Business Advisor	 <b>E. E.</b>
 <b>Terence A. Kelly, PhD</b> CEO Perception Neuroscience	 <b>Ian Massey, DPhil</b> CEO GABA Therapeutics	 <b>Deborah Mash, PhD</b> CEO DemeRx	 <b>Tom Bradshaw</b> CEO Neuronasal	 <b>Matthew Pando, PhD</b> CEO Recognify

**~150** FTEs / consultants across atai's companies      **50** Professionals in atai core team      **Core atai team collectively led**      **13** NDAs through regulatory approval



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

**Digital Therapeutics**

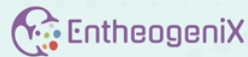


- ✓ **Wholly owned digital therapeutics platform** dedicated to providing more comprehensive, personalized care management with potential to secure stronger IP protection

**Psyber**

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

**AI Enabled Drug Discovery**



- ✓ **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

**Form Biomarker**

**Ps**

- ✓ **Metabolomics** to develop p

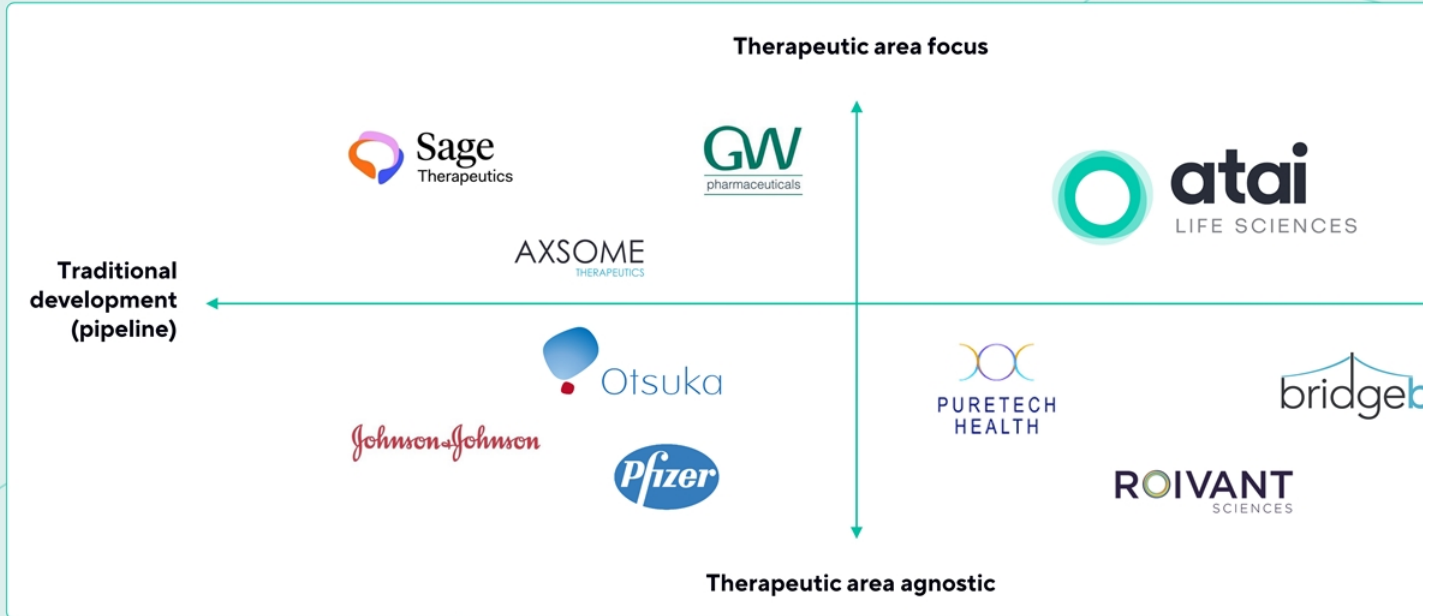
**Inr**

- ✓ **Joint venture** direct-to-bra

**Int**

- ✓ **Partnership** Innovative tr

# Decentralized drug development approach with deep therapeutic focus on mental health disorders



# We are initially focused on mental health disorders (DSM-V) with unmet patient need and significant market opportunities



