



Pioneering the
development of highly
effective mental health
treatments to transform
patient outcomes.

CORPORATE PRESENTATION



March 2025

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atai is addressing significant unmet patient needs in mental health disorders so that everyone, everywhere can live a more fulfilled life

1

5 clinical-stage programs: four psychedelic programs and one non-psychedelic program

2

Multiple Phase 2 readouts expected over the next 12 months: clinical trial results anticipated across our core drug development programs and strategic investments

3

Runway into 2027: expect cash, short-term securities, and public equity holdings to be sufficient to fund operations into 2027¹

Our vision is being delivered through a **robust pipeline** of development programs and strategic investments **across a range of compounds and psychiatric indications**

Programs	Primary Indication	Preclin	Phase 1	Phase 2	Phase 3
Core Psychedelic Programs					
VLS-01 DMT	Treatment Resistant Depression (TRD)	█		█	
EMP-01 R-MDMA	Social Anxiety Disorder (SAD)	█		█	
Novel 5-HT2A Receptor Agonists (inc. non-hallucinogenic neuroplastogens)	Undisclosed	█			
Beckley Psytech Strategic Investment					
BPL-003 Mebufotenin benzoate	TRD	█		█	
ELE-101 Psilocin	Major Depressive Disorder (MDD)	█		█	
Non-psychedelic Program (via majority ownership in Recognify Life Sciences)					
RL-007 Pro-cognitive neuromodulator	Cognitive Impairment Associated with Schizophrenia (CIAS)	█		█	



Abbreviations: DMT = N,N-Dimethyltryptamine; R-MDMA = R enantiomer of 3,4-Me thylenedi oxymethamphetamine

Fully funded through multiple near-term milestones

ACHIEVED AND ANTICIPATED UPCOMING MILESTONES^{1,2}

Programs	Q1'25	Q2'25	Q3'25	Q4'25	Q1'26
VLS-01 DMT	✓ Ph 2 (TRD) trial initiation				● Ph 2 (TRD) data
EMP-01 R-MDMA		✓ Ph 2a (SAD) initiation			● Ph 2a (SAD) data
BPL-003 Mebufotenin benzoate	✓ Ph 2a (AUD) OL data	● Ph 2a (TRD) SSRI OL data	● Ph 2b (TRD) data		
RL-007 ¹ Pro-cognitive neuromodulator			● Ph 2b (CIAS) data		

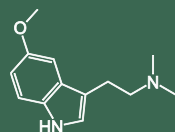


Abbreviations: OL = Open-label; TRD = Treatment Resistant Depression; SAD = Social Anxiety Disorder; AUD = Alcohol Use Disorder; CIAS = Cognitive Impairment in Schizophrenia
 1. All dates provided are as estimated; 2. Trial initiation defined as central regulatory and ethics approval

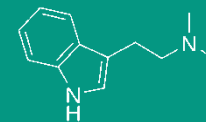
Short-Acting Psychedelics



BPL-003 and VLS-01 are novel, short-duration psychedelic candidates developed to optimize patient access for TRD



BPL-003
Mebufotenin benzoate

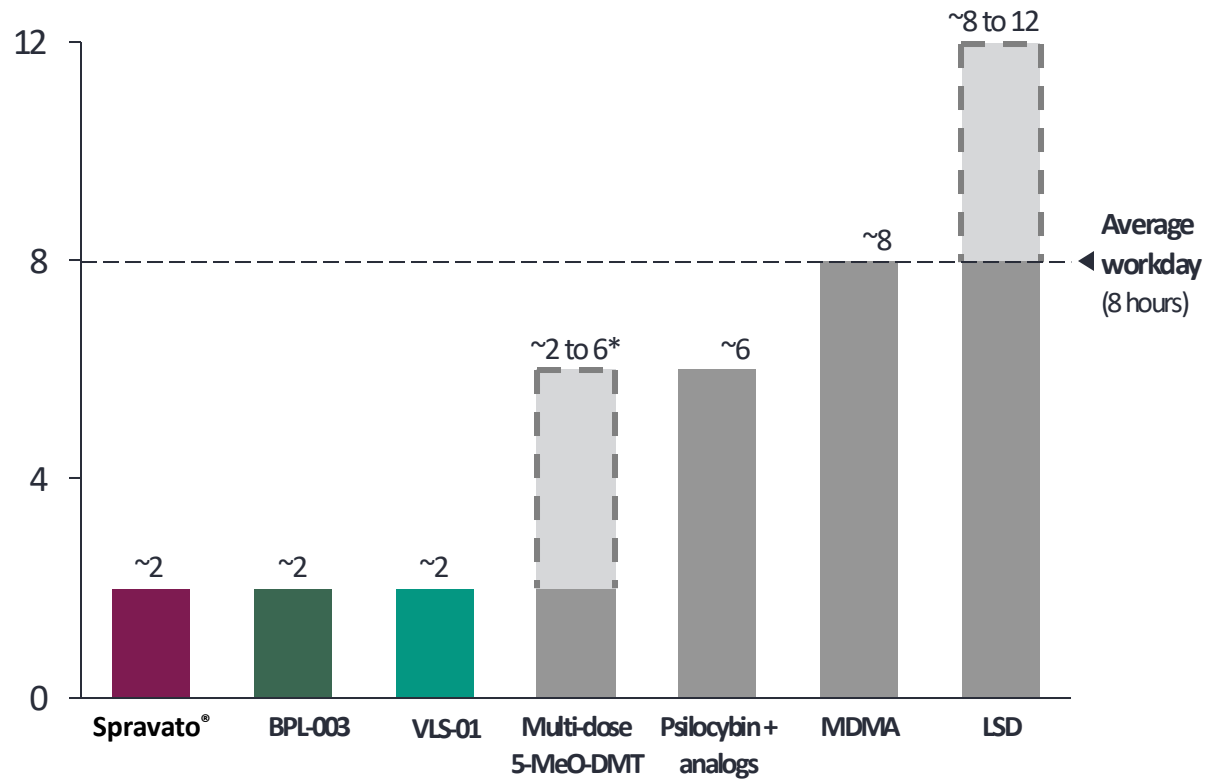


VLS-01
DMT

TARGET POSITION	First-in-class short-duration psychedelic	Best-in-class route of administration and tolerability for DMT
PHARMACOLOGY (5-HT _{2A} : 5-HT _{1A} binding affinity ¹)	5-HT _{1A} /5-HT _{2A} receptor agonist (1 : 0.009)	5-HT _{2A} receptor agonist (1 : 3.4)
FORMULATION	Nasal spray (transmucosal)	Buccal film (transmucosal)
TREATMENT DURATION	~2 hours	~2 hours
DEVELOPMENT STAGE	Phase 2b; topline data anticipated mid '25 IND approved	Phase 2; topline data anticipated Q1 '26 IND approved
INTELLECTUAL PROPERTY	COM and Methods; additional pending	COM and Methods; additional pending

BPL-003 and VLS-01 have the potential to leverage Spravato® 2-hour in-clinic treatment paradigm in depression

ANTICIPATED TIME TO RESOLUTION OF SUBJECTIVE EFFECTS¹
(in hours) *Illustrative*



KEY TAKEAWAYS

- 1 Predictable 2-hour treatment:** the potential to fit into the 2-hour in-clinic treatment paradigm established by Spravato
- 2 Established infrastructure and reimbursement:** potential to immediately leverage Spravato's reimbursement pathways and >4,500 certified clinics²
- 3 Extended durability reduces patient burden:** 1-2 doses of a psychedelic therapy provides a sustained effect, simplifying the dosing schedule compared to esketamine's once-weekly regimen
- 4 Significantly improves use of infrastructure:** lower dosing frequency compared to esketamine will lower provider burden, and improve payer receptivity

TRD

VLS-01

(BUCCAL FILM DMT) FOR TRD



VLS-01 (buccal film DMT) patent-protected formulation, designed to fit into established ~2-hour interventional psychiatry treatment paradigm for TRD



Optimized transmucosal buccal film formulation : Phase 1 study demonstrated favorable safety & tolerability and an IV-like PK profile, which may support a more scalable patient / provider experience



Short duration psychedelic effect: Phase 1 data suggests subjective effects experienced for ~2 hours, potentially enabling VLS-01 to fit into interventional psychiatry paradigm established by Spravato®



Potential for rapid onset and durable efficacy: Prior clinical evidence with DMT has generated sustained, clinically meaningful improvement on depressive symptoms¹



