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): January 4, 2024

ATAI LIFE SCIENCES N.V.

(Exact name of registrant as specified in its charter)

The Netherlands	**001-40493**	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Wallstraße 16
10179 Berlin, Germany
(Address of principal executive offices) (Zip Code)

+49 89 2153 9035
(Registrant's telephone number, including 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 Stock Market LLC (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.

As previously disclosed, on January 4, 2024, atai Life Sciences N.V. (the "Company") announced a strategic investment in Beckley Psytech Limited (the "Strategic Investment"), the collaboration of which aims to accelerate the development of Beckley Psytech's two clinical-stage, patent-protected, short-duration psychedelic candidates, BPL-003 and ELE-101, by adding them to atai's mental health innovation platform.

The Company intends to post an investor presentation containing updates regarding the Strategic Investment and other programs to its website at https://ir.atai.life/news-events/presentations, a copy of which is also being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained under Item 7.01 of this Current Report on Form 8-K and the investor presentation attached hereto as Exhibits 99.1, is deemed to be "furnished" and 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 The information set forth in this Item 7.01, including Exhibit 99.1, shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1*	Investor Presentation, dated January 4, 2024.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

* Furnished herewith.

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: January 4, 2024

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

Exhibit 99.1

atai LIFE SCIENCES

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

Company Overview – January 2024

Disclaimer

All references in this presentation to “we”, “us”, “our”, “atai”, or the “Company” refer to ATAI Life Sciences N.V. and its consolidated subsidiaries, unless the context otherwise requires. This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered under by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended.. 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 are subject to a number of risks, uncertainties and assumptions, including without limitation the important factors described in the section titled “Risk Factors” in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission (“SEC”), as updated by our subsequent filings with the SEC, that may cause our actual results, performance or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements. 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 or of any individual competitor and our future performance are necessarily subject to uncertainty and risk due to a variety of factors, including those described above. These and other factors could cause results to differ materially from those expressed in the estimates made by independent parties and by us. Industry publications, research, surveys and studies generally state that the information they contain has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and uncertainties as the other forward-looking statements in this presentation.

This presentation contains excerpts of testimonials from individuals who have been treated with compounds or derivatives of the compounds underlying our product candidates in the context of third-party studies or otherwise that are solely intended to be illustrative and not representative of the potential for beneficial results of such compounds. Our product candidates are in preclinical or clinical stages of development and none of our product candidates have been approved by the FDA or any other regulatory agency.

Any trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of the products or services of the Company.

atai Life Sciences: Healing mental health disorders so that everyone everywhere can live a more fulfilled life

1. Mental health disorders are one of the largest global health burdens; in 2019, 1 in every 8 people, or 970 million people, around the world were living with a mental disorder[1]

2. atai's objective is to achieve clinically meaningful and sustained behavioral change in mental health patients by developing rapid-acting and durable therapeutics

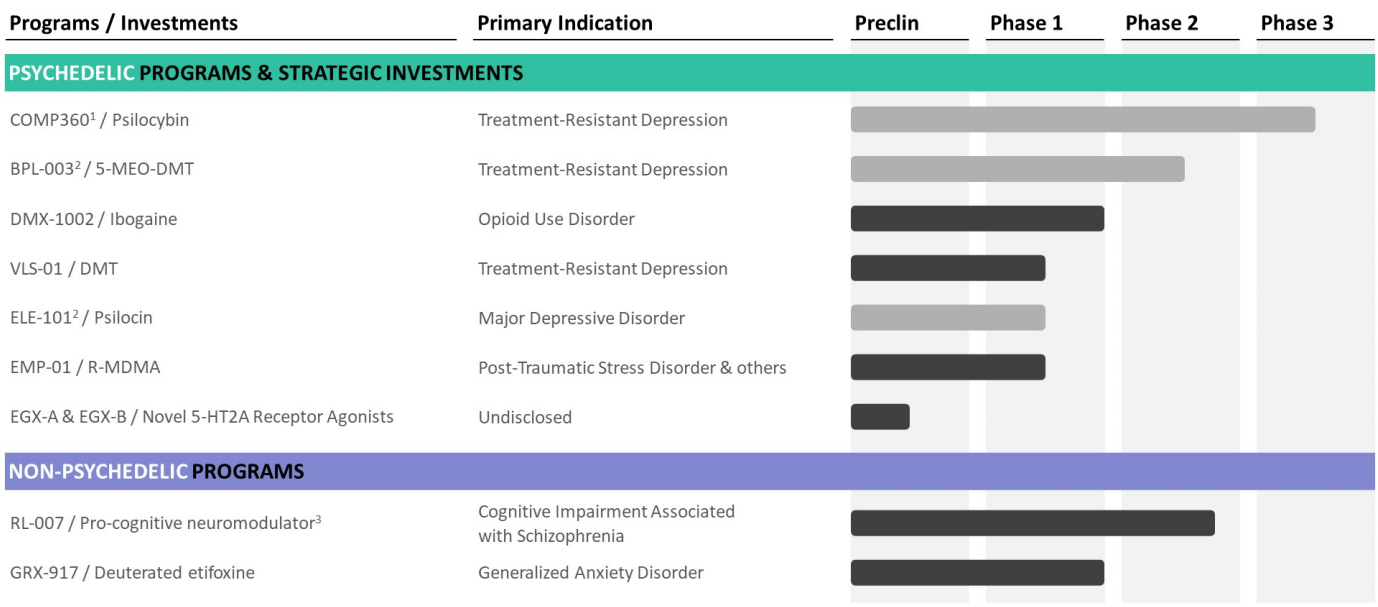
3. Eight clinical-stage drug development programs and strategic investments, each with a robust package of prior clinical evidence

4. Validated operating model and ability to capture value: IPO of COMPASS Pathways in 2020 and licensing deal between Otsuka and atai subsidiary Perception Neuroscience in 2021

5. Cash, marketable securities, and committed term loan funding are expected to provide runway into 2026[2]

1. World Health Organization
2. Committed term loan funding includes $45M of additional capital that can be drawn not subject to milestones under the facility with Hercules Capital; marketable securities includes money market funds, U.S. Treasury securities, commercial paper, corporate notes/bonds, U.S. government agencies securities, and public equities

Our strategy will be delivered through a robust portfolio of psychedelic and non-psychedelic drug development programs and strategic investments



[1] Strategic Investment in Compass Pathways

[2] Strategic Investment in Beckley PsyTech

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

atai Life Sciences: Operational Focus & Program Guidance

We expect to deliver several meaningful R&D milestones across our key programs over next 18 months[3]