**~300m**

**Patients with Depression (global)<sup>1</sup>**

~33% of patients are resistant to front line treatments



**~40m**

**Patients with Anxiety Disorders (US)<sup>2</sup>**

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



**~18m**

**Patients with Cognitive Impairment Associated with Schizophrenia (global)<sup>3</sup>**

No pharmacological treatments approved for CIAS



**~20m**

**Patients with Substance Use Disorder (US)<sup>4</sup>**

~75% of patients relapse within one year of treatment

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 Brain Injury", NCBI (2020)

# Robust Ability to Block Strategy: IP, regulatory and restrictive covenants create framework for excluding would-be competitors



**Robust Specialty  
Pharma IP Strategy**



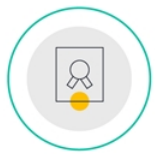
**Drug & Digital  
Combo  
Therapeutics  
Exclusivity  
Strategy**



**Differential  
De-scheduling**



**Strategic  
Restrictive  
Covenants**

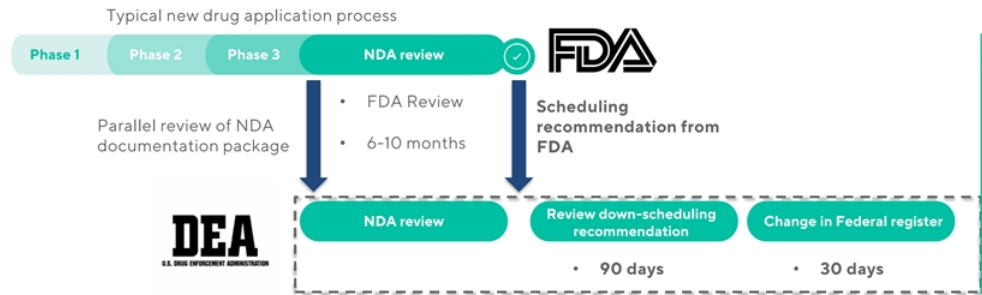


**Leading IP and  
Regulatory  
Advisors**

# FDA evaluates NDAs and shares a recommendation with DEA on down-scheduling of the particular compound

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

**Successful precedents** include GHB and THC



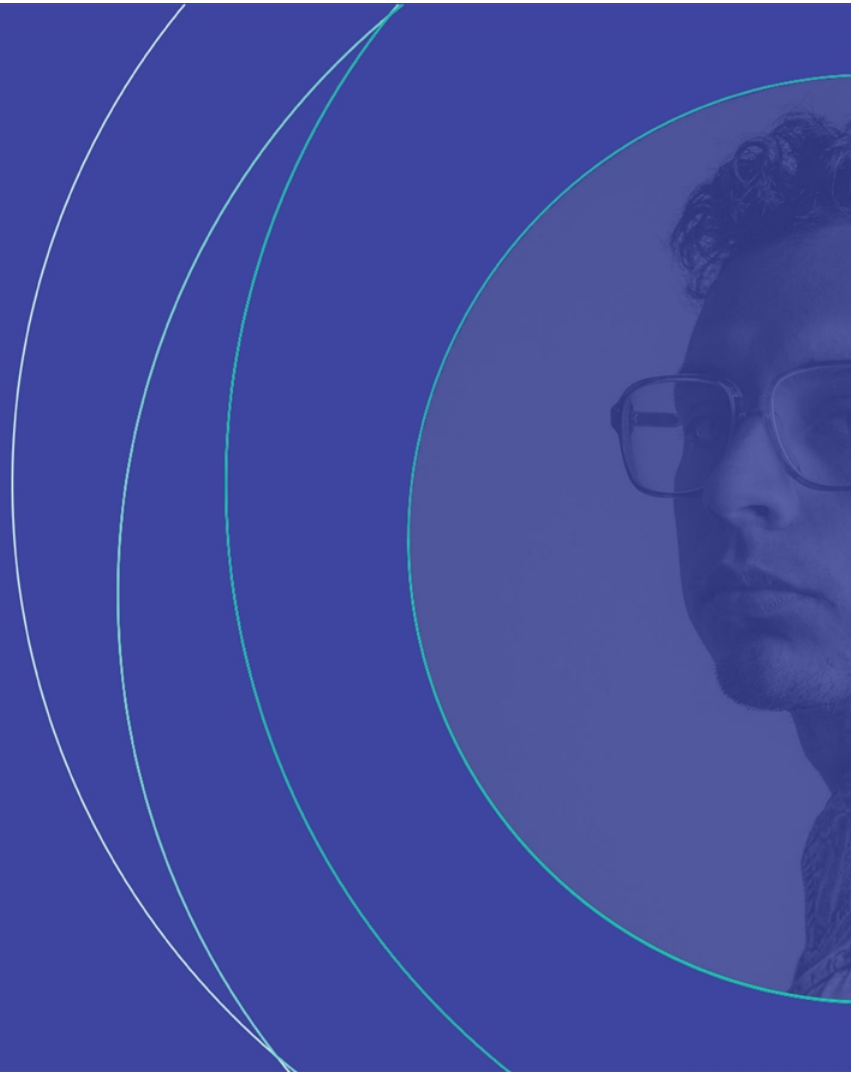
	Jazz Pharmaceuticals	UniMed UniHealth PHARMACEUTICALS
<b>Brand name</b>	Xyrem	Marinol (Dronabinol)
<b>Compound</b>	Sodium oxybate (sodium salt of GHB*)	THC (delta-9-tetrahydrocannabinol in sesame oil)
<b>Indication</b>	Narcolepsy	Chemotherapy-induced nausea
<b>Launch</b>	2002	1985

