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): June 5, 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 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 8.01 Other Events.

On June 5, 2024, atai Life Sciences N.V. (the "Company") posted to the Company's corporate website at *www.atai.life* an investor presentation (the "Investor Presentation") to be used from time to time in meetings with investors and analysts. A copy of the Investor Presentation is attached as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Investor Presentation, dated June 5, 2024.
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: June 5, 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 – June 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 o which any factor, or combination of factors, may cause actual r materially from those contained in any forward-looking statements In light of these risks, uncertainties and assumptions, the forward and circumstances discussed in this presentation may not occur an could differ materially and adversely from those anticipated or forward-looking statements. We caution you therefore against re forward-looking statements, and we qualify all of our forward-look by these cautionary statements.

The forward-looking statements included in this presentation are n the date hereof. Although we believe that the expectations re forward-looking statements are reasonable, we cannot guarantee results, levels of activity, performance or events and circumstanc the forward-looking statements will be achieved or occur. Moreov nor our advisors nor any other person assumes responsibility for th completeness of the forward-looking statements. Neither we no undertake any obligation to update any forward-looking state reason after the date of this presentation to conform these staten results or to changes in our expectations, except as may be requir should read this presentation with the understanding that our results, levels of activity, performance and events and circums materially different from what we expect.

Unless otherwise indicated, information contained in this presentat our industry, competitive position and the markets in which we op on information from independent industry and research organ third-party sources and management estimates. Management derived from publicly available information released by indepe

Highlights

atai Life Sciences: Healing mental health disorders so tha more fulfilled life

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

2. atai's objective is to enable mental health patients to achieve clinically n through developing innovative, rapid-acting and durable therapeutics.

3. Eight clinical-stage psychedelic and non-psychedelic programs and strate of prior clinical evidence.

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

5. Cash and cash equivalents, marketable securities, and committed term l 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. T securities, and public equities

Drug Development Programs and Strategic Investments

Our strategy to be delivered through a robust portfolio c drug development programs and strategic investments

Programs / Investments	Primary Indication
PSYCHEDELIC PROGRAMS & STRATEGIC INVESTMENTS	
COMP360[1] / Psilocybin	Treatment-Resistant Depression
BPL-003[2] / 5-MEO-DMT	Treatment-Resistant Depression
VLS-01 / DMT	Treatment-Resistant Depression
ELE-101[2] / Psilocin	Major Depressive Disorder
IBX-210 / Ibogaine	Opioid Use Disorder
EMP-01 / R-MDMA	Undisclosed
EGX-A & EGX-B / Novel 5-HT2A Receptor Agonists	Undisclosed
NON-PSYCHEDELIC PROGRAMS	
RL-007 / Pro-cognitive neuromodulator[3]	Cognitive Impairment Associated with Schizophrenia
GRX-917 / Deuterated etifoxine	Generalized Anxiety Disorder

[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)-(+)

Upcoming Catalysts

We expect to deliver several meaningful R&D milestones programs and strategic investments through 2024 and 20

Achieved and expected milestor
(2024-25)

H1'24

- ✓ **VLS-01**
  Ph 1b first participant dosed
- ✓ **BPL-003**
  Ph 2a OL (TRD) Part 1 data
- **ELE-101**
  Ph 1/2a OL (MDD) initial data
- ✓ **COMP360**
  Ph 2 (PTSD) data (Spring '24)

H2'24

- **VLS-01**
  Ph 1b topline data
- **BPL-003**
  Ph 2a OL (AUD) data (mid'24)
- **COMP360**
  Ph 3 (TRD) Pivotal Trial 1 topline dat
- **BPL-003**
  Ph 2b (TRD) patient recruitment completed
- **IBX-210**
  Ph 1/2a initiation
- **VLS-01**
  Ph 2 initiation (around YE'24)

1. All dates provided are as estimated

Programs in Depression

BPL-003, VLS-01, COMP360, ELE-101

atai's Depression Portfolio Comparison

A diverse portfolio of differentiated psychedelic assets t patients who suffer from depression

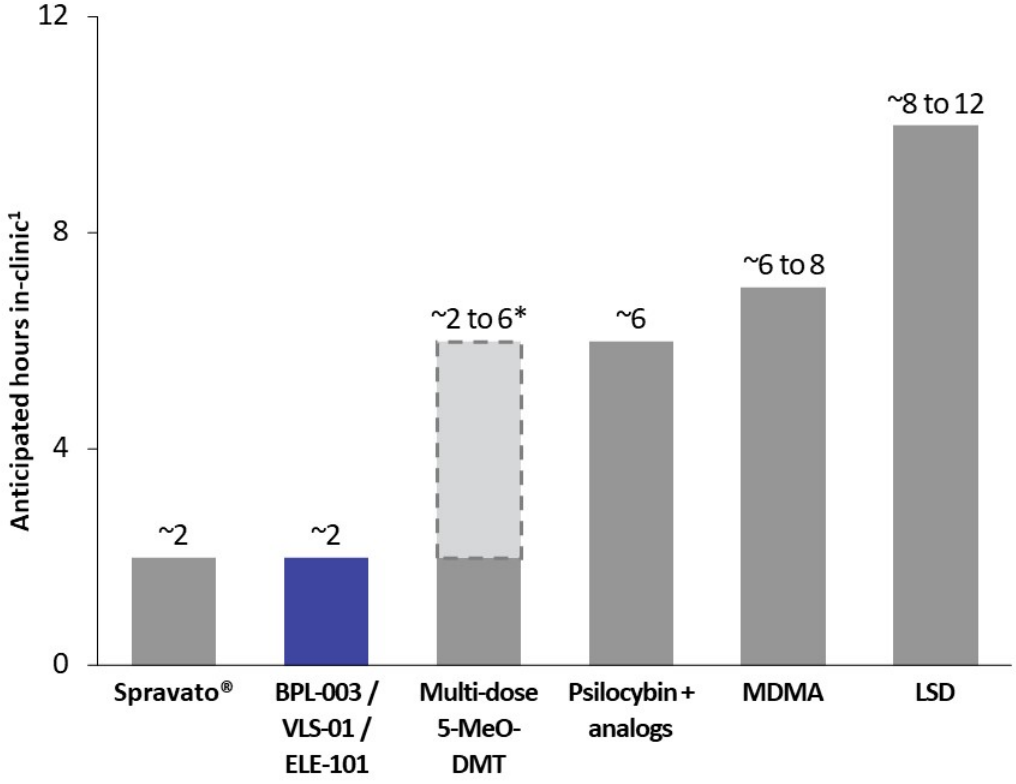
Associated Program	Compound	Primary Indication	Route of Administration	Receptor (5-HT2A :
BPL-003	5-MeO-DMT	TRD	Intranasal	
VLS-01	DMT	TRD	Oral transmucosal film	
COMP360	Psilocybin[2]	TRD	Oral	
ELE-101	Psilocin	MDD	Intravenous	

