



**AtaiBeckley Announces Positive  
Topline Data from the Phase 2b  
Open-Label Extension Study of  
BPL-003 in Patients with  
Treatment-Resistant Depression**

*November 10, 2025*

# Disclaimer

The following disclaimer applies to this Presentation. For the purposes of this disclaimer, “Presentation” means this document, its contents or any part of it, any oral presentation, any question or answer session and any written or oral material discussed or distributed during the Presentation meeting. The purpose of this Presentation is to provide an overview of AtaiBeckley (the “Company”).

The information in this Presentation is not intended to form the basis of any contract. This Presentation does not constitute an offer or invitation for the sale, issuance or purchase of securities or any businesses or assets described in it, nor does it give or purport to give legal, tax or financial advice. Nothing herein shall be taken as constituting the giving of investment advice or an inducement to enter into investment activity in any jurisdiction and this Presentation is not intended to provide, and must not be taken as, the basis of any decision and should not be considered as an invitation, inducement, solicitation or recommendation to purchase, underwrite, subscribe for or otherwise acquire any securities of the Company. The recipient must make its own independent assessment and such investigations as it deems necessary. Save as set out below, the Presentation has been prepared on the basis of information held by the Company and also from publicly available information. This information, which does not purport to be comprehensive, has not been independently verified by or on behalf of the Company. The Presentation does not constitute an audit or due diligence review and should not be construed as such.

The Company nor any of such its respective directors, officers, employees, affiliates, advisers or agents (the “Associates”) accepts any responsibility, obligation or liability whatsoever for, or makes any representation or warranty, express or implied, as to, and no reliance should be placed on, the fairness, truth, fullness, accuracy, completeness or correctness of, the information in this Presentation or whether any information has been omitted from the Presentation or as to any other information relating to the Company, whether written, oral or in a visual or electronic form, and howsoever transmitted or made available or for any loss howsoever arising from any use of this Presentation, its contents or otherwise arising in connection therewith. Except where otherwise indicated in the Presentation, the information provided therein is based on matters as they exist at the date of preparation of the Presentation and not as of any future date and will be subject to updating, revision, verification and amendment without notice and such information may change materially. Neither the Company nor any of its Associates is under an obligation to update, revise or keep current the information contained in this Presentation to which it relates or to provide the recipient of this Presentation with access to any additional information that may arise in connection with it and any opinions expressed in this Presentation are subject to change without notice.

Nothing contained in this Presentation is or should be relied upon as a promise or representation as to the future.

## Speakers on today's call:



**Srinivas Rao, M.D., Ph.D.**  
Co-Founder &  
Chief Executive Officer



**Kevin Craig, M.D.**  
Chief Medical Officer



**Robert Conley, M.D.**  
Chief Research &  
Development Officer

# Open-label extension of the BPL-003 Phase 2b clinical trial demonstrated additional and durable antidepressant effects after a second dose

1

A 12 mg dose of BPL-003 administered 8 weeks after an initial 12 mg, 8 mg or 0.3 mg dose in the core study of the Phase 2b clinical trial produced additional rapid, clinically meaningful antidepressant effects in patients with treatment-resistant depression (TRD), which were sustained for up to 8 weeks

---

2

Patients who received an active dose (either 8 mg or 12 mg) of BPL-003 in the core study of the Phase 2b clinical trial, achieved a response rate of 63% and a remission rate of 48% at Week 8 (Week 16 of the Phase 2b clinical trial)

---

3

BPL-003 was generally well-tolerated, with the majority of TEAEs occurring on the day of dosing, classified as mild or moderate, and transient in nature

---

4

BPL-003 has the potential to fit into the established 2-hour interventional psychiatry treatment paradigm

---

5

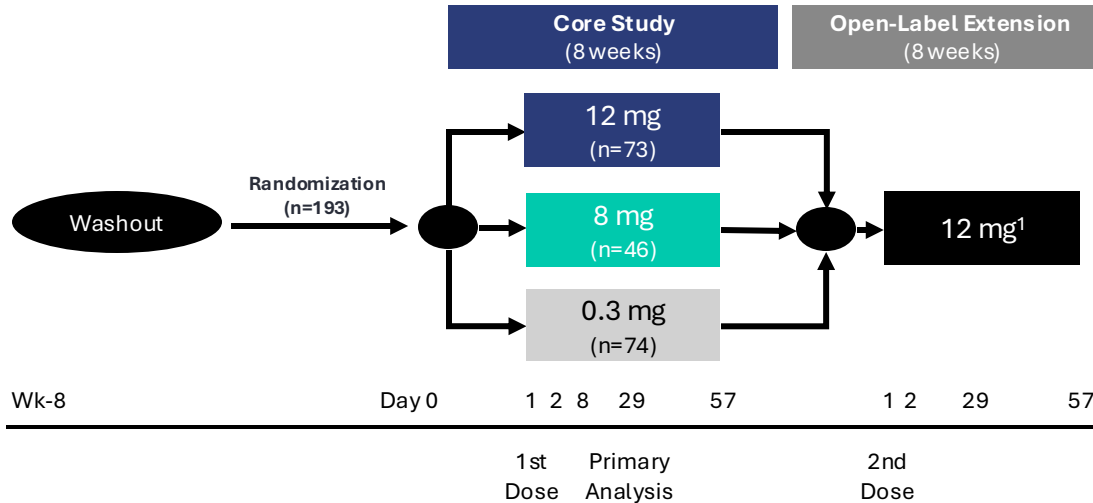
BPL-003 was granted Breakthrough Therapy designation by the U.S. Food and Drug Administration for TRD, in recognition of its potential to deliver substantial improvement over existing therapies

# BPL-003 Phase 2b Clinical Trial Overview



# Randomized, quadruple-masked Phase 2b clinical trial of BPL-003 in patients with moderate to severe TRD, with an open-label extension