Source: FDA website  
\* GHB = γ-hydroxybutyric acid



# Depression

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# Depression

## Opportunity Overview

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



## Treatment options for TRD

Antidepressants

Augmentation therapy<sup>1</sup>

S-ketamine

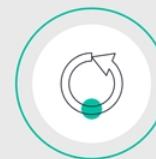
Somatic therapy<sup>2</sup>

High-intensity psychological interventions



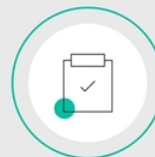
**~300m**

Global sufferers of depression<sup>3</sup>



**~60-70%**

Likelihood of relapse from current SoC<sup>4</sup>



**2**

Approved drugs for TRD (Spravato, Symbyax)



**\$8bn+**

Relative market oppo (antidepressant sa 2025)<sup>6</sup>

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 psychological and physiological effects of psilocybin in healthy humans: a do (2004)

5. Pandarakalam, 2018; Sussman et al., 2018; Gaynes et al., 2019

6. Evaluate Pharma (as of 19.03.2021)

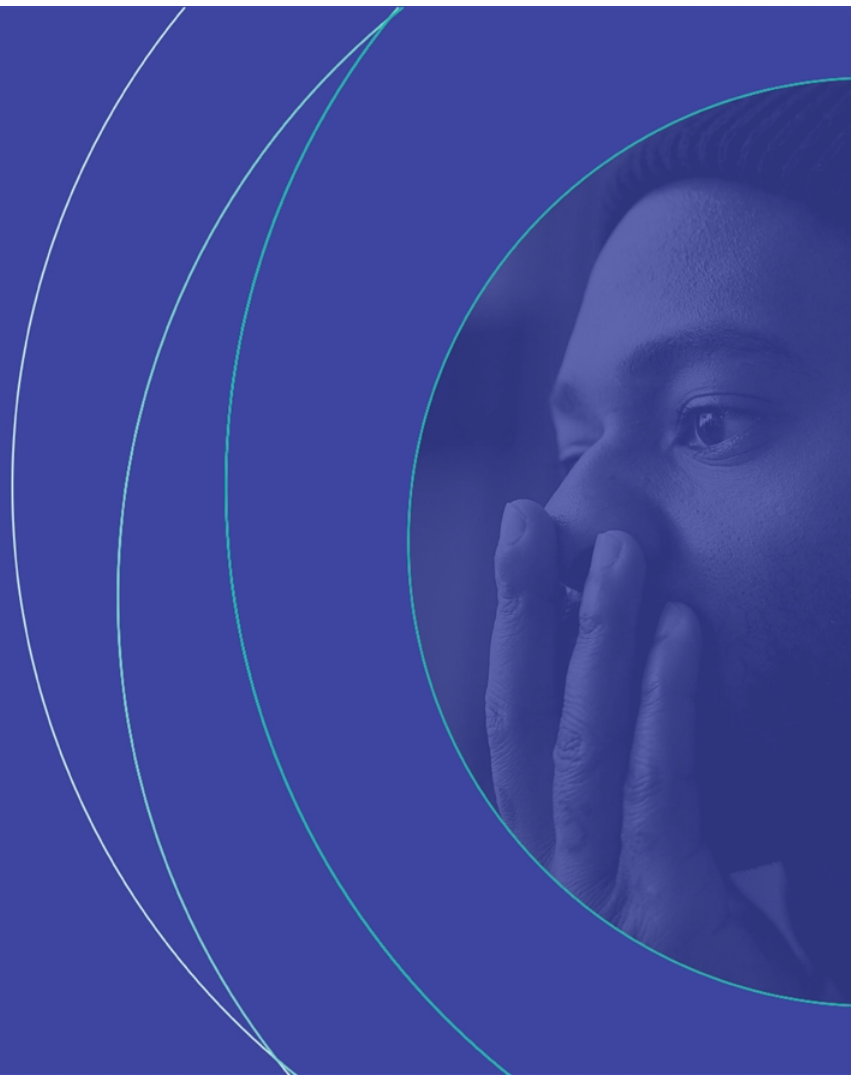
# atai is targeting depression via **multiple complementary approaches**