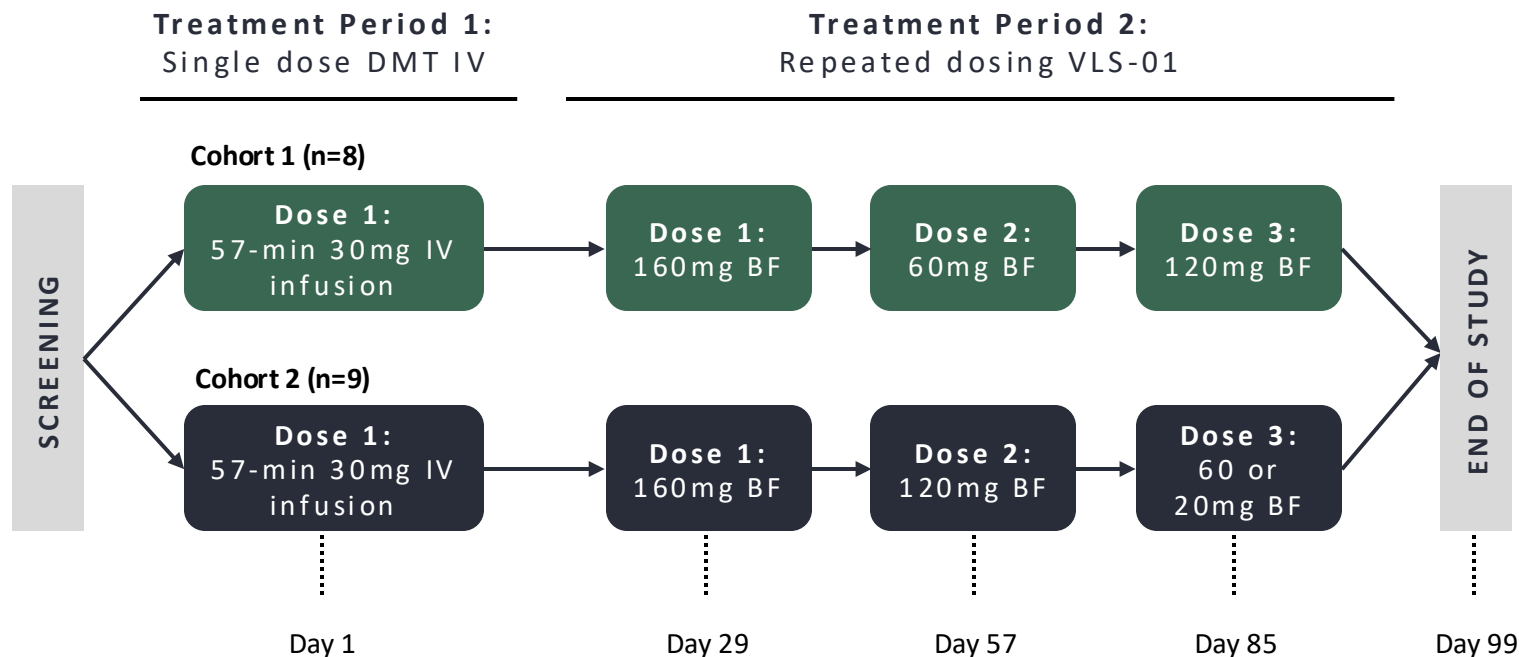
Patent protected formulation: Issued patents and pending applications covering compositions and methods of use (expiry anticipated 2042²)

Phase 1b trial investigating the PK, PD, safety and tolerability of **optimized buccal film formulation** compared to DMT IV

VLS-01 | Phase 1b Clinical Trial Design

VLS-01 PHASE 1B – STUDY DESIGN

KEY TAKEAWAYS



Study Design:

- Open-label, dose ranging study of an optimized buccal film formulation of VLS-01 in healthy volunteers
- Enrolled 17 healthy participants
- Tested 160mg, 120mg, 60mg, or 20mg of VLS-01

Primary Endpoint:

- Plasma and urine PK characteristics

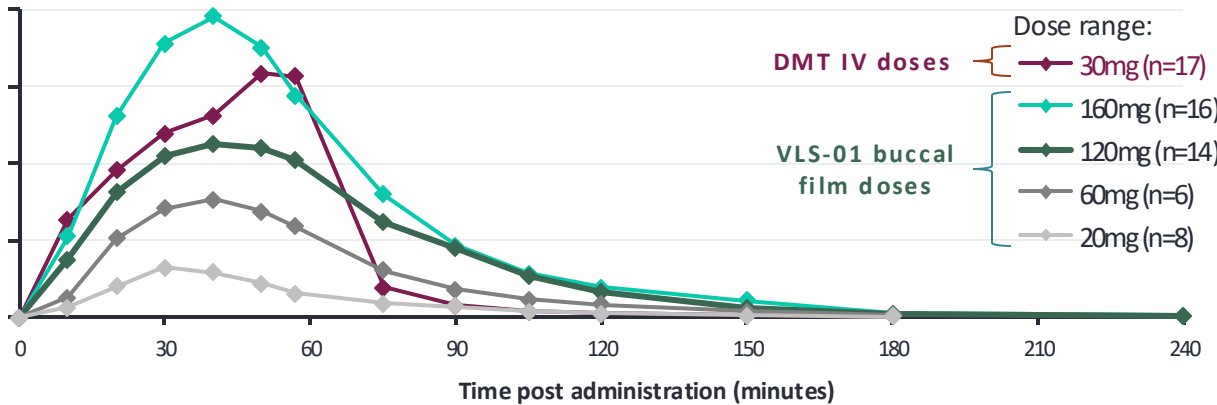
Key Secondary Endpoints:

- Safety and tolerability
- Subjective acute PD drug effects

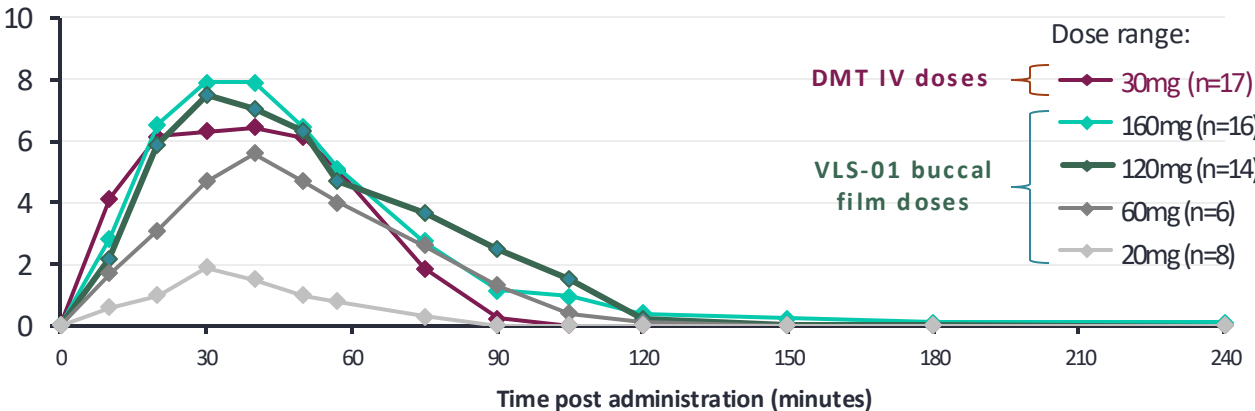
Higher doses demonstrated **plasma concentrations** comparable to DMT IV and **robust subjective effects** that resolved in ~2 hours

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

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



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



KEY TAKEAWAYS

Pharmacokinetics (PK)

- C-Max was dose-proportional and comparable between the higher VLS-01 doses (120mg and 160mg) and the 30mg DMT IV dose
- VLS-01 rapidly reached peak plasma concentration (T-Max) within 30-45 minutes

Pharmacodynamics (PD):

- Dose-dependent effects, with robust subjective effects seen at the VLS-01 120mg and 160mg doses
- 13/14 participants in the 120mg cohort achieved SIRS scores greater than 7
- Perceptual effects generally fully resolved within 90-120 mins

Abbreviations: IV = Intravenous; PK / PD = Pharmacokinetic / Pharmacodynamic; C-Max = maximum (or peak) serum concentration; T-Max = time it takes for a drug to reach the maximum concentration (C-Max)

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 and results may change



Well-tolerated safety profile, with all adverse events classified as either **mild or moderate**, and most **resolving on the day of dosing**