PSYCHEDELIC PROGRAMS & STRATEGIC INVESTMENTS

NON-PSYCHEDELIC PROGRAMS

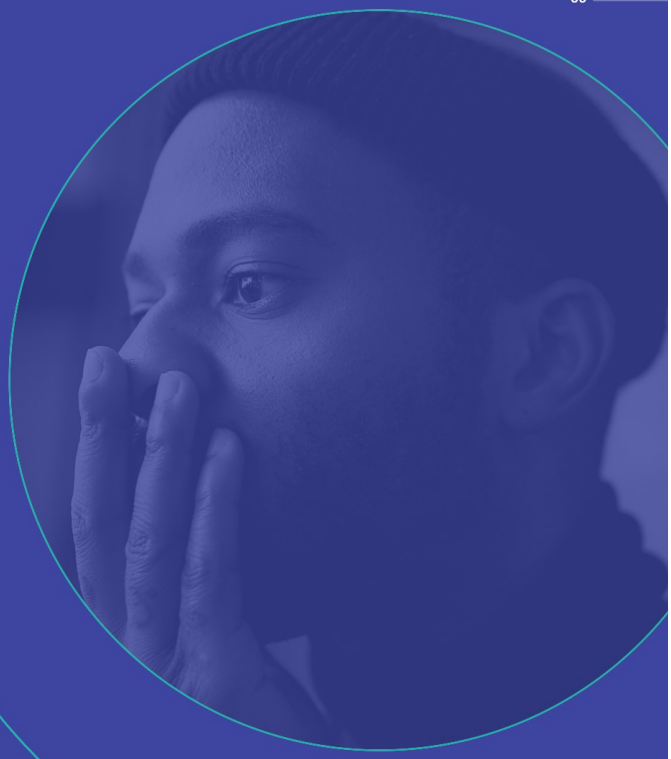
COMP360[1] (Psilocybin)	BPL-003[2] (5-MEO-DMT)	VLS-01 (DMT)	DMX-1002 (Ibogaine)	ELE-101[2] (Psilocin)	EMP-01 (R-MDMA)	RL-007 (Pro-Cognitive Neuromodulator)	GRX-917 (Deuterated etifoxine)
☑ Successful outcome of Ph 2b trial in TRD	☑ Successful outcome of Ph 1 trial	☑ Initial Ph 1 results in 2Q'23	☑ Initial Phase 1 results in 3Q '23	❑ Ph 1/2a OL (MDD) – data in 1H'24	☑ Ph 1 trial initiated in 3Q'22	☑ Successful outcome of Ph 2a trial in CIAS	☑ Ph 1 topline results in 1Q'23
❑ Ph 2 (PTSD) – data Spring '24	❑ Ph 2a OL (TRD) data in 1H'24	☑ Additional Ph 1 data in 3Q'23	❑ Submit FDA meeting request in 1H'24		☑ Ph 1 results in 4Q '23	☑ Ph 2b first patient dosed in 1Q'23	☑ Late breaking presentation at 2023 SOBP annual meeting
❑ Ph 3 (TRD) – Pivotal Trial 1 topline data summer '24	❑ Ph 2a OL (AUD) data in mid-'24	❑ Ph 1b first participant dosed in 1H'24				❑ Topline Ph 2b data mid-'25	
❑ Ph 3 (TRD) - Pivotal Trial 2 topline data mid-'25	❑ Ph 2b (TRD) data in 2H'24						

1. Strategic Investment in Compass Pathways
2. Strategic Investment in Beckley PsyTech
3. All dates provided are as estimated

Abbreviations: PTSD = Post-Traumatic Stress Disorder; CIAS = Cognitive Impairment Associated with Schizophrenia; TRD = Treatment Resistant Depression; AUD = Alcohol Use Disorder; MDD = Major Depressive Disorder

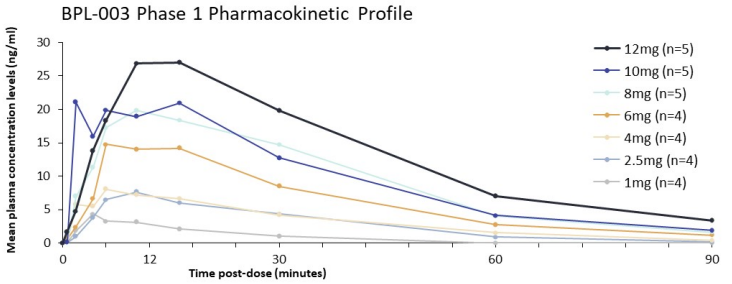
BPL-003

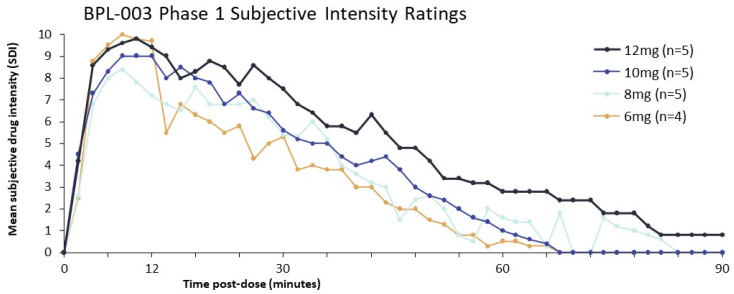
(5-MeO-DMT) for TRD & Alcohol Use Disorder



BPL-003: Intranasal 5-MeO-DMT

Results from completed Phase 1 SAD study showed BPL-003 had a favorable safety profile and was well tolerated whilst demonstrating dose proportionate PK/PD profile





Abbreviations: SAD = Single Ascending Dose; PK = Pharmacokinetic; PD = Pharmacodynamic

Key Findings

Safety

- All adverse events (AEs) were mild (89.5%) or moderate (10.5%); no Serious AEs occurred
- Most common AEs (>10%) : nasal discomfort, nausea, vomiting, and headache

Pharmacokinetics (PK)

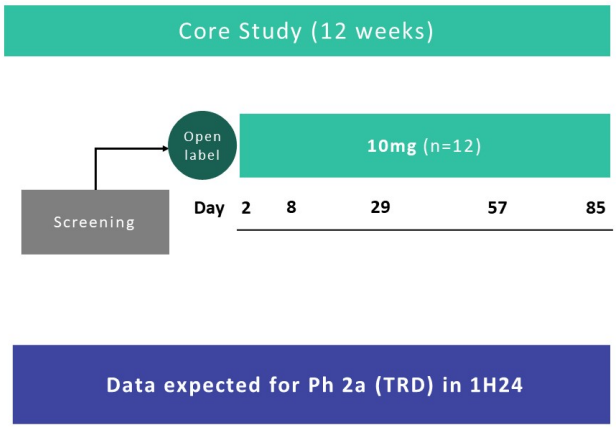
- Exposure was dose-proportionate
- Rapid onset: mean Tmax of 6-17 min
- Short duration: mean t1/2 of 15-30 min

Pharmacodynamics (PD)

- Subjects were psychedelic naive
- All subjects on doses ≥6mg achieved intensity scores ≥7
- Perceptual effects generally fully resolved within 60 - 90 mins

BPL-003 Phase 2a Clinical Trial Design

BPL-003 Phase 2a is an open-label monotherapy study in TRD patients



Key Inclusion Criteria

» Patients with moderate-severe treatment resistant depression

» Montgomery-Asberg Depression Rating Scale (MADRS) score ≥24

» Willing and able to discontinue current antidepressants

Key Objectives:

Primary Endpoint:

» Safety and tolerability of BPL-003 monotherapy

Key Secondary Endpoints:

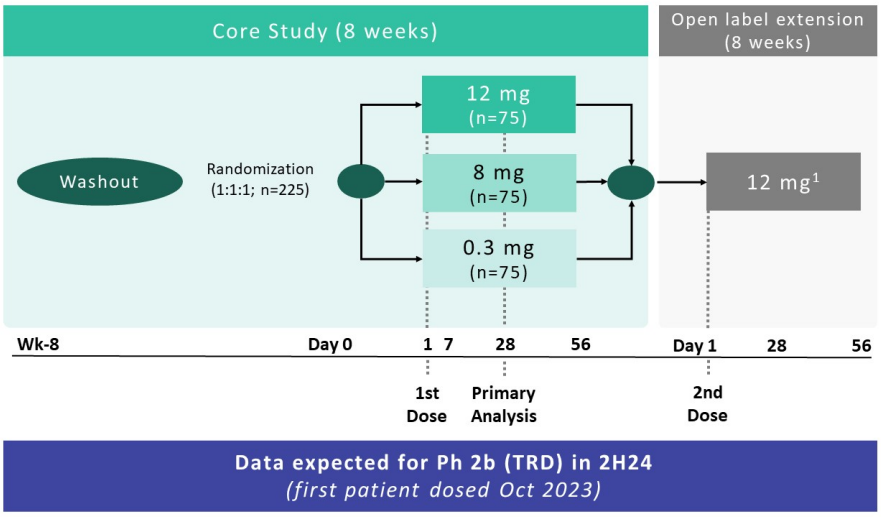
» MADRS change at Day 2, 8, 29, 57 and 85

» CGI-S, PGIC, EQ-5D

Abbreviations: MADRS = Montgomery–Åsberg Depression Rating Scale; CGI-S = Clinical Global Impressions-Severity; PGIC = Patient's Global Impression of Change; EQ-5D = EuroQol-5D