	<b>Company</b>
	<b>Compound</b>
<b>Population / Drug class</b>	<b>Indication</b>
	<b>MoA Target / Drug Class</b>
<b>Convenience / Use</b>	<b>Potential for at home use</b>
	<b>Concomitant SSRI therapy</b>
	<b>In-clinic duration</b>
<b>Commercial</b>	<b>Distribution channels</b>

Depression		
COMPASSION Navigating Mental Health Pathways	VIRIDIA LIFE SCIENCES	PERCEPTION NEUROSCIENCE
COMP360	DMT	R-ketamine
TRD	TRD	TRD
5-HT2A-R agonist	5-HT2A-R agonist	Glutamatergic modulator
⊗	⊗	⊕
⊗	⊗	⊕
6-8 hours	~2 hours	N/A
New clinics infrastructure	S-ketamine/ psilocybin clinics	Pharmacies

# Cognitive Impairment Associated with Schizophrenia

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# 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<sup>1</sup>



~84%

of schizophrenia patients suffer from significant cognitive impairment<sup>2</sup>



~\$155bn+

Estimated annual US economic burden due to schizophrenia<sup>4</sup>



\$13bn+

Relative market opportunity (antipsychotic sales 2025)<sup>5</sup>

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 & Mortensen, "Excess early mortality in schizophrenia" (2014)

4. Cloutier et al., "The Economic Burden of Schizophrenia in the United States in 2013" (2016)

5. EvaluatePharma (as of 19.03.2021)

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, combining a history of signal of pro-cognitive effects in humans

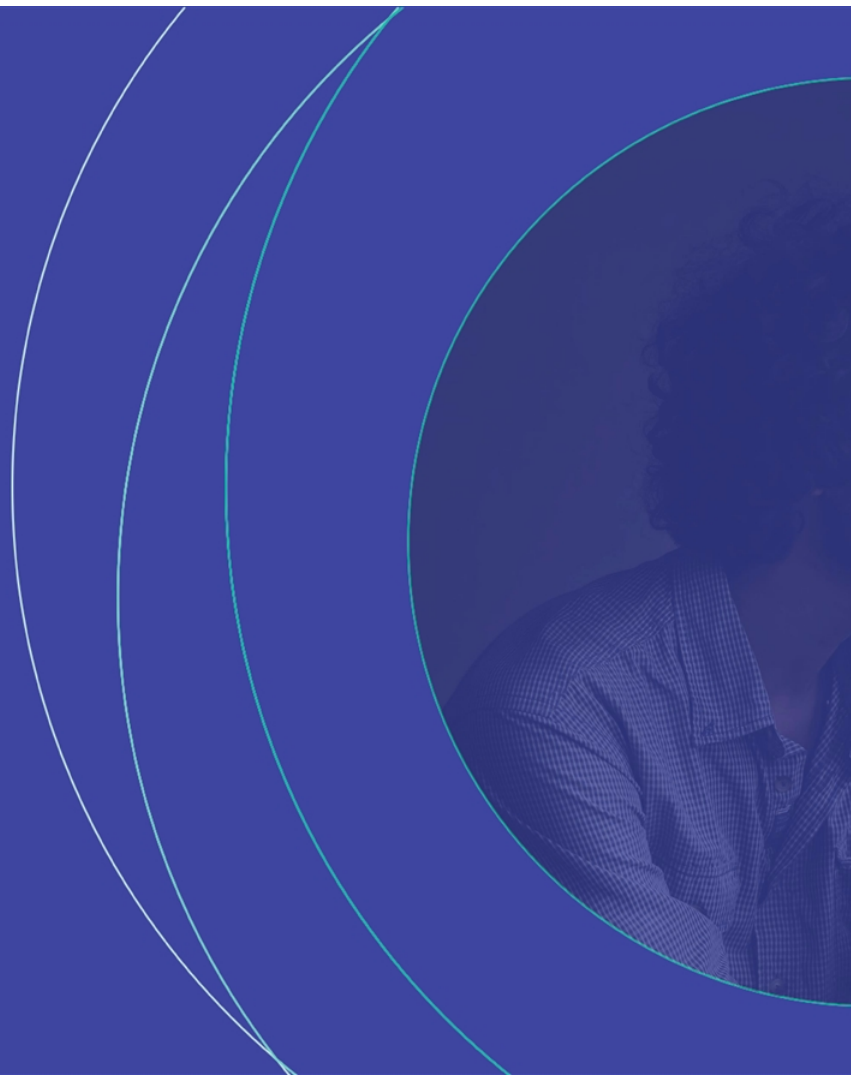
Overview of Leading Clinical Stage Competitors for Cognitive Impairment Associated with Schizophrenia (CIAS)

