

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

**Company Overview – September 2023** 



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



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



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



Six clinical-stage drug development programs, each with a robust package of prior clinical evidence



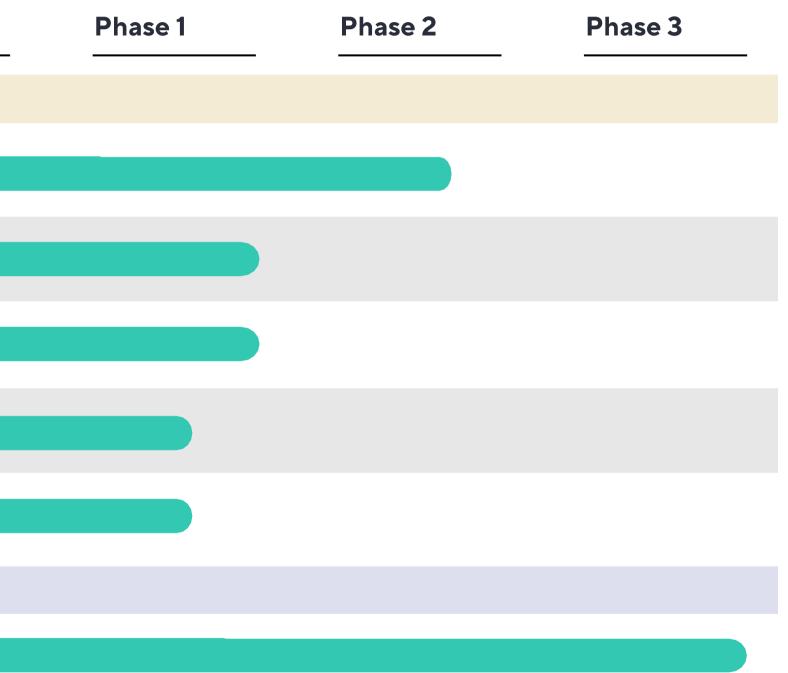
Validated operating model and ability to capture value: IPO of COMPASS Pathways in 2020 and licensing deal between Otsuka and atai subsidiary Perception Neuroscience in 2021



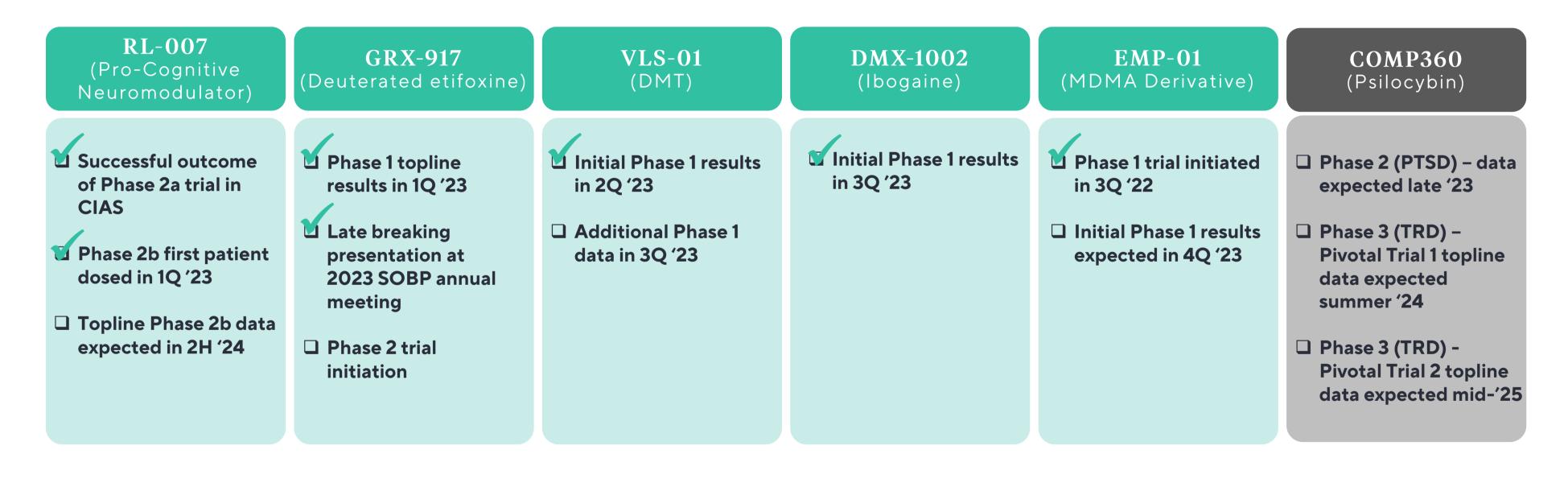
Strong cash position with anticipated cash runway into H1′26, including access to Hercules facility<sup>2</sup>

# Our strategy will be delivered through a robust pipeline of drug development programs across several mental health indications with large unmet need

