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): November 13, 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)

+498921539035
(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 2.02. Results of Operations and Financial Condition.

On November 13, 2024, ATAI Life Sciences N.V. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2024 and provided a corporate and clinical update. A copy of the press release is being furnished to the Securities and Exchange Commission as Exhibit 99.1 to this Current Report on Form 8-K ("Form 8-K").

The information in this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) 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 (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01. Regulation FD Disclosure.

On November 13, 2024, the Company posted an updated investor presentation under the "Investors" portion of its website at https://ir.atai.life/news-events/presentations, a copy of which is also being furnished as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2. Other than as indicated herein, information contained on the Company's website is not incorporated into, and does not form a part of this Form 8-K.

The information in Item 7.01 of this Form 8-K (including Exhibit 99.2) shall not be deemed "filed" for purposes of Section 18 of 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1*	Press Release of ATAI Life Sciences N.V., dated November 13, 2024.
99.2*	Atai Company Presentation, dated November 13, 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: November 13, 2024

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

By: /s/ Srinivas Rao, M.D.
Name: Srinivas Rao, M.D.
Title: Co-Chief Executive Officer

Exhibit 99.1

atai Life Sciences Reports Third Quarter 2024 Financial Results and Provides Corporate Updates

- *The United States Food and Drug Administration cleared the investigational new drug application for VLS-01 (buccal film DMT); atai expects to initiate a Phase 2 study in treatment-resistant depression patients around YE'24*

- *Remain on track to initiate a Phase 2 study of EMP-01 (oral R-MDMA) in social anxiety disorder patients around YE'24*

- *Cash, marketable securities, and committed term loan funding expected to fund operations into 2026*

NEW YORK and BERLIN, November 13, 2024 – atai Life Sciences (NASDAQ: ATAI) ("atai" or "Company"), (NASDAQ: ATAI) ("atai" or "Company"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today announced third quarter 2024 financial results and provided corporate updates.

"As we approach the end of 2024, we continue to see progress and momentum across our pipeline, both with our wholly-owned programs and strategic investments," stated Dr. Srinivas Rao, Co-Chief Executive Officer and Co-founder of atai. "We are on track to initiate Phase 2 trials for VLS-01 and EMP-01 around year-end and we look forward to topline Phase 2b data from Beckley Psytech's BPL-003 in the second quarter of 2025. Our team is focused on executing these trials with the utmost scientific rigor and is driven by our goal of being the leader in developing new psychedelic treatment options to mental health patients in need of innovative, safe and effective solutions."

Recent Clinical Highlights

VLS-01: N,N-dimethyltryptamine (DMT) for Treatment-Resistant Depression (TRD)

- VLS-01 is a proprietary oral transmucosal film formulation of DMT applied to the buccal surface designed to fit within a two-hour in-clinic treatment paradigm.
- The United States Food and Drug Administration (FDA) cleared the investigational new drug (IND) application for VLS-01, allowing the Company to proceed with its plans to initiate a randomized, double-blind, placebo-controlled Phase 2 study to assess the safety, efficacy and durability of response of repeated doses of VLS-01 buccal film in patients with TRD.
- The Phase 2 study is expected to initiate the study in U.S. around year-end 2024.

EMP-01: R-enantiomer of 3,4-methylenedioxy-methamphetamine (R-MDMA) for Social Anxiety Disorder (SAD)

- EMP-01 is an oral formulation of R-MDMA that demonstrated a unique, dose-dependent subjective effect profile in a Phase 1 trial that was generally found to be more similar to classical psychedelics than to racemic MDMA.
- atai expects to initiate an exploratory, randomized, double-blind, placebo-controlled Phase 2 study to assess the safety, tolerability and efficacy of EMP-01 in adults with SAD around year-end 2024.

- SAD is an area of high unmet medical need with approximately 18 million people in the U.S. diagnosed in the past year and no novel molecules approved in over two decades.

IBX-210: Intravenous (IV)-Ibogaine for Opioid Use Disorder (OUD)
- IBX-210 is a novel IV formulation of ibogaine, which is an indole alkaloid with potential for clinical benefit for substance use disorder.
- Completed productive FDA pre-IND meeting to initiate discussions and alignment on a modern ibogaine IND.
- atai plans to run additional non-clinical studies prior to launching a Phase 1b study.

Novel 5-HT2A Receptor Agonists
- Discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD using artificial intelligence (AI)/machine learning (ML)-informed drug design and medicinal chemistry.
- Presented data at the Society for Neuroscience (SfN) annual meeting aimed to show that these compounds are promising chemical starting points for new analogs with further improved 5-HT2AR vs. 5-HT2BR agonist selectivity that maintain translational antidepressant-like activity with potential for non-hallucinogenic effects.

RL-007: Pro-Cognitive Neuromodulator for Cognitive Impairment Associated with Schizophrenia (CIAS)
- RL-007 is an orally bioavailable compound that has demonstrated pro-cognitive effects in multiple pre-clinical and clinical studies, including two Phase 1 and two Phase 2 trials.
- The ongoing Phase 2b study is evaluating 20mg and 40mg of RL-007 vs. placebo in patients living with CIAS. Topline results are expected mid-2025.

Recent Corporate Updates

Completed the acquisition of IntelGenx Corp.
- IntelGenx is a drug delivery company focused on the development and manufacturing of novel oral thin film products for the pharmaceutical market and manufactures VLS-01 (buccal film DMT).
- Neither equity nor cash from the Company was used to acquire IntelGenx.

Anticipated Upcoming R&D Catalysts
- H2’24
  - VLS-01 TRD: Phase 2 initiation (around YE’24)
  - EMP-01 SAD: Phase 2 initiation (around YE’24)
  - BPL-003 alcohol use disorder (AUD): Phase 2a topline open-label data
  - ELE-101 major depressive disorder (MDD): Phase 2a topline open-label data

- 2025
  - BPL-003 TRD: Phase 2b topline data (Q2’25)
  - RL-007 cognitive impairment associated with schizophrenia (CIAS): Phase 2b topline data (mid’25)

- VLS-01 TRD: Phase 2 topline data (around YE'25)
- EMP-01 SAD: Phase 2 topline data (around YE'25)

Consolidated Financial Results

Cash, cash equivalents, and short-term securities (primarily US treasuries and government agency securities): As of September 30, 2024, the Company had cash, cash equivalents, restricted cash and short-term securities of $101.0 million compared to $154.2 million as of December 31, 2023. The decrease of $53.2 million was primarily driven by $58.1 million net cash used in operating activities, $10.0 million for the Beckley Psytech investment, and $7.7 million investment to advance our programs; partially offset by $16.1 million in proceeds from the partial sale of our ADSs holdings in Compass Pathways, and $5.0 million in proceeds from our committed term loan with Hercules Capital, Inc. The Company expects its cash, short-term securities, public equity holdings, and committed term loan facility to be sufficient to fund operations into 2026.

Research and development (R&D) expenses: R&D expenses were $12.4 million for the three months ended September 30, 2024, as compared to $13.3 million for the same prior year period. The year-over-year decrease of $0.9 million was primarily attributable to a decrease of $2.7 million in R&D personnel-related expenses, partially offset by an increase of $1.7 million in program-specific expenses. Within program-specific expenses, the increase was primarily driven by additional clinical trial expenses in the current year. The Company is anticipating R&D spend to increase as its R&D programs progress into later stage clinical trials.

General and administrative (G&A) expenses: G&A expenses for the three months ended September 30, 2024, were $10.3 million as compared to $13.6 million in the same prior year period. The year-over-year decrease of $3.3 million was primarily attributable to a $3.5 million decrease in personnel-related expenses and administrative costs. The Company expects the reduction in G&A spend over prior years to continue.

Net income (loss): Net loss attributable to stockholders for the three months ended September 30, 2024, was $26.3 million, which included $2.0 million of non-cash change in fair value of notes receivables and other investments and $5.0 million of non-cash share-based compensation. Net income attributable to stockholders for the three months ended September 30, 2023 was $44.2 million, which included a $69.0 million non-cash change in fair value of other investments related to an accounting change of our Compass Pathways plc investment and $8.3 million of non-cash share-based compensation.

About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders and was founded as a response to the significant unmet need and lack of innovation in the mental health treatment landscape. atai is dedicated to efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines to achieve clinically meaningful and sustained behavioral change in mental health patients. atai's vision is to heal mental health disorders so that everyone, everywhere can live a more fulfilled life. For more information, please visit www.atai.life.

Forward-looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "anticipate," "initiate," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements include express or implied statements relating to, among other things: our business strategy and plans; the potential, success, cost and timing of development of our product candidates, including the progress of preclinical and clinical trials and related milestones; expectations regarding our strategic investment in Beckley Psytech and other investments; expectations regarding our cash runway; and the plans and objectives of management for future operations, research and development and capital expenditures.

Forward-looking statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties that could cause actual results to differ materially from those projected, 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 such factors may be updated from time to time in atai's other filings with the SEC. atai disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by applicable law.

Contact Information
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IR@atai.life

Media Contact:
PR@atai.life

-- Financial Statements Attached --

ATAI LIFE SCIENCES N.V.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
	(unaudited)		(unaudited)	
License revenue	$ 40	$ 87	$ 313	$ 296
Operating expenses:				
Research and development	12,377	13,290	36,513	48,047
General and administrative	10,265	13,631	36,226	44,159
Total operating expenses	22,642	26,921	72,739	92,206
Loss from operations	(22,602)	(26,834)	(72,426)	(91,910)
Other income (expense), net	(3,861)	70,681	(36,795)	70,944
Net income (loss) before income taxes	(26,463)	43,847	(109,221)	(20,966)
Benefit from (provision for) income taxes	178	(238)	163	(588)
Losses from investments in equity method investees, net of tax	(26)	(238)	(2,000)	(3,199)
Net income (loss)	(26,311)	43,371	(111,058)	(24,753)
Net loss attributable to noncontrolling interests	(25)	(873)	(747)	(2,821)
Net income (loss) attributable to ATAI Life Sciences N.V. stockholders	$ (26,286)	$ 44,244	$ (110,311)	$ (21,932)
Net income (loss) per share attributable to ATAI Life Sciences N.V. stockholders — basic	$ (0.16)	$ 0.28	$ (0.69)	$ (0.14)
Net income (loss) per share attributable to ATAI Life Sciences N.V. stockholders — diluted	$ (0.16)	$ 0.25	$ (0.69)	$ (0.14)
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — basic	160,621,817	155,792,490	159,973,201	155,793,601
Weighted average common shares outstanding attributable to ATAI Life Sciences N.V. stockholders — diluted	160,621,817	177,565,973	159,973,201	155,793,601