[1] Besnard et al. 2012 // [2] Psilocybin is not present in the body in meaningful concentrations after oral consumption // Abbreviations: TRD = Treatment Resistant Depression; MDD = Major Depressive Disorder

Commercial Positioning

atai's focus is on psychedelics with the potential to lever psychiatry treatment paradigm successfully established

Anticipated in-clinic time based on duration of subjective effects[1]
(in hours) *Illustrative*



1. BPL-0 depre admir parad

2. We ar allows patier durati

3. This m and tr clinics logisti

1. Subject to further validation through future clinical studies and real-world evidence
2. https://www.spravatohcp.com/#find-a-center

* If multi-dose required

BPL-003

(5-MeO-DMT) for TRD & AUD

Strategic Investment into Beckley Psytech

BPL-003: Phase 1 Results

Beckley Psytech's BPL-003 had a favorable safety profile
1 SAD study, with no observed serious or severe adverse

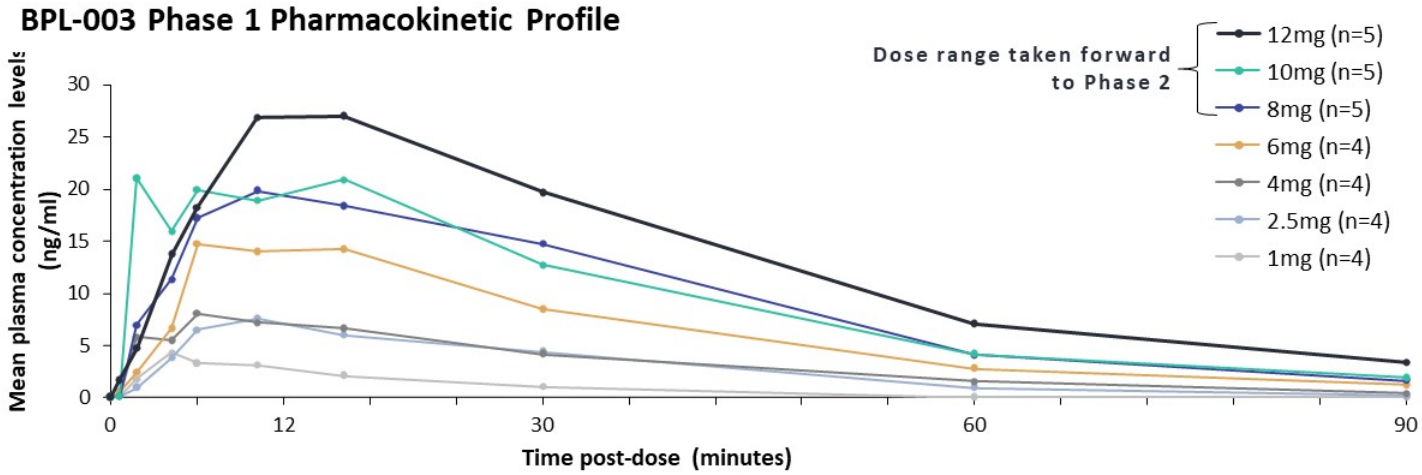
BPL-003 Phase 1 Treatment-Emergent Adverse Events (TEAEs)[1]

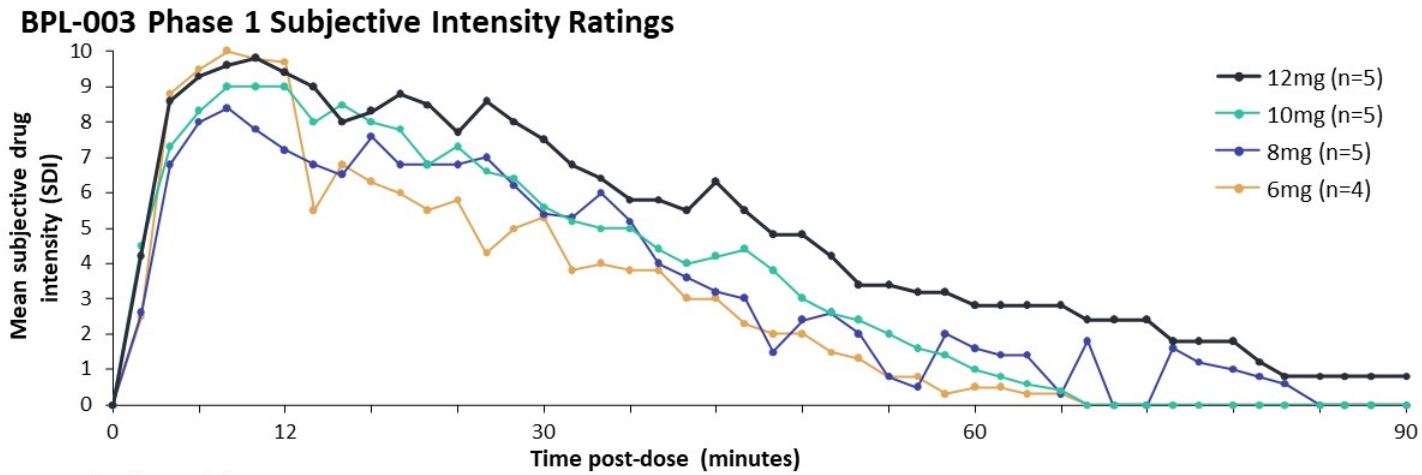
	Placebo N=13	BPL-003 dose (N=31)						Total N=44
		1 mg N=4	2.5 mg N=4	4mg N=4	6 mg N=4	8 mg N=5	10mg N=5	12 mg N=5	
Any TEAEs	2	1	1	4	3	4	2	4	21
Nasal discomfort			1	2	2	2		3	10
Nausea				2	1	2	1	1	7
Vomiting				2		1		2	5
Headache	1			1		2			4
Administration site pain						1	1		2
Chest discomfort						1			1
Dizziness							1		1
Pyrexia	1								1
Gastroenteritis		1							1
Back pain				1					1
Hypoesthesia					1				1
Limb discomfort					1				1
Tremor						1			1
Lacrimation Increased								1	1
Restlessness								1	1

[1] n = number of subjects reporting at least one TEAE in that category, % - rounded proportion of cohort total

BPL-003: Phase 1 Results

Results from the completed BPL-003 Phase 1 study dem
PK/PD profile with perceptual effects generally resolving