					
Therapy	RL-007	SEP-363856	BI-425809	NBI-1065844	PF-03
Primary Indication	CIAS	Schizophrenia	CIAS	Schizophrenia	CIAS
MoA	GABA / nicotinic modulator	TAAR1 agonist	GlyT1 inhibitor	DAAO inhibitor	GlyT1i
Current Phase	II	III	II	II	II
Notes	Previously assessed in over 500 subjects for other indications with no serious adverse events observed	Breakthrough therapy designation, being developed for schizophrenia but recently demonstrated small improvements in cognitive measures	Completed Phase II with positive results	Failed to achieve primary endpoint of easing the negative symptoms of schizophrenia, but met secondary endpoints of cognitive improvement	Ongoing

Note: GABA = Gamma aminobutyric acid; TAAR1 = trace amine-associated receptor; GlyT1 = Glycine Transporter 1; AAO = D Amino Acid Oxidase; AMPA = α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid  
Sources: GlobalData, Evaluate Pharma (both as of 2021)

# Substance Use Disorder

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# 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)



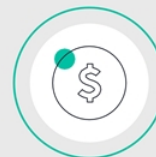
**~20m**

**US sufferers of SUD in 2017<sup>1</sup>**



**~2m**

**US sufferers of OUD in 2017<sup>1</sup>**



**\$787bn**

**Societal cost associated with OUD in US<sup>3</sup>**



**~75%**

**of patients undergo therapy experience within one year<sup>4</sup>**

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 use disorder and the value of aversion" (2020)  
4. Sinha, "New Findings on Biological Factors Predicting Addiction Relapse Vulnerability" (2011)











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 become the first modifying treatment for OUD, minimizing risk of relapse

	Therapy	Mechanism of Action	Single Therapeutic Episode	No Opioid Effect
<p><b>Disease Modification</b></p> <p>Single dose administered in monitored setting, providing both withdrawal support and oneiric experience with goal of complete remission</p>	<p>Ibogaine (DMX-1002)</p> 	Mixed MoA		
<p><b>Withdrawal Support<sup>2</sup></b></p> <p>Therapies given for symptomatic management during supervised withdrawal (detoxification)</p>	Clonidine	Alpha-2 agonist		
	Lofexidine	Alpha-2 agonist		
<p><b>Medication Assisted Therapy<sup>1</sup></b></p> <p>Daily therapy given in substitution of opioid in outpatient setting in attempt to wean off from opioid</p>	Methadone	Mu-agonist		
	Buprenorphine	Partial Mu-agonist		
	Naltrexone	Mu-antagonist		