VLS-01 | Phase 1b Results

VLS-01 PHASE 1B – SAFETY RESULTS^A

No. of participants with drug-related TEAE (>10%):	DMT IV	VLS-01 (buccal film)				Total (N=62)
	30mg (N=17)	160mg (N=16)	120mg (N=14)	60mg (N=7)	20mg (N=8)	
Headache	1 (6%)	4 (25%)	4 (29%)		1 (13%)	10 (16%)
Dissociation	1 (6%)	5 (31%)	3 (21%)			9 (15%)
Euphoric mood	1 (6%)	3 (19%)	4 (29%)		1 (13%)	9 (15%)
Nausea		5 (31%)	1 (7%)	1 (14%)		7 (11%)
Emotional distress	1 (6%)	3 (19%)				4 (6%)
Feeling drunk			3 (21%)		2 (25%)	5 (8%)
Feeling hot	2 (12%)					2 (3%)
Anxiety	2 (12%)					2 (3%)
Dizziness		1 (6%)		1 (14%)		2 (3%)
Vomiting		2 (13%)				2 (3%)
Myocardial ischemia ¹					1 (13%)	1 (2%)
Abdominal pain				1 (14%)		1 (2%)
Oral Discomfort		2 (13%)				2 (3%)
At least one severe TEAE						0
At least one serious TEAE						0
At least one TEAE leading to discontinuation	1 (6%)					1 (2%)

KEY TAKEAWAYS

1

The most common TEAEs were headache, dissociation, euphoric mood and nausea; adverse events were transient with most resolving on the day of dosing

2

Blood pressure and heart rate increases were transient and mostly resolved within 90 min without intervention. None were considered clinically significant

3

Results from the C-SSRS showed participants experienced no increase in suicidal thoughts, intentions or behaviours

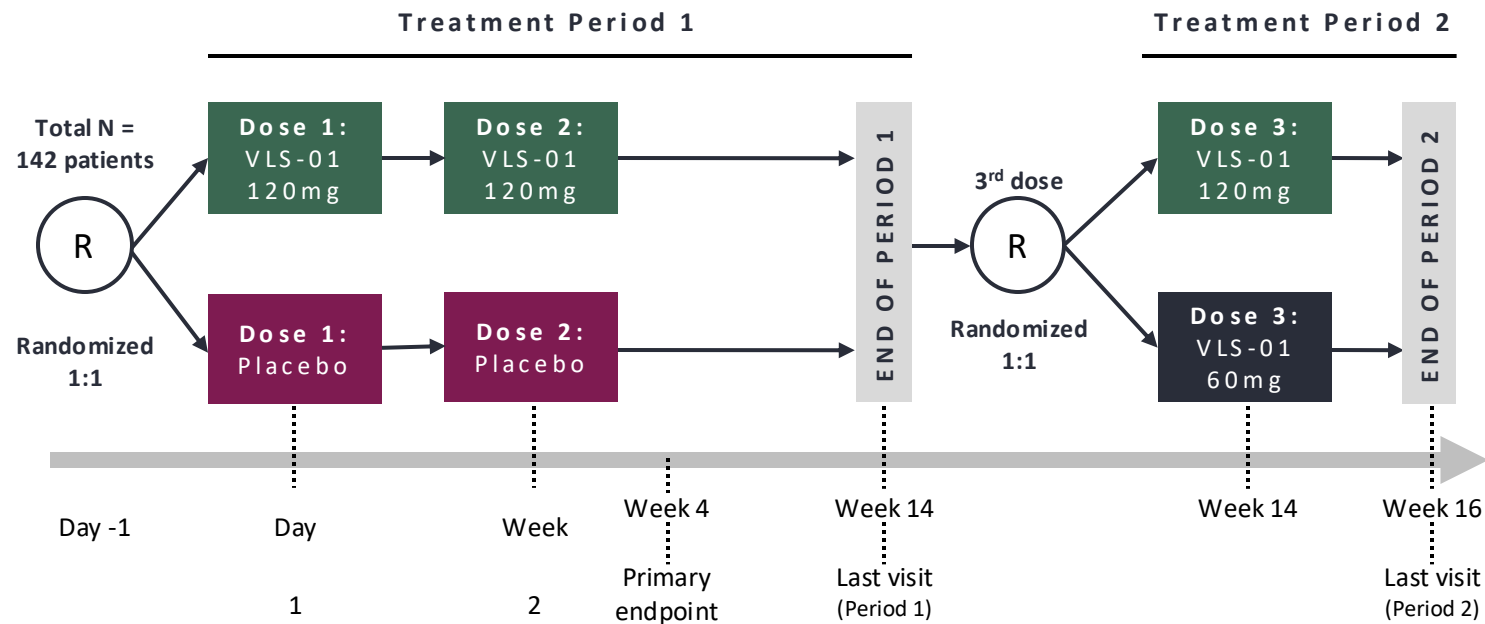
4

Overall impressions from healthy volunteers in the 120mg group was that VLS-01 was well-tolerated and psychologically meaningful with reports of increased self-reflection

Phase 2 Elumina Trial: randomized, double-blind, placebo-controlled trial to assess the efficacy of repeated doses of VLS-01 in patients with TRD

VLS-01 | Phase 2 Clinical Trial Design

VLS-01 PHASE 2 – STUDY DESIGN



KEY TAKEAWAYS

Study Design:

- Moderate to severe TRD
- Patient must be willing to discontinue current antidepressants
- No use of psychedelics within 6 months of screening¹
- Psychological support pre- and post-dose

Primary Endpoint:

- Change from Baseline in MADRS total score at Week 4

Key Secondary Endpoints:

- Change from Baseline in MADRS total score at Week 6 and Week 14
- Response and remission rates
- Safety and tolerability

TRIAL STATUS

First patient dosed **March 2025**

Topline data anticipated **Q1 2026**



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

SAD

EMP-01

(R-MDMA) FOR
SOCIAL ANXIETY DISORDER



EMP-01 (R-MDMA), a moiety that is **pharmacologically distinct** from both racemic MDMA and S-MDMA



Unexpected subjective effects: in a Phase 1 trial, EMP-01 was found to be significantly more psychedelic-like than MDMA, with a more "inward focused" experience.



Beneficial psychological effects: EMP-01 administration in healthy volunteers resulted in dose-dependent increases in emotional breakthroughs and measures of self-compassion, both factors associated with reduction in anxiety symptoms.



Well-tolerated : EMP-01 was generally well tolerated, with no severe or serious adverse events observed. Third-party animal studies indicate that R-MDMA may have fewer adverse effects compared to racemic MDMA¹.



First-to-market potential: no other companies in the psychedelic or psychedelic-like space are targeting the SAD indication.

Anxiety Disorders

EMP-01 | Disease Overview

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

Anxiety in numbers

Includes:

Generalized Anxiety Disorder (GAD)

Social Anxiety Disorder (SAD)

Panic Disorder

~40m

Suffer from anxiety disorders in the US¹

#1

Most common mental health disorder in the US²

~\$42bn

Annual societal cost of anxiety disorders in the US³

URGENT NEED FOR INNOVATION

~18m

SAD patients in the US

Approximately 7.1% of US adults, or ~18 million individuals, suffered from Social Anxiety Disorder (SAD) in the past year⁴

69%

Moderate to severe impairment is common

Of adults with SAD in the past year, 30% had serious impairment, 39% had moderate impairment, and 31% had mild impairment⁴

35%

Low recovery rate

Only 35% of patients with SAD recovered after 10 years of prospective follow-up⁵

0

No novel molecules approved for SAD in over 20 years

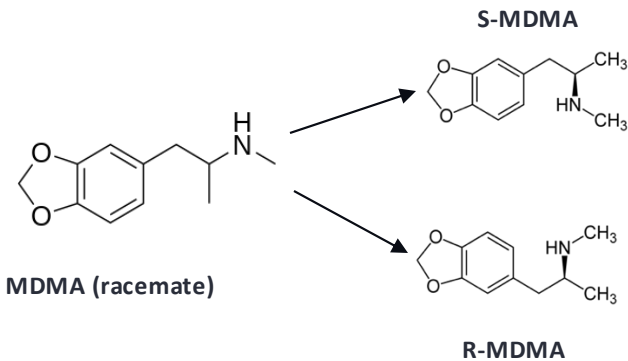
Most recent FDA approvals of novel molecules for SAD were Effexor (2003), Zoloft (2002) and Paxil (1999)⁶

R-MDMA has unique pharmacological benefits to racemic MDMA, and with a lower risk for adverse effects