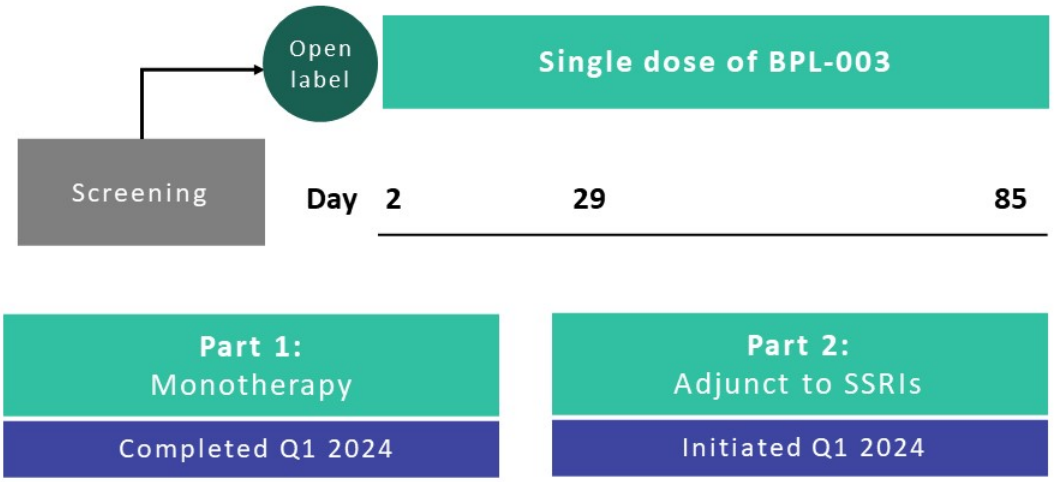




Source: internal Beckley Psytech data
Abbreviations: SAD = Single Ascending Dose; PK = Pharmacokinetic; PD = Pharmacodynamic

BPL-003: Phase 2a Clinical Trial Design

Completed Part 1 of an open-label Phase 2a study inves monotherapy for TRD patients



STUDY DETAILS

- Open-label st patients with

KEY INCLUSION

- Montgomery
- **Part 1:** willing
- **Part 2:** on cu

KEY OBJECTIVES

Primary Endpoi

- Safety and to

Other Secondar

- MADRS chan
- Remission an

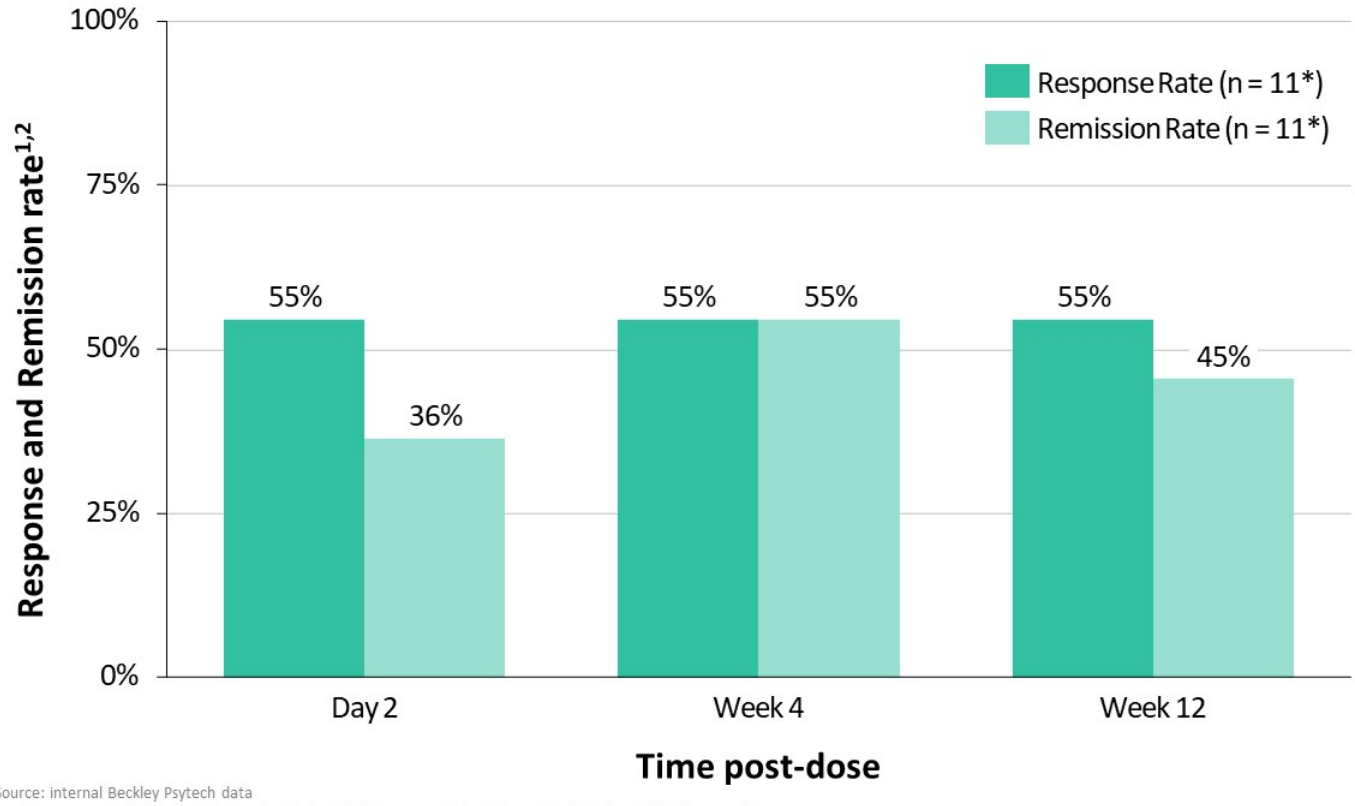
Abbreviations: MADRS = Montgomery–Åsberg Depression Rating Scale

BPL-003: Phase 2a Results

BPL-003 produced meaningful clinical response and dur
single dose, and was generally well tolerated with no se