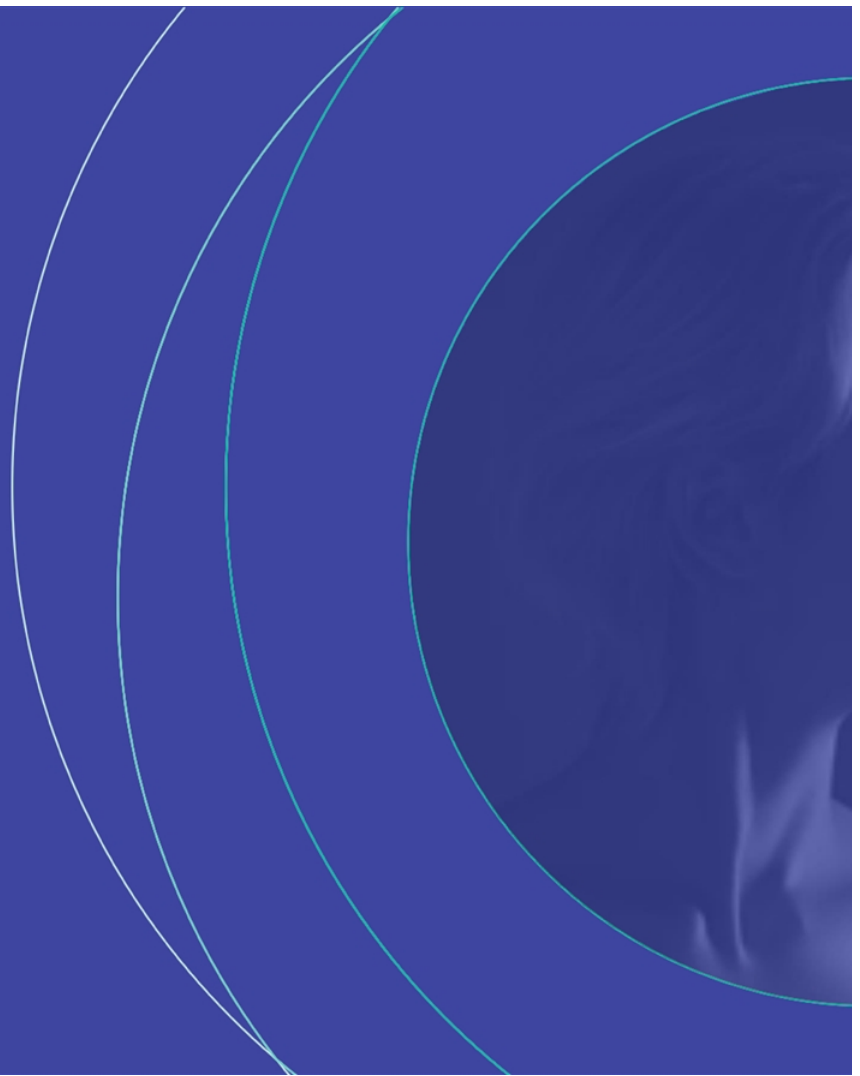
Source: GlobalData, Evaluate Pharma (both as of 2021)

1. Current Standard of Care

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

# Anxiety

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# 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



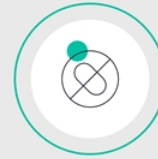
**~40m**

**Anxiety disorder sufferers in the US<sup>1</sup>**



**#1**

**Most common mental health disorder in the US<sup>1</sup>**



**<50%**

**Less than half of patients with Anxiety disorder in the US receive treatment<sup>2</sup>**



**\$42bn+**

**Annual societal cost of anxiety disorders in the US<sup>3</sup>**

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 disadvantages<sup>1</sup>:

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 in Generalized Anxiety Disorder (GAD) with rapid onset and favorable safety profile