EMP-01

Unique Profile of R-MDMA

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}

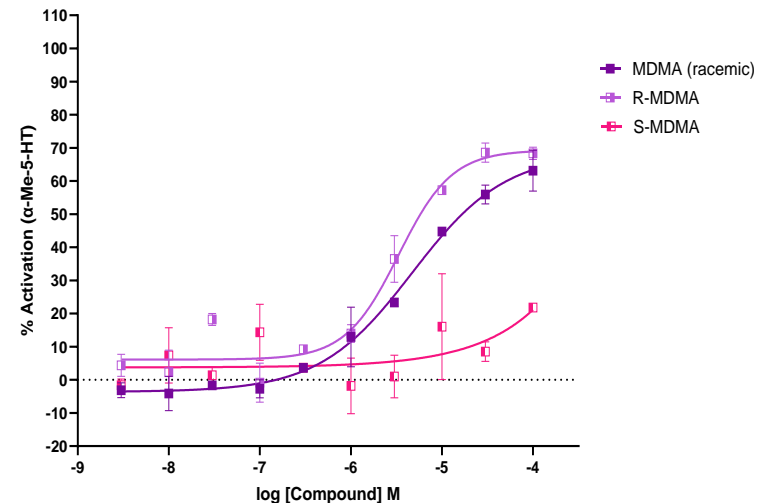
Yet, unlike racemic MDMA, it does not appear to increase locomotor activity, produce signs of neurotoxicity, or increase body temperature in animal models¹

Differences are hypothesized to arise from:

- R-MDMA has reduced amphetamine-like pharmacology than S-MDMA
- R-MDMA is a partial agonist at 5-HT_{2A} receptors

Validated unique pharmacology

Human 5-HT_{2A} receptor activation study³

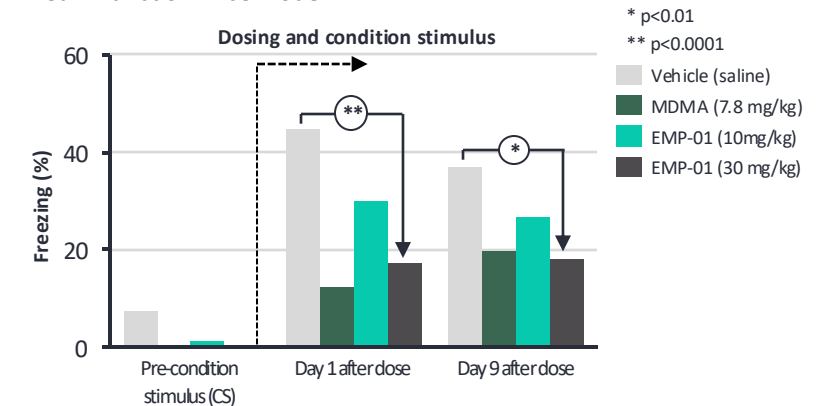


R-MDMA (EMP-01) shows significantly greater activity at the 5-HT_{2A} receptor compared to racemic MDMA and S-MDMA

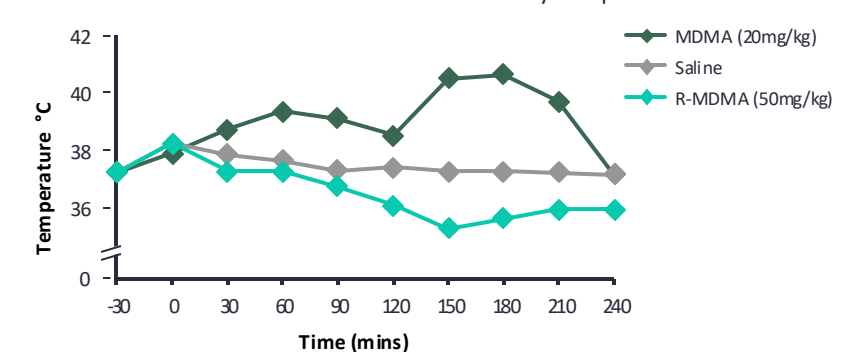
EMP-01 also demonstrated inducement of a mouse head twitch response, suggesting R-MDMA may generate a more psychedelic-like, internal subjective experience

Efficacy signals with fewer adverse effects

Fear Extinction Mice model⁴



Effects of racemic MDMA and R-MDMA on body temp¹ (Third party study)



EMP-01 was **generally well-tolerated** with no severe or serious adverse events observed in a Phase 1 study

EMP-01 | Phase 1 Results

EMP-01 PHASE 1 SAFETY RESULTS¹

	Placebo N=8	EMP-01 dose (N=24)				Total N=32
		75 mg (N=6)	125 mg (N=6)	175 mg (N=6)	225 mg (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

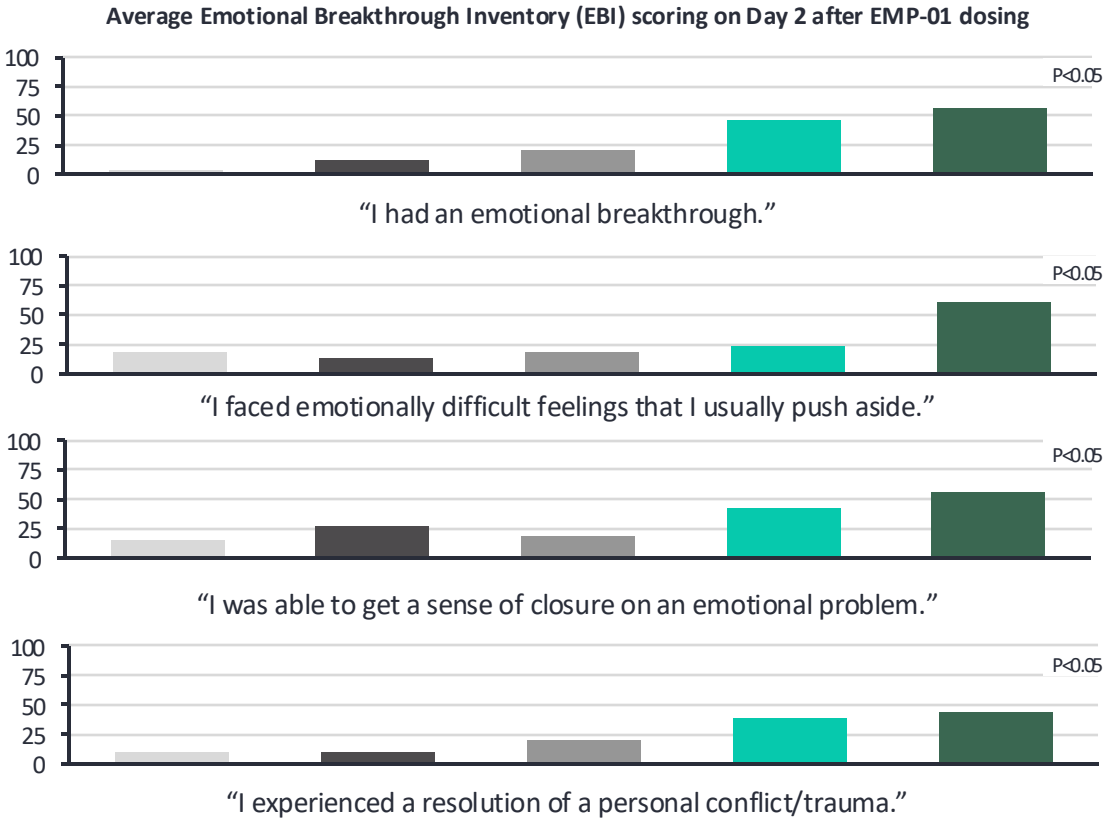
KEY TAKEAWAYS

- 1 Single-ascending dose, double-blinded, placebo-controlled Phase 1 study enrolling 32 healthy participants and testing EMP-01 or placebo in a 6+2 design
- 2 Observed changes in both pulse and blood pressure were in the expected range and were only slightly dose dependent
- 3 Body temperature remained in the normal range across all cohorts (hyperthermia is a known side effect of racemic MDMA)
- 4 Results from the C-SSRS showed participants experienced no increase in suicidal thoughts, intentions or behaviours
- 5 Only 1/24 participants (4%) experienced bruxism, grinding of teeth, which is a common side effect of racemic MDMA

EMP-01 demonstrated **dose-dependent** increases in acute **emotional breakthroughs** and increased measures of **self-compassion** observed at Week 1

EMP-01 | Phase 1 Results

EMP-01 PHASE 1 PHARMACODYNAMIC (PD) RESULTS



KEY TAKEAWAYS

1

225mg dose of EMP-01 showed statistically significant increases in emotional breakthroughs.