Program	Primary Indication	Preclinical
CORE CLINICAL PROGRAMS		
RL-007 / Pro-cognitive neuromodulator <sup>1</sup>	Cognitive Impairment Associated With Schizophrenia	
GRX-917 / Deuterated etifoxine	Generalized Anxiety Disorder	
DMX-1002 / Ibogaine	Opioid Use Disorder	
VLS-01/DMT	Treatment-Resistant Depression	
EMP-01 / MDMA derivative	Post-Traumatic Stress Disorder	
LIMITED TO EQUITY INTEREST		
COMP360 / Psilocybin (Compass Pathways; \$CMPS)	TRD (PTSD and AN in Phase 2)	



## atai Life Sciences: Operational Focus & Program Guidance We expect to deliver several meaningful R&D milestones anticipated across our key programs through 2024



### **\$227M** in cash as of 6/30/23 provides expected runway into **1H 2026**

RL-007 for Cognitive Impairment



## **Product Overview:** RL-007 for Cognitive Impairment Demonstrated consistent pro-cognitive effects in prior clinical trials, with a favorable safety profile in >500 subjects

PRODUCT	Oral, pro-cognitive neuromodulator	Leadi
INDICATIONS	<i>Lead:</i> Cognitive impairment associated with schizophrenia <i>Potential expansions:</i> Cognitive disorders including Alzheimer's dementia and/or Autism	<ul> <li>Cog</li> <li>cha</li> <li>Suc</li> </ul>
INTELLECTUAL PROPERTY	Issued composition of matter, formulation and method of use IP	belo
CURRENT STATUS	Phase 2a CIAS trial completed in H2′21 Phase 2b first patient dosed in 1Q′23 Phase 2b data expected H2′24	<ul> <li>CIA</li> <li>mor</li> <li>No</li> </ul>

### **RL-007 Key Potential Product Features**

Pro-cognitive effects demonstrated across four prior clinical studies, including two Phase 1 and two Phase 2 trials

- Consistent "inverted-U" dose response across clinical & preclinical studies
- Demonstrated safety & tolerability with no evidence of sedative side effects across the 10 clinical studies in >500 subjects

gnitive impairment associated with schizophrenia (CIAS) is aracterized by attention, learning, memory, and exec function deficits

AS is a common and major cause of disability in schizophrenia, with ore than 80% of patients showing significant impairment<sup>2</sup>





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

### indication overview

ich deficits result in cognitive function around 2.5 standard deviations low the mean of the general population<sup>4</sup>

### o FDA approved treatments<sup>3</sup>

### **Global disease burden**

~24m

**Global sufferers of** Schizophrenia<sup>1</sup>

## >80%

**Patients with Schizophrenia** experiencing significant cognitive impairment<sup>2</sup>



<sup>1.</sup> World Health Organization

## **Clinical Evidence:** Efficacy in Canine Model & Phase 1 Study of Cognitive Impairment

RL-007 demonstrated efficacy and produced a consistent, inverted-U response curve

### Background

- Scopolamine challenge is a validated preclinical and clinical model for the induction of cholinergic dependent cognitive deficits.
- Pro-cognitive drugs are delivered in combination with scopolamine and assessed on cognitive endpoints relative to scopolamine alone.

### Key Takeaways

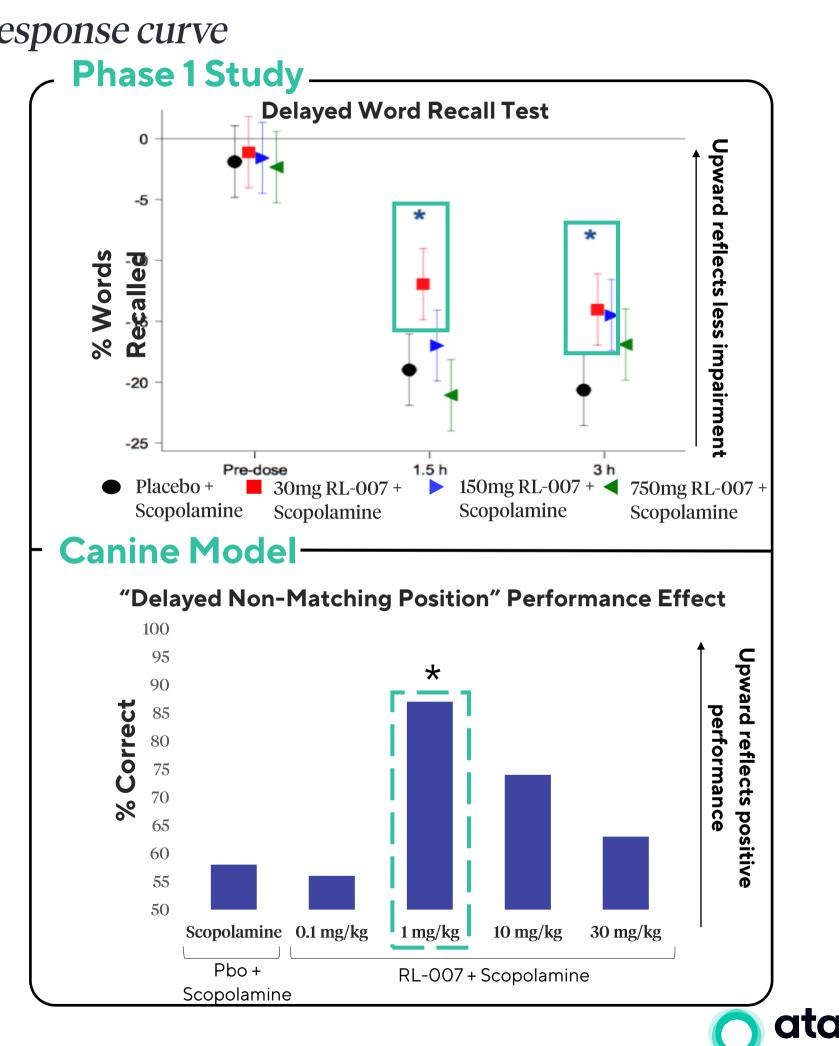
In both the Phase 1 study and the Canine Model study, intermediate doses of RL-007 resulted in statistically significant effects on cognitive endpoints.