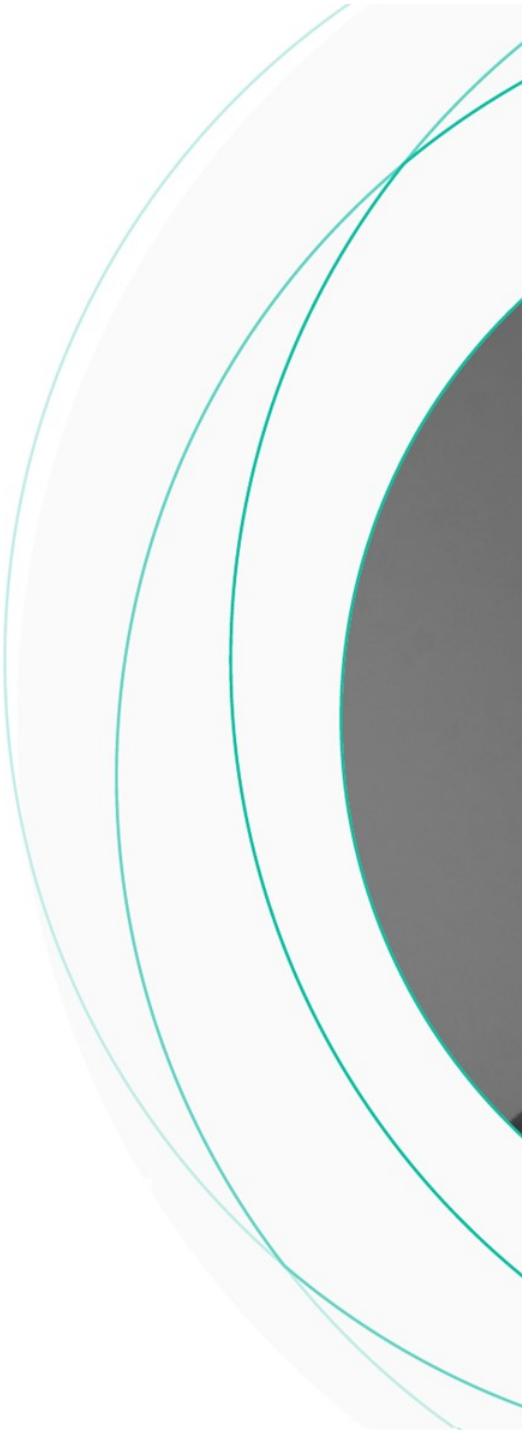
ATAI LIFE SCIENCES N.V.
CONDENSED CONSOLIDATED BALANCE SHEET
(Amounts in thousands)

	September 30, 2024 (unaudited)	December 31, 2023 (1)
Assets		
Cash and cash equivalents	$ 29,963	$ 45,034
Securities carried at fair value	55,957	109,223
Short term restricted cash for other investments	15,000	-
Committed investment funds	-	25,000
Prepaid expenses and other current assets	7,454	5,830
Short term notes receivable - related party, net	5,700	505
Property and equipment, net	865	981
Operating lease right-of-use asset, net	1,032	1,223
Other investments held at fair value	45,227	89,825
Other investments	33,893	1,838
Long term notes receivable - related party, net	-	97
Convertible notes receivable - related party	-	11,202
Other assets	2,428	2,720
Total assets	$ 197,519	$ 293,478
Liabilities and Stockholders' Equity		
Accounts payable	$ 4,880	$ 4,589
Accrued liabilities	11,953	15,256
Current portion of lease liability	257	275
Short term convertible promissory notes and derivative liability - related party	925	—
Short term convertible promissory notes and derivative liability	1,481	—
Other current liability	147	—
Contingent consideration liability - related parties	650	620
Contingent consideration liability	1,388	1,637
Noncurrent portion of lease liability	808	990
Convertible promissory notes and derivative liability - related party	—	164
Convertible promissory notes and derivative liability	—	2,666
Long term debt, net	20,336	15,047
Other liabilities	8,378	7,918
Total stockholders' equity attributable to ATAI Life Sciences N.V. stockholders	145,720	242,962
Noncontrolling interests	596	1,354
Total liabilities and stockholders' equity	$ 197,519	$ 293,478

(1) The condensed consolidated financial statements as of and for the year ended December 31, 2023 are derived from the audited consolidated financial statements as of that date.

atai LIFE SCIENCES

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



Company Overview – November 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, anticipated milestones and timelines for our non-clinical, pre-clinical studies and clinical trials 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 events and circumstances discussed in this presentation may not o results could differ materially and adverse from those anticipated o forward-looking statements. We caution you therefore against relying o looking statements, and we qualify all of our forward-looking state cautionary statements.

The forward-looking statements included in this presentation are mad date hereof. Although we believe that the expectations reflected in the statements are reasonable, we cannot guarantee that the future r activity, performance or events and circumstances reflected in the statements will be achieved or occur. Moreover, neither we nor our a other person assumes responsibility for the accuracy and completeness looking statements. Neither we nor our advisors undertake any obligatio forward-looking statements for any reason after the date of this conform these statements to actual results or to changes in our expecta may be required by law. You should read this presentation with the un our actual future results, levels of activity, performance and events an may be materially different from what we expect.

Unless otherwise indicated, information contained in this presentation industry, competitive position and the markets in which we opera information from independent industry and research organizations, o sources and management estimates. Management estimates are deriv available information released by independent industry analysts and o sources, as well as data from our internal research, and are based on ass by us upon reviewing such data, and our experience in, and knowledge and markets, which we believe to be reasonable. In addition, projectio and estimates of the future performance of the industry in which we o individual competitor and our future performance are necessarily subje and risk due to a variety of factors, including those described above. factors could cause results to differ materially from those expressed i

Executive Summary and Key Highlights

atai Life Sciences: addressing significant unmet patient n that everyone, everywhere can live a more fulfilled life

1. **Significant unmet need:** mental health disorders are one of the largest g out of every two people in the world will develop a mental health disorc

2. **Novel approach:** our objective is to enable patients to achieve clinically therapeutics with rapid-onset, durable effects and a focus on interventi

3. **7 clinical-stage programs:** seven active clinical-stage psychedelic and no package of prior clinical evidence.

4. **5+ clinical readouts expected over the next 18 months:** several anticipa development programs and strategic investments through 2024 and 202

5. **Runway into 2026:** cash and cash equivalents, marketable securities, an provide funding into 2026.[2]

1. McGrath et al, "Age of onset and cumulative risk of mental disorders: a cross-national analysis of population surveys from 29 countries", The Lancet Psychiatry, 2023,
2. Marketable securities includes money market funds, U.S. Treasury securities, commercial paper, corporate notes/bonds, U.S. government agencies securities, and public equities; term loan funding from Her milestones

Programs Overview

Our vision is being delivered through a robust pipeline o strategic investments across a range of compounds and

Programs	Primary Indication	Preclin	Phas
RL-007[1] Pro-cognitive neuromodulator	Cognitive Impairment Associated with Schizophrenia		
VLS-01 DMT	Treatment Resistant Depression		
EMP-01 R-MDMA	Social Anxiety Disorder		
IBX-210 Ibogaine	Opioid Use Disorder		
Novel 5-HT2A Receptor Agonists (incl. non-hallucinogenic neuroplastogens)	Undisclosed		
STRATEGIC INVESTMENTS			
COMP360[2] Psilocybin	Treatment Resistant Depression		
BPL-003[3] 5-MeO-DMT	Treatment Resistant Depression		
ELE-101[3] Psilocin	Major Depressive Disorder		

Abbreviations: DMT = N,N-Dimethyltryptamine; R-MDMA = R enantiomer of 3,4-Methylenedioxymethamphetamine; 5-MeO-DMT = 5-methoxy-N,N-dimethyltryptamine

1. Majority ownership stake in Recognify Life Sciences
2. Strategic Investment in Compass Pathways
3. Strategic Investment in Beckley Psytech
4. All dates provided are as estimated
5. Trial initiation defined as central regulatory and ethics approval

Upcoming Catalysts

We are funded through all expected milestones across o strategic investments for 2024 and 2025

Achieved and anticipated milesto
(2024-25)

H1'24

- ✓ **VLS-01**
  Ph 1b first participant dosed
- ✓ **BPL-003**
  Ph 2a (TRD) OL Part 1 data
- ✓ **ELE-101**
  Ph 1 topline data
- ✓ **COMP360**
  Ph 2 (PTSD) topline data

H2'24

- ✓ **VLS-01**
  Ph 1b topline data
- ○ **BPL-003**
  Ph 2a (AUD) topline OL data
- ○ **ELE-101**
  Ph 2a (MDD) topline OL data
- ○ **VLS-01**
  Ph 2 (TRD) initiation (around YE'24)
- ○ **EMP-01**
  Ph 2 (SAD) initiation (around YE'24)

Abbreviations: OL = Open-label; TRD = Treatment Resistant Depression; MDD = Major Depressive Disorder; PTSD = Post Traumatic Stress Disorder; AUD = Alcohol Use Disorder; YE = Year-end; CIAS = Cognitive Impairment ir

1. All dates provided are as estimated
2. Trial initiation defined as central regulatory and ethics approval

RL-007 for Cognitive Impairment

SUMMARY: RL-007

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	GABA/nicotinic modulator
INDICATIONS	Primary: CIAS Potential: Cognitive disorders including Alzheimer's dementia and/or Autism
TARGET POSITION	Adjunctive treatment to standard of care for schizophrenia patients with cognitive impairment
ACHIEVED & EXPECTED MILESTONES[1]	Phase 2a CIAS trial completed in H2'21 Phase 2b first patient dosed in 1Q'23 Phase 2b topline data in mid'25
INTELLECTUAL PROPERTY	Issued composition of matter, formulation and method of use patents

RL-007 is a potential
investigated in >500
consistent cognitive

Significant unmet need

Reproducibility of effec
two Phase 2 trials

Tolerability: No drug-re
exposures and minimal

Add-on therapy to stan
administered as an adju

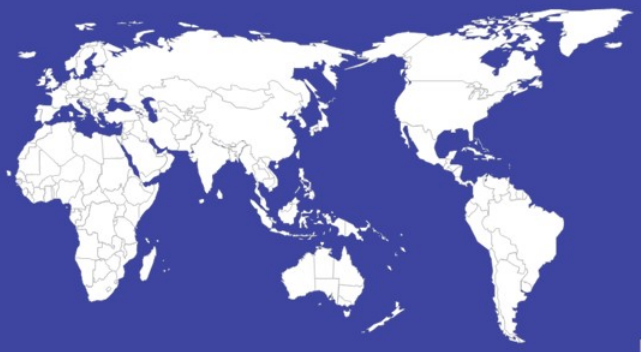
Note: CIAS = Cognitive impairment associated with schizophrenia
1. All dates provided for expected milestones are estimated

RL-007: Disease Overview

CIAS & Schizophrenia

Cognitive impairment associated with schizophrenia (CIAS) is a core feature of schizophrenia, accounts for much of the impaired functioning associated with the disorder and is not responsive to existing treatments

CIAS & Schizophrenia in numbers



~24m

Global sufferers of Schizophrenia[1]

15th

Leading cause of disability worldwide (2016)[2]

~$155bn

U.S. economic burden from adults with CIAS or Schizophrenia (direct + indirect costs)[3]

URGENT NEED F

~80%

Co

Cog
sch
imp

~10%

Sc

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and

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FD

As

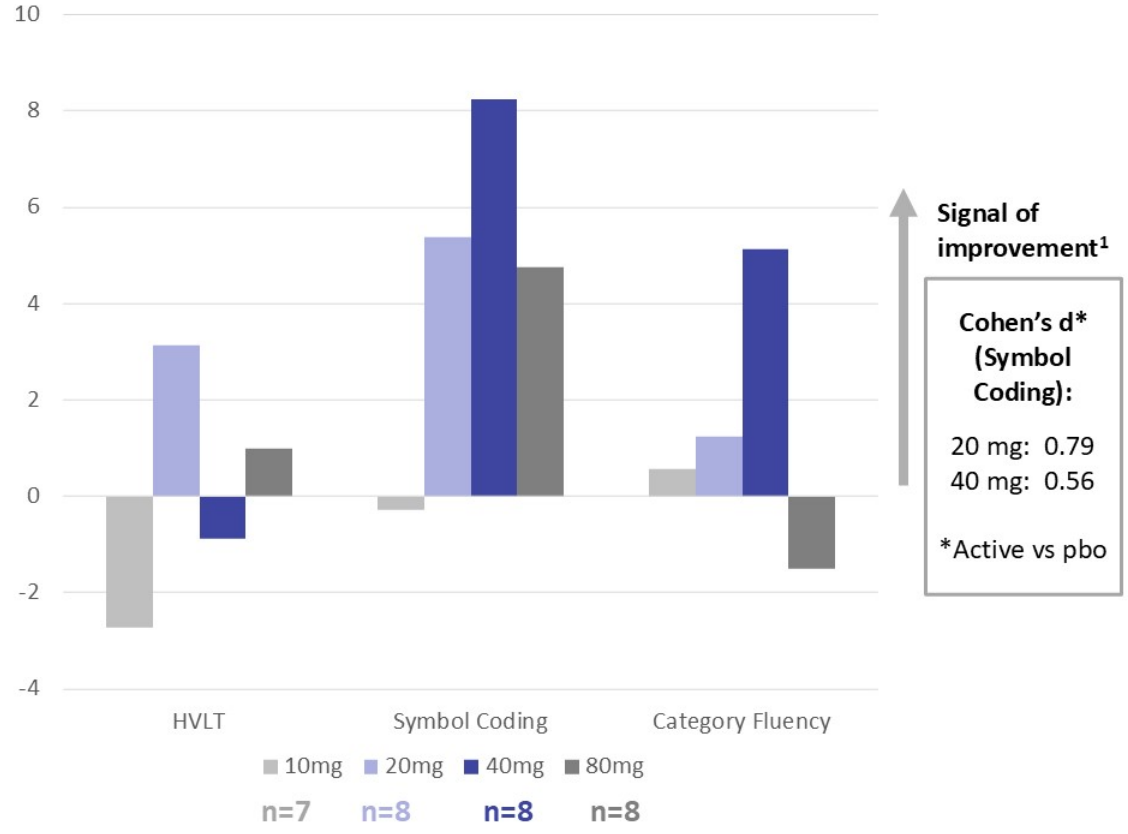
1. World Health Organization
2. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016
3. Cloutier et al, The economic burden of schizophrenia in the United States in 2013. J Clin Psychiatry 2016;77(6):764-771
4. Bora et al, Cognitive Impairment
5. Holm M et al, Employment amo
6. GlobalData (as of 11/15/2022)