## PHASE 2B CLINICAL TRIAL DESIGN



### KEY INCLUSION CRITERIA

- Patients with moderate to severe TRD
- Hamilton Depression Scale (HAM-D)  $\geq 19$
- Willing and able to discontinue current antidepressants<sup>2</sup>

### KEY DETAILS

#### PRIMARY ENDPOINT:

- MADRS change from baseline at Week 4 (Day 29), 12 mg vs. 0.3 mg

#### OTHER SECONDARY ENDPOINTS:

- MADRS change from baseline at Day 2, Week 1 & Week 8
- MADRS change from baseline for 8mg vs 0.3 mg at Week 4
- Responder and remission rates

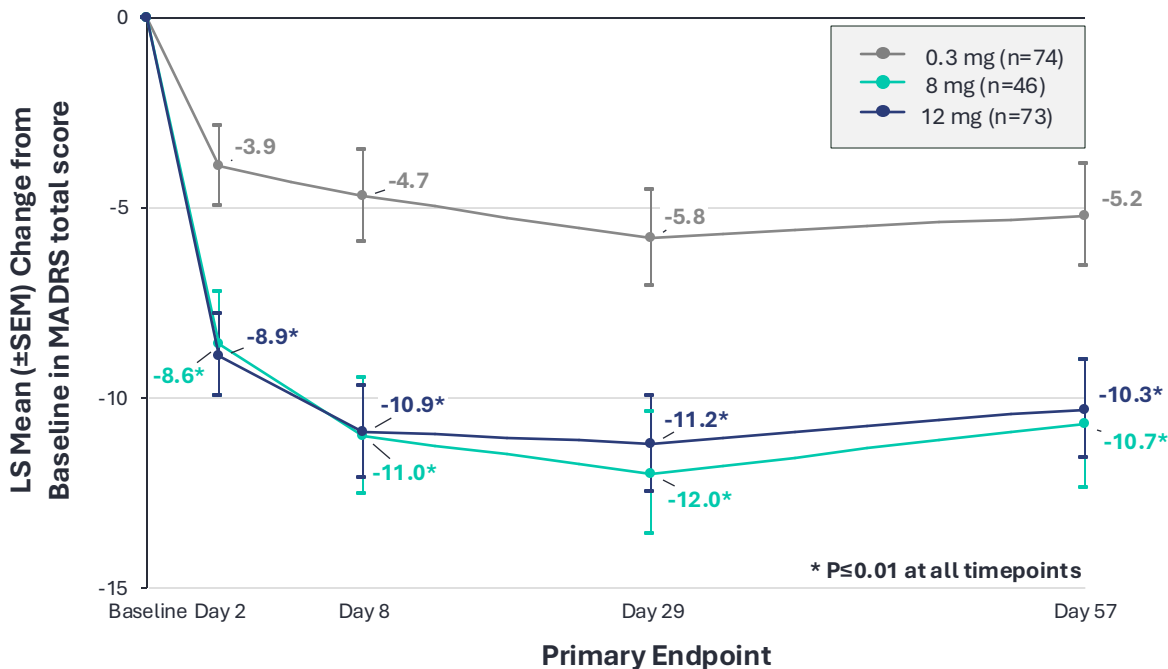
1. Patients entering the open-label extension were randomized to receive either a single 12mg dose or a biphasic 4mg and 8mg dose approximately 10 minutes apart;

2. Patients were washed out as applicable

Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale

# Core study final results: Single-dose of BPL-003 met primary endpoint, with effects sustained out to Week 8

## CHANGE FROM BASELINE IN MADRS TOTAL SCORE – 12 MG & 8 MG VS. 0.3 MG



### KEY TAKEAWAYS

#### Primary endpoint:

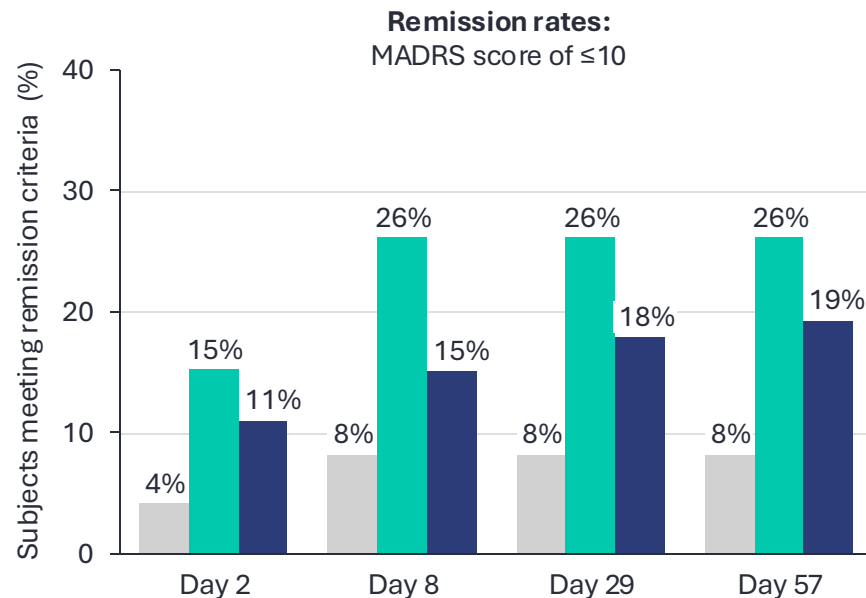
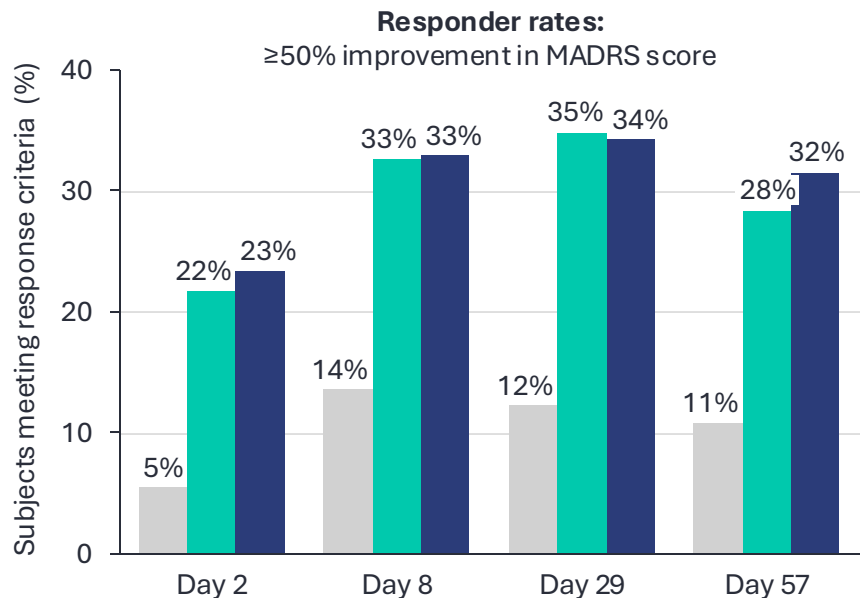
- Statistically significant MADRS difference observed at Day 29 (Week 4) following a single 8 mg or 12 mg dose vs. 0.3 mg:

Treatment Arm	MADRS change (Day 29)		P-value
	From baseline	Compared to 0.3mg	
8mg	-12.0	-6.2	<0.01
12mg	-11.2	-5.3	<0.01

- Efficacy was statistically significant as early as Day 2, with durable response through Week 8 (Day 57) for 8 mg and 12 mg dose vs. 0.3 mg
- 8 mg dose demonstrated comparable efficacy to 12 mg, suggesting it may be sufficient to achieve maximal therapeutic benefit

# Core study final results: 8 mg dose of BPL-003 produced rapid & lasting clinical response in >30% of patients, with 26% in remission at Week 8

## RESPONDER & REMISSION RATES FOR SINGLE DOSE BPL-003



**KEY:** 0.3mg (N=74) 8mg (N=46) 12mg (N=73)

# Core study final results: BPL-003 was generally well-tolerated, adverse events were transient, with no drug-related serious adverse events

## TREATMENT-EMERGENT ADVERSE EVENTS IN CORE STUDY

	0.3 mg (N=74)	8 mg (N=46)	12 mg (N=73)	Overall (N=193)
<b>TEAEs</b>	<b>N participants (%)</b>			
Any TEAE	54 (73%)	35 (76%)	62 (85%)	151 (78%)
Any Drug Related TEAE	25 (34%)	32 (70%)	60 (82%)	117 (61%)
Any Drug Related Serious TEAE	0 (0%)	0 (0%)	0 (0%)	0 (0%)
<b>Most Reported Drug Related TEAEs(≥10% of subjects)</b>				
Nausea	1 (1%)	13 (28%)	27 (37%)	41 (21%)
Headache	7 (10%)	9 (20%)	20 (27%)	36 (19%)
Administration site pain	5 (7%)	8 (17%)	16 (22%)	29 (15%)
Blood pressure increased <sup>1</sup>	1 (1%)	6 (13%)	15 (21%)	22 (11%)
Administration site discomfort	2 (3%)	5 (11%)	12 (16%)	19 (10%)
Anxiety	2 (3%)	2 (4%)	10 (14%)	14 (7%)
Vomiting	0 (0%)	6 (13%)	9 (12%)	15 (8%)

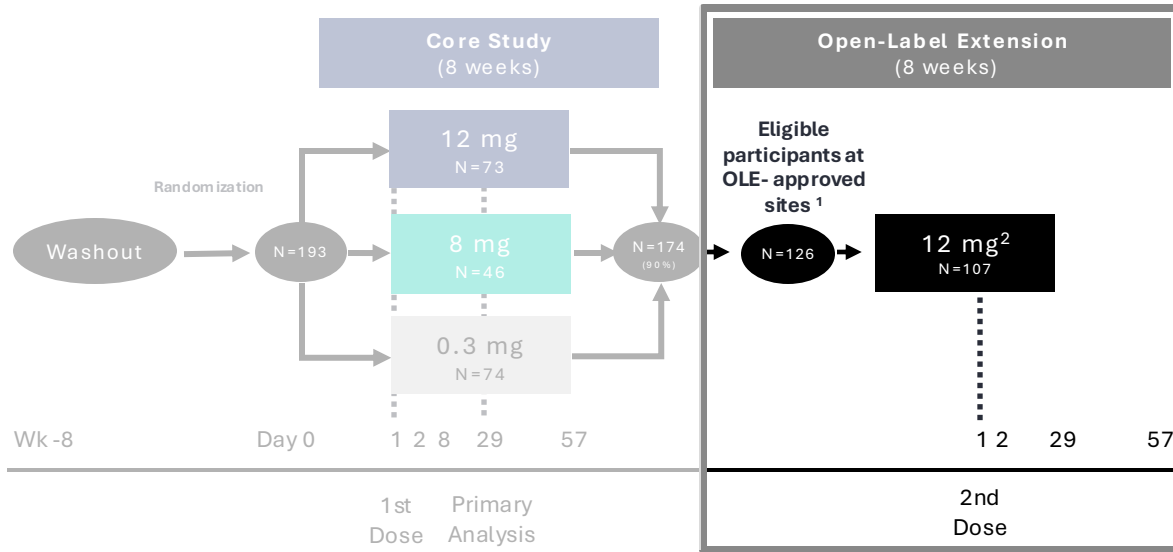
## KEY TAKEAWAYS

- >99% of TEAEs were **mild or moderate** with no drug related Serious Adverse Events (SAEs)
- Dose related increases in TEAEs suggest the 8 mg dose was better tolerated than the 12mg dose
- Majority of TEAEs occurred on the day of dosing
- Blood pressure and heart rate increases were transient with mean levels returning to baseline within ~1 hour
- Majority of patients were deemed ready for discharge at the 90-minute post-dose assessment