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Across both studies, an inverted U-shape dose response curve was demonstrated, with intermediate doses performing better on cognitive endpoints relative to both high and low doses.

## 3

In the Phase 1 scopolamine challenge study: "The effects on delayed word recall were more marked than seen with the target clinical dose of Aricept (donepezil), the most widely prescribed anti-Alzheimer's drug."<sup>1</sup>



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

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

Background

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

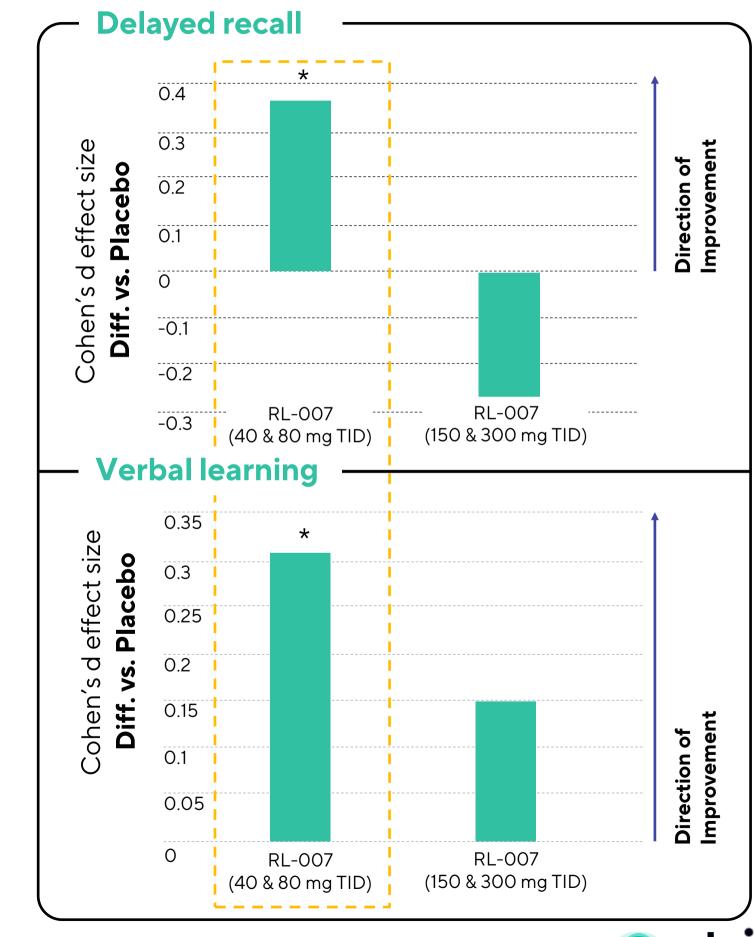
### Key Takeaways

RL-007 showed statistically significant pro-cognitive effects on learning and memory within the "Intermediate-Dose escalation" 40mg to 80mg arm.

The 40 to 80mg arm patients also reported a statistically significant improvement on the Cognitive and Physical Function Questionnaire (p = 0.021)

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Inverted U-shaped dose response whereby intermediate doses yield greater clinical activity is replicated and consistent with from prior clinical and preclinical studies





## **Clinical Evidence:** Efficacy Signals Reproduced in Phase 2a Study in CIAS atai's Phase 2a study in CIAS demonstrated positive cognitive signals on a subset of MCCB neurocognitive endpoints

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Background

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

### Key Takeaways

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

Importantly, Symbol Coding is the most sensitive subcomponent and correlates with overall performance on the MCCB neurocognitive composite, the latter being a registrational endpoint and the primary endpoint for the on-going Phase 2b study of RL-007.