BPL-003 PHASE 2A INITIAL RESULTS

Response and remission rate[1] in TRD patients after a single dose of BPL-003



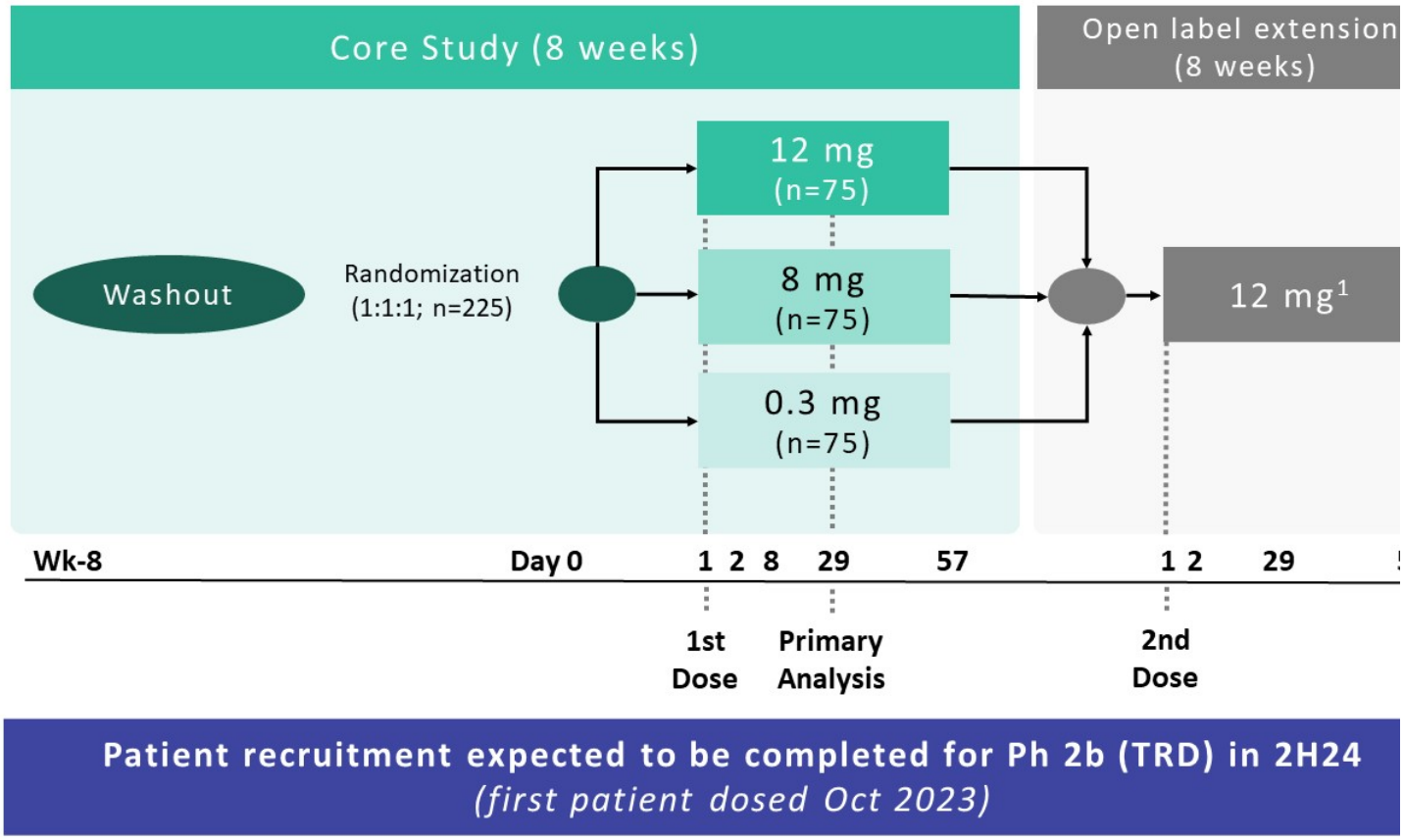
Source: internal Beckley Psytech data

1. Response rate defined as ≥50% reduction in MADRS score and Remission rate defined as MADRS score ≤10

* Prior to data analysis, one subject (from total of 12 patients) was determined not to meet multiple per protocol eligibility criteria and was excluded from the efficacy analysis.

BPL-003: Phase 2b Clinical Trial Design

BPL-003 is actively recruiting for its ongoing Phase 2b st
masked, monotherapy study in 225 moderate to severe



Patient recruitment expected to be completed for Ph 2b (TRD) in 2H24
(first patient dosed Oct 2023)

[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

VLS-01: Product Overview

Potential for rapid onset, durable efficacy, and designed treatment paradigm

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	Phase 1b first participant dosed in 1Q'24 Phase 1b trial results anticipated in 2H'24 Phase 2 study anticipated to initiate around YE'24

VLS-01 Key Product Features

- Short duration of psychedelic effect with improved tolerability and convenience from OTF delivery relative to other psychedelics in development for depression
- Designed for rapid onset, sustained efficacy, and to fit within a two-hour in-clinic treatment paradigm
- Optimized OTF formulation is designed to improve the PK profile and the patient and provider experience

Lead indicati

- Depressio individual
- Treatmen antidepre
- FDA appr long-term

Global diseas

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

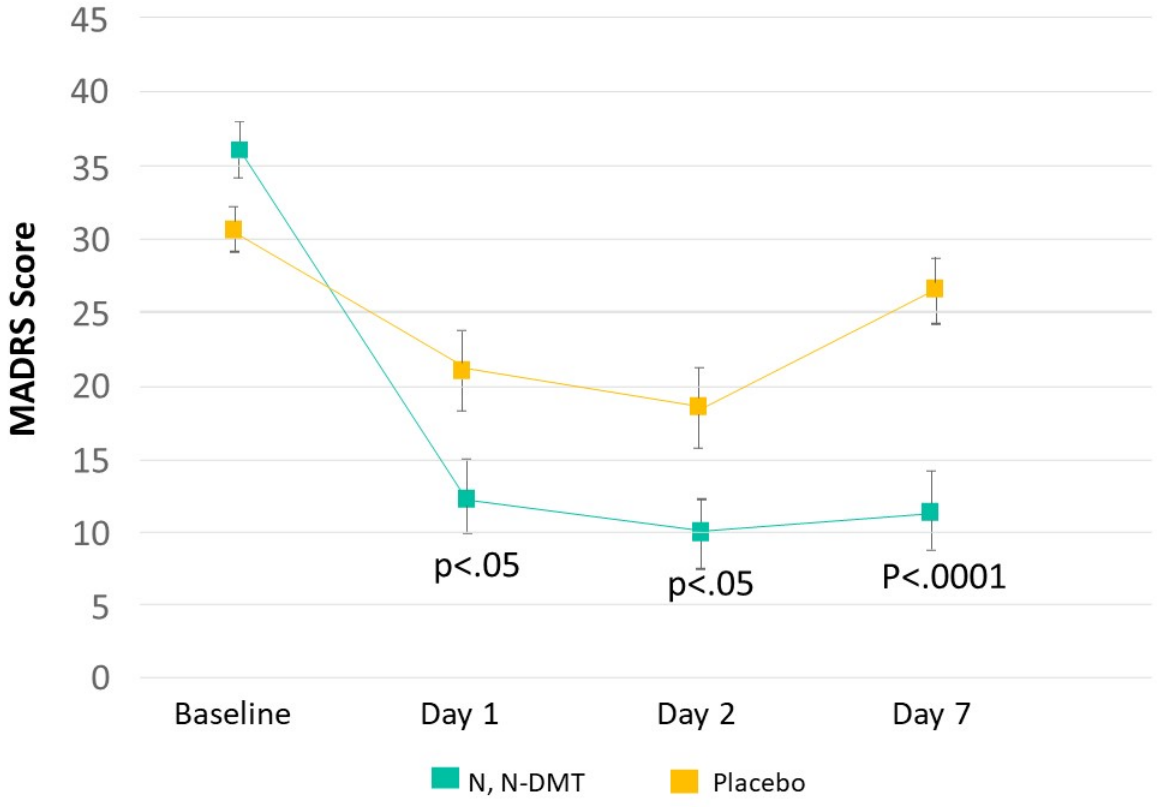
Abbreviations: OTF = Oral transmucosal film; PK = Pharmacokinetic; PCT = Patent Cooperation Treaty

VLS-01: Efficacy in Randomized Control Trial of DMT in TRD

Double-blind, randomized placebo-controlled trial with D demonstrated rapid & statistically significant changes on