1. Includes the preferred terms Blood pressure increased, Blood Pressure diastolic increased and Blood pressure systolic increased  
Abbreviations: TEAEs = Treatment Emergent Adverse Events

# Open-label extension (OLE) study designed to assess the safety and efficacy of a 12 mg dose of BPL-003, given 8 weeks after initial dose

## PHASE 2B OPEN-LABEL EXTENSION CLINICAL TRIAL DESIGN



### KEY DETAILS

- Primarily designed to assess safety of a second dose of BPL-003
- Efficacy assessed at multiple time points by centralized, blinded raters
- 8-week long observation period to demonstrate durability of effect
- Participants were provided psychological support, but not active psychotherapy

1. Eligibility for the OLE study required completion of the core study and regulatory & ethics approval of the OLE protocol at the participants' site. 126 out of 174 total completers were at sites with OLE protocol approval and were eligible to enter the OLE portion of the study and 107 received a BPL-003 dose; 2. 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

# BPL-003 OLE Topline Results

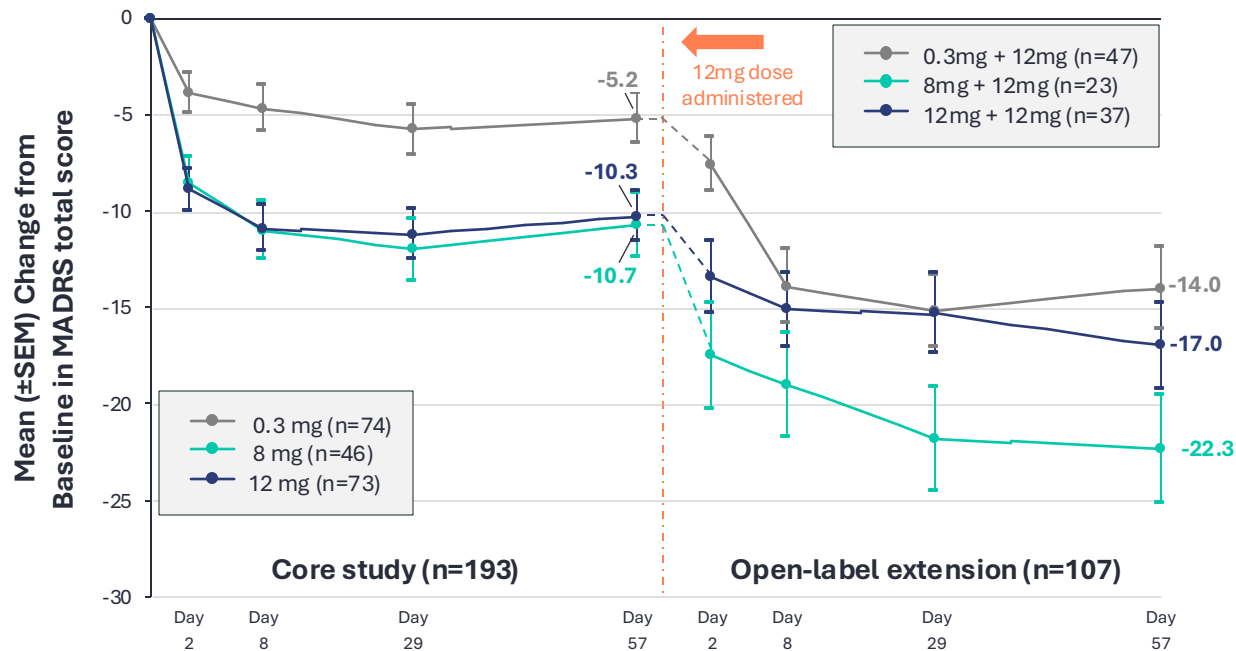


# Demographics and baseline characteristics for the OLE study

	<i>Overall (N=107)</i>
<b>Patient Disposition</b>	
Age, years, mean (SD)	40.0 (10.0)
Female, n (%)	62 (58%)
Race, White, n (%)	100 (94%)
Completed OLE study, n (%)	95 (89%)
<b>Baseline Disease Characteristics</b>	
Core Phase: MADRS Total Score, mean (SD)	33.0 (5.9)
OLE Phase: MADRS Total Score, mean (SD)	24.1 (11.2)
<b>Baseline Depressive Episode History</b>	
Time since initial diagnosis, years, mean (SD)	12.9 (9.3)
No. of lifetime episodes, mean (SD)	4.2 (4.4)
Duration of current episode, years, mean (SD)	2.8 (3.1)
No. of failed antidepressant medications in current episode, mean (SD)	2.4 (0.7)
No. of participants who washed out antidepressants during core screening, n (%)	72 (67%)

# Second dose of BPL-003 produced additional clinically meaningful antidepressant effects, sustained for a further 8 weeks