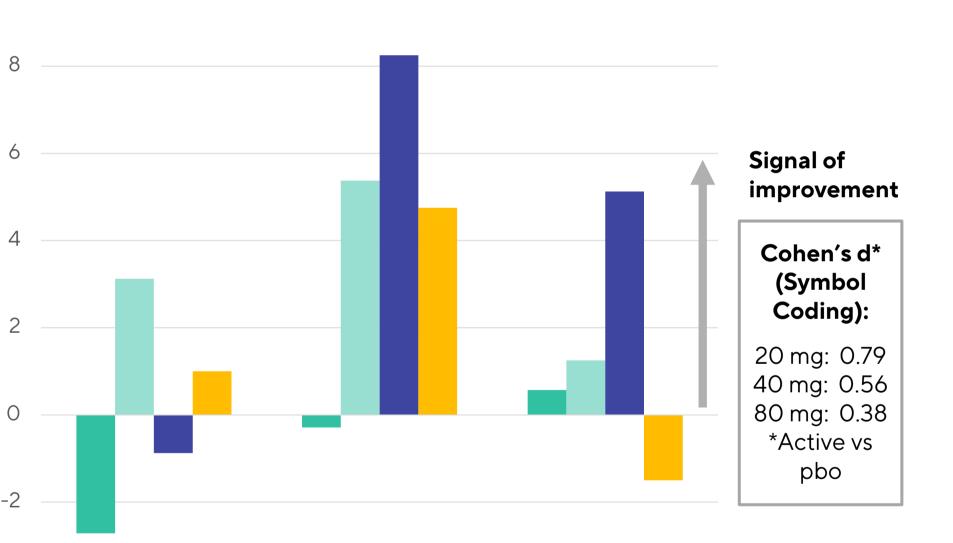
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In addition, gEEG data was consistent with the prior clinical evidence and demonstrated increases in amplitude in the alpha band and in the alpha-slow wave index, markers of alertness believed to correlate with aspects of cognition.

### PHASE 2a TRIAL - EFFICACY DATA ON COMPONENTS MCCB COMPOSITE

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







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## **Clinical Evidence:** RL-007 Safety Profile

Demonstrated safety & tolerability, including no evidence of sedation across 10 clinical studies in >500 subjects



RL-007 is well-tolerated with a favorable safety profile demonstrated across 10 clinical studies in >500 patients dosed, including up to the highest single dose of 3000mg and daily multi-dose of 900mg TID



In two-placebo controlled Phase 2 studies in over 250 patients RL-007 was dosed up to 300mg TID for six months, rates of headache and gastrointestinal issues were comparable to placebo, representing a differentiated profile from certain competitor programs in development for CIAS



RL-007 does not induce sedation, which is distinct from GABA agonists

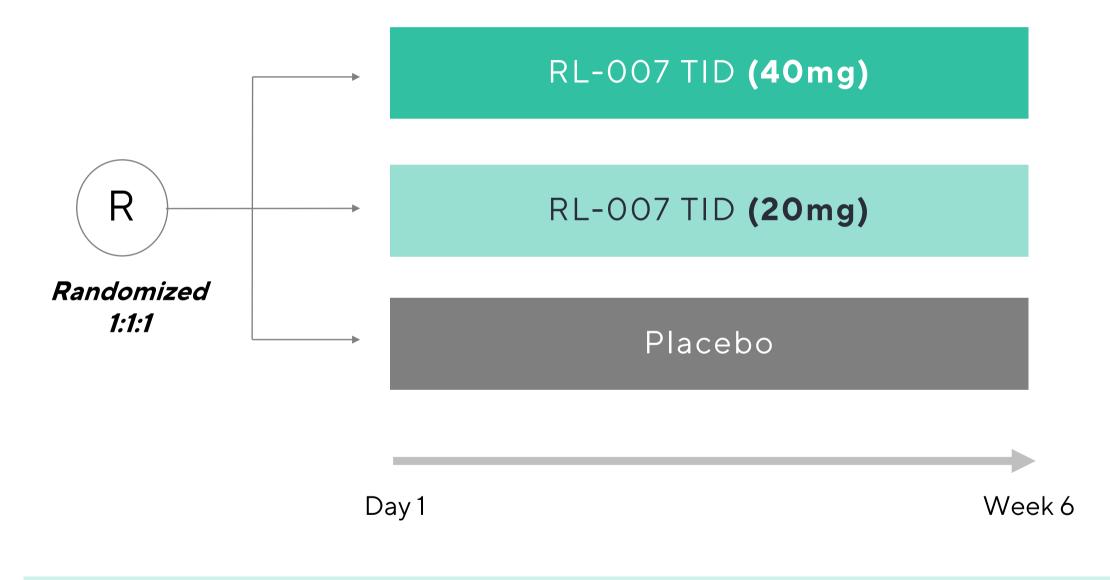


Initial Phase 2a CIAS study confirmed safety and tolerability profile in schizophrenia patients, including on-top of standard of care, with no evidence of safety concerns on any of the safety measures (ECG, labs, physical exam, C-SSRS<sup>1</sup>, vitals, AEs)