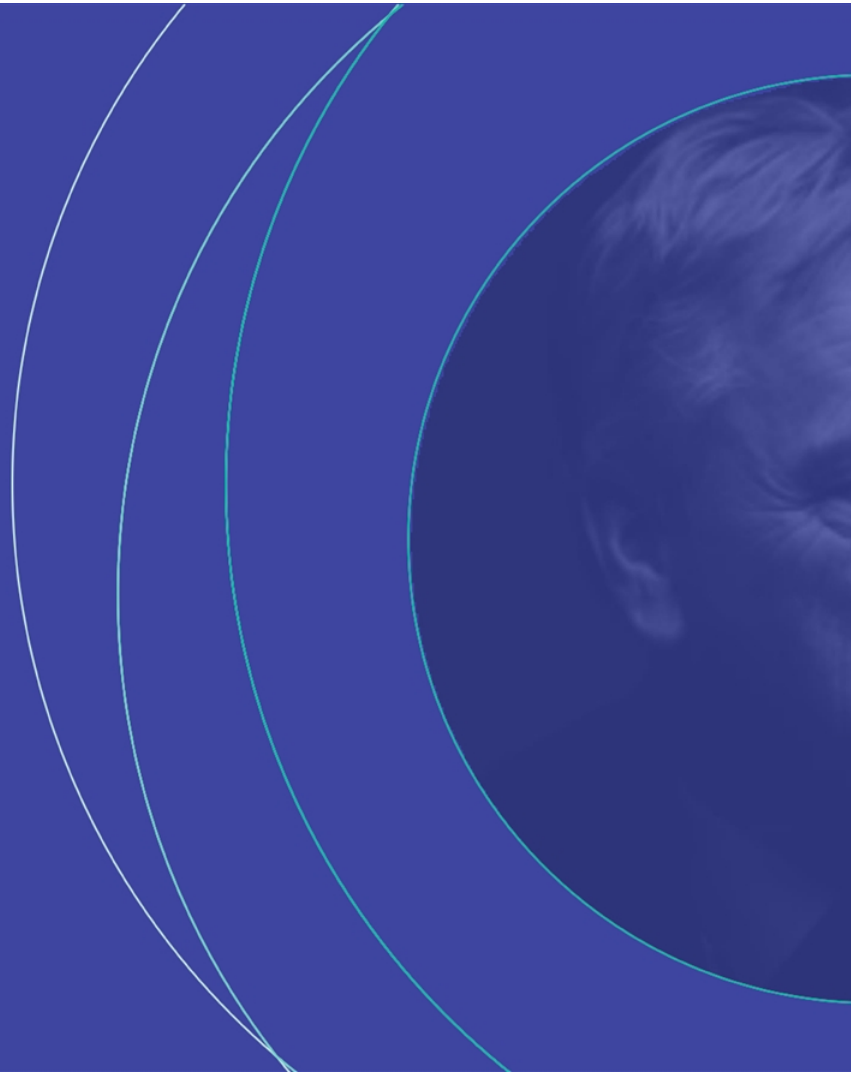
Overview of Current Therapeutic Options for Generalized Anxiety Disorder

Class	Examples	Mechanism of action	Favorable safety profile	Rapid Onset	High Efficacy
<b>Benzoxazine</b>	deu-etifoxine (GRX-917) 	GABA <sub>A</sub> Channel and TSPO Potentiation			
<i>Anticipated pharmacological profile</i>					
<b>Selective Serotonin Reuptake Inhibitor (SSRI)</b>	Escitalopram	SERT blockade			
<b>Serotonin and Norepinephrine Reuptake Inhibitor (SNRI)</b>	Venlafaxine	SERT AND NET blockade			
<b>Benzodiazepines</b>	Alprazolam	GABA <sub>A</sub> Potentiation			
<b>Tricyclic Antidepressant (TCA)</b>	Imipramine	Mixed MoA			
<b>Azapirones</b>	Buspirone	partial 5-HT <sub>1A</sub> agonist			
<b>Gabapentinoid</b>	Pregablin	VDCC inhibition			

Note: GABA = Gamma aminobutyric acid, SERT = serotonin transporter, NET = serotonin transporter; MoA = Mechanism of Action; 5HT<sub>1A</sub> = serotonin 1A receptor; VDCC = voltage-gated calcium channel  
 Source: GlobalData, Evaluate Pharma (both as of 19.03.2021)  
 1. DeMartini et al., "Generalized Anxiety Disorder" (2019)

# Traumatic Brain Injury

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# 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 US<sup>1</sup>



~57k

Annual TBI-related deaths in US<sup>2</sup>



5.3m

Americans live with TBI related disabilities<sup>3</sup>



70-90%

of patients continue to prolonged neurocognitive dysfunctions<sup>4</sup>

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 Congress: Traumatic Brain Injury in the United States", CDC (1999)