BPL-003 Phase 2b Clinical Trial Design

BPL-003 Phase 2b is a randomized, double-blind, single-dose monotherapy study in moderate to severe TRD patients



Data expected for Ph 2b (TRD) in 2H24
(first patient dosed Oct 2023)

Key Inclusion Criteria

- Patients with treatment-resistant depression
- Hamilton Depression Scale (HAM-D) >= 19
- Willing and able to discontinue current antidepressants

Key Objectives:

Primary Endpoint:

- MADRS change from baseline at day 28

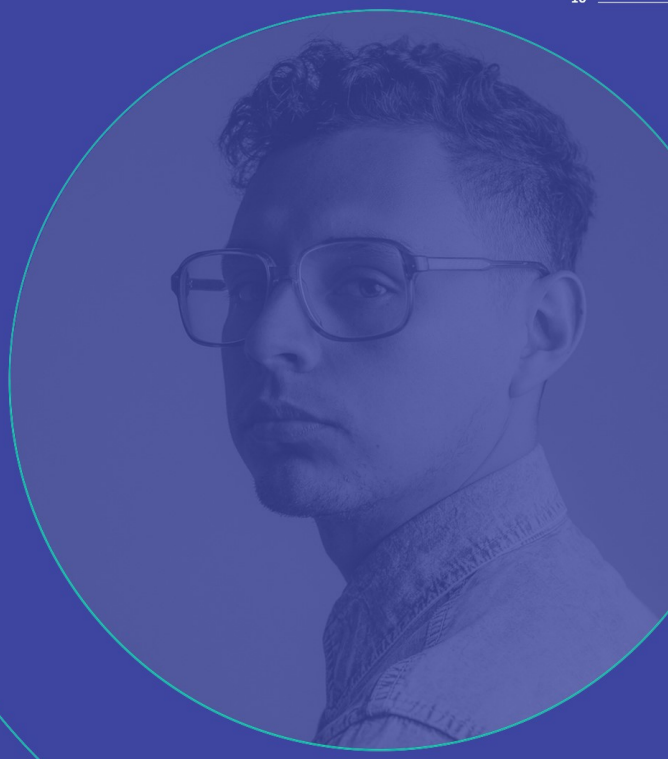
Key Secondary Endpoints:

- MADRS change at Day 1, 7 and 56
- CGI-S, PGIC, EQ-5D

[1] Patients entering the open-label extension are randomized 1:1 to receive either a single 12mg dose or a biphasic 4mg and 8mg dose approximately 10 minutes apart
Abbreviations: MADRS = Montgomery–Åsberg Depression Rating Scale; CGI-S = Clinical Global Impressions-Severity; PGIC = Patient's Global Impression of Change; EQ-5D = EuroQol-5D

VLS-01

(DMT)
for TRD



Product Overview: VLS-01 for Depression

Designed for a potential rapid, sustained reduction in depressive symptoms from a single dose

PRODUCT	DMT (N,N-Dimethyltryptamine) in an oral transmucosal film (OTF)
INDICATIONS	*Lead:* Treatment Resistant Depression *Potential expansions:* Eating Disorders, Substance Use Disorders
INTELLECTUAL PROPERTY	Granted U.S. patent covering OTF administration of DMT, supported by several pending U.S. and PCT patent applications
CURRENT STATUS	Final Phase 1 data reported in 3Q '23 Phase 1b first participant expected in 1H '24[3]

VLS-01 Key Product Features

- Designed for rapid onset and sustained efficacy after single dose
- Short duration of psychedelic effect (~30 to 45 minutes) with improved tolerability and convenience from OTF delivery relative to other psychedelics in development for depression

Lead indication overview

- Depression is a mood disorder that affects the thoughts and behavior of an individual, leading to psychological, physical, and social problems
- Treatment resistant depression (TRD) is diagnosed after two failed courses of antidepressants
- FDA approved depression treatments can be characterized by a slow onset, long-term side effects and inadequate response rate

Global disease burden

~300m

Global sufferers of depression in 2019[1]

33%

Patients who have inadequate response or relapse after current treatments[2]

1. World Health Organization
2. Salzer, "National Estimates of Recovery-Remission From Serious Mental Illness", Psychiatry Online (2018)
3. Health Volunteer Study

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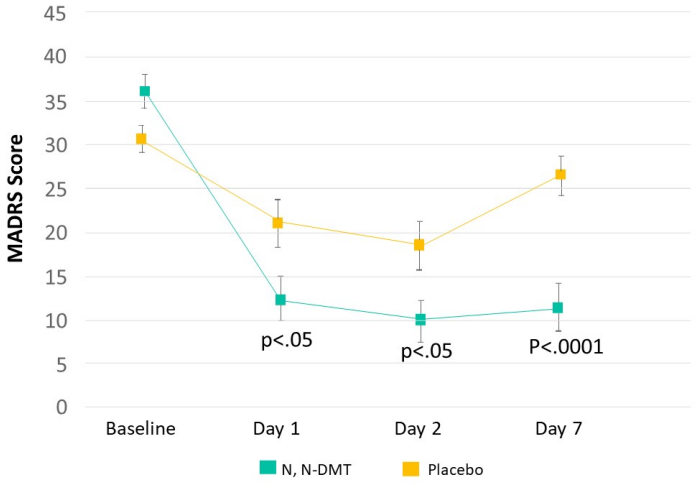
Clinical Evidence: Efficacy in Randomized Control Trial of DMT in TRD

Double-blind, randomized placebo-controlled trial with DMT in 29 patients with treatment-resistant-depression

PRIOR CLINICAL EVIDENCE (THIRD PARTY STUDY[1])

Double-blind, randomized placebo-controlled trial of Ayahuasca (DMT is major active ingredient) in 29 patients with TRD



Note: TRD = Treatment Resistant Depression; DMT = N,N-Dimethyltryptamine
1. Palhano-Fontes et al. "Rapid antidepressant effects of the psychedelic ayahuasca in treatment-resistant depression", Psychol Med (2019)

Key Takeaways

1. **Summary:** A single administration of .36 mg/kg met both primary and key secondary efficacy endpoints by demonstrating rapid and statistically significant changes on depression severity measures of HAM-D & MADRS
2. **Primary endpoint (HAM-D - not shown):** N,N-DMT arm achieved the primary endpoint of a statistically significant difference in depression severity relative to placebo (p<.05).
3. **Key secondary endpoint (MADRS – see left):** rapid and statistically significant differences were observed at all timepoints assessed, including as early as Day 1 and through Day 7. MADRS is a potential registrational endpoint.
4. There were **no serious adverse events reported**.

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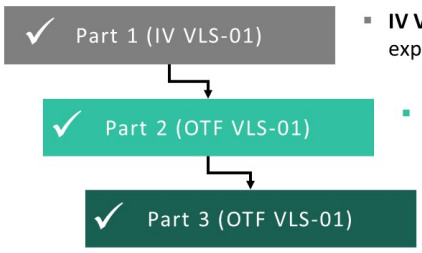
VLS-01 Phase 1: Clinical Trial Design & Results

VLS-01 was well-tolerated with a favorable safety profile, with dose-dependent increases in exposure confirmed

STUDY DESIGN:



Phase 1 PK / PD RESULTS:

- **IV VLS-01:** PK / PD results were consistent with the known pharmacological profile of DMT, producing robust exposure-dependent increases in the subject intensity of psychedelic experience.
- **OTF VLS-01:** Produced generally dose-dependent increases in exposure, approaching that seen with IV administration, alongside subjective psychedelic experiences in the majority of patients.
- **OTF VLS-01:** 160mg with a backing layer via buccal administration experienced the most robust and consistent increases in exposure and subjective effects compared to the other OTF cohorts, with results comparable to the 30 mg IV cohort of DMT.