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## Clinical Trial Design: RL-007 Phase 2b Study Randomized, placebo-controlled study of RL-007 in ~234 patients with CIAS



### **Trial status:** First patient dosed in 1Q'23, Topline data anticipated H2'24

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

### **Primary Endpoint**:

- MCCB neurocognitive composite score at Week 6

### **Key Secondary Endpoints:**

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

# VLS-01 for Depression



## **Product Overview:** VLS-01 for Depression

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

PRODUCT	DMT (N,N-Dimethyltryptamine) in an oral transmucosal film (OTF)	Lead
INDICATIONS	<i>Lead:</i> Treatment Resistant Depression <i>Potential expansions:</i> Eating Disorders, Substance Use Disorders	≻ De an
INTELLECTUAL PROPERTY	Granted U.S. patent covering OTF administration of DMT, supported by several pending U.S. and PCT patent applications	> Tre
CURRENT STATUS	Initial Phase 1 results in 2Q '23 Additional Phase 1 data expected 3Q'23	> FD on:

### **VLS-01 Key Product Features**

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





### d indication overview

Pepression is a mood disorder that affects the thoughts and behavior of n individual, leading to psychological, physical, and social problems

reatment resistant depression (TRD) is diagnosed after two failed ourses of antidepressants

DA approved depression treatments can be characterized by a slow nset, long-term side effects and inadequate response rate

### Global disease burden

## ~300m

**Global sufferers of** depression in 2019<sup>1</sup>

## 33%

Patients who have inadequate response or relapse after current treatments<sup>2</sup>

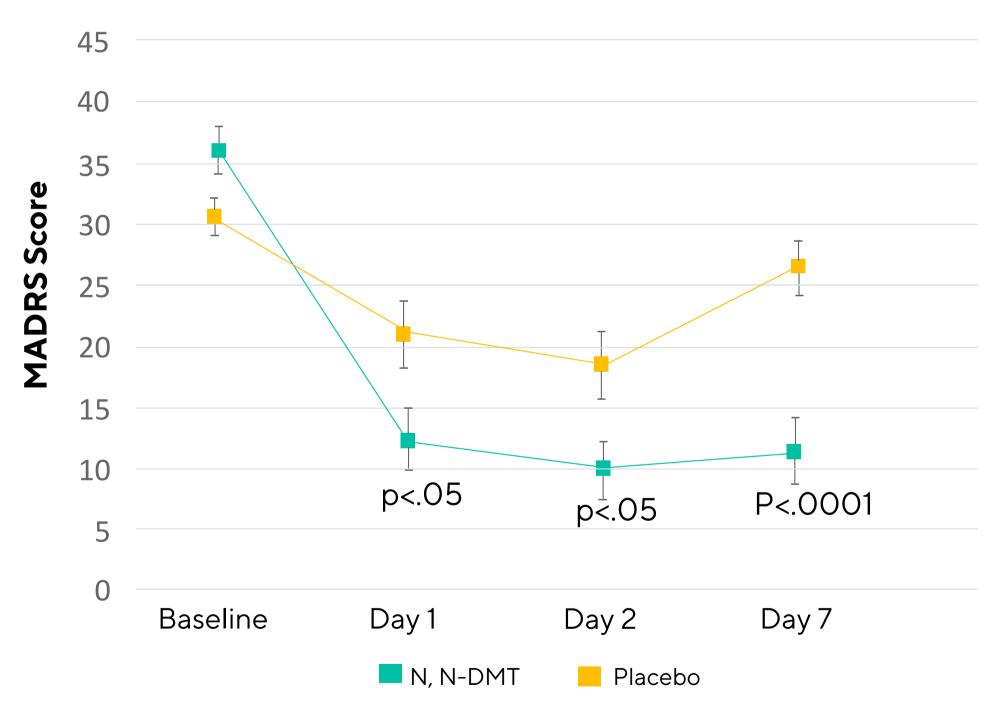


## **Clinical Evidence:** Efficacy in Randomized Control Trial of DMT in TRD

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

### **PRIOR CLINICAL EVIDENCE** (THIRD PARTY STUDY<sup>1</sup>)

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



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

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

### Key Takeaways



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**Summary:** A single administration of .36 mg/kg met both primary and key secondary efficacy endpoints by demonstrating rapid and statistically significant changes on depression severity measures of HAM-D & MADRS