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



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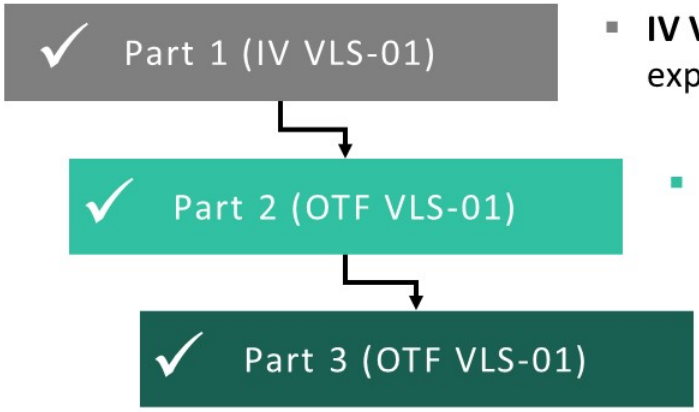
Note: TRD = Treatment Resistant Depression; DMT = N,N-Dimethyltryptamine

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

VLS-01: Phase 1 Clinical Trial Design & Results

Phase 1 results of VLS-01 showed it was safe and well-to increases in exposure

STUDY DESIGN:



Phase 1 PK / PD RESULTS:

- **IV VLS-01:** PK / PD results were consistent with the exposure-dependent increases in the subject inter
- **OTF VLS-01:** Produced generally dose-depend administration, alongside subjective psychede
- **OTF VLS-01:** 160mg with a backing layer consistent increases in exposure and sub results comparable to the 30 mg IV coho

Program status: Phase 1b first participant dosed in Q1 24. Phase 2 study in TRD patients anticipated to i

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

COMP 360

(Psilocybin) for TRD, PTSD and Anorexia

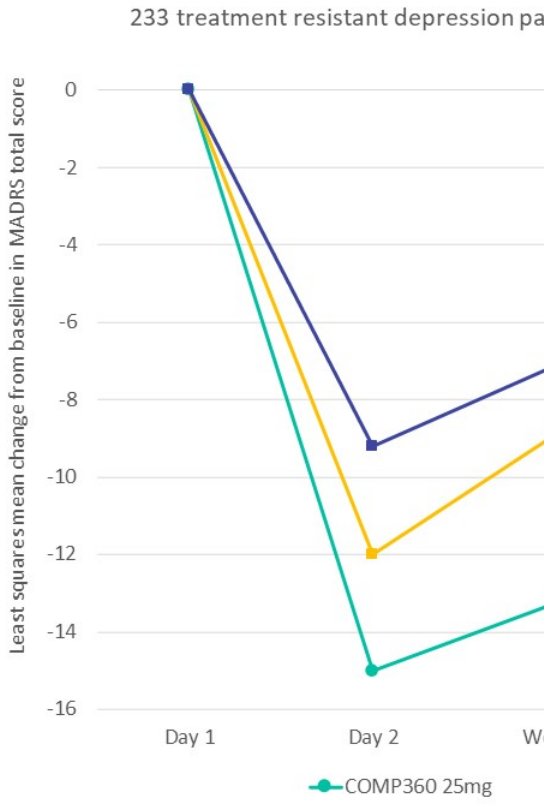
Strategic Investment into Compass Pathways

SUMMARY: COMP360

OWNERSHIP	9,565,774 shares[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 tri
reduction in depressiv

PRIOR EVIDENCE IN HUMANS (COMP360 PHASE 2b)



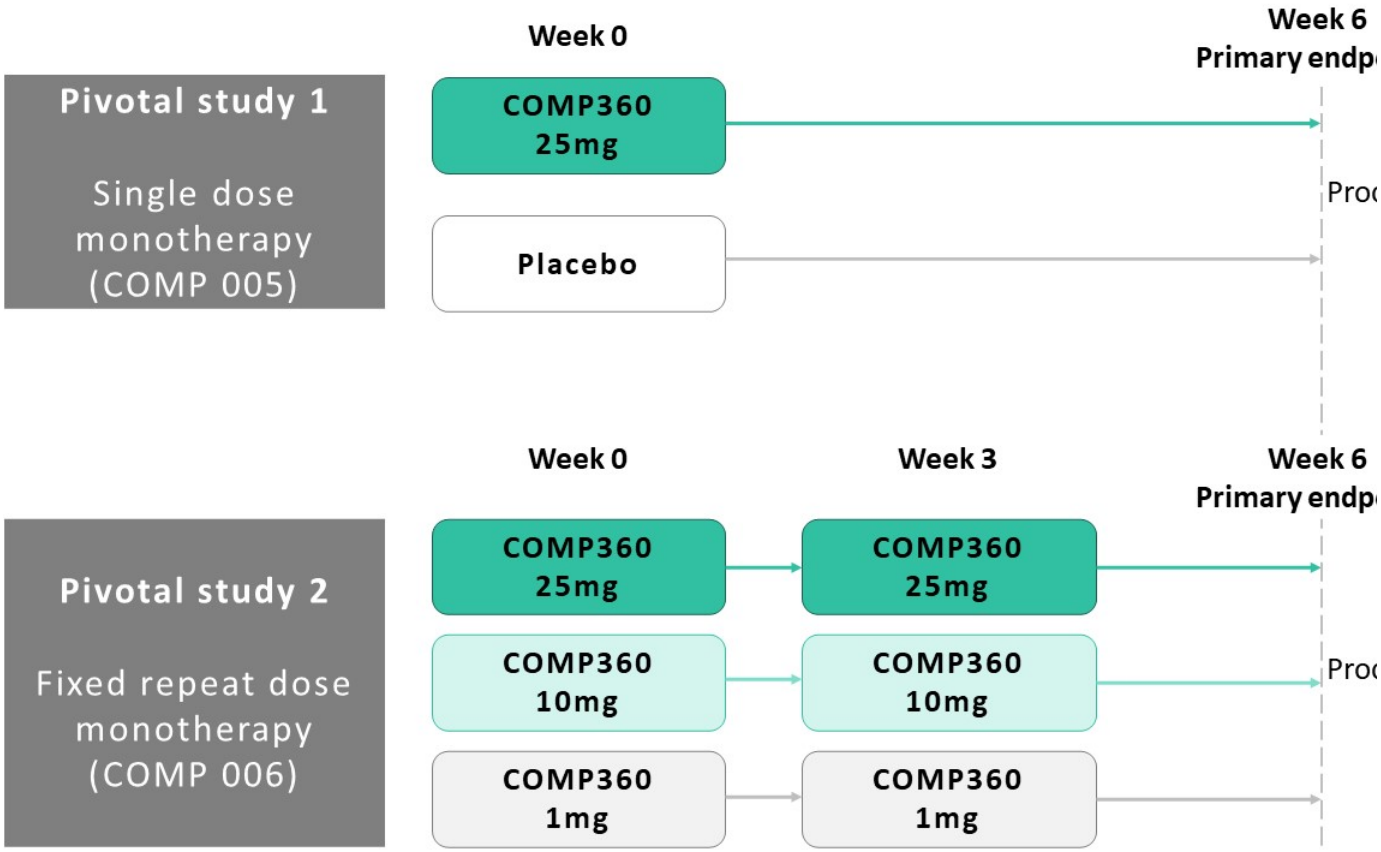
Note: MADRS = Montgomery-Åsberg Depression Rating Scale; COMP360 = a pro
psilocybin therapy, COMP360 is administered in conjunction with psychological s