RL-007: Phase 2a Results

atai's Phase 2a study in CIAS demonstrated RL-007's pot on a subset of MCCB neurocognitive endpoints

PHASE 2A TRIAL - EFFICACY DATA ON COMPONENTS MCCB COMPOSITE

T-Scores (Normalized for age, gender, and education level)



Signal of improvement[1]

Cohen's d* (Symbol Coding):

20 mg: 0.79
40 mg: 0.56

*Active vs pbo

1. Day 2 "pre-RL-007" was compared to Day 4 "post-RL-007"
Abbreviations: MCCB = MATRICS™ Consensus Cognitive Battery

Key Takeaway

1. Cogniti cohort: followe

2. Study d sub-co Test, B

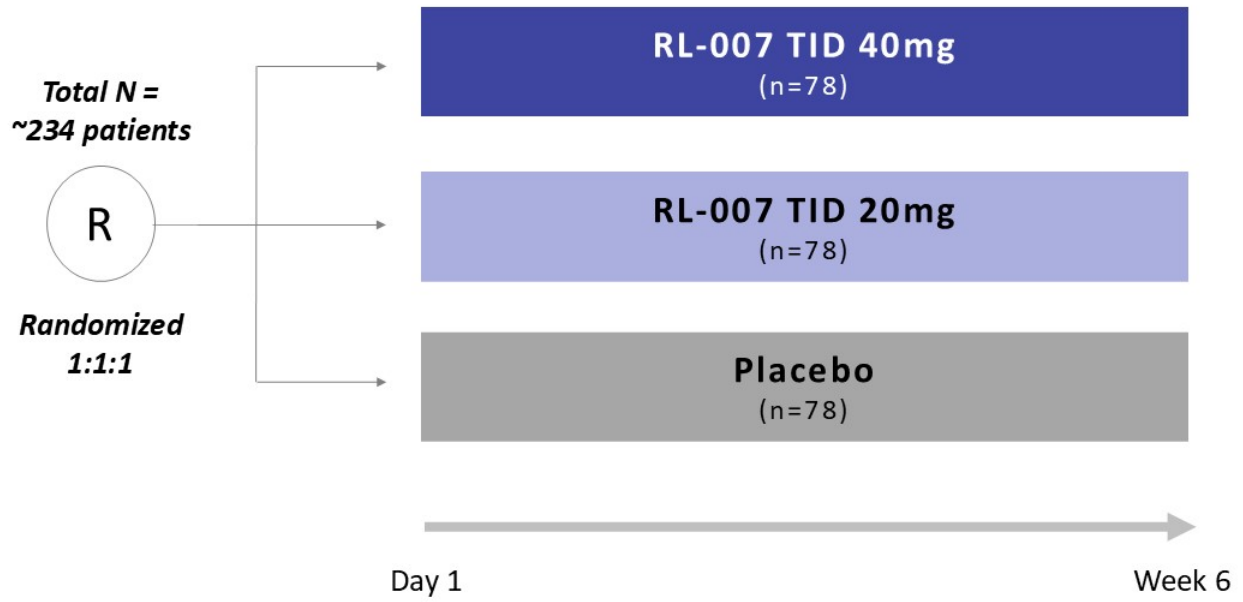
3. On the score, 40mg d

4. qEEG d and in correla

RL-007: Phase 2b Study Design

A randomized, placebo-controlled study of RL-007 is cur with CIAS with topline data anticipated in mid'2025

PHASE 2B STUDY DESIGN



Pr
-
Ot
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-

Trial status: First patient dosed i
Topline data anticipated mid

Abbreviations: MCCB = MATRICS™ Consensus Cognitive Battery, TID = 3x/day dosing,

VLS-01

(DMT) for TRD

SUMMARY: VLS-01

PRODUCT	N,N-Dimethyltryptamine (DMT) in an oral transmucosal film (VLS-01) DMT is the active psychedelic moiety in ayahuasca
PHARMA-COLOGY	5-HT2A receptor agonist
INDICATIONS	Primary: TRD Potential: GAD, AUD
TARGET POSITION	Short-duration psychedelic treatment with the potential to have a best-in-class route of administration and tolerability
ACHIEVED & EXPECTED MILESTONES[1]	Phase 1b last participant completed 1H'24 Phase 1b trial results in 2H'24 IND approved by U.S. FDA in 2H'24 Phase 2 (TRD) study initiation around YE'24
INTELLECTUAL PROPERTY	Issued patent covering oral transmucosal films of DMT, supported by several pending and PCT patent applications

VLS-01 has potential fo efficacy in treating TRD around a 2-hour in-clini

Optimized OTF formula
profile were demonstra
support a more scalabl

Short duration of psycl
experienced for ~2 hou
interventional psychiat

Rapid onset and durab
VLS-01 has potential to
on depressive sympton

Patent protected form
transmucosal films of D

Abbreviations: DMT = N,N-Dimethyltryptamine; TRD= Treatment Resistant
Pharmacokinetic/Pharmacodynamic; PCT = Patent Cooperation Treaty; OTF

1. All dates provided for expected milestones are estimated. Trial initiatio
2. Palhano-Fontes F et al, Rapid antidepressant effects of the psychedelic
3. Exclusive of possible patent term adjustments or extensions or other fo

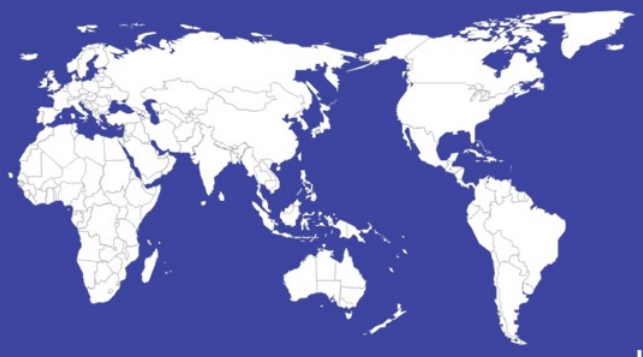
VLS-01: Disease Overview

Depression

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**

Depression in numbers



~300m

Global sufferers of depression[1]

2nd

Leading cause of disability worldwide (2019)[2]

~$300Bn

U.S. economic burden from adults with MDD (direct + indirect costs)[3]

URGENT NEED F

~33%

Inade

A third o
relapse

4-12 weeks

Slow o

Frontline
onset (4

~25%

Severe

25% of p
"extreme
term sid
sleepine

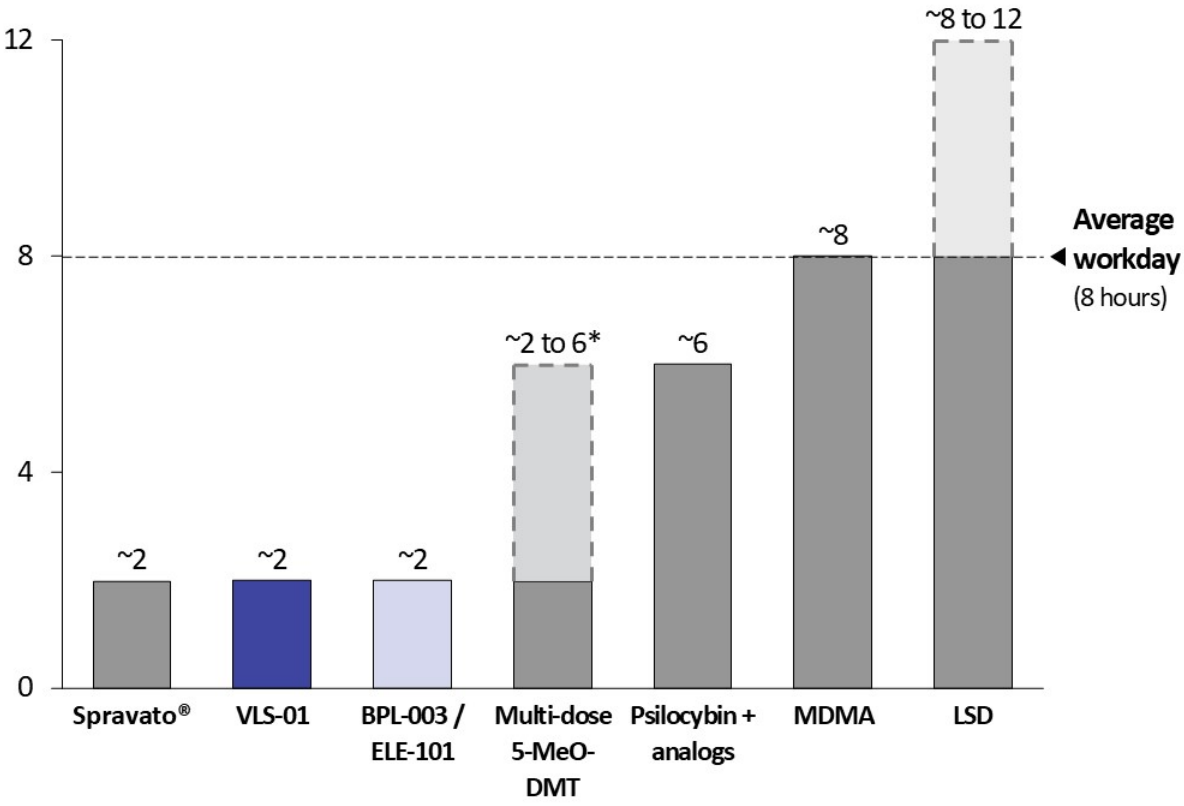
1. World Health Organization (2020)
2. World Health Organization – Disease Burden 2000-2019 (2020)
3. Greenberg et al., "The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018)" (2021)
4. Salzer, "National Estimates of Re
5. Tew et al., "Impact of prior treat
6. Cascade et al., "Real-World Data

VLS-01: Commercial Potential

A key differentiator for VLS-01 from other psychedelic-li
to leverage the 2-hour in-clinic treatment paradigm esta

ANTICIPATED TIME TO RESOLUTION OF SUBJECTIVE EFFECTS[1]