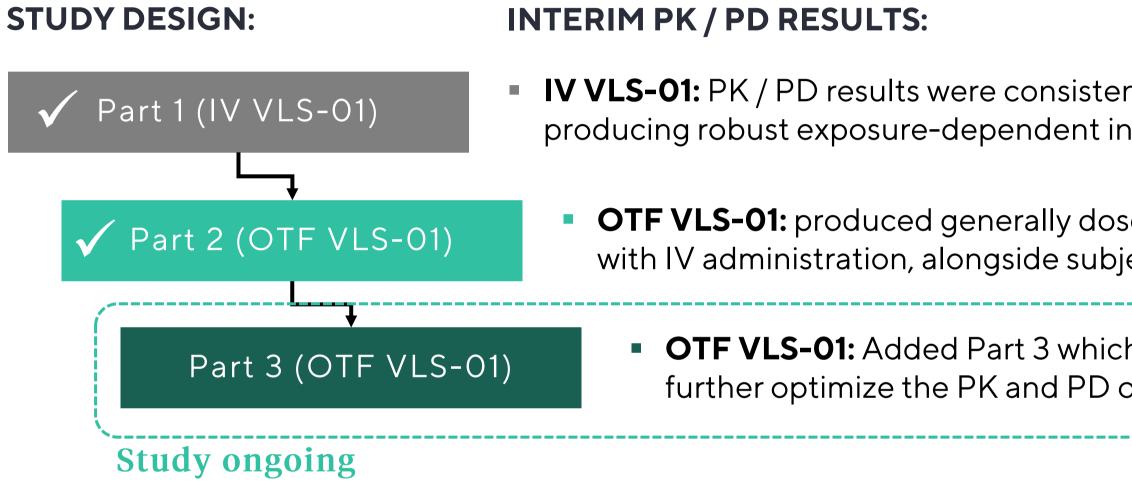
**Primary endpoint (HAM-D - not shown):** N,N-DMT arm achieved the primary endpoint of a statistically significant difference in depression severity relative to placebo (p<.05).

**Key secondary endpoint (MADRS – see left):** rapid and statistically significant differences were observed at all timepoints assessed, including as early as Day 1 and through Day 7. MADRS is a potential registrational endpoint.

There were no serious adverse events reported.



## VLS-01 Phase 1: Clinical Trial Design & Interim Results Part 1 (IV) and Part 2 (OTF): well-tolerated with a favorable safety profile; Part 3 added to further optimize PK and PD



### **INTERIM SAFETY RESULTS:**

In Part 1 (IV) and Part 2 (OTF), VLS-01 was well-tolerated and had a favorable safety profile, with no serious or severe AEs reported

### **Trial status:** Part 3 on-going - updated data anticipated 3Q'23

IV VLS-01: PK / PD results were consistent with the known pharmacological profile of DMT, producing robust exposure-dependent increases in the subject intensity of psychedelic experience

**OTF VLS-01:** produced generally dose-dependent increases in exposure, approaching that seen with IV administration, alongside subjective psychedelic experiences in the majority of patients

• **OTF VLS-01:** Added Part 3 which will explore additional dose ranging and is expected to further optimize the PK and PD of our proprietary OTF formulation



DMX-1002 for Substance Use Disorder

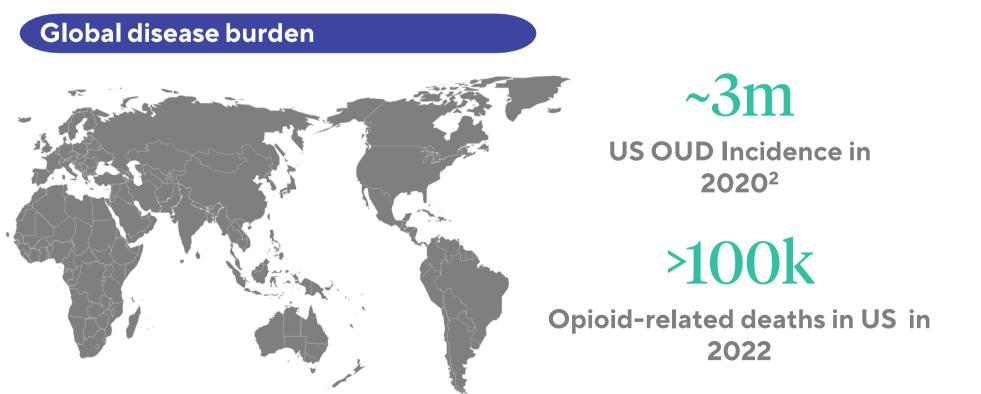


## Product Overview: DMX-1002 for Opioid Use Disorder Designed to have a rapid, sustained reduction in depressive symptoms through psychedelic effects

PRODUCT	DMX-1002 is an oral formulation of ibogaine, which is an indole alkaloid with potential for clinical benefit through oneirophrenic effects	Lead
INDICATIONS	<i>Lead:</i> Opioid Use Disorder ("OUD") <i>Potential expansions:</i> Add'I Substance Use Disorders, PTSD, TBI <sup>4</sup>	inak (inc
INTELLECTUAL PROPERTY	Issued and pending method of treatment claims for OUD	Cur sup (me
CURRENT STATUS	Phase 1 results reported in Q3′23 Engage regulatory authorities to assess efficacy study in OUD	ach add of p