## CHANGE FROM BASELINE IN MADRS TOTAL SCORE – EXPLORATORY<sup>1</sup>



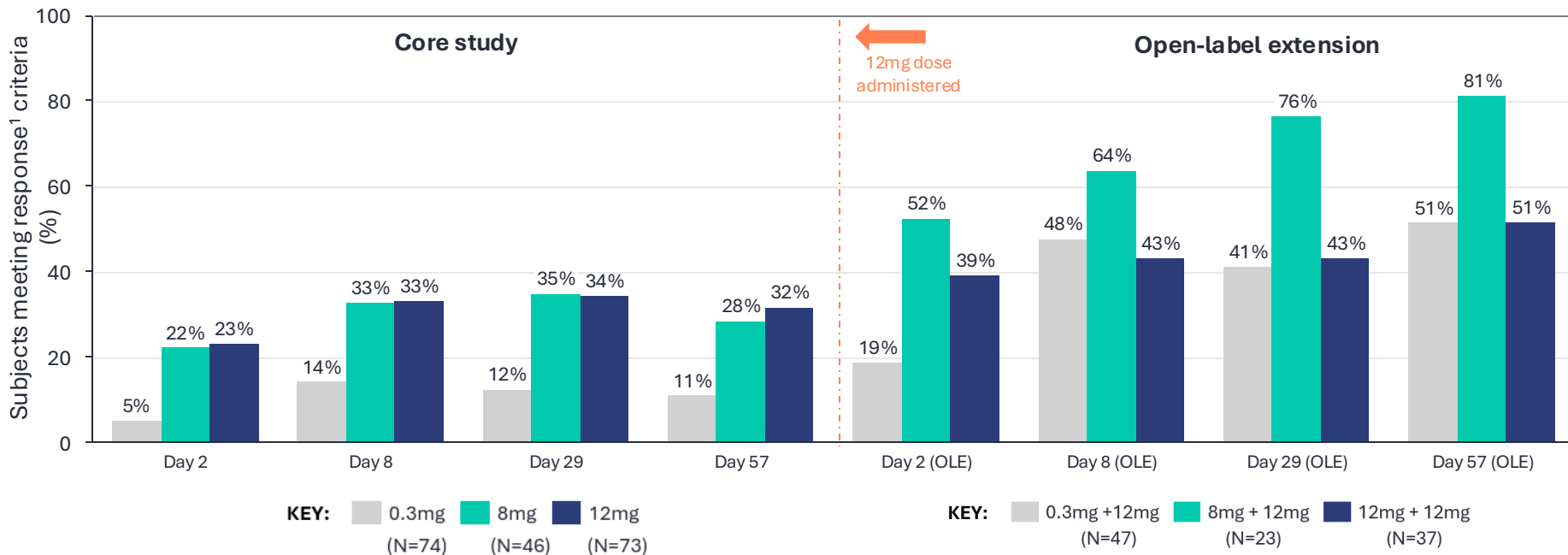
### KEY TAKEAWAYS

- All patients who entered the OLE study received a 12 mg dose of BPL-003, regardless of MADRS score
- Patients who received **0.3 mg in the core study** showed MADRS reductions in line with the antidepressant effects seen in patients who received an active dose in the core study
- Patients who received an **active dose in the core study (either 8 mg or 12 mg)** showed mean reduction in MADRS score of 19.0 points at Day 57 in the OLE compared to baseline at the start of the Phase 2b clinical trial
- **8 mg dose selected for Phase 3 studies**

<sup>1</sup> Core study efficacy analyses were conducted using a mixed model for repeated measures (MMRM); open-label extension results are based on observed data  
Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-Label Extension

# Responder rates continued to improve following a second dose of BPL-003

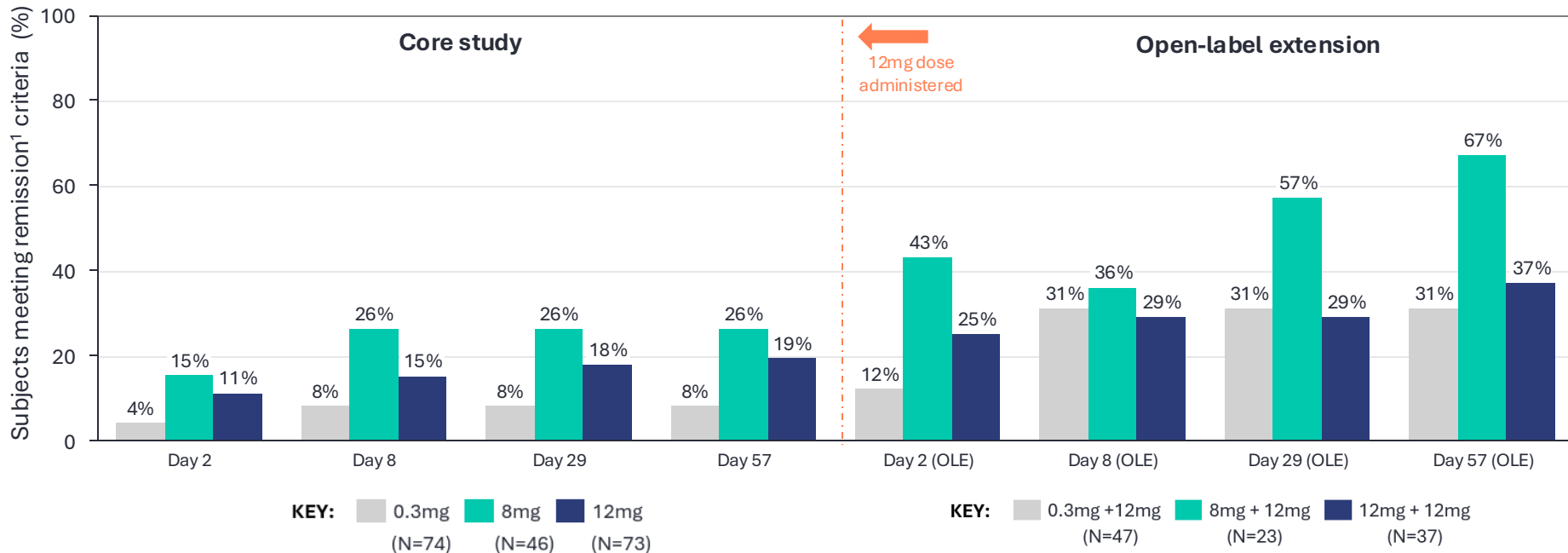
## RESPONDER RATES FOLLOWING SECOND DOSE OF BPL-003 IN OLE - EXPLORATORY



1. Response defined as  $\geq 50\%$  improvement in MADRS score  
 Abbreviations: MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension

# Remission rates continued to improve following a second dose of BPL-003

## REMISSION RATES FOLLOWING SECOND DOSE OF BPL-003 IN OLE - EXPLORATORY



1. Remission defined as MADRS score of  $\leq 10$

Abbreviation: MADRS = Montgomery-Åsberg Depression Rating Scale; OLE = Open-label extension