Emotional breakthroughs have been shown to mediate efficacy in depression and anxiety studies involving classical psychedelics¹

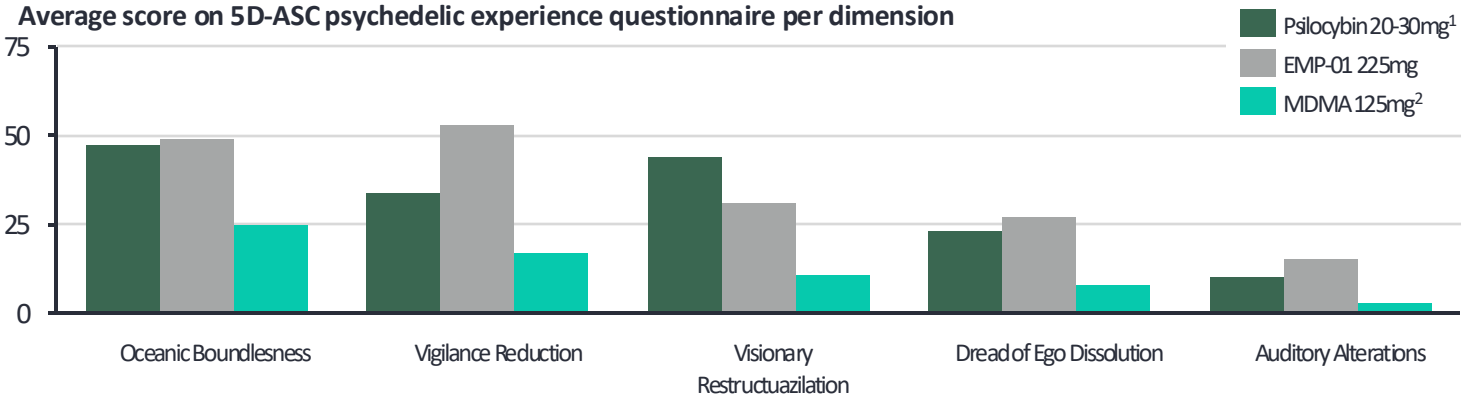
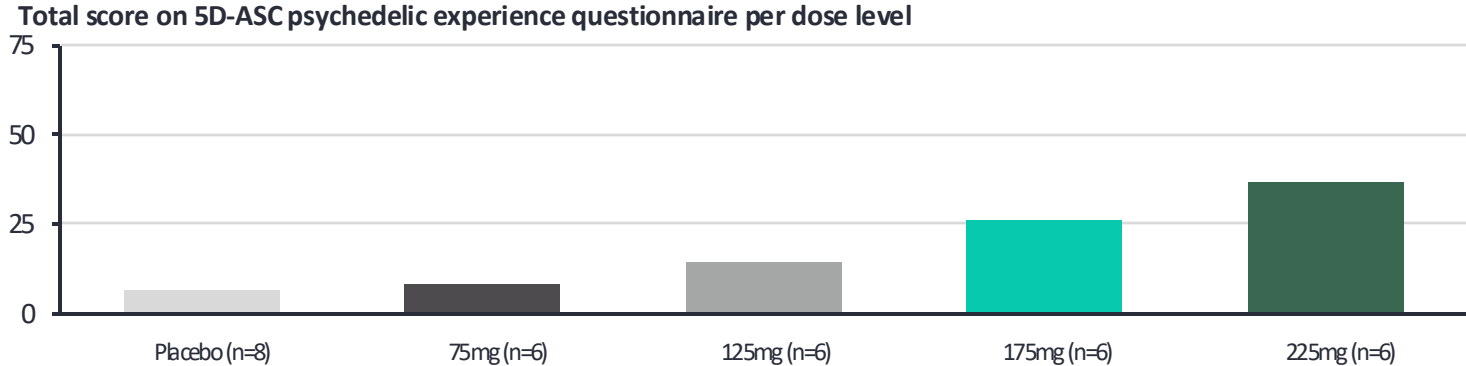
2

Some measures of self-compassion also significantly increased with the 225mg dose of EMP-01 at the 1-week follow-up visit. SAD patients report lower levels of self-compassion than healthy controls and social anxiety symptom severity is correlated with lower self-compassion²

EMP-01 demonstrated a **dose-dependent, psychedelic-like experience** with a subjective effect profile more like classical psychedelics than MDMA

EMP-01 | Phase 1 Results

EMP-01 PHASE 1 PHARMACODYNAMIC (PD) RESULTS



KEY TAKEAWAYS

- 1 EMP-01 demonstrated a unique, dose-dependent subjective effect profile
- 2 The qualitative profile of the effects (based on 5D-ASC questionnaire) were generally found to be more like classical psychedelics (i.e., psilocybin or LSD) than MDMA. Classic psychedelics have also been shown to be effective in treating the symptoms of anxiety³, as has MDMA⁴
- 3 Study facilitators reported that EMP-01 appeared to produce a more inward-focused and "peaceful" experience in participants compared to their experience facilitating MDMA therapies

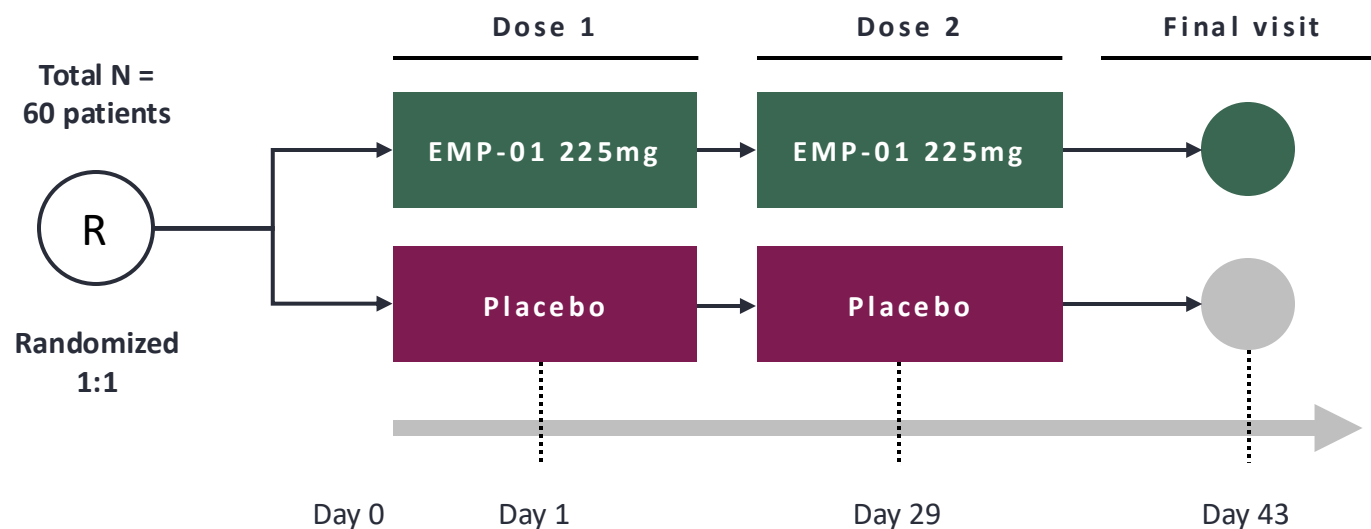


1. Hasler et al, 2004, Vollenweider et al, 2007
 2. Holze et al., 2020; Schmid et al., 2021; Angerer et al., 2023; Hysek et al., 2011; Hysek et al., 2012; Hysek et al., 2012;
 3. Vollenweider FX, Smallridge JW. Classic Psychedelic Drugs: Update on Biological Mechanisms. Pharmacopsychiatry. 2022;
 4. 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, double-blind, placebo-controlled pilot study. Psychopharmacology (Berl). 2018

Exploratory Phase 2a, placebo-controlled study to assess the safety and efficacy of two 225mg doses of EMP-01 in adults with SAD

EMP-01 | Phase 2a Study Design

EMP-01 PHASE 2A STUDY DESIGN



Study Design:

- Phase 2a, randomized, double-blind, placebo-controlled study
- Adult participants diagnosed with Social Anxiety Disorder (SAD)
- Liebowitz Social Anxiety Scale (LSAS) total score ≥ 70 at screening

Primary Endpoint:

- Safety and tolerability (baseline to Day 43)

Secondary Endpoint:

- Change in LSAS total score (baseline to Day 43)

Exploratory Endpoints:

- Subjective drug effects scales
- Change from baseline in clinician and patient rated anxiety, depression, and health status scales and proportion of treatment responders
- PK of EMP-01 and its metabolites

TRIAL STATUS

Trial initiated
in Q1 2025

Topline data
anticipated Q1 2026

TRD

BPL-003

(MEBUFOTENIN BENZOATE) FOR TRD &
AUD

STRATEGIC INVESTMENT INTO BECKLEY PSYTECH



Strategic Investment Terms

Acquired **approximately 1/3** of **Beckley Psytech** for a **\$50m** total investment, in January 2024