(in hours) *Illustrative*



Key Takeaw

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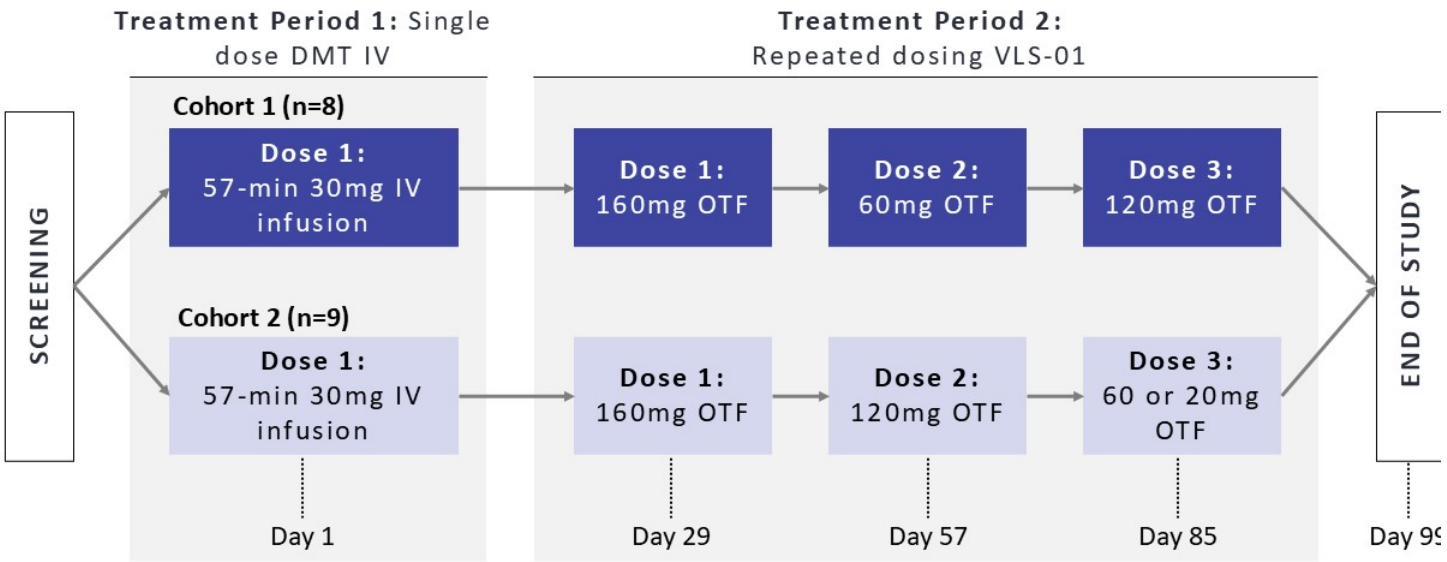
1. Subject to further validation through future clinical studies and real-world evidence
2. https://www.spravatohcp.com/#find-a-center
* If multi-dose required

VLS-01: Phase 1b Clinical Trial Design

We have completed dosing in a Phase 1b trial investigati
tolerability of an optimized buccal formulation of VLS-01

VLS-01 PHASE 1B STUDY DESIGN



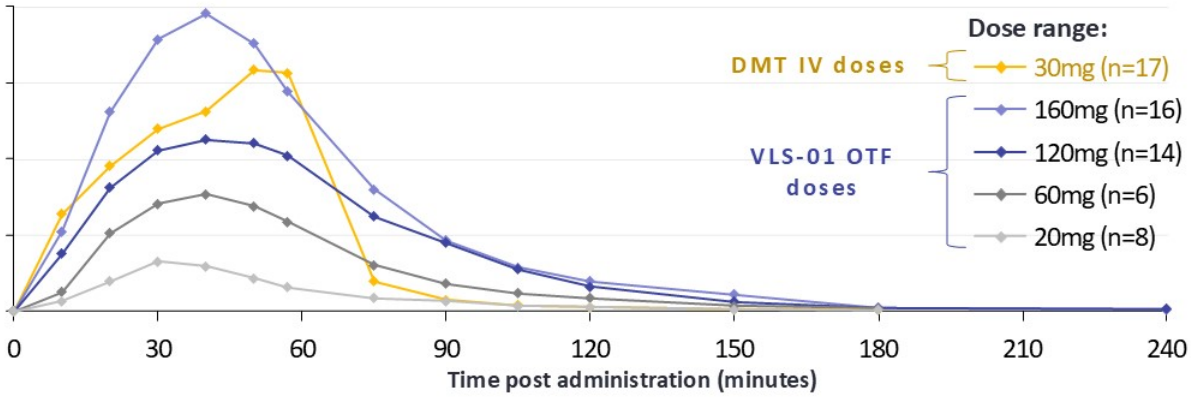
Abbreviations: IV = Intravenous; OTF = Oral Transmucosal Film; PK / PD = Pharmacokinetic / Pharmacodynamic

VLS-01: Phase 1b Results

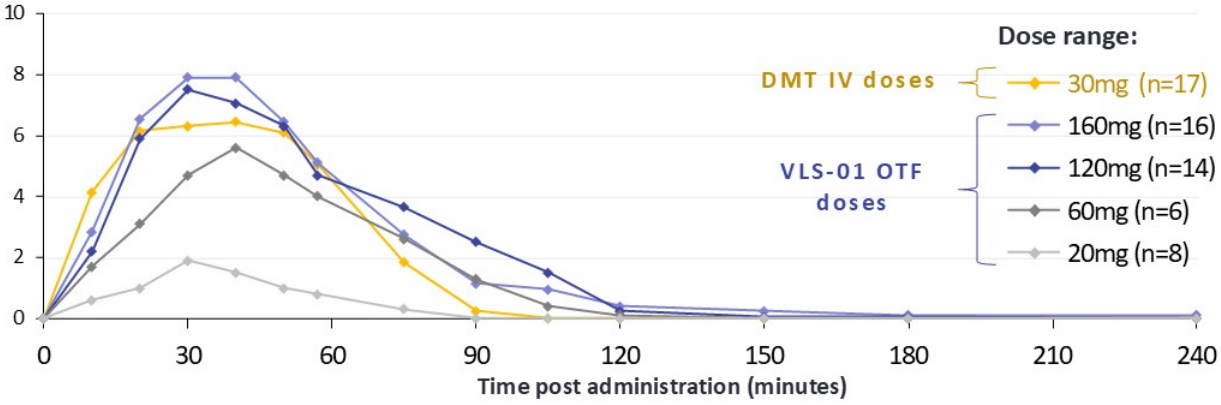
Higher doses of VLS-01 demonstrated a plasma concentr and robust subjective effects that resolved in ~2 hours

VLS-01 PHASE 1B – PRELIMINARY PK/PD RESULTS[1]

DMT plasma concentration over time (ng/ml) post administration



Subjective Intensity Rating Scale (SIRS) scores (0 to 10) post administration



Abbreviations: IV = Intravenous; OTF = Oral Transmucosal Film; PK / PD = Pharmacokinetic / Pharmacodynamic; C-Max = maximum (or peak) serum concentration; T-Max =time it takes for a drug to reach
Draft Delivery Version 0.1 [Data cut-off: 2024-06-17]. Study data has been source data verified by the study monitor and queries resolved prior to creating the draft tables but the database is not yet locke

Key Takea

Pharmacc

- C h I
- V (

Pharmacc

- D a
- 1 g
- P n

VLS-01: Phase 1b Results

Optimized VLS-01 OTF had a favourable safety profile in Ph1 classified as either mild or moderate, and most resolving on

VLS-01 PHASE 1B PRELIMINARY SAFETY RESULTS[a,b]

No. of participants with drug-related TEAE (>10%):	DMT IV	VLS-01				Total (N=62)
	30mg (N=17)	160mg (N=16)	120mg (N=14)	60mg (N=7)	20mg (N=8)	
Headache	1 (6%)	5 (31%)	4 (29%)		1 (13%)	11 (18%)
Dissociation	1 (6%)	5 (31%)	3 (21%)			9 (15%)
Euphoric mood	1 (6%)	3 (19%)	3 (21%)			7 (11%)
Nausea		5 (31%)	1 (7%)	1 (14%)		7 (11%)
Emotional distress	1 (6%)	3 (19%)				4 (6%)
Feeling drunk			2 (14%)		1 (13%)	3 (5%)
Feeling hot	2 (12%					2 (3%)
Anxiety	2 (12%)					2 (3%)
Dizziness		1 (6%)		1 (14%)		2 (3%)
Vomiting		2 (13%)				2 (3%)
Abdominal pain				1 (14%)		1 (2%)
At least one severe TEAE						0
At least one serious TEAE[1]						0[1]
At least one TEAE leading to discontinuation	1 (6%)					1 (2%)

Key

1

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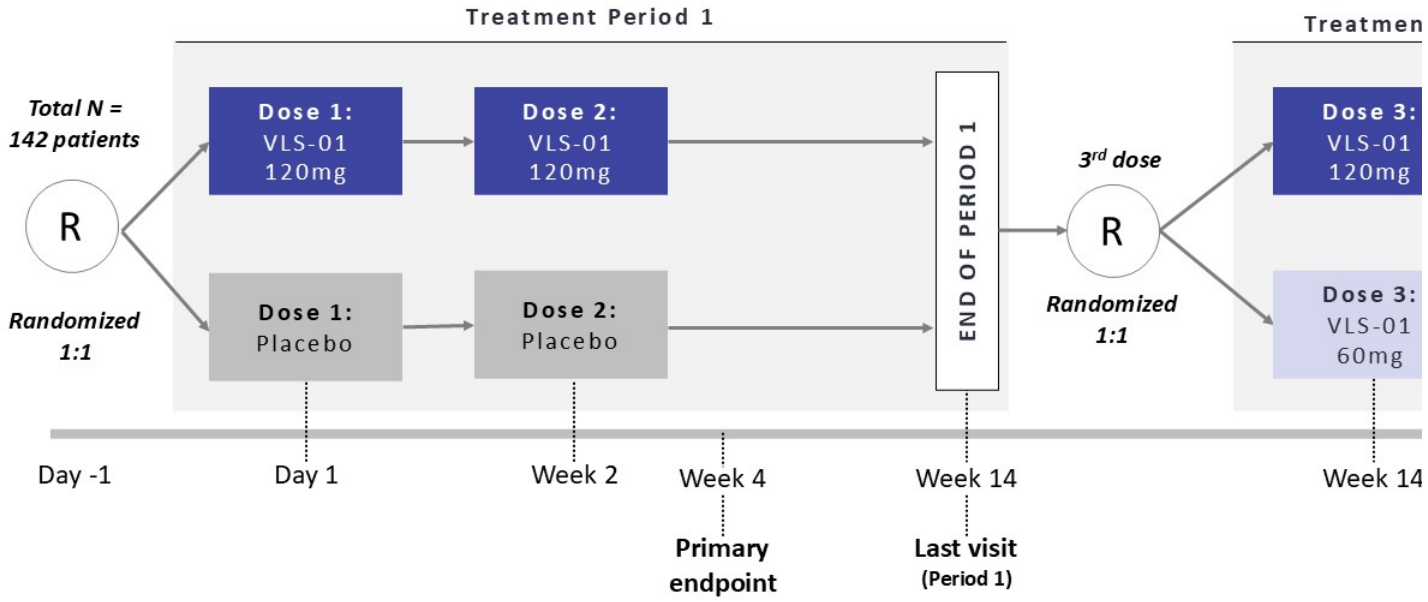
1. Please note one (1) SAE as per feedback from the FDA, of unknown origin and subject to ongoing, collaborative discussion with the agency

Abbreviations: OTF = Oral Transmucosal Film
a. Treatment Emergent Adverse Events (TEAEs) are defined as adverse events that occurred following the first administration of study medication
b. Draft Delivery Version 0.1 [Data cut-off: 2024-06-17]. Study data has been source data verified by the study monitor and queries resolved prior to creating the draft tables but the database is not yet locked

VLS-01: Phase 2 Study Design

We are now initiating a randomized, double-blind, place
assess the efficacy of repeated doses of VLS-01 in ~142 p

VLS-01 PHASE 2 STUDY DESIGN (PRELIMINARY)



Trial status: Trial initiation expected arou
Topline data anticipated around yea

Abbreviations: MADRS = Montgomery-Asberg Depression Rating Scale

1. Patients are also excluded if they report any lifetime use of DMT or DMT-containing drugs, or report a history of > 2 lifetime administrations of any other psychedelic drug
2. Trial initiation defined as central regulatory and ethics approval

EMP-01 (R-MDMA) for Social Anxiety Disorder

SUMMARY: EMP-01

PRODUCT	Oral formulation of the R-enantiomer of MDMA (EMP-01)
PHARMA-COLOGY	Monoamine releaser and reuptake inhibitor with prominent effects on serotonin (5-HT)
TARGET POSITION	First-in-class psychedelic-like compound for treatment of Social Anxiety Disorder (SAD)
INDICATIONS	Primary: SAD Potential: Other anxiety disorders, autism spectrum disorders, PTSD
ACHIEVED & EXPECTED MILESTONES[1]	Phase 1 study completed in Q1 2024 Phase 2 trial initiation around YE'24 Phase 2 study results around YE'25
INTELLECTUAL PROPERTY	Issued patent covering MDMA enantiomers and processes for their preparation, supported by several pending patent applications

EMP-01 is an oral formu that is pharmacological S-MDMA

Unexpected subjective e be significantly more psy focused" experience.