Program status: Phase 1b FSI expected in 1H '24

Note: IV = Intravenous; OTF = Oral Transmucosal Film; PK / PD = Pharmacokinetic / Pharmacodynamic; DMT = N,N-Dimethyltryptamine

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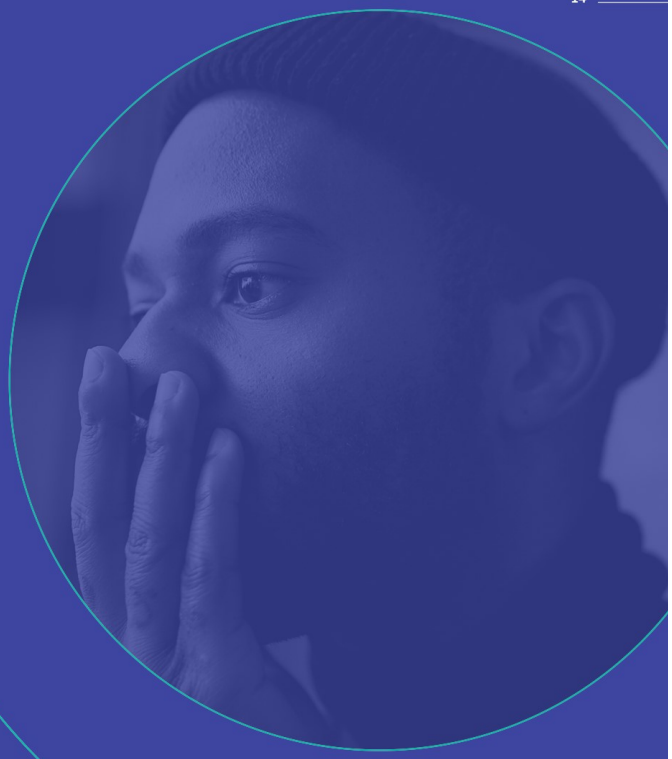
COMP 360

(psilocybin) for TRD, PTSD and Anorexia

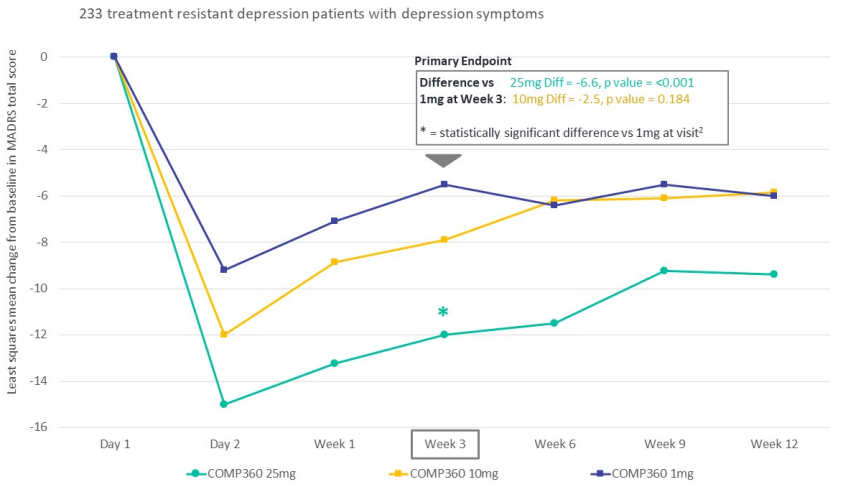


SUMMARY: COMP360

OWNERSHIP	15.5%[1]
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, Anorexia Nervosa, PTSD Potential: Major Depressive Disorder, Autism, Bipolar Disorder, Chronic Cluster Headache
CURRENT STATUS	Phase 3 pivotal trial 1 data expected summer-24 Phase 3 pivotal trial 2 data expected mid-25
INTELLECTUAL PROPERTY	Proprietary formulation of synthetic psilocybin, COMP360
HIGHLIGHT	COMP360 demonstrated efficacy in reducing depressive symptom severity with rapid and durable response in Phase 2b study

COMP360 Phase 2b trial showed a rapid, sustained reduction in depressive symptoms

PRIOR EVIDENCE IN HUMANS (COMP360 PHASE 2b)

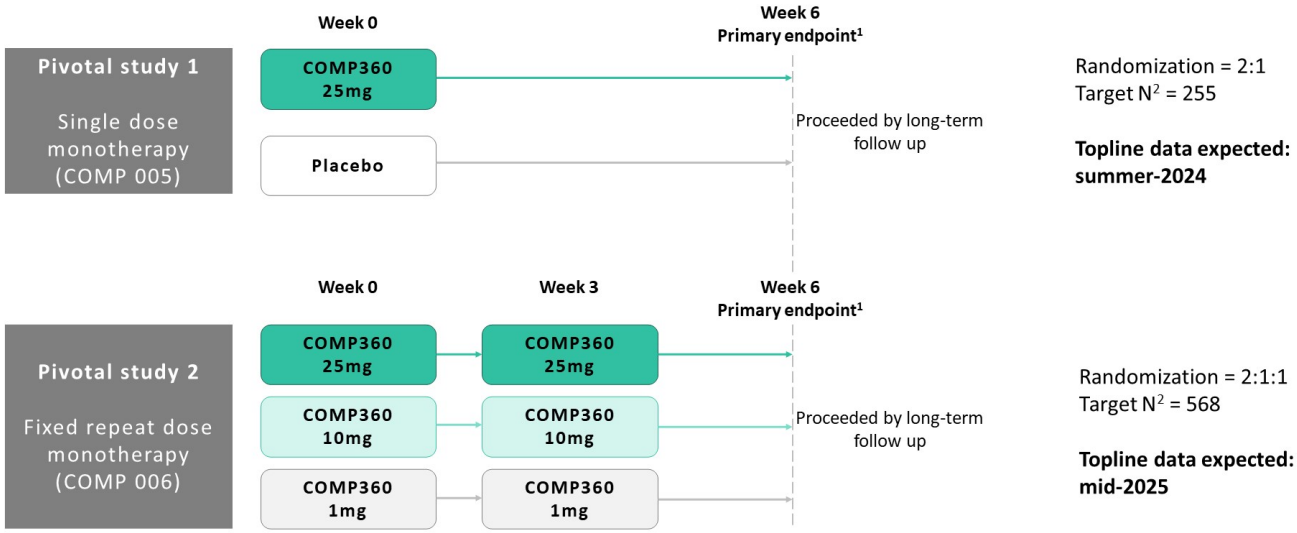


Note: MADRS = Montgomery-Åsberg Depression Rating Scale; COMP360 = a proprietary high-purity, polymorphic crystalline formulation of psilocybin; In COMPASS's model of psilocybin therapy, COMP360 is administered in conjunction with psychological support from specially trained therapists.

1. Ownership percentage as of Sep 30th, 2023
2. Post-hoc analysis showed results were also positive at the other time points listed for 25mg dose, however, the nonsignificant finding for the comparison between the 10mg group and the 1mg group terminated significance testing based on the prespecified hierarchical test procedure for all subsequent key secondary efficacy end points.