### **DMX-1002 Key Product Features**

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



<sup>1.</sup> Focus of pending U.S. and PCT applications are (i) additional claims around OTF administration of DMT (ii) DMT compositions exhibiting unique PK profiles following administration and (iii) new DMT salts and polymorphic forms, including DMT succinate (VLS-01) World Health Organization

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

### indication overview

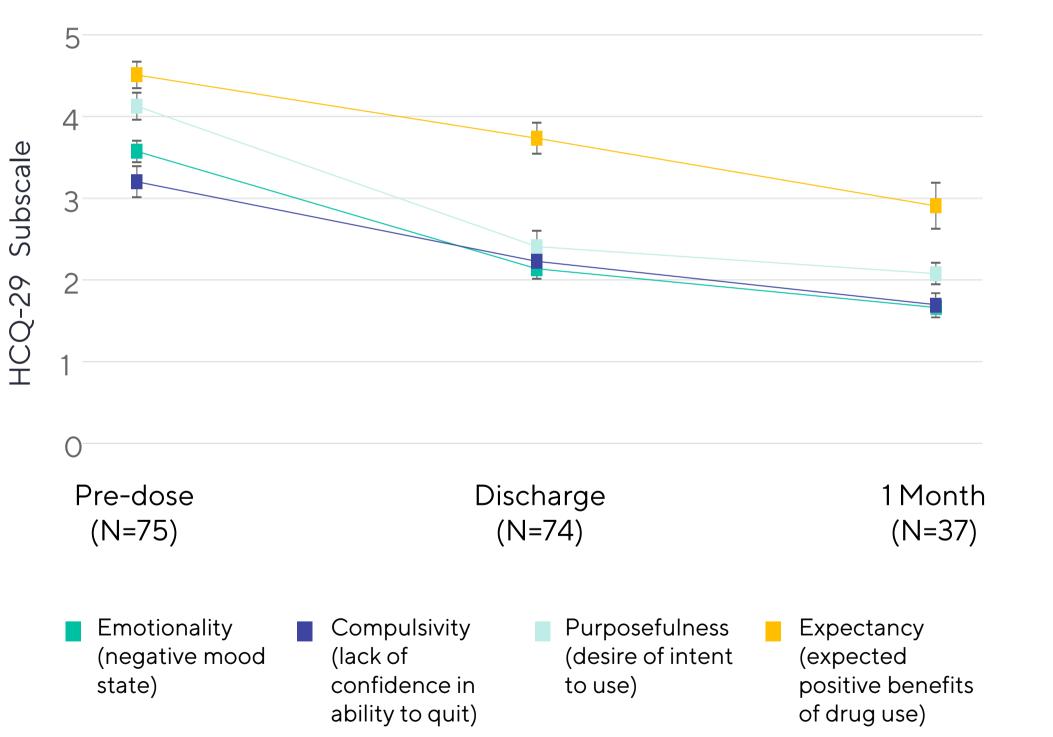
Ibstance use disorders are highly prevalent and characterized by an ability to control the use of a legal or illegal drugs, such as opioids cluding prescription opioids) or alcohol.

urrent standard of care for OUD primarily consists of psychosocial pport and synthetic full and partial opioid receptor agonists nethadone & buprenorphine), where approximately 30% of patients hieve treatment success (defined as >80% illicit opioid free weeks). In Idition, long-acting opioid antagonists (naltrexone) lead to a proportion patients achieving treatment success.



## **Clinical Evidence:** Efficacy of ibogaine in Open-Label Safety and Efficacy Study Results from an open-label study of 8-12 mg/kg of ibogaine in patients seeking detoxification from opioids and cocaine

### **PRIOR CLINICAL EVIDENCE** (THIRD PARTY STUDY<sup>1</sup>)



Self-reported dimensions of craving

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

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

Key Takeaways

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

2

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

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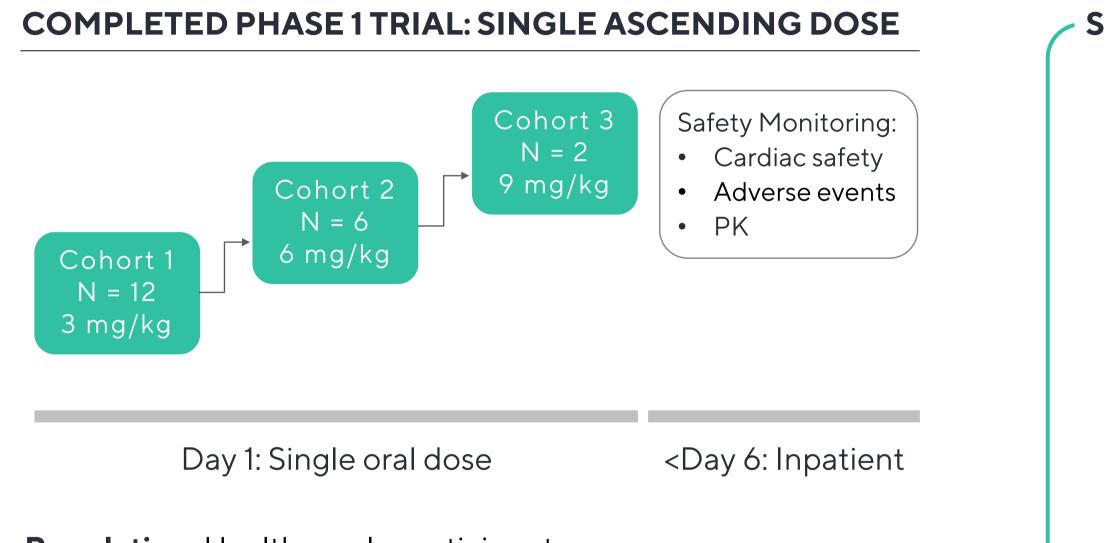
Efficacy - Post-Acute Withdrawal Syndrome: signs and symptoms at post dose assessments were reduced compared to pre-dose baseline withdrawal severity measures. Objective signs of opioid withdrawal were mild and none were exacerbated at later time points.