1. Ownership as of March 27th, 2024
2. Post-hoc analysis showed results were also positive at the other time points
group and the 1mg group terminated significance testing based on the presp

COMP360: Phase 3 Trial Designs

COMPASS Pathways is currently conducting a Phase 3 piv
expected in 4Q 2024 and mid 2025

Pivotal Phase 3 Trial Designs



Source: Compass Pathways Capital Markets Day presentation as of May 11th, 2023

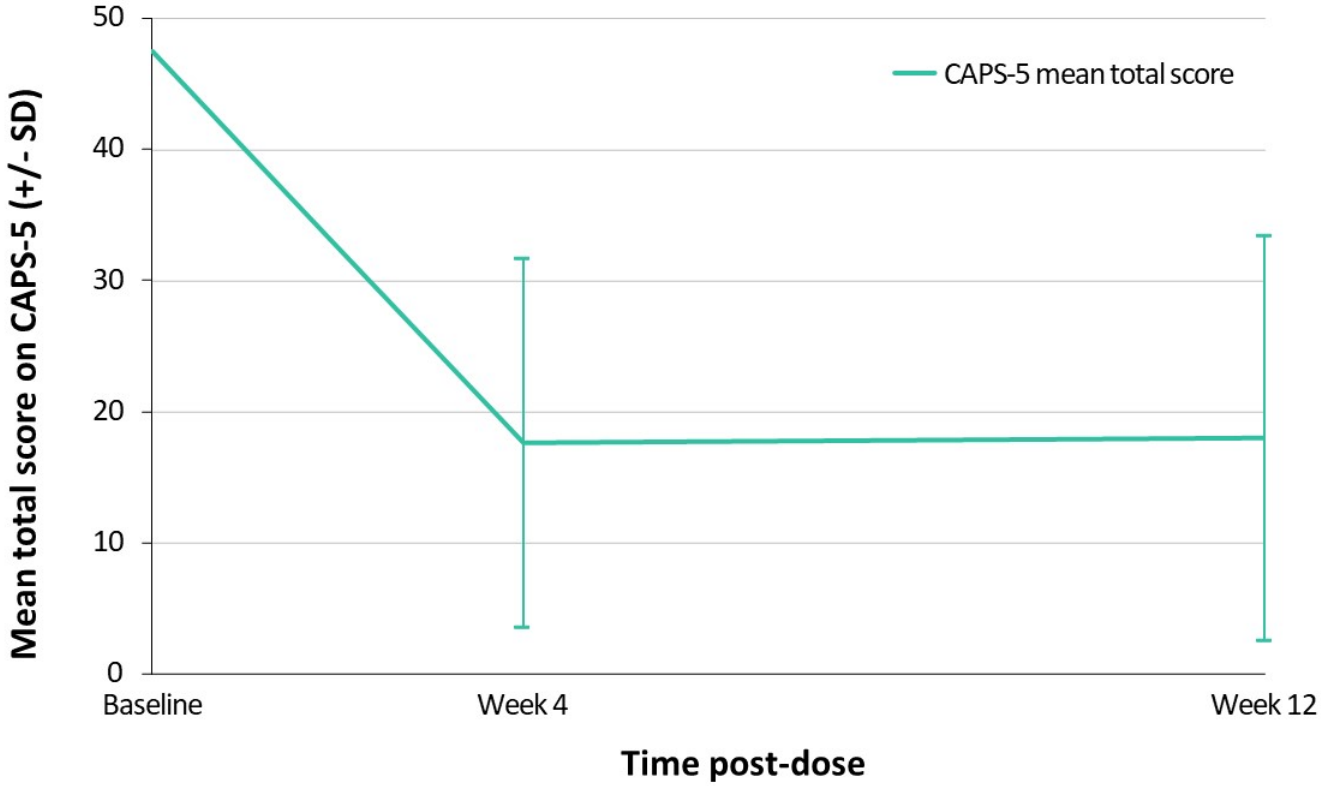
1. Primary endpoint = Change from baseline in MADRS total score at week 6
2. The participant population (TRD definition and core inclusion / exclusion criteria) remains unchanged compared to Phase 2b

COMP360: Phase 2 PTSD Results

Open-label phase 2 study of COMP360 in post-traumatic early onset and sustained improvement in PTSD sympto

COMP360 PHASE 2 PTSD STUDY TOPLINE RESULTS

Summary of change in CAPS-5 mean total score



Source: Compass Pathways

1. NCT05312151
2. Response rate defined as a reduction of ≥ 15 points in CAPS-5 score
3. Remission rate defined as a total CAPS-5 ≤ 20
4. Mean SDS total score of 22.7 at baseline