COMPASS Pathways is currently conducting a Phase 3 pivotal program, with topline data expected in summer-2024 and mid-2025

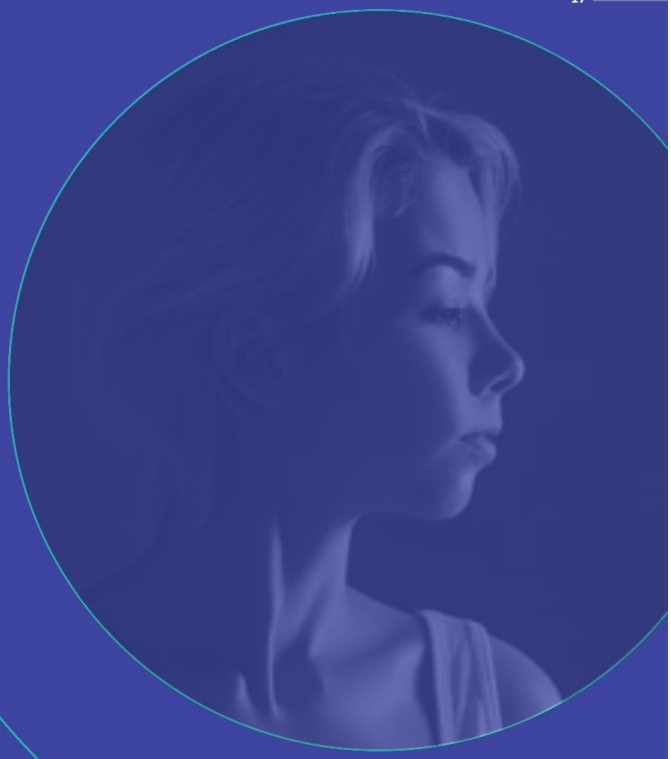
Pivotal Phase 3 Trial Designs



Source: Compass Pathways Capital Markets Day presentation as of May 11th, 2023
1. Primary endpoint = Change from baseline in MADRS total score at week 6
2. The participant population (TRD definition and core inclusion / exclusion criteria) remains unchanged compared to Phase 2b

ELE-101

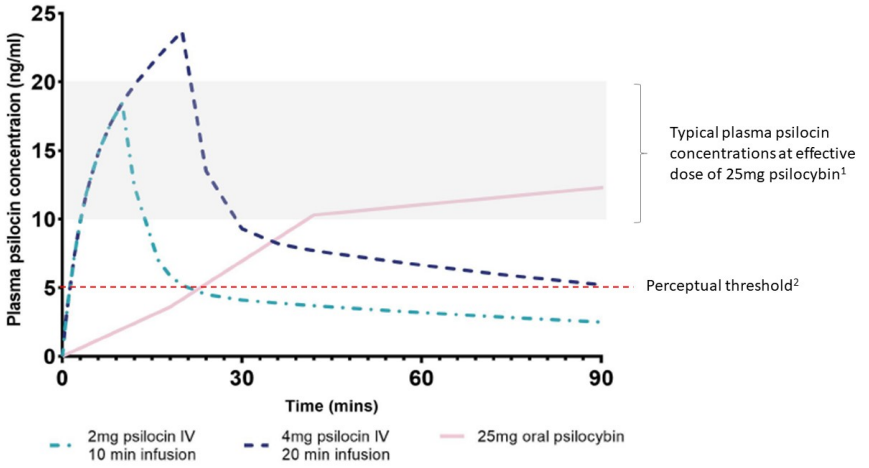
(psilocin)
for MDD



ELE-01: IV Psilocin

Potential benefits of psilocybin's active moiety in an optimized delivery and treatment model

Psilocin pharmacokinetics for
IV psilocin (simulated) vs. oral psilocybin[1]



Expected benefits of IV psilocin vs oral psilocybin:

- Reduced variability
- Shorter-half life = shorter duration of psychedelic effect, anticipated to be <2 hours

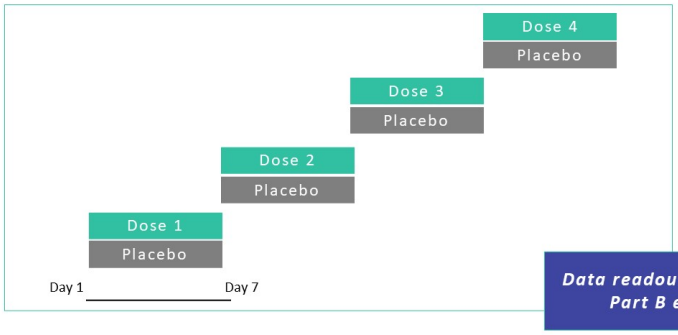
[1] Psilocin simulations based on primary data from Brown et al. 2017, Madsen et al. 2019, Hasler et al. 1997, and Carhart-Harris et al. 2011.
[2] Holze F. et al (2023). Pharmacokinetics and Pharmacodynamics of Oral Psilocybin Administration in Healthy Participants. Clin Pharmacol Ther.

ELE-101 Phase 1/2a Clinical Trial Design

Randomized, Phase 1 dose-escalation study in healthy volunteers followed by Phase 2a open-label study in MDD

ELE-101 Phase 1/2a – Part A

Single Ascending Dose



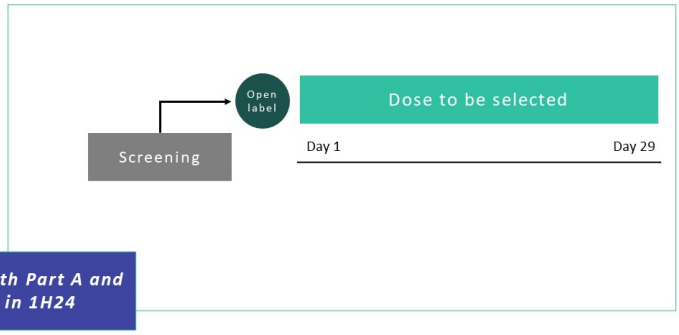
Key Objectives:

- Safety and tolerability
- Assessment of PK & PD
  - Target concentration of psilocin in <2 minutes
  - Consistency of subjective intensity

Data readouts for both Part A and Part B expected in 1H24

ELE-101 Phase 1/2a – Part B

Open-label MDD cohort



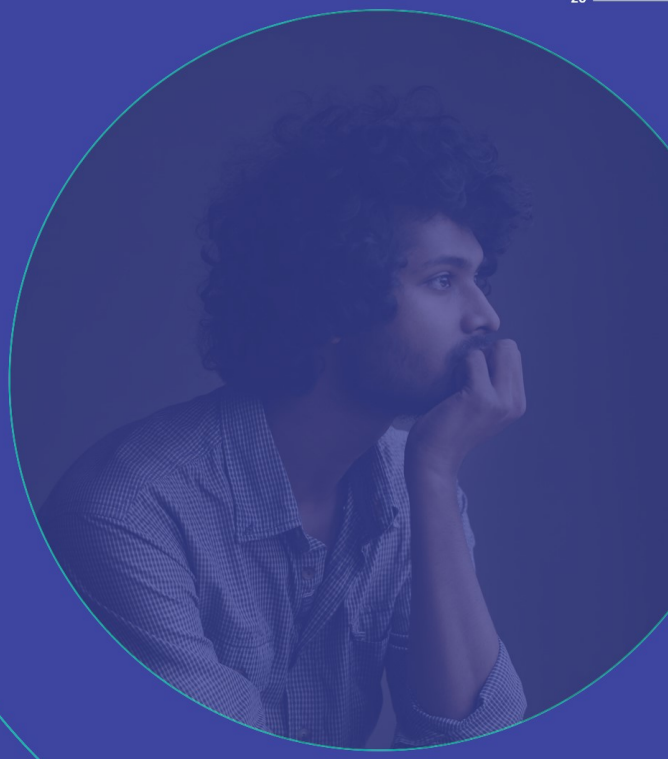
Key Objectives:

- Safety and tolerability of ELE-101 in patients with moderate to severe MDD
- Key Secondary Endpoints:
  - Assessment of MADRS change (Day 2, 4, 6, 15, 29)
  - CGI-S, PGIC

Abbreviations: MADRS = Montgomery–Åsberg Depression Rating Scale; PK = Pharmacokinetics; PD = Pharmacodynamics; CGI-S = Clinical Global Impressions-Severity; PGIC = Patient's Global Impression of Change; MDD = Major Depressive Disorder

DMX-1002

(ibogaine) for Substance Use Disorder



Product Overview: DMX-1002 for Opioid Use Disorder

Designed to have a rapid, sustained reduction in depressive symptoms through psychedelic effects

PRODUCT	DMX-1002 is an oral formulation of ibogaine, which is an indole alkaloid with potential for clinical benefit through oneirophrenic effects
INDICATIONS	*Lead:* Opioid Use Disorder ("OUD") *Potential expansions:* Add'l Substance Use Disorders, PTSD, TBI[1]
INTELLECTUAL PROPERTY	Issued and pending method of treatment claims for OUD
CURRENT STATUS	Phase 1 results reported in Q3'23 Expect to submit FDA meeting request in 1H'24