Beneficial psychological resulted in dose-depend of self-compassion, both

Well tolerated: EMP-01 v adverse events observed. have fewer adverse effec

First-to-market potential psychedelic-like space are

Abbreviations: SAD = Social Anxiety Disorder; PTSD = Post Traumatic Stres

1. All dates provided for expected milestones are estimated. Trial initiatio
2. Curry DW, Young MB, Tran AN, Daoud GE, Howell LL. Separating the ag without signs of neurotoxicity in mice. Neuropharmacology. 2018 Jan

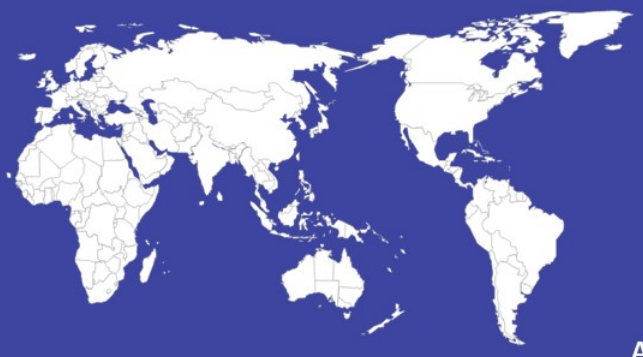
EMP-01: Disease Overview

Anxiety Disorders

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

- Generalized Anxiety Disorder (GAD)
- Social Anxiety Disorder (SAD)
- Panic Disorder

Anxiety in numbers



~40m

Suffer from anxiety disorders in the US[1]

#1

Most common mental health disorder in the US[2]

~$42bn

Annual societal cost of anxiety disorders in the US[3]

URGENT NEED F

~18m

SAD p

Approxir
from Soc

69%

Mode

Of adults
had mod

35%

Low re

Only 35%
follow-u

0

No nov

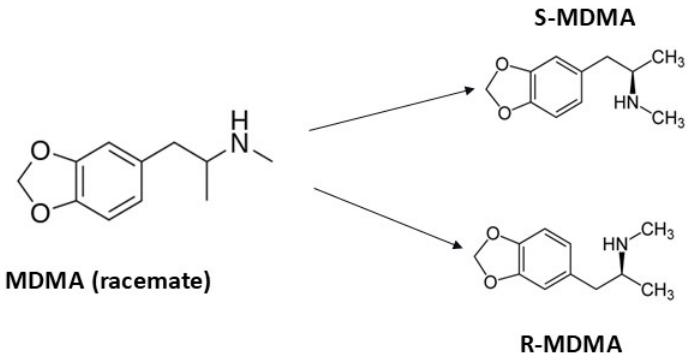
Most rec
(2003), Z

1. Anxiety and Depression Association of America (2021)
2. National Alliance on Mental Illness (2021)
3. DeVane et al., "Anxiety Disorders in the 21st Century: Status, Challenges, Opportunities, and Comorbidity With Depression", AJMC (2005)
4. National Institute of Mental Health
5. Keller MB. Social anxiety disord
6. GlobalData (as of 06.26.2024).

EMP-01: Unique Profile of R-MDMA

Our findings present the possibility that R-MDMA may o to racemic MDMA, and with a lower risk for adverse effe

Profile of R- vs. racemic MDMA



Similar to the racemic MDMA, R-MDMA has been shown to **significantly increase social interaction in both animal models and exploratory human studies**[1, 2]

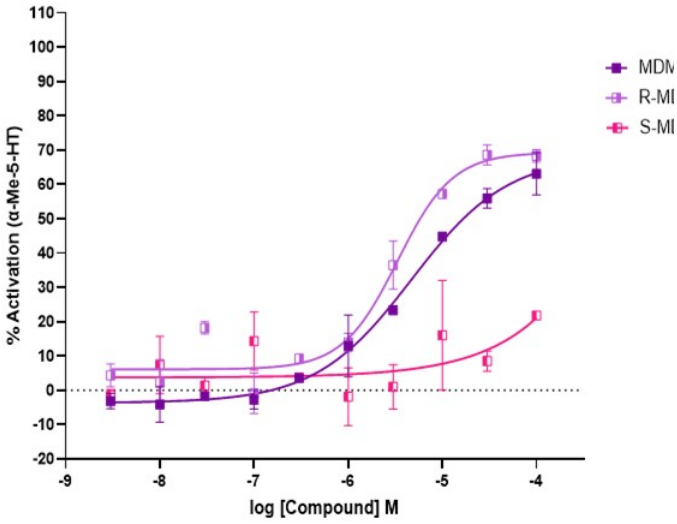
Yet, unlike racemic MDMA, it does not appear to increase locomotor activity, produce signs of neurotoxicity, or increase body temperature in animal models[1]

Differences are hypothesized to arise from:

- R-MDMA has reduced amphetamine-like pharmacology than S-MDMA
- R-MDMA is a partial agonist at 5-HT2A receptors

Validated unique pharmacology

Human 5-H2TA receptor activation study[3]



R-MDMA (EMP-01) shows significantly greater activity at the 5- receptor compared to racemic MDMA and S-MDMA

EMP-01 also demonstrated inducement of a mouse head twitch response, suggesting R-MDMA may generate a more psychedeli internal subjective experience

1. Curry DW, Young MB, Tran AN, Daoud GE, Howell LL. Separating the agony from ecstasy: R(-)-3,4-methylenedioxymethamphetamine has prosocial and therapeutic-like effects without signs of neu
2. Danforth AL, Grob CS, Struble C, Feduccia AA, Walker N, Jerome L, Yazar-Klosinski B, Emerson A. Reduction in social anxiety after MDMA-assisted psychotherapy with autistic adults: a randomiz
3. CHO-K1 overexpressing human 5-HT2a receptors are incubated with test compound for 1 hour at 37*C, with lithium chloride causing IP1 accumulation upon 5-HT2a agonism
4. Fear extinction test models the ability of the compound to facilitate the therapeutic effect of exposure-based therapy; exposure-based therapy is sometimes used in the clinical management of sc

EMP-01: Phase 1 Results

In a completed Phase 1 study, EMP-01 was generally wel adverse events observed

EMP-01 PHASE 1 SAFETY RESULTS[1]

	Placebo N=8	EMP-01 dose (N=24)				Total N=32
		75mg (N=6)	125mg (N=6)	175mg (N=6)	225mg (N=6)	
Participants with at least one drug-related TEAEs[2]	1	2	1	4	6	14
Nausea	1		1	3	3	8
Headache		1			1	2
Vomiting				1	1	2
Fatigue		1		1		2
Pain in jaw				1		1
Dizziness					1	1
Tremor				1		1
Chills					1	1
Feeling hot					1	1
Palpitations		1				1
Bruxism					1	1

Key Takeaw

1 S 1 p

2 C e

3 B (

4 R ir

5 C te

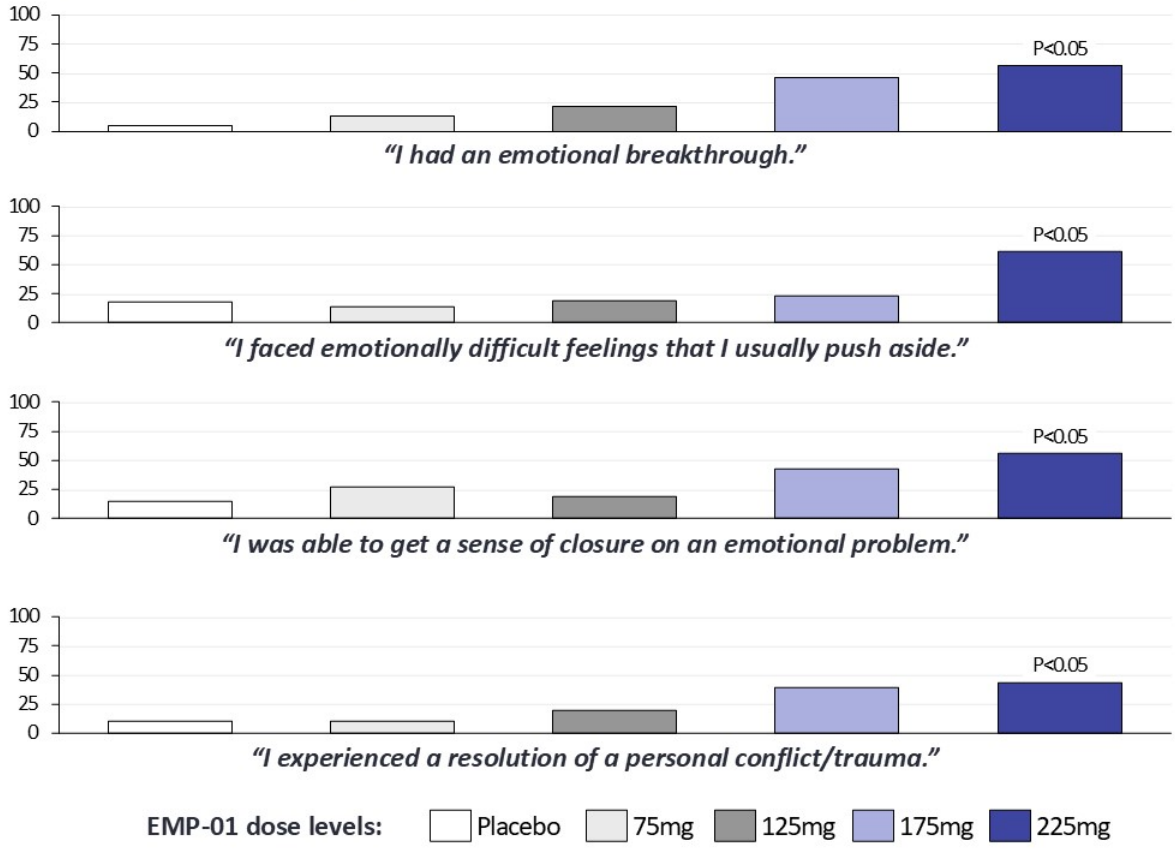
1. Treatment Emergent Adverse Events (TEAEs) are defined as adverse events that occurred following the first administration of study medication. If a participant has multiple occurrences of a TEAE, t given Preferred Term.
2. Drug related TEAEs defined as any TEAE that was deemed to have either a "possible", "probable" or "definite" relationship to the study drug