Includes 1:1 warrant coverage at **30%** premium, if exercised would result in just under **50%** of outstanding equity

3 of 9 seats on **Beckley Psytech's Board of Directors** with the ability to increase further, proportionate to our shareholding

Time-limited right of first refusal (ROFR) on any **future change of control sale**

Indefinite right of first negotiation (ROFN) on **share or asset purchases**

BPL-003 (intranasal mebufotenin benzoate) potential to become **first-in-class short-duration psychedelic** treatment with **rapid-acting** and **durable antidepressant effects**



Short duration of subjective effects: BPL-003 is a short duration psychedelic, with acute effects resolving in ~2 hours, supporting greater commercial scalability



Rapid & durable efficacy after a single dose: In the Phase 2a open-label study in 11 patients, 55% achieved clinical response on Day 2 after a single dose, and this rate of response was maintained at Week 12



First to market potential: First short-duration psychedelic to receive FDA Investigational New Drug (IND) approval for a Phase 2 clinical trial



Patent protected compound: Issued and pending patents covering mebufotenin benzoate salt and polymorphs (2040/1 expiry¹)

BPL-003 had a **favorable safety profile** and was **well-tolerated**, with no observed serious or severe adverse events

BPL-003

Phase 1 Results

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

KEY TAKEAWAYS

- 1 There were no severe or serious adverse events observed, and 89.5% TEAEs were mild and 10.5% were moderate in severity.
- 2 Most common TEAEs (>10%) were nasal discomfort, nausea, vomiting, and headache. TEAEs did not appear to correlate with dose.
- 3 There were no clinically significant findings for laboratory parameters, vital signs, ECGs or physical examinations.
- 4 Blood pressure and heart rate increases were transient and resolved within 90 min without intervention. None were considered clinically significant.
- 5 Results from the C-SSRS showed participants experienced no increase in suicidal thoughts, intentions or behavior.

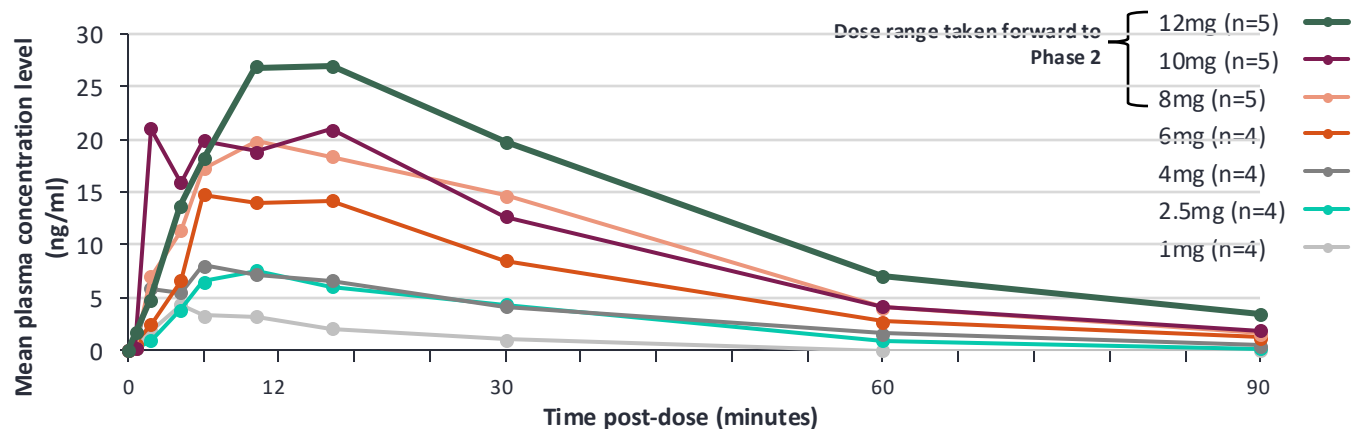
PK/PD results demonstrated a **dose proportional profile** with perceptual effects generally **resolving within 60-90 min**

BPL-003

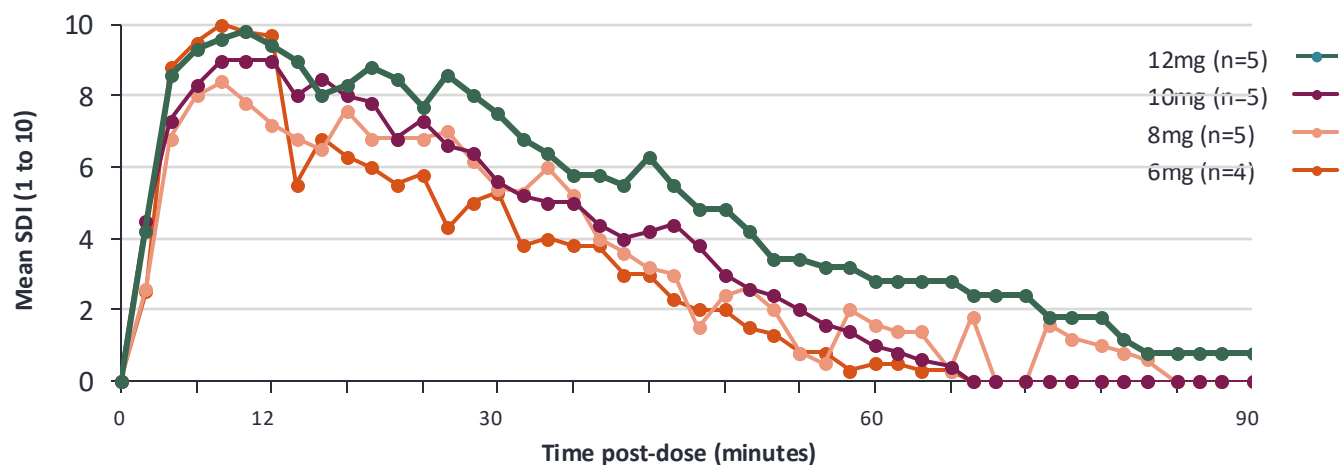
Phase 1 Results

BPL-003 PHASE 1 RESULTS

BPL-003
Phase 1
Pharmacokinetic
Profile



BPL-003 Phase 1
Subjective Drug
Intensity (SDI)
Rating



KEY TAKEAWAYS

Pharmacokinetics (PK)

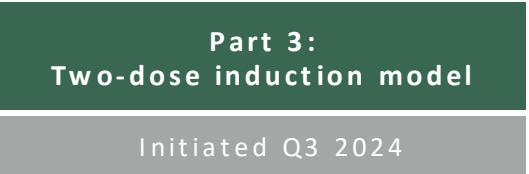
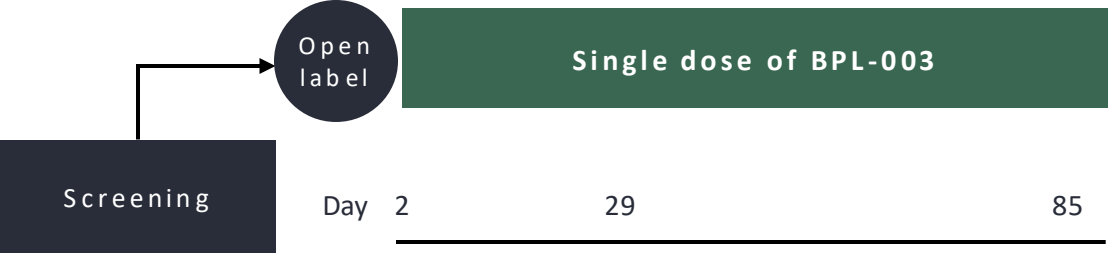
- Exposure was dose-proportional
- Rapid onset with mean Tmax of 6-17 min
- Mean half life of 15-30 min

Pharmacodynamics (PD):

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

Completed Part 1 of the open-label Phase 2a study investigating BPL-003 for patients with TRD

BPL-003 PHASE 2A – TRIAL DESIGN



Study Details:

- Open-label study evaluating a single dose of BPL-003 nasal spray, in patients with moderate-to-severe TRD
- Parts 1 & 3 are in patients not on anti-depressants, Part 2 is in patients who are also taking select SSRIs to explore effects of co-administration
- Psychological support during preparation, dosing and integration

Key Inclusion Criteria:

- Montgomery-Asberg Depression Rating Scale (MADRS) score ≥ 24
- Part 1 & 3: willing and able to discontinue current antidepressants
- Part 2: on current stable dose of antidepressant SSRI therapy