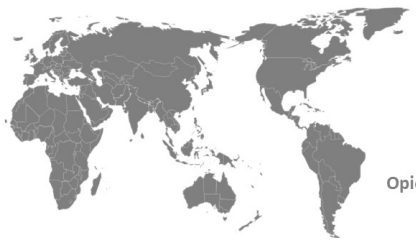
DMX-1002 Key Product Features

- A single dose of ibogaine delivered in a monitored setting may support withdrawal and long-term relapse prevention in Opioid Use Disorder patients
- *Prior clinical evidence:*
  - In third-party open label studies, ibogaine was associated with significantly reduced opioid cravings, both at discharge and at one month post treatment, as well as improved mood in patients with OUD
  - In addition, a double-blind, placebo-controlled study in subjects with cocaine use disorder demonstrated a statistically significant benefit on urine confirmed relapse of a single administration of ibogaine compared to placebo

Lead indication overview

- Substance use disorders are highly prevalent and characterized by an inability to control the use of a legal or illegal drugs, such as opioids (including prescription opioids) or alcohol.
- Current standard of care for OUD primarily consists of psychosocial support and synthetic full and partial opioid receptor agonists (methadone & buprenorphine), where approximately 30% of patients achieve treatment success (defined as >80% illicit opioid free weeks). In addition, long-acting opioid antagonists (naltrexone) lead to a proportion of patients achieving treatment success.

Global disease burden



~3m

US OUD Incidence in 2020[2]

>100k

Opioid-related deaths in US in 2022

1. Post traumatic stress disorder and traumatic brain injury, respectively
2. World Health Organization
3. Salzer, "National Estimates of Recovery-Remission From Serious Mental Illness", Psychiatry Online (2018)

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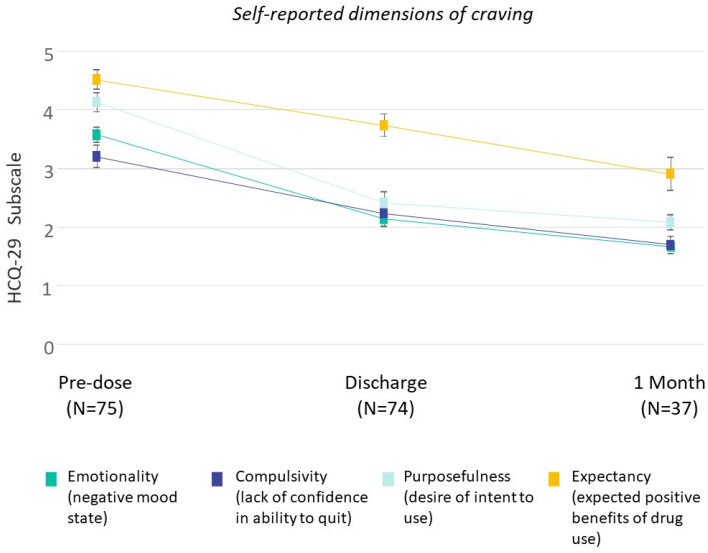
Clinical Evidence: Efficacy of ibogaine in Open-Label Safety and Efficacy Study

Results from an open-label study of 8-12 mg/kg of ibogaine in patients seeking detoxification from opioids and cocaine

PRIOR CLINICAL EVIDENCE (THIRD PARTY STUDY[1])



Note: TRD = Treatment Resistant Depression; DMT = N,N-Dimethyltryptamine
1 Mash et al., "Ibogaine Detoxification Transitions Opioid and Cocaine Abusers Between Dependence and Abstinence: Clinical Observations and Treatment Outcomes" (2018)

Key Takeaways

1. **Summary:** A single-dose of ibogaine showed reductions in self-reported opioid cravings in 74 opioid dependent patients.

2. **Efficacy – Relapse Prevention (shown left):** Opioid dependent patients had significant reductions in the mean scores of four HCQ-29 domains of craving measured at program discharge and out to 1 month for patients continuing through study completion. Cravings are an important mediator of relapse.

3. **Efficacy – Post-Acute Withdrawal Syndrome:** signs and symptoms at post dose assessments were reduced compared to pre-dose baseline withdrawal severity measures. Objective signs of opioid withdrawal were mild and none were exacerbated at later time points.

4. **Safety:** Ibogaine was reported to be well tolerated with no serious adverse events.

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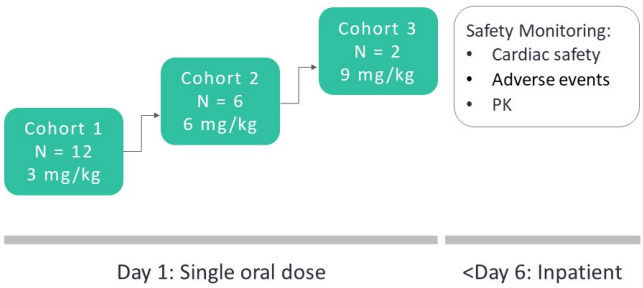
Phase 1 Study: DMX-1002 Trial Design & Results Summary

Demonstrated safety level and plasma concentrations of DMX-1002 in line with previous trials

COMPLETED PHASE 1 TRIAL: SINGLE ASCENDING DOSE



Population: Healthy male participants

Design: Single-blinded, cross-over study. All participants received placebo first, followed by DMX-1002 at a second visit

SUMMARY OF PHASE 1 RESULTS

Potential therapeutic plasma levels

- DMX-1002's 9 mg/kg achieved plasma concentrations in line with those described in previous studies where therapeutic effects were observed

No serious adverse events reported

- Nearly all adverse events were mild-to-moderate (>94%), consistent with prior trials of ibogaine

Asymptomatic QTc Prolongation

- One of two participants in cohort 3, asymptomatic QTc prolongation was observed, with no cardiac arrythmias. The QTcF change of 90-94ms resolved without intervention or sequelae

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SUMMARY

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

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 & best in-class treatment for OUD, minimizing risk of relapse

	Therapy	Mechanism of Action	Single Therapeutic Episode	No Opioid Side Effects	Minimal Abuse Potential	High Adherence / Low Risk of Relapse
Sustained relapse prevention Single dose administered in monitored setting, providing both withdrawal support and oneiric experience driving sustained remission	Ibogaine (DMX-1002) **DemeRx**	Cholinergic, glutamatergic and monoaminergic receptor modulator	✓	✓	✓	✓
Medication Assisted Therapy[1] Daily therapy given in substitution of opioid in outpatient setting in attempt to wean off from opioid	Methadone	Mu-agonist				✓
	Buprenorphine	Partial Mu-agonist				✓
	Naltrexone	Mu-antagonist		✓	✓	
Withdrawal Support[2] Therapies given for symptomatic management during supervised withdrawal (detoxification)	Clonidine	Alpha-2 agonist	✓	✓	✓	
	Lofexidine	Alpha-2 agonist	✓	✓	✓	

Note: OUD = Opioid Use Disorder
Source: Publicly available information, including company websites and clinicaltrials.gov, GlobalData, Evaluate Pharma (both as of 2022)
1. Current Standard of Care
2. Rarely used given high rates of relapse. Used primarily in institutional or penitentiary settings