EMP-01: Phase 1 Results

In Phase 1 study, dose-dependent increases in acute em measures of self-compassion observed 1 week post EMP

EMP-01 PHASE 1 PHARMACODYNAMIC (PD) RESULTS

Average Emotional Breakthrough Inventory (EBI) scoring on Day 2 after EMP-01 dosing



Key Takeaw

1

2

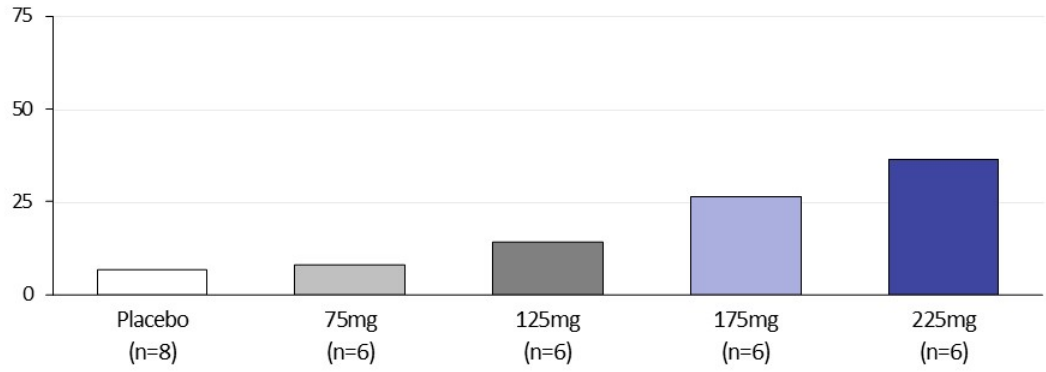
1. GM Goodwin et al, 2022, Roseman et al, 2019, https://med.uth.edu/psychiatry/2024/04/01/fda-grants-breakthrough-status-to-lsd-formula-and-opens-a-new-frontier-in-the-generalized-anxiety-di
2. Werner et al, 2012, Blackie and Kovovski, 2018, Madaki and Koszychi, 2020

EMP-01: Phase 1 Results

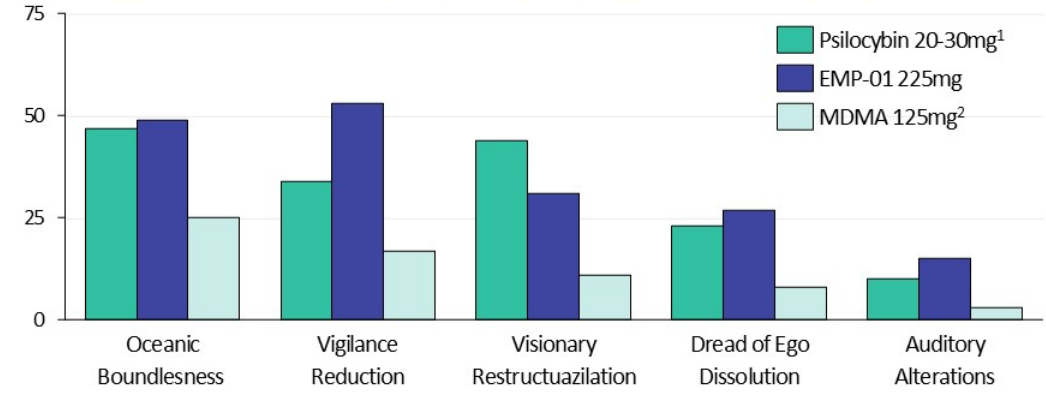
In Phase 1 study, EMP-01 also demonstrated a dose-dep with a subjective effect profile more like classical psyche

EMP-01 PHASE 1 PHARMACODYNAMIC (PD) RESULTS

Total score on 5D-ASC psychedelic experience questionnaire per dose level



Average score on 5D-ASC psychedelic experience questionnaire per dimension



Key Takeaw

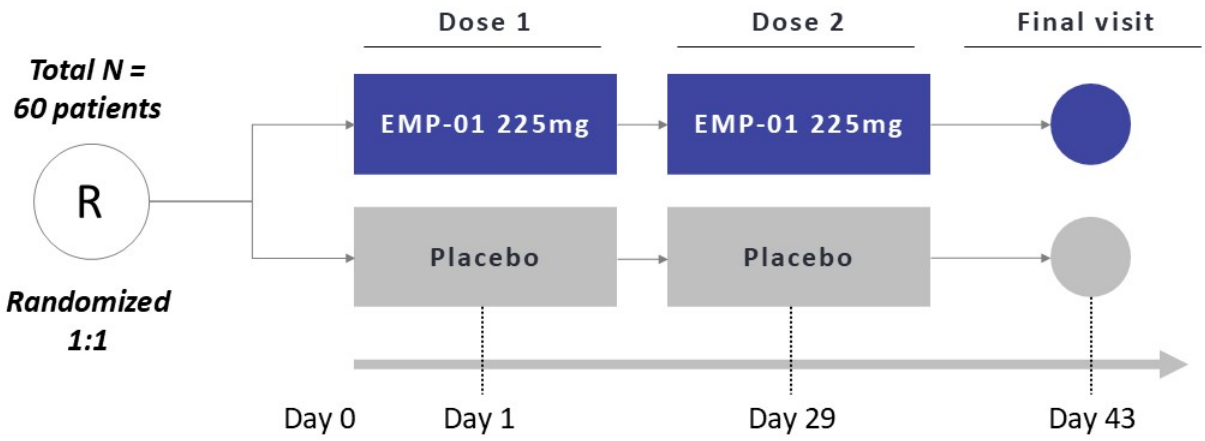
1. E p
2. T q p C t
3. S n c

1. Hasler et al, 2004, Vollenweider et al, 2007
2. Holze et al., 2020; Schmid et al., 2021; Angerer et al., 2023; Hysek et al., 2011; Hysek et al., 2012; Hysek et al., 2012
3. Vollenweider FX, Smallridge JW. Classic Psychedelic Drugs: Update on Biological Mechanisms. Pharmacopsychiatry. 2022
4. Danforth AL, Grob CS, Struble C, Feduccia AA, Walker N, Jerome L, Yazar-Klosinski B, Emerson A. Reduction in social anxiety after MDMA-assisted psychotherapy with autistic adults: a randomized,

EMP-01: Phase 2 Study Design

We are initiating an exploratory Phase 2a, placebo-contr
efficacy of two 225 mg doses of EMP-01 versus placebo i

EMP-01 PHASE 2A STUDY DESIGN (PRELIMINARY)



Desig
- Ph
- Ac
- Lie

Prima
- Sa

Other
- LS
- Ch sc

Trial status: Trial initiation expected arour
Topline data anticipated around yea

Abbreviations: LSAS = Liebowitz Social Anxiety Scale
1. Trial initiation defined as central regulatory and ethics approval

IBX-210

(IV-Ibogaine) for Opioid 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 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, oral 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 oral ibogaine compared to placebo

Lead indicati

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

Global diseas

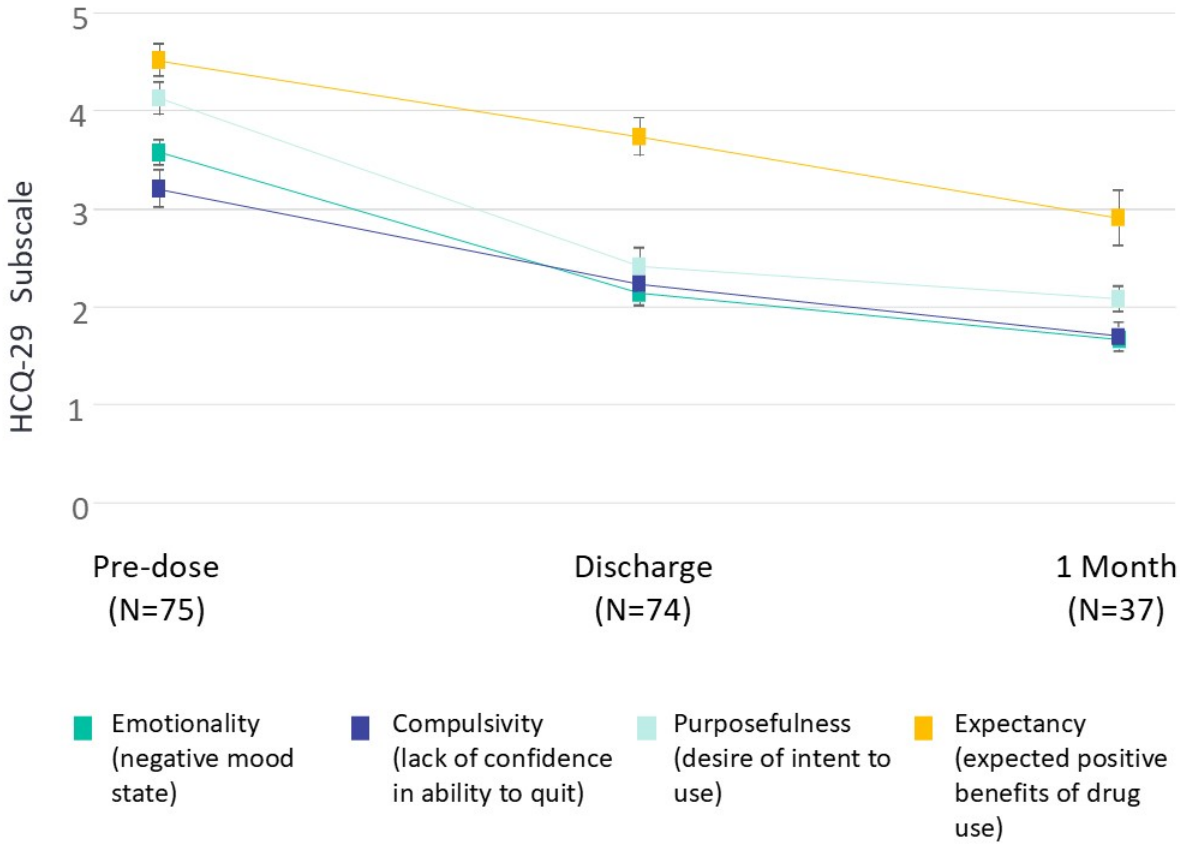
1. Post traumatic stress disorder and traumatic brain injury, respectively
2. World Health Organization
3. Salzer, "National Estimates of Recovery-Remission From Serious Mental Illness", Psychiatry Online (2018)

Clinical Evidence: Efficacy & safety of oral ibogaine in o

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



1

2

3

4

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)**	**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

BPL-003

(5-MeO-DMT) for TRD & AUD

Strategic Investment into Beckley Psytech

SUMMARY: BPL-003

STRATEGIC INVESTMENT	35.5% ownership[1] of Beckley Psytech
PRODUCT	5-MeO-DMT salt form in dry powder nasal spray device
PHARMA-COLOGY	5-HT2A / 5-HT1A Receptor agonist
INDICATIONS	Primary: TRD Potential: AUD
TARGET POSITION	First-to-market with 5-MeO-DMT
ACHIEVED & EXPECTED MILESTONES[2]	Ph2b (TRD) topline data in Q2'25 Ph2a open-label (AUD) data in H2'24
INTELLECTUAL PROPERTY	Granted composition of matter and methods of use patents; numerous pending claims

BPL-003 has the pot
short-duration psyc
acting and durable a

Short duration of subj
acute effects resolving
psychedelics

Rapid & durable effica
of patients achieved cl
response was maintair

First to market potent
Investigational New Dr

Abbreviations: TRD = Treatment Resistant Depression, AUD = Alcohol Use

1. As of January 4th 2024. Terms of the strategic investment also include the company and an indefinite right of first negotiation for BPL-003 ar
2. All dates provided for expected milestones are estimated

BPL-003: Phase 1 Results

BPL-003 had a favorable safety profile and was well tole observed serious or severe adverse events