# BPL-003 was generally well-tolerated, with majority of adverse events characterised as mild or moderate and transient in nature

## TREATMENT-EMERGENT ADVERSE EVENTS IN OLE STUDY - EXPLORATORY

	Overall (N=107)
TEAEs	N participants (%)
Any TEAE	92 (86%)
Any Drug Related TEAE	85 (79%)
Any Drug Related Serious TEAE	1 (1%)
Most Reported Drug Related TEAEs (≥10% of subjects)	
Nausea	30 (28%)
Headache	24 (22%)
Administration site pain	18 (17%)
Administration site discomfort	17 (16%)
Blood pressure increased <sup>1</sup>	14 (13%)
Anxiety	14 (13%)
Vomiting	11 (10%)
Psychomotor hyperactivity	11 (10%)

### KEY TAKEAWAYS

- Majority of TEAEs occurred on day of dosing and were classified as **mild or moderate in severity** and **transient in nature**
- Most commonly reported side effects included nausea, headache, administration site pain, administration site discomfort, blood pressure increases and anxiety
- One serious drug-related AE was reported which resolved with additional in-patient monitoring and support<sup>2</sup>
- Average time to meet readiness-for-discharge criteria was within 2 hours of dosing

1. Includes the preferred terms: Blood pressure increased and Blood pressure systolic increased; 2. One serious drug-related adverse event was reported where a participant who had received 0.3 mg in the core study experienced dissociation and suicidal ideation requiring inpatient monitoring and support after receiving 12 mg of BPL-003 in the OLE study. The symptoms were considered resolved the next day.  
Abbreviations: TEAEs = Treatment Emergent Adverse Events; AE = adverse event; OLE = open-label extension

# Key achievements and upcoming catalysts for the BPL-003 program

## What BPL-003 has demonstrated so far:

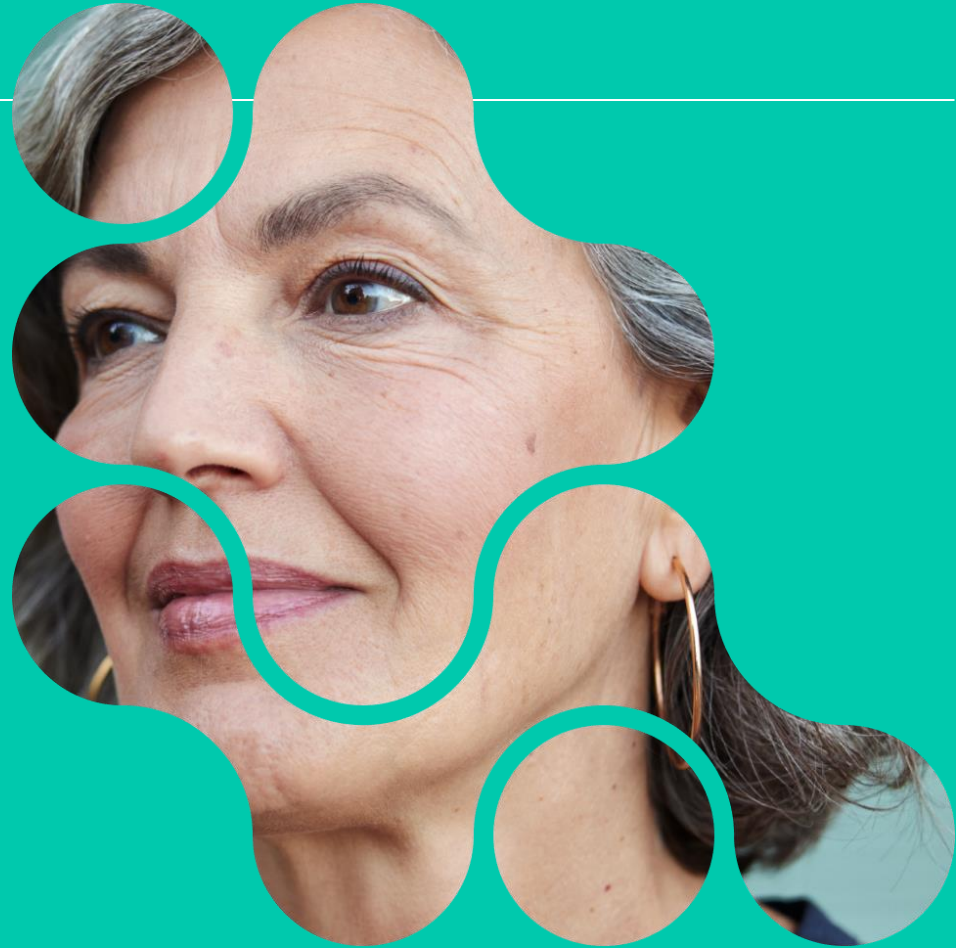
- ✓ Rapid, robust, and durable antidepressant effect out to 4 months after only two doses
- ✓ Favorable tolerability profile and acceptability data
- ✓ POC data in adjunctive patients and 2-dose induction model shows similar tolerability and potential for improved efficacy
- ✓ Short psychedelic duration therapy with a 2-hour in-clinic treatment time; potential to fit into the established interventional psychiatry treatment paradigm
- ✓ Granted Breakthrough Therapy designation by U.S. FDA
- ✓ Support for advancement of 8mg dose to Phase 3

## Anticipated upcoming program catalysts:

- ❑ Provide feedback from FDA End-of-Phase 2 meeting: Q1 2026
- ❑ Initiate Phase 3 studies, pending outcome of FDA meeting: Q2 2026