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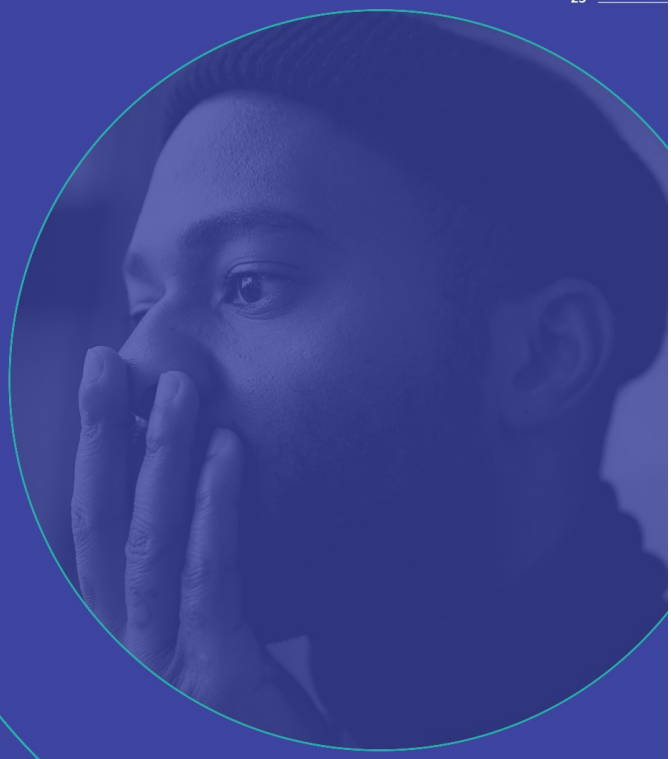
RL-007 for Cognitive Impairment



Product Overview: RL-007 for Cognitive Impairment

Demonstrated consistent pro-cognitive effects in prior clinical trials, with a favorable safety profile in >500 subjects

PRODUCT	Oral, pro-cognitive neuromodulator
INDICATIONS	*Lead:* Cognitive impairment associated with schizophrenia *Potential expansions:* Cognitive disorders including Alzheimer's dementia and/or Autism
INTELLECTUAL PROPERTY	Issued composition of matter, formulation and method of use IP
CURRENT STATUS	Phase 2a CIAS trial completed in H2'21 Phase 2b first patient dosed in 1Q'23 Phase 2b data expected in mid'25

RL-007 Key Potential Product Features

- Pro-cognitive effects demonstrated across four prior clinical studies, including two Phase 1 and two Phase 2 trials
- Consistent "inverted-U" dose response across clinical & preclinical studies
- Demonstrated safety & tolerability with no evidence of sedative side effects across the 10 clinical studies in >500 subjects

Lead indication overview

- Cognitive impairment associated with schizophrenia (CIAS) is characterized by attention, learning, memory, and exec function deficits
- Such deficits result in cognitive function around 2.5 standard deviations below the mean of the general population[4]
- CIAS is a common and major cause of disability in schizophrenia, with more than 80% of patients showing significant impairment[2]
- **No FDA approved treatments[3]**

Global disease burden

~24m

Global sufferers of Schizophrenia[1]

>80%

Patients with Schizophrenia experiencing significant cognitive impairment[2]

1. World Health Organization
2. Bora et al, Cognitive Impairment in Schizophrenia and Affective Psychoses: Implications for DSM-V Criteria and Beyond
3. GlobalData (as of 6/1/2023)
4. Schaffer et al., 2013

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Clinical Evidence: Efficacy on Cognitive Endpoints in a Phase 2 Study

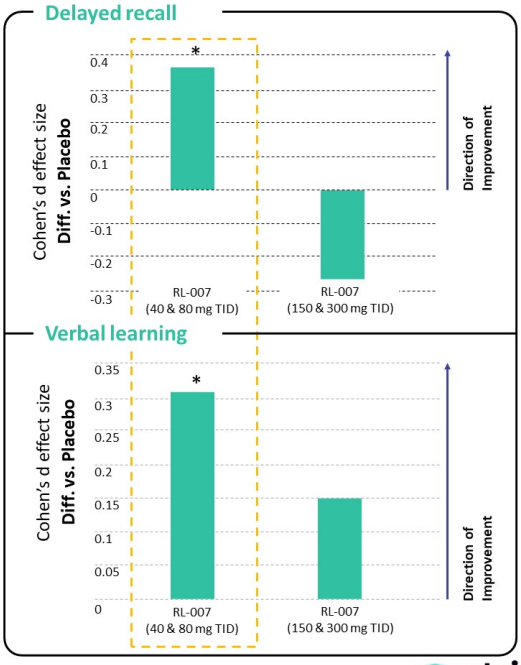
Third-Party Phase 2 study in DPNP showed statistically significant positive cognitive signals (exploratory endpoints)

Background

- Phase II, randomized, placebo-controlled, crossover clinical study in subjects with diabetic peripheral neuropathic pain (DPNP) that assessed improvements in verbal learning and memory as an exploratory endpoint
- 4-week placebo periods were compared to 4-week RL-007 periods
  - "Intermediate-dose escalation" RL-007 40mg (first week) to 80mg (n=60)
  - "High-dose escalation" RL-007 150mg (first week) to 300mg (n=60)

Key Takeaways

1. RL-007 showed statistically significant pro-cognitive effects on learning and memory within the "Intermediate-Dose escalation" 40mg to 80mg arm.
2. The 40 to 80mg arm patients also reported a statistically significant improvement on the Cognitive and Physical Function Questionnaire (p = 0.021)
3. Inverted U-shaped dose response whereby intermediate doses yield greater clinical activity is replicated and consistent with from prior clinical and preclinical studies



Note: * = P< 0.05 vs Placebo;
N=60 patients/treatment group; dosed TID = 3x/day dosing; randomized, cross-over design

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Clinical Evidence: Efficacy Signals Reproduced in Phase 2a Study in CIAS

atai's Phase 2a study in CIAS demonstrated positive cognitive signals on a subset of MCCB neurocognitive endpoints

Background

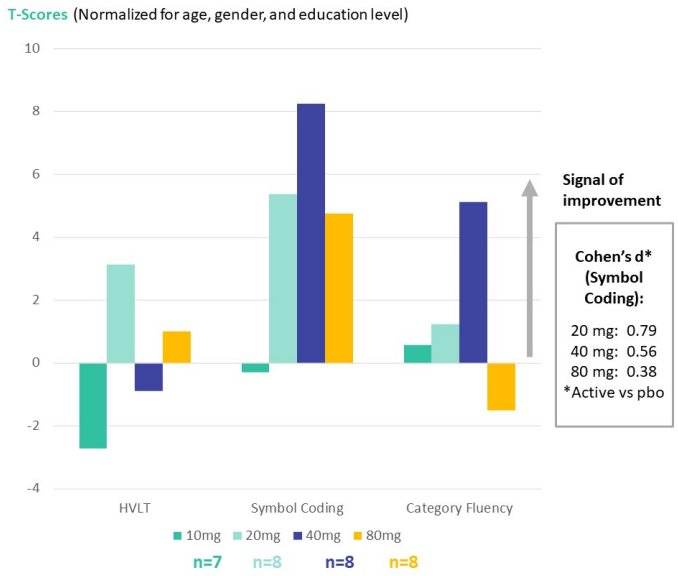
- Cognitive function was assessed in 31 patients with CIAS across four RL-007 cohorts (10, 20, 40 & 80mg). Patients received four doses of placebo followed by six doses of RL-007 over 4-days. Day 2 "pre-RL-007" was compared to Day 4 "post-RL-007".
- The primary objectives of the single-blinded study was to confirm safety on-top of SOC and to identify signals of cognitive benefit in patients with CIAS, including on three MCCB sub-component neurocognitive tests, HVLT[1], BACS Symbol Coding & Category Fluency

Key Takeaways

1. Study demonstrated dose-related trends for improvements on each MCCB neurocognitive endpoints, including a Cohen's d effect size of 0.79, 0.56 and 0.38 at the 20mg, 40mg, and 80mg, respectively, on the BACS Symbol Coding test.
2. Importantly, Symbol Coding is the most sensitive subcomponent and correlates with overall performance on the MCCB neurocognitive composite, the latter being a registrational endpoint and the primary endpoint for the on-going Phase 2b study of RL-007.
3. In addition, qEEG data was consistent with the prior clinical evidence and demonstrated increases in amplitude in the alpha band and in the alpha-slow wave index, markers of alertness believed to correlate with aspects of cognition.