BPL-003 PHASE 1 SAFETY DATA

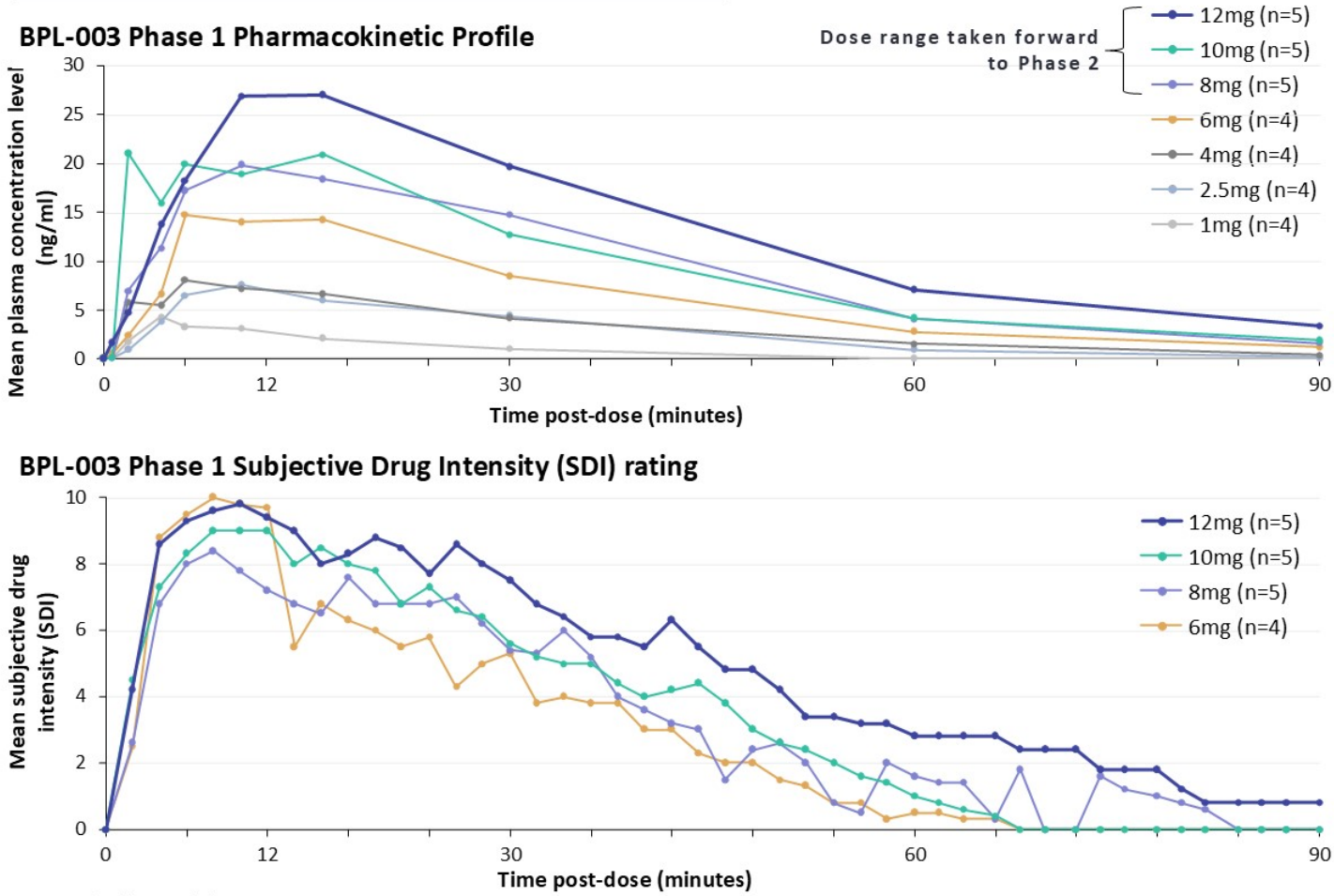
	Placebo N=13	BPL-003 dose (N=31)						Total N=44
		1 mg N=4	2.5 mg N=4	4mg N=4	6 mg N=4	8 mg N=5	10mg N=5	12 mg N=5	
Any TEAEs[1]	2	1	1	4	3	4	2	4	21
Nasal discomfort			1	2	2	2		3	10
Nausea				2	1	2	1	1	7
Vomiting				2		1		2	5
Headache	1			1		2			4
Administration site pain						1	1		2
Chest discomfort						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 partcipants reporting at least one TEAE in that category, % - rounded proportion of cohort total
Abbreviations: TEAE = Treatment Emergent Adverse Events, ECG = Electrocardiogram, C-SSRS = Columbia-suicide severity rating scale

BPL-003: Phase 1 Results

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

BPL-003 PHASE 1 RESULTS

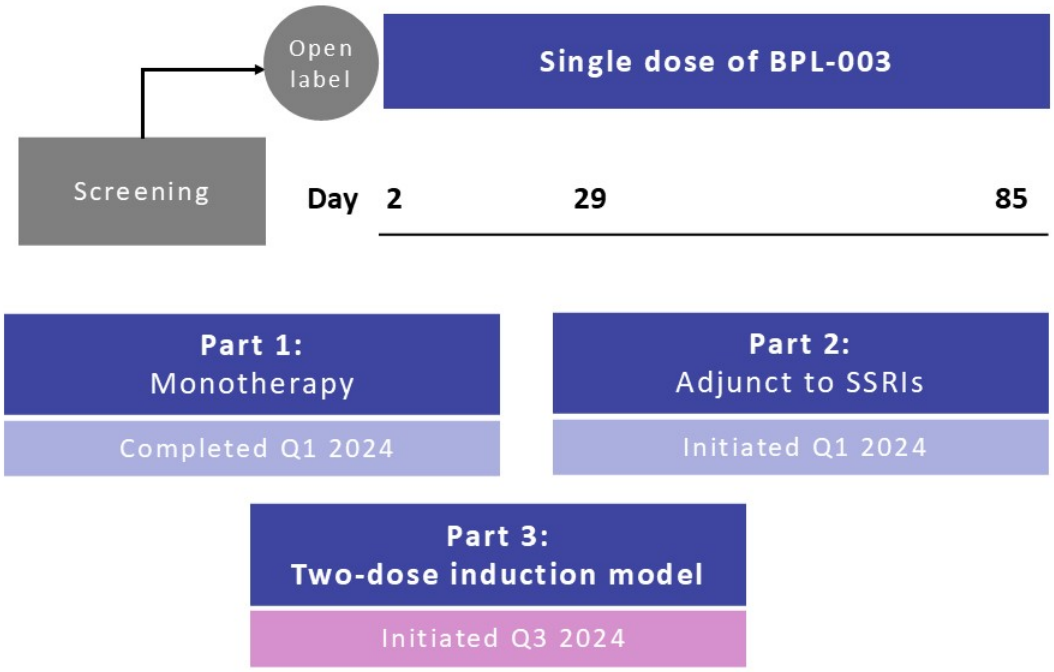


Source: internal Beckley Psytech data
Abbreviations: SAD = Single Ascending Dose; PK = Pharmacokinetic; PD = Pharmacodynamic

BPL-003: Phase 2a Clinical Trial Design

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

BPL-003 PHASE 2A STUDY DESIGN



STUDY DETAILS

- Open-label stud moderate-to-se
- Parts 1 & 3 are i taking select SS
- Psychological su

KEY INCLUSION CR

- Montgomery-A
- **Part 1 & 3:** willi
- **Part 2:** on curre

KEY OBJECTIVES

Primary Endpoint:

- Safety and toler

Other Secondary E

- MADRS change
- Remission and r

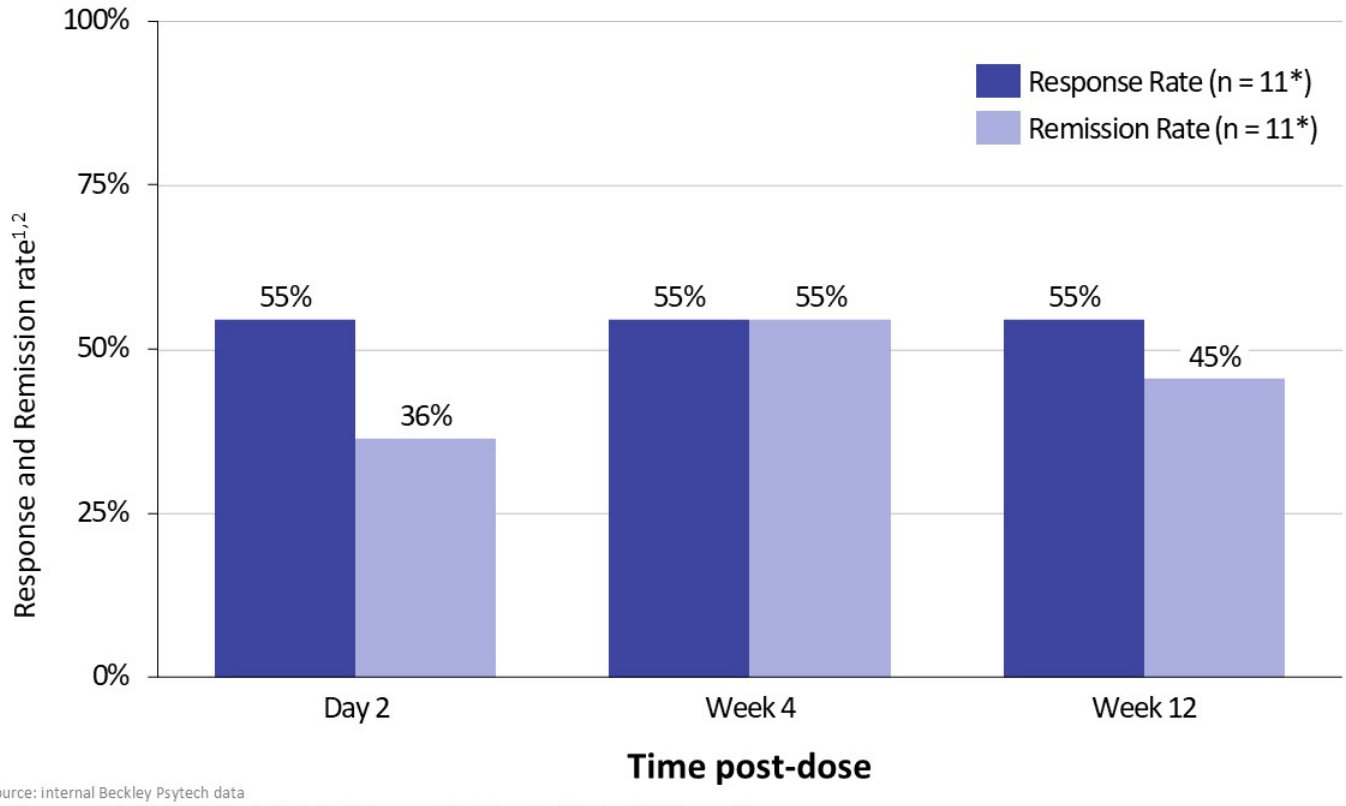
Abbreviations: MADRS = Montgomery–Åsberg Depression Rating Scale