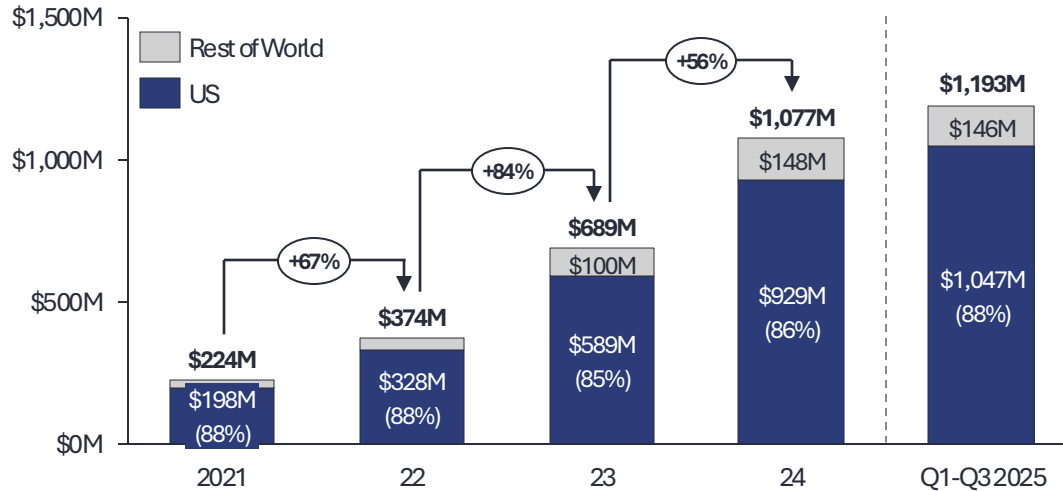
# BPL-003

## Opportunity and Competitive Landscape



# Spravato® (esketamine) achieved blockbuster status and established the 2-hour in-clinic interventional psychiatry treatment paradigm

## SPRAVATO REPORTED GLOBAL ANNUAL SALES<sup>3</sup> (2021 – Q3'25)



**JNJ now highlights SPRAVATO as a “key franchise” guiding \$3 - 3.5 billion in annual sales by 2028**

### 2-hour dosing protocol with established infrastructure

- Patients monitored for at least 2 hours at each treatment session
- Delivered intranasally under the supervision of a healthcare provider
- >5,000 certified clinics<sup>1</sup>
- ~40-50K US patients treated in 2024<sup>2</sup>

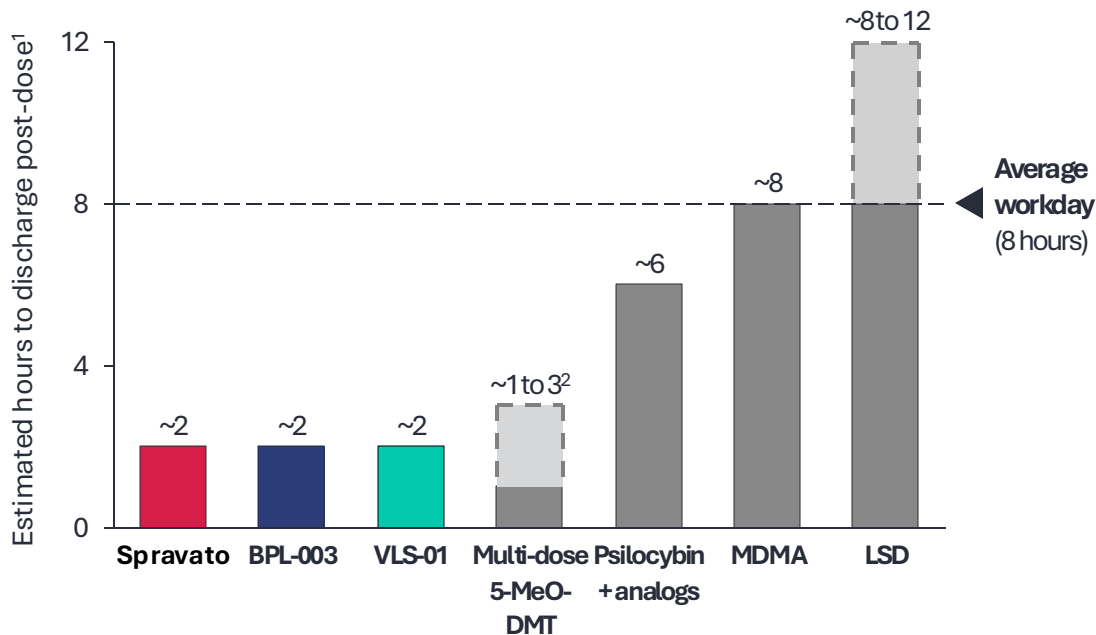
### Potential for many administrations per year

- Weeks 1 to 4: twice per week
- Weeks 5 to 8: once weekly
- Week 9 and after: every two weeks or once weekly

1. <https://www.spravato.com/spravato-available-treatment-centers/>; 2. Based on global annual sales and gross to net pricing assumptions; 3. Johnson&Johnson Q4 and Full-Year 2024 Results: <https://www.investor.jnj.com/news/news-details/2025/Johnson--Johnson-Reports-Q4-and-Full-Year-2024-Results/default.aspx>

# BPL-003 is uniquely designed to leverage the 2-hour in-clinic interventional psychiatry treatment paradigm established by Spravato®