1. Hopkins Verbal Learning Test

PHASE 2a TRIAL - EFFICACY DATA ON COMPONENTS MCCB COMPOSITE



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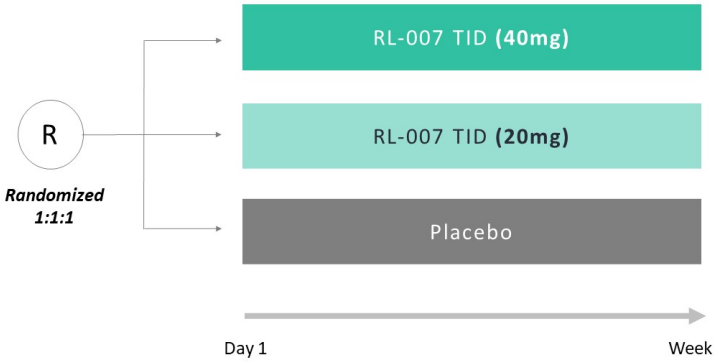
Clinical Trial Design: RL-007 Phase 2b Study

Randomized, placebo-controlled study of RL-007 in ~234 patients with CIAS



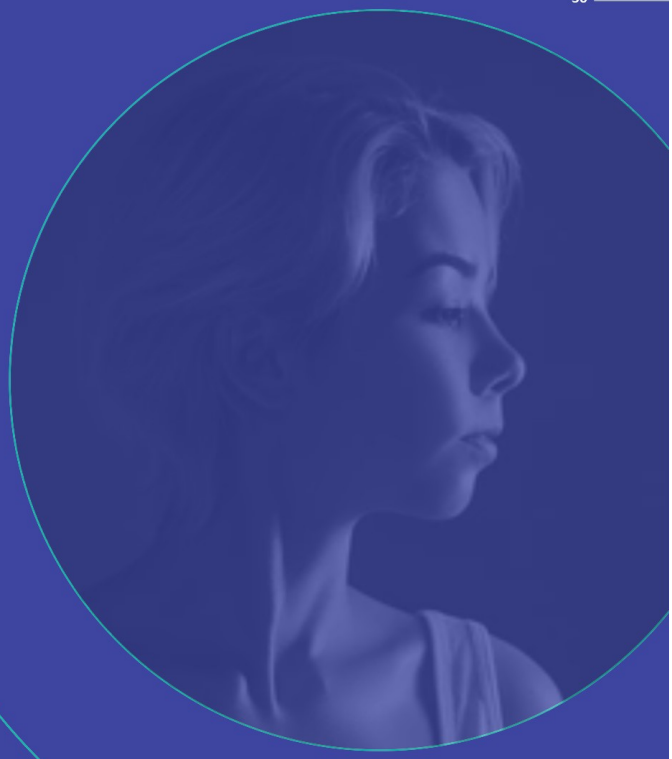
Primary Endpoint:
- MCCB neurocognitive composite score at Week 6

Key Secondary Endpoints:
- Select Individual Components of MCCB, including BACS Symbol Coding
- Clinical Global Impression Score

Trial status: First patient dosed in 1Q'23, Topline data anticipated mid'25

Note: MCCB = MATRICS Consensus Cognitive Battery; BACS = Brief Assessment of Cognition in Schizophrenia; CIAS = Cognitive Impairment Associated with Schizophrenia; TID = 3x/day dosing

GRX-917 for Anxiety Disorders



Product Overview: GRX-917 for Anxiety Disorders

Designed to have rapid onset of anxiolytic activity but without the negative side effects seen with benzodiazepines

PRODUCT	Deuterated etifoxine HCl oral dosage form (GRX-917)
INDICATIONS	Lead: Anxiety Disorders (e.g., GAD, SAD, PTSD, etc.)
INTELLECTUAL PROPERTY	Issued composition of matter on deuterated etifoxine (GRX-917) and corresponding methods of use
CURRENT STATUS	Phase 1 trial completed in H2'22 Exploring partnership and external funding opportunities

GRX-917 Key Product Features

- Demonstrated rapid onset activity of anxiolytic activity (non-deuterated etifoxine approved in France)
- Review of ~14m prescriptions in France underscores the strong safety track record for etifoxine
- Differentiated tolerability profile, with limited sedative, addictive and/or cognitive impairing properties, unlike benzodiazepines

Lead indication overview

- Anxiety disorders develop when feelings of apprehension and unease persist over an extended period and potentially worsen over time
- 50% of US patients go untreated as a result of sub-optimal treatment options[2]
- **No** FDA approved novel treatments over the past decade[3]

Global disease burden

~300m

Anxiety disorder sufferers in 2019[1]

#1

Most common mental health disorder[1]

1. World Health Organization
2. Anxiety and Depression Association of America (2021)
3. GlobalData (as of 6/1/2023) - All recent approvals by the FDA have been reformulations of long-standing antidepressant and benzodiazepine options

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Phase 1 Study: GRX-917 Trial Design & Results Summary

Demonstrated a rapid and dose-dependent PK/PD effect along with a favourable safety profile

COMPLETED PHASE 1 TRIAL

Part 1: Single Ascending Dose

TREATMENT	SAFETY/PK/PD
42 healthy subjects: 5 cohorts 25mg to 500mg	**PD Endpoint:** qEEG

Part 2: Multiple Ascending Dose

TREATMENT	SAFETY/PK/PD
60 healthy subjects: 5 cohorts 100mg to 300mg BID	**PD Endpoint:** qEEG

SUMMARY OF PHASE 1 RESULTS

Target engagement demonstrated

- Dose-dependent increases in qEEG beta power

Safe & well-tolerated

- Well-tolerated with no dose limiting toxicities, with adverse effects comparable to that of placebo

Sedation comparable to placebo

- Sedation in-line with placebo, which was consistent with EEG results and which did not show decreases in qEEG alpha power

Note: PK / PD = Pharmacokinetic / Pharmacodynamic; qEEG = Quantitative electroencephalography; BID = Twice daily

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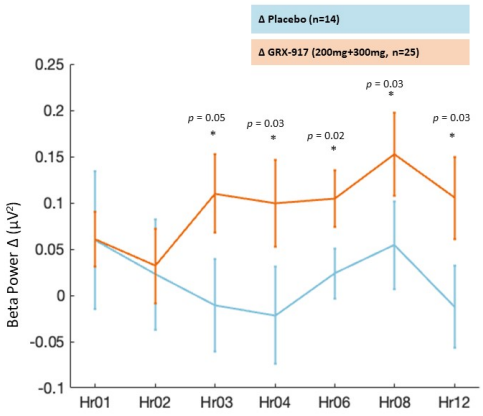
Phase 1 Study: GRX-917 Pharmacodynamic Evidence of Target Engagement

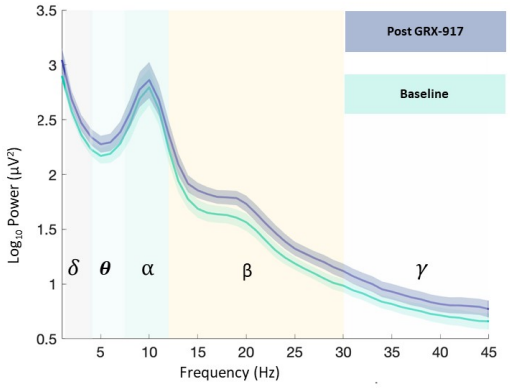
Beta power increase is in line with pharmacodynamic efficacy of exogenous neurosteroids and benzodiazepines

Beta Power Increase



Sensitivity Analysis: Line plot showing Beta power Δ (mean±SEM) at each hour for placebo and GRX-917 (combined 200mg and 300mg cohorts).

Beta Power Increase + No Alpha Decrease



Calculation of Difference Wave: Difference Waves (Δ = post minus pre) were compared between GRX-917 and Placebo at each hour and frequency of interest.

Beta power increase indicates potential for anxiolytic activity, while absence of Alpha power reduction suggests basis for less sedation than with benzodiazepines

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