ELE-101

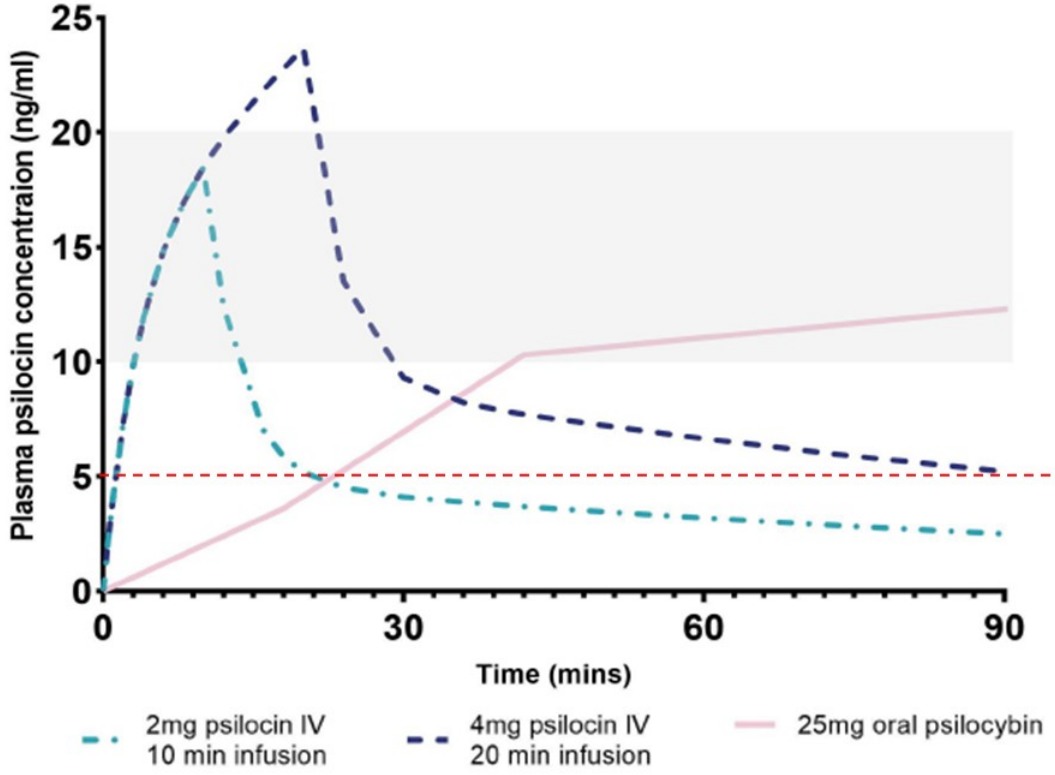
(Psilocin) for MDD

Strategic Investment into Beckley Psytech

ELE-01: IV Psilocin

Potential benefits of psilocybin's active moiety in an opti

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



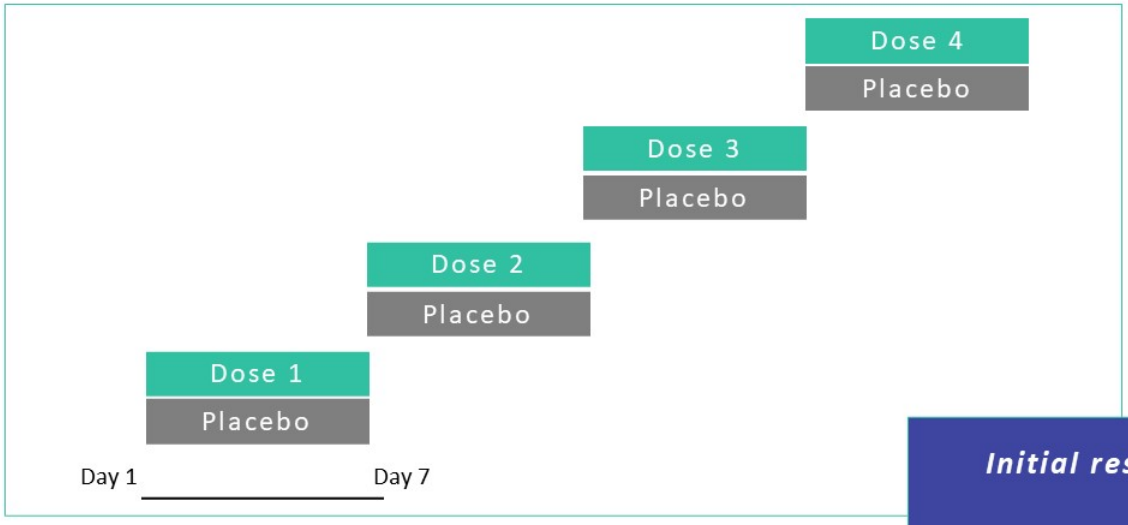
[1] Psilocin simulations based on primary data from Brown et al. 2017, Madsen et al . 2019, Hasler et al. 1997, and Carhart-Harris et al. 2011.
[2] Holze F. et al (2023). Pharmacokinetics and Pharmacodynamics of Oral Psilocybin Administration in Healthy Participants. Clin Pharmacol Ther.

ELE-101: Phase 1/2a Clinical Trial Design

Randomized, Phase 1 dose-escalation study in healthy vo open-label study in MDD

ELE-101 Phase 1/2a – Part A

Single Ascending Dose



Initial results anticipated in H1 2024

Key Objectives:

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

ELE-101 I

Open-labe

Key Objec

- Safety a severe
- Key Sec
  - Ass
  - CGI-

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 = Majo

IBX-210

(IV-Ibogaine) for Substance Use Disorder

Product Overview: IBX-210 for Opioid Use Disorder

A single dose of ibogaine may support withdrawal and long-term relapse preventi

PRODUCT	IBX-210 is a novel IV 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 oral ibogaine study completed in 3Q 23 IBX-210 Phase 1/2a study anticipated to initiate in H2 2024

IBX-210 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 indicati

- Substance control the opioids) or
- Current st synthetic f buprenorp success (d opioid ant treatment

Global diseas

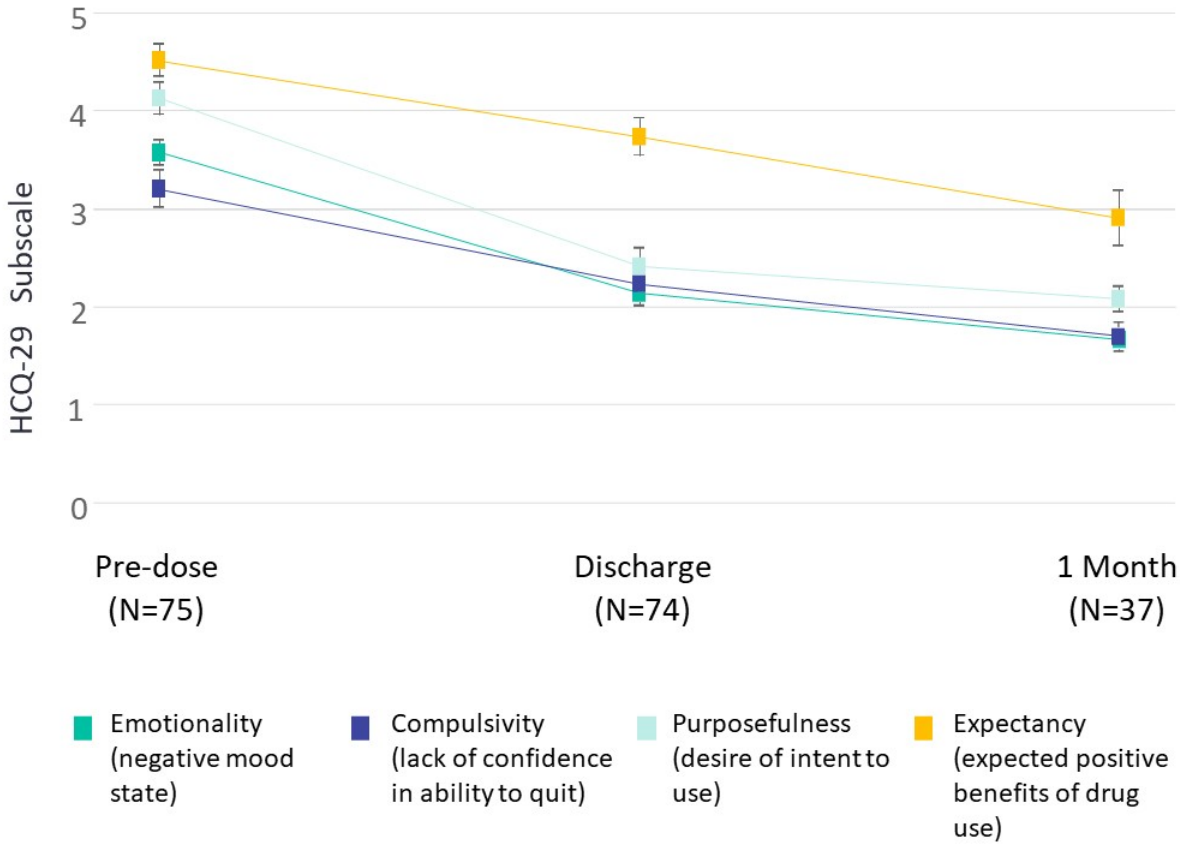
1. Post traumatic stress disorder and traumatic brain injury, respectively
2. World Health Organization
3. Salzer, "National Estimates of Recovery-Remission From Serious Mental Illness", Psychiatry Online (2018)