BPL-003: Phase 2a TRD 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



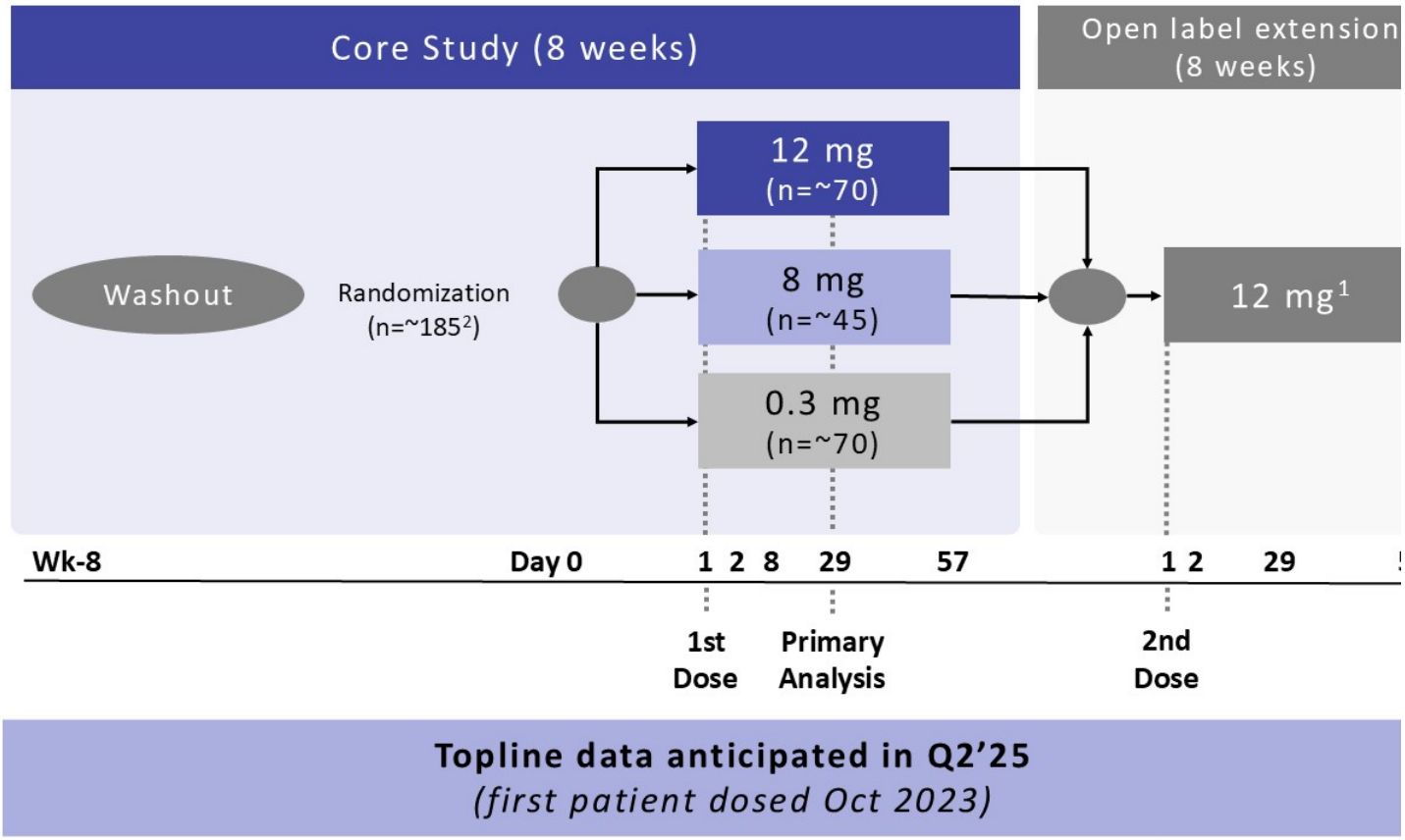
Source: internal Beckley Psytech data

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

* Prior to data analysis, one participant (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 TRD Clinical Trial Design

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



Topline data anticipated in Q2'25
(first patient dosed Oct 2023)

[1] Patients entering the open-label extension are randomized to receive either a single 12mg dose or a biphasic 4mg and 8mg dose approximately 10 minutes apart. [2]Total N changed due to an adjustment in the randomi
Abbreviations: MADRS = Montgomery–Åsberg Depression Rating Scale; CGI-S = Clinical Global Impressions-Severity; PGIC = Patient's Global Impression of Change; EQ-5D = EuroQol-5D

ELE-101

(Psilocin) for MDD

Strategic Investment into Beckley Psytech

SUMMARY: ELE-101

STRATEGIC INVESTMENT	35.5% ownership[1] of Beckley Psytech
PRODUCT	Psilocin salt form administered via IV infusion
PHARMA-COLOGY	5-HT2A Receptor agonist
INDICATIONS	Primary: TRD Potential: Anorexia Nervosa, PTSD
TARGET POSITION	Best-in-class psilocin formulation with significantly shorter treatment duration, and reduced inter-subject variability compared to oral formulations of psilocybin
ACHIEVED & EXPECTED MILESTONES[3]	Phase 1 topline data announced in H1 2024 Phase 2a OL (MDD) data in H2 2024
INTELLECTUAL PROPERTY	Granted composition of matter and methods of use patents; numerous pending claims

ELE-101 could offer the
in a more consistent, co
paradigm of approxima

Proven therapeutic pot
has already demonstrat

Optimized formulation:
reducing inter-subject v
experience

Short duration of subje
much shorter duration c

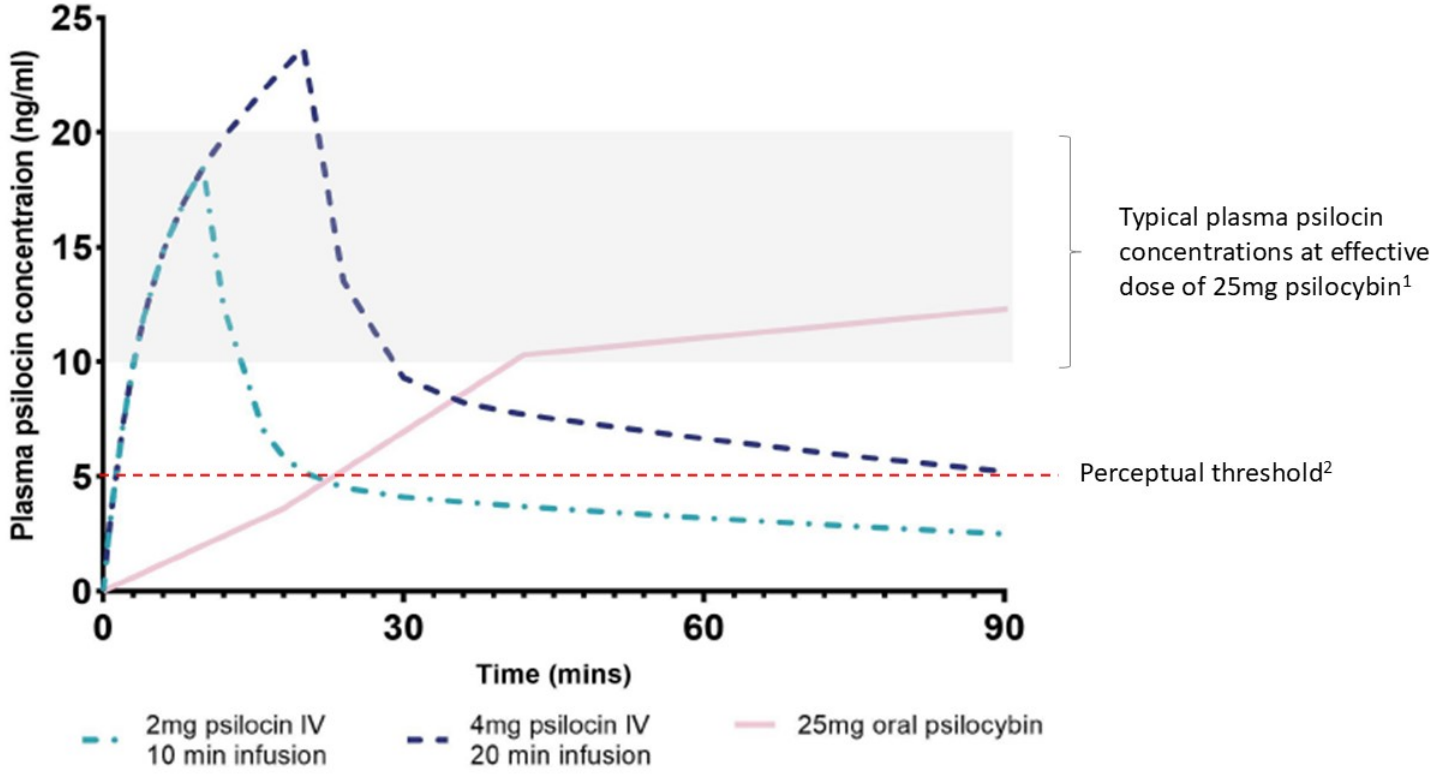
Patent protected: paten
benzoate salt

Abbreviations: TRD = Treatment Resistant Depression; PTSD = Post Traum
1. As of January 4th
2. Goodwin et al, 2022; Raison et al, 2023
3. All dates provided for expected milestones are estimated

ELE-01: IV Psilocin

ELE-101 is design to demonstrate potential benefits of ps optimized delivery and treatment model

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



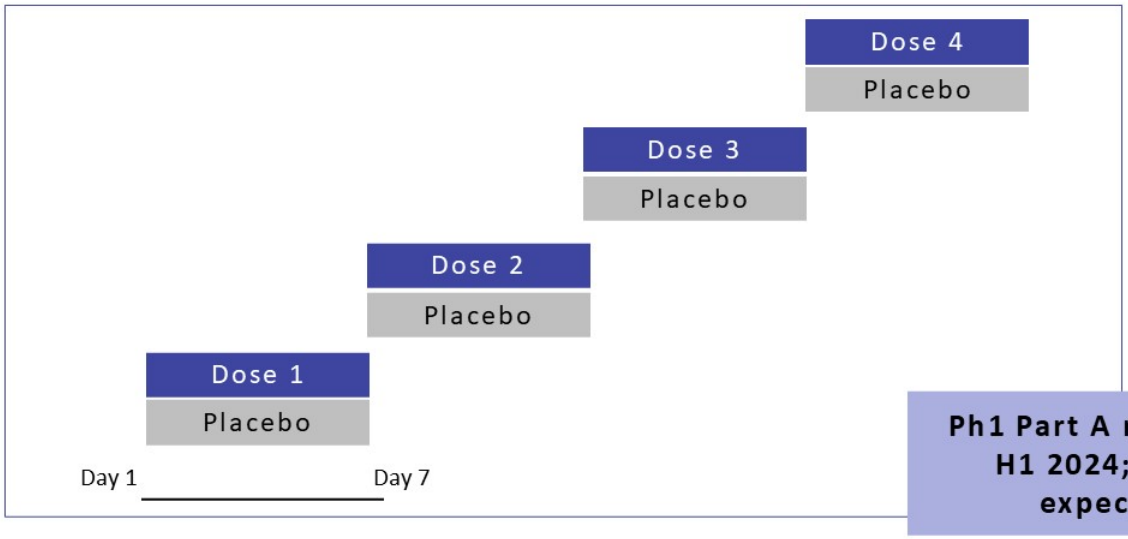
[1] Psilocin simulations based on primary data from Brown et al. 2017, Madsen et al . 2019, Hasler et al. 1997, and Carhart-Harris et al. 2011.
[2] Holze F. et al (2023). Pharmacokinetics and Pharmacodynamics of Oral Psilocybin Administration in Healthy Participants. Clin Pharmacol Ther.

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

A Phase 1/2a study is currently underway: Part A, a dose volunteers, is complete and dosing has initiated for Part

ELE-101 Phase 1/2a – Part A

Single Ascending Dose



ELE-101 Pl

Open-labe

Ph1 Part A results announced in H1 2024; Ph2a Part B data expected in H2 2024

Topline data[1]:

- Well-tolerated with no serious or severe adverse events (AE)
- Demonstrated a dose-proportional PK profile, leading to reduced inter-subject variability compared to oral psilocybin
- Induced high-intensity, short-duration psychedelic experiences, suggesting a potential treatment time of ~two hours in the clinic

Key Object

- Safety a MDD
- Key Sec
  - Asse
  - CGI-

1. Full data from the Phase 1 study is expected to be published at a later date

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 De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