Key Objectives:

- Primary Endpoint:**
- Safety and tolerability of BPL-003 8
- Other Secondary Endpoints:**
- MADRS change through Week 12
 - Remission and response rates through Week 12

BPL-003 produced **meaningful clinical response** and **durable remission rates** after just a single dose, and was generally **well-tolerated** with no serious adverse events

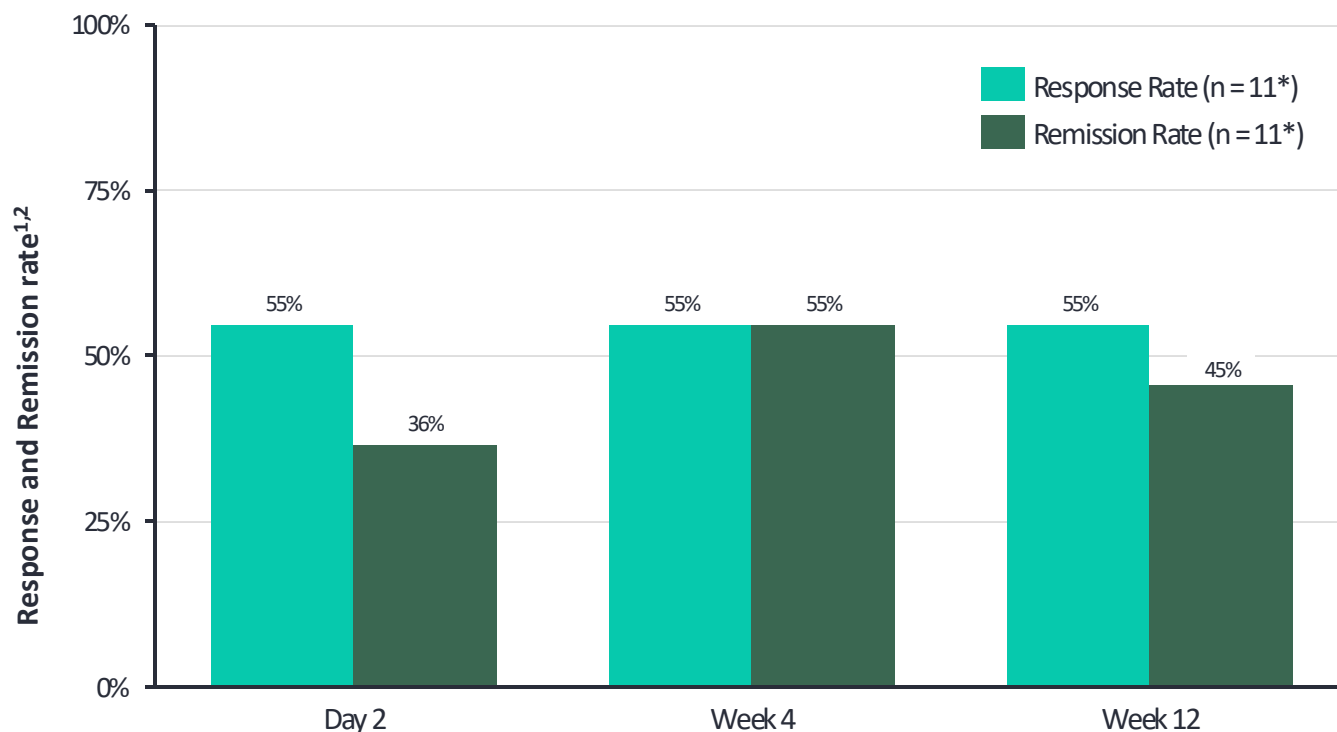
BPL-003

Phase 2a TRD Results

BPL-003 PHASE 2A – RESULTS

KEY TAKEAWAYS

Response and remission rate¹ in TRD patients after a single dose of BPL-003



1

55% of patients achieved clinical response on Day 2 and this rate of response was maintained at Week 12

2

At Week 4, 55% of patients achieved both clinical remission and response

3

Acute effects resolved within an average time of less than 2 hours

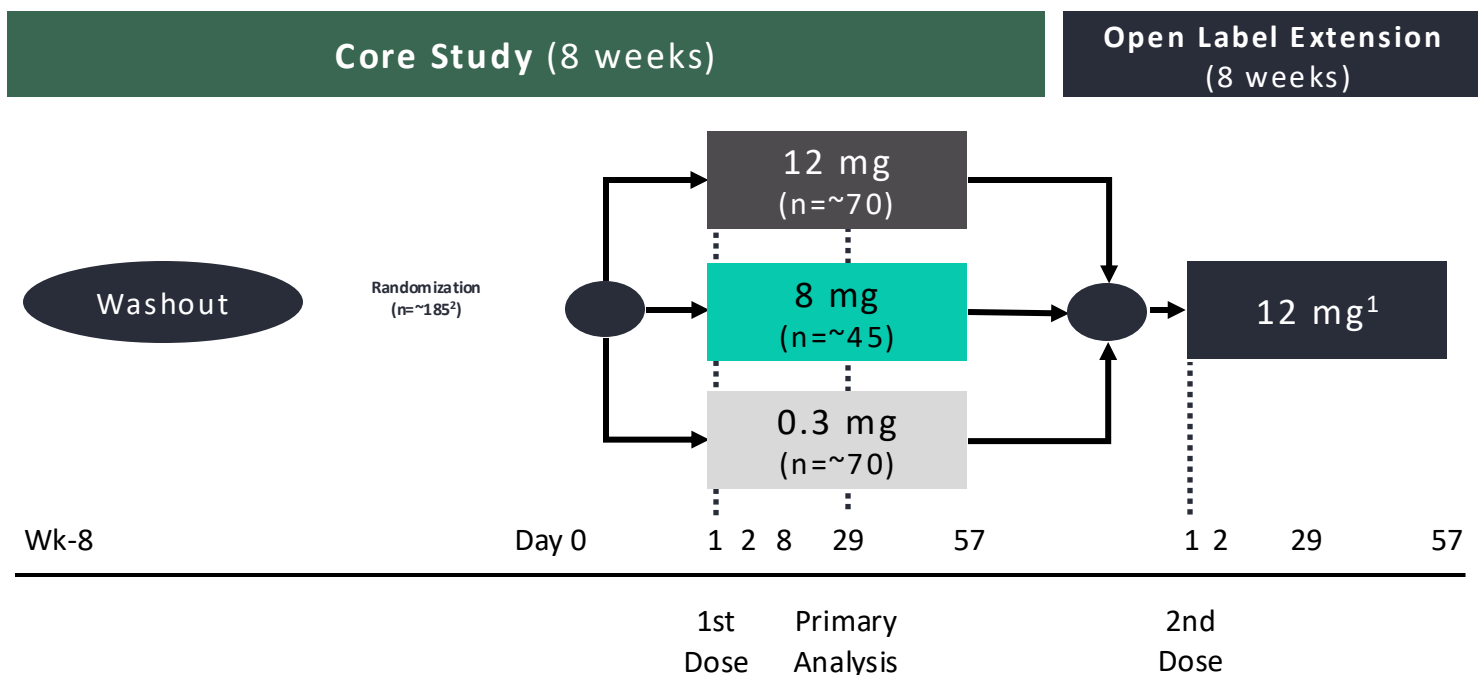
4

Most common AEs (>10%) were nasal discomfort, headaches, nausea and vomiting, broadly consistent with Phase 1 findings

BPL-003 randomized, quadruple-masked, monotherapy **Phase 2 study** in moderate to severe TRD patients

BPL-003 | Phase 2b Clinical Trial Design

BPL-003 PHASE 2B – CLINICAL TRIAL DESIGN



Key Inclusion Criteria:

- Patients with moderate to severe TRD
- Hamilton Depression Scale (HAM-D) ≥ 19
- Willing and able to discontinue current antidepressants

Key Objectives:

Primary Endpoint:

- MADRS change from baseline at Week 4, 12mg vs. 0.3mg

Other Secondary Endpoints:

- MADRS change from baseline at Day 2, Wk 1 & Wk 8
- MADRS change from baseline for 8mg vs 0.3mg
- CGI-S, PGIC, EQ-5D

TRIAL STATUS

Topline data anticipated
mid-2025



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 randomization ratio and lower than anticipated dropout rate
Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; CGI-S = Clinical Global Impressions-Severity; PGIC = Patient's Global Impression of Change; EQ-5D = EuroQoL-5D