Clinical Evidence: Efficacy of ibogaine in Open-Label Saf

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

PRIOR CLINICAL EVIDENCE (THIRD PARTY STUDY[1])

Self-reported dimensions of craving



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Note: TRD = Treatment Resistant Depression; DMT = N,N-Dimethyltryptamine; HCQ = Heroin Craving Questionnaire

1 Mash et al., "Ibogaine Detoxification Transitions Opioid and Cocaine Abusers Between Dependence and Abstinence: Clinical Observations and Treatment Outcomes" (2018)

SUMMARY

IBX-210 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

IBX-210 has the potential to bec
treatment for OUD, minimizing

	Therapy	Mecha
Sustained relapse prevention Single dose administered in monitored setting, providing both withdrawal support and oneiric experience driving sustained remission	Ibogaine (IBX-210) **DemeRx**	Cholinergic, monoaminergi
Medication Assisted Therapy[1] Daily therapy given in substitution of opioid in outpatient setting in attempt to wean off from opioid	Methadone	Mu
	Buprenorphine	Partial
	Naltrexone	Mu-a
Withdrawal Support[2] Therapies given for symptomatic management during supervised withdrawal (detoxification)	Clonidine	Alph
	Lofexidine	Alph

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

RL-007 for Cognitive Impairment

Product Overview: RL-007 for Cognitive Impairment

Demonstrated consistent pro-cognitive effects in prior clinical trials, with a favora

PRODUCT	Oral, pro-cognitive neuromodulator
INDICATIONS	*Lead:* Cognitive impairment associated with schizophrenia (CIAS) *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 indicati

- Cognitive attention,
- Such defic the mean
- CIAS is a c 80% of pa
- **No FDA ap**

Global diseas

1. World Health Organization
2. Schaffer et al., 2013
3. Bora et al, Cognitive Impairment in Schizophrenia and Affective Psychoses: Implications for DSM-V Criteria and Beyond
4. GlobalData (as of 31/12/2023)

Clinical Evidence: Efficacy on Cognitive Endpoints in a P

Third-Party Phase 2 study in DPNP showed statistically significant positive cogni

Background

- Phase 2, 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

Clinical Evidence: Efficacy Signals Reproduced in Phase

atai's Phase 2a study in CIAS demonstrated positive cognitive signals on a subse

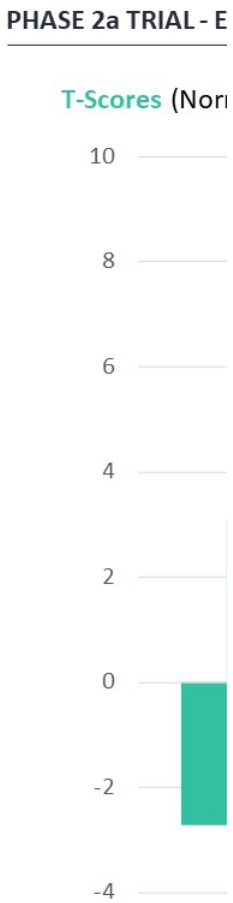
Background

- 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

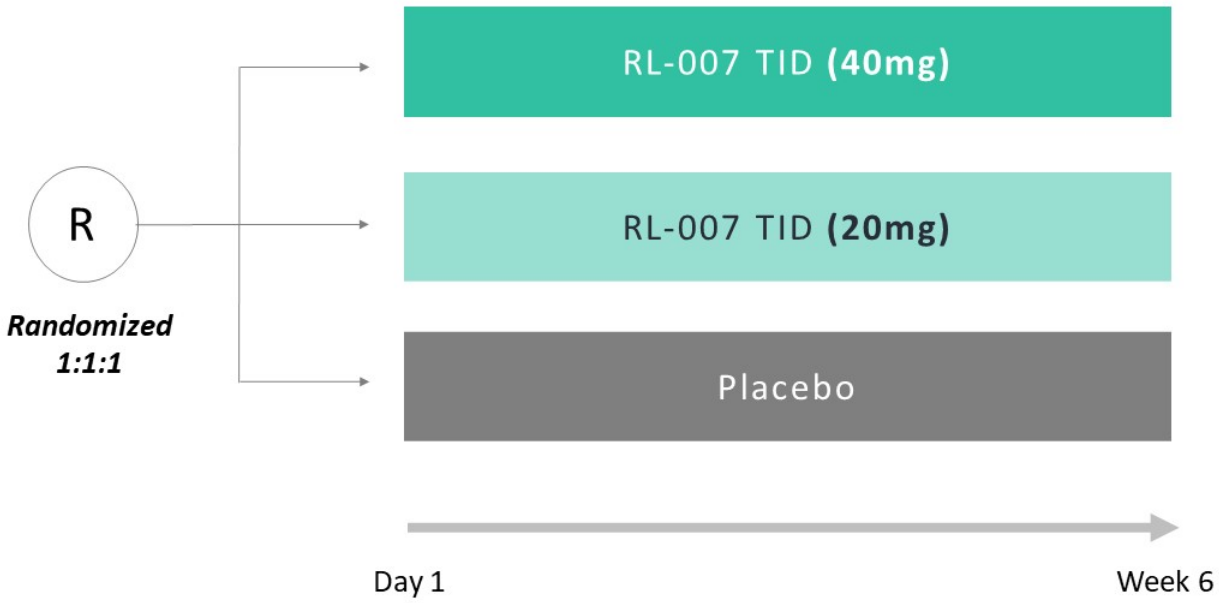
1. Study demonstrated dose-related trends for improvements on each MCCB neurocognitive endpoints, including a Cohen's d effect size of 0.79, 0.56 and 0.38 at the 20mg, 40mg, and 80mg, respectively, on the BACS Symbol Coding test.
2. Importantly, Symbol Coding is the most sensitive subcomponent and correlates 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



Clinical Trial Design: RL-007 Phase 2b Study

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



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Trial status: First patient dosed i
Topline data anticipated mid

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 ef

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 indicati

- Anxiety di over an ex
- 50% of US
- **No** FDA ap

Global diseas

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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