4. Hoffer et al., "Repositioning drugs for traumatic brain injury", Journal of Biomedical Science (2014)

# Selected CNS indications of interest for psychedelic therapeutics

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 indications<sup>1</sup>

Indication	Estimated 2026 Market Size (\$BN)	Academic Publications
<b>Eating disorders</b>	7.4*	Positive effects of psychedelics on depression and eating disorder <sup>2</sup>
<b>Obsessive-Compulsive Disorder</b>	3.7*	Safety, tolerability, and efficacy of psilocybin in 9 patients with obsessive-compulsive disorder <sup>5</sup>
<b>Attention Deficit Hyperactivity Disorder</b>	3.3	Perceived outcomes of psychedelic microdosing as a treatment for substance use disorders <sup>3</sup>
<b>Autism Spectrum Disorders</b>	1.4*	Lysergic acid diethylamide (LSD) promotes social behavior through mTORC1 in the excitatory neurotransmission <sup>4</sup>
<b>Multiple Sclerosis</b>	21.1	Psychedelics and immunomodulation: novel approaches and therapeutic opportunities <sup>11</sup>
<b>Ischemic/Hypoxic Brain Injury</b>	20.0	The Endogenous Hallucinogen and Trace Amine N, N-Dimethyltryptamine (DMT) Displays Potent Protective Effects against Hypoxia via Sigma-1 Receptor Activation in Human P and Microglia-Like Immune Cells <sup>7</sup>
<b>Alzheimer's Disease</b>	10.6	Psychedelics as a Treatment for Alzheimer's Disease Dementia <sup>9</sup>
<b>Migraine Headache</b>	9.6	Exploratory Controlled Study of the Migraine-Suppressing Effects of Psilocybin and LSD <sup>10</sup>
<b>Parkinson's Disease</b>	2.4	Neuroprotective potential of Ayahuasca and untargeted metabolomics analyses: applicability to Parkinson's disease <sup>8</sup>
<b>Amyotrophic lateral sclerosis</b>	1.0	Psychedelics as a novel approach to treating autoimmune conditions <sup>2</sup>
<b>Cluster Headache</b>	0.3	Response of cluster headache to psilocybin and LSD <sup>10</sup>
	<b>80</b>	

\* Company estimate based on worldwide incidence

Source: EvaluatePharma for all indications with exception of Eating disorders, Autism spectrum disorder, and obsessive-compulsive disorder, for which there are no currently calculated based on estimated worldwide incidence and current yearly average cost of antidepressant therapy

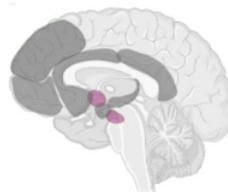
1. Flanagan & Nichols, "Psychedelics as anti-inflammatory agents" (2018). 2. Spriggs et al., "Positive effects of psychedelics on depression and wellbeing scores in individuals with eating disorders" (2018). 3. Spriggs et al., "Perceived outcomes of psychedelic microdosing as self-managed therapies for mental and substance use disorders" (2020). 4. De Gregorio et al., "Lysergic acid diethylamide (LSD) promotes social behavior through mTORC1 in the excitatory neurotransmission" (2021). 5. Moreno et al., "Safety, tolerability, and efficacy of psilocybin in 9 patients with obsessive-compulsive disorder" (2015). 6. Katchborian-Neto et al., "Neuroprotective potential of Ayahuasca and untargeted metabolomics analyses: applicability to Parkinson's disease" (2020). 7. Vann Jones & O'Kelly, "Psychedelics as a Treatment for Alzheimer's Disease Dementia" (2020). 8. Katchborian-Neto et al., "Neuroprotective potential of Ayahuasca and untargeted metabolomics analyses: applicability to Parkinson's disease" (2020). 9. Thompson et al., "Psychedelics as a novel approach to treating autoimmune conditions" (2020). 10. Schindler et al., "Exploratory Controlled Study of the Migraine-Suppressing Effects of Psilocybin and LSD" (2006). 11. Schindler et al., "Psychedelics and immunomodulation: novel approaches and therapeutic opportunities" (2015).

# atai aims to develop novel **disease-modifying strategies** to restore mental health by focusing on neuroplasticity

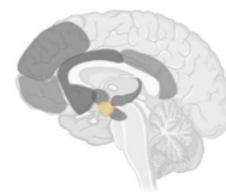
## Standard of Care



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

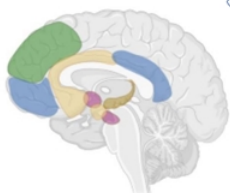


- 2 **Buprenorphine**  
 ↓ **RN** Opioid receptor agonists for maintenance; drawbacks: respiratory depression and maintained dependency.



- 3 **Benzodiazepines**  
 ↓ **AN**: sedation, amnesia, impaired motor performance; withdrawal.

## atai LIFE SCIENCES



- 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 emotions from **CC**.

- Default Mode Network (**DMN**): Self awareness
- Cognitive Control (**CC**): Decision making, executive functions
- Reward Network (**RN**): Pleasure
- Affective Network (**AN**): Fear response, social interaction, learning, processing emotions



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

**Florian Brand** | CEO | atai life sciences

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