CIAS

RL-007

FOR COGNITIVE IMPAIRMENT WITH
SCHIZOPHRENIA



RL-007 is a potential **pro-cognitive neuromodulator**, investigated in >500 participants and demonstrating **consistent cognitive effects** and **good tolerability**



Significant unmet need: currently, no approved treatments for lead CIAS indication



Reproducibility of effect: Pro-cognitive effects demonstrated in two Phase 1 and two Phase 2 trials



Tolerability: No drug-related serious adverse events in over 500 study participant exposures and minimal potential for drug-drug interactions (DDIs)



Add-on therapy to standard of care: clean DDI profile means it can likely be administered as an adjunctive to standard of care atypical antipsychotics

CIAS & Schizophrenia

RL-007

Disease Overview

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 Schizophrenia¹

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 FOR INNOVATION

~18m Cognitive impairment is very common⁴

Cognitive impairment is a common and major cause of disability in schizophrenia, with more than 80% of patients showing significant impairment

35% Schizophrenia patient employment rate

Five years following diagnosis, only 10% of schizophrenia patients have employment; being unemployed is primarily related to lower cognitive and social functioning⁵

0 FDA approvals for CIAS

As of November 2024, there are no FDA approved treatments for CIAS⁶

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

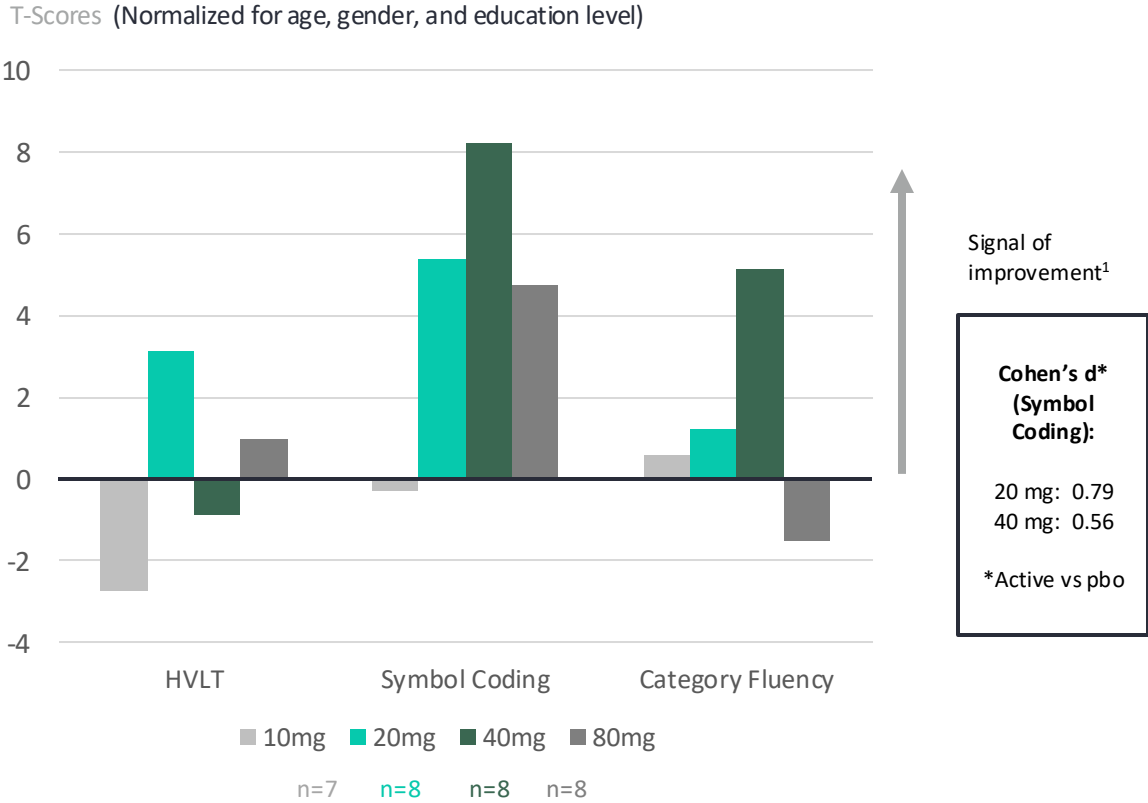
4. Bora et al, Cognitive Impairment in Schizophrenia and Affective Psychoses: Implications for DSM-V Criteria and Beyond

5. Holm M et al, Employment among people with schizophrenia or bipolar disorder: 2021

6. GlobalData (as of 11/15/2022)

RL-007 demonstrated potential to **improve cognitive signals** on a subset of MCCB neurocognitive endpoints

RL-007 PHASE 2A TRIAL - EFFICACY DATA ON COMPONENTS MCCB COMPOSITE



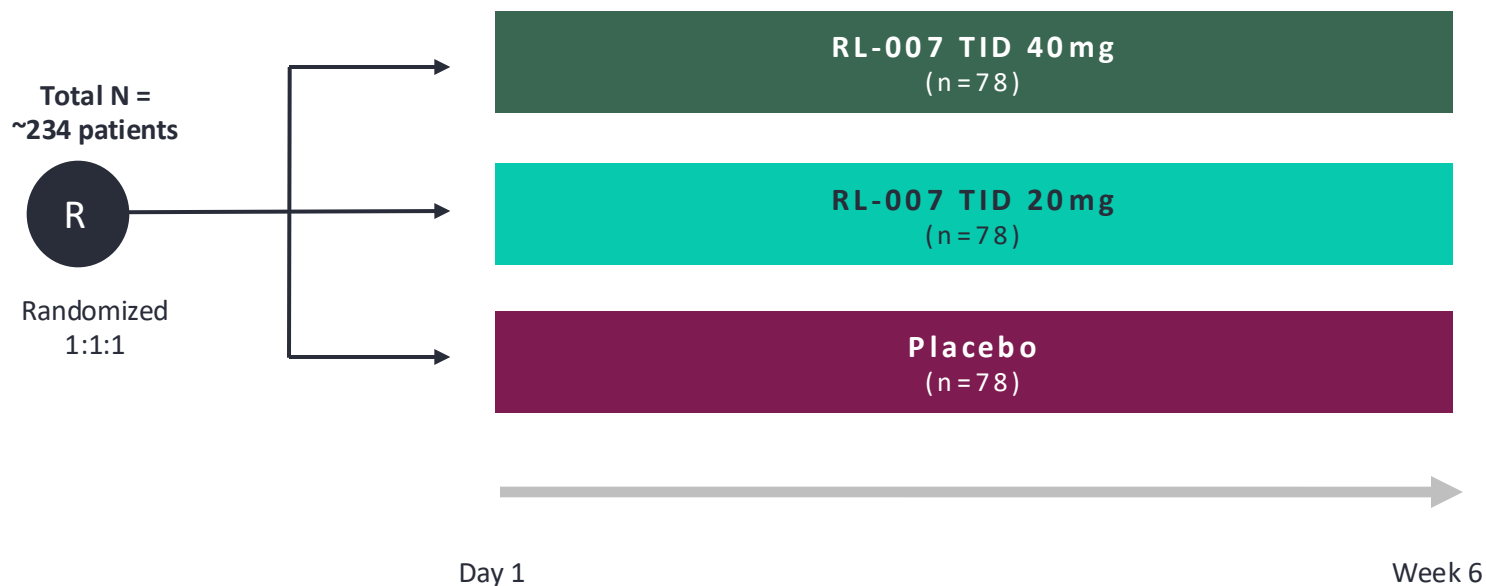
KEY TAKEAWAYS

- 1 Cognitive function was assessed in 31 patients with CIAS across four cohorts (10, 20, 40 & 80mg). Patients received four doses of placebo followed by six doses of RL-007 over 4-days¹
- 2 Study demonstrated dose-related trends for improvements on each MCCB sub-component neurocognitive test completed: Hopkins Verbal Learning Test, BACS Symbol Coding & Category Fluency
- 3 On the BACS Symbol Coding test, the best correlate of the MCCB total score, a Cohen's d effect size of 0.79 and 0.56 was seen at the 20mg and 40mg doses respectively versus placebo
- 4 qEEG data also 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.

A randomized, placebo-controlled **Phase 2b study** of RL-007 is currently underway in ~234 patients with CIAS with topline **data anticipated in mid-2025**

RL-007 | Phase 2b Study Design

RL-007 PHASE 2B – STUDY DESIGN



Primary Endpoint:

- MCCB neurocognitive composite score at Week

Key Secondary Endpoints:

- Select Individual Components of MCCB, including BACS Symbol Coding
- Clinical Global Impression Score

TRIAL STATUS

First patient dosed
in Q1 2023

Topline data anticipated
mid-2025