## ANTICIPATED TIME TO DISCHARGE FROM CLINIC POST-DOSE<sup>1</sup> (Illustrative)

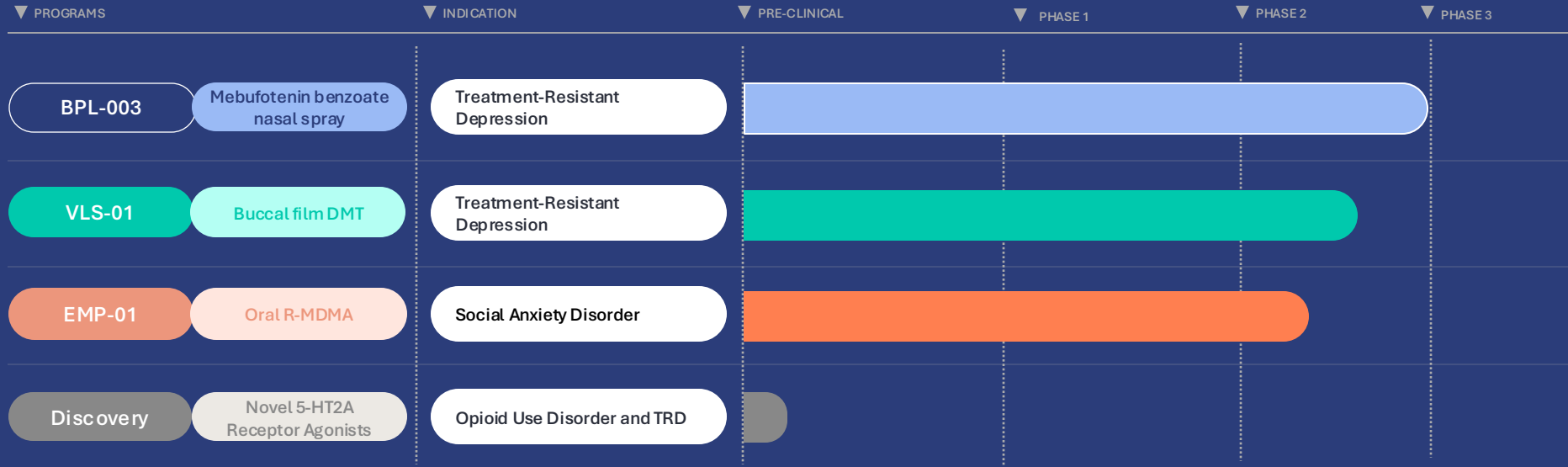


## ASPECTS SUPPORTING COMMERCIAL POTENTIAL

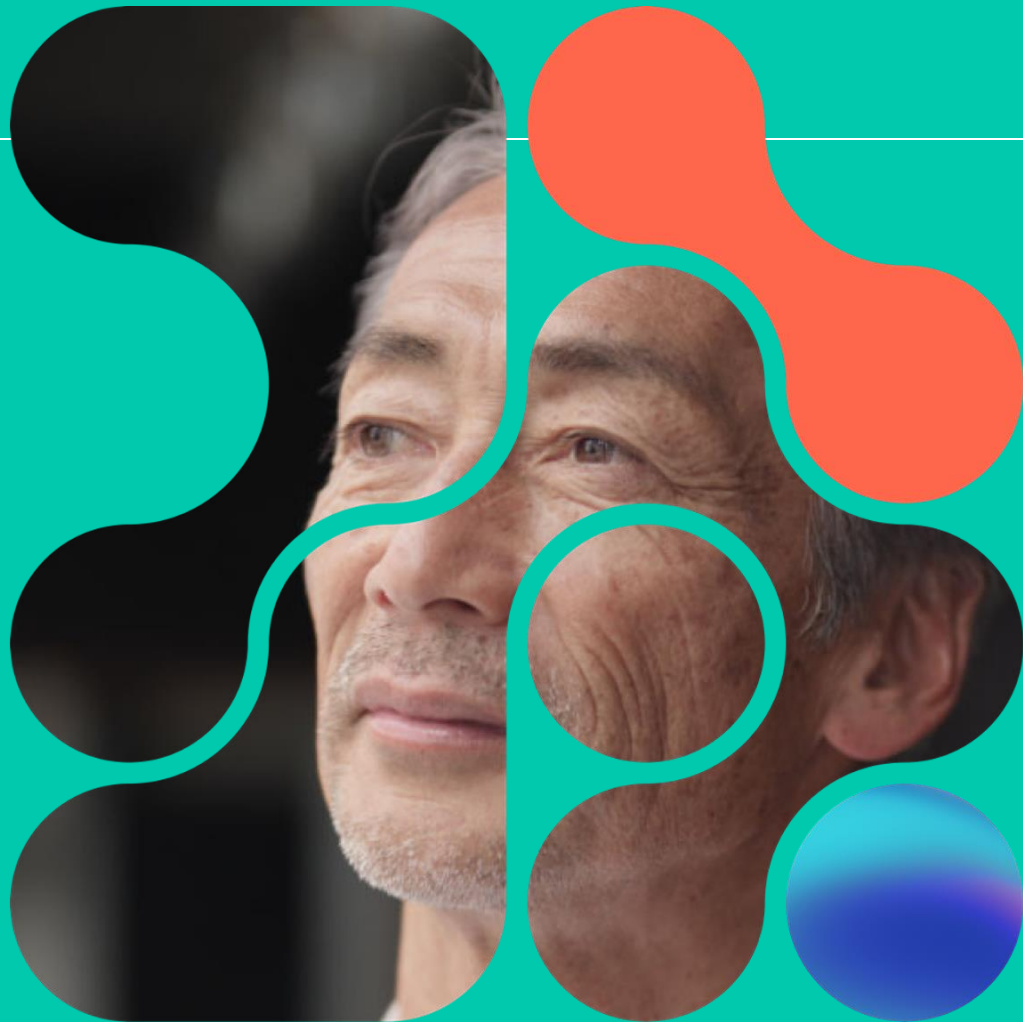
- **Predictable 2-hour treatment:** the potential to fit into the 2-hour in-clinic treatment paradigm established by Spravato
- **Potential extended durability:** 1-2 doses of a psychedelic treatment provides a sustained effect, simplifying the dosing schedule compared to Spravato (once weekly or biweekly)
- **Scalability limits of other psychedelics:** longer duration psychedelics like psilocybin, or multi-dose models, require extended clinic time and therapist involvement
- **Potential to significantly improve use of infrastructure:** lower dosing frequency compared to Spravato, and avoiding full day occupancy requirements of other psychedelics, could lower provider burden and improve payer receptivity

1. Subject to further validation through future clinical studies and real-world evidence; 2. If multi-dose required

# AtaiBeckley's pipeline of novel psychedelic-based neuroplastogens is designed to address urgent unmet needs in mental health



# Q&A





**Thank you**