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



## Phase 1 Study: DMX-1002 Trial Design & Results Summary Demonstrated safety level and plasma concentrations of DMX-1002 in line with previous trials



**Population:** Healthy male participants

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

### SUMMARY OF PHASE 1 RESULTS

### Potential therapeutic plasma levels

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

### No serious adverse events reported

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

### **Asymptomatic QTc Prolongation**

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



### **SUMMARY**

DMX-1002 could potentially become a paradigmshifting therapy for **Opioid Use Disorder (OUD)** 

**Current standard of** care for OUD is medication therapy, requiring opioid substitutes that carry significant side effects

**Current strategies for** withdrawal support have high rates of relapse

## DMX-1002 has the potential to become the first & best in-class treatment for OUD, minimizing risk of relapse

	Therapy	Mechanism of Action	Single Therapeutic Episode	No Opioid Side Effects	Minimal Abuse Potential	High Adherence / Low Risk of Relapse
Sustained relapse prevention Single dose administered in monitored setting, providing both withdrawal support and oneiric experience driving sustained remission	Ibogaine (DMX-1002) <b>DemeRx</b>	Cholinergic, glutamatergic and monoaminergic receptor modulator	0		0	0
Medication Assisted Therapy <sup>1</sup>	Methadone	Mu-agonist				
Daily therapy given in substitution of opioid in outpatient setting in attempt	Buprenorphine	Partial Mu-agonist				
to wean off from opioid	Naltrexone	Mu-antagonist				
Withdrawal Support <sup>2</sup> Therapies given for	Clonidine	Alpha-2 agonist	$\bigcirc$	$\bigcirc$		
symptomatic management during supervised withdrawal (detoxification)	Lofexidine	Alpha-2 agonist				

Note: OUD = Opioid Use Disorder

Source: Publicly available information, including company websites and clinicaltrials.gov, GlobalData, Evaluate Pharma (both as of 2022) 1. Current Standard of Care

2. Rarely used given high rates of relapse. Used primarily in institutional or penitentiary settings





GRX-917 for Anxiety Disorders



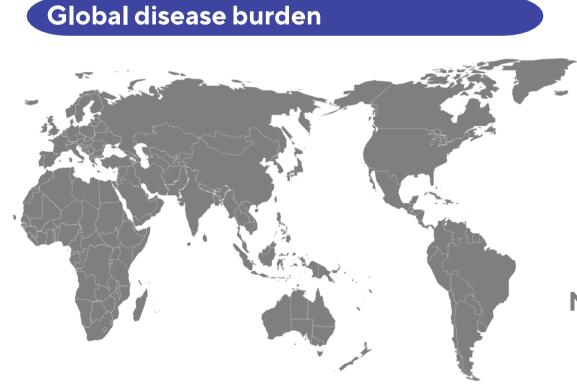
## **Product Overview:** GRX-917 for Anxiety Disorders Designed to have rapid onset of anxiolytic activity but without the negative side effects seen with benzodiazepines

PRODUCT	Deuterated etifoxine HCI oral dosage form (GRX-917)	Lead in
INDICATIONS	Lead: Anxiety Disorders (e.g., GAD, SAD, PTSD, etc.)	Anxi pers
INTELLECTUAL PROPERTY	Issued composition of matter on deuterated etifoxine (GRX-917) and corresponding methods of use	> 50% opti
CURRENT STATUS	Phase 1 trial completed in H2′22 Phase 2 in anxiety disorders being planned	> <b>No</b> F

### **GRX-917 Key Product Features**

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

Anxiety and Depression Association of America (2021)



### indication overview

xiety disorders develop when feelings of apprehension and unease rsist over an extended period and potentially worsen over time

% of US patients go untreated as a result of sub-optimal treatment tions<sup>2</sup>

FDA approved novel treatments over the past decade<sup>3</sup>

## ~3()()m

**Anxiety disorder** sufferers in 2019<sup>1</sup>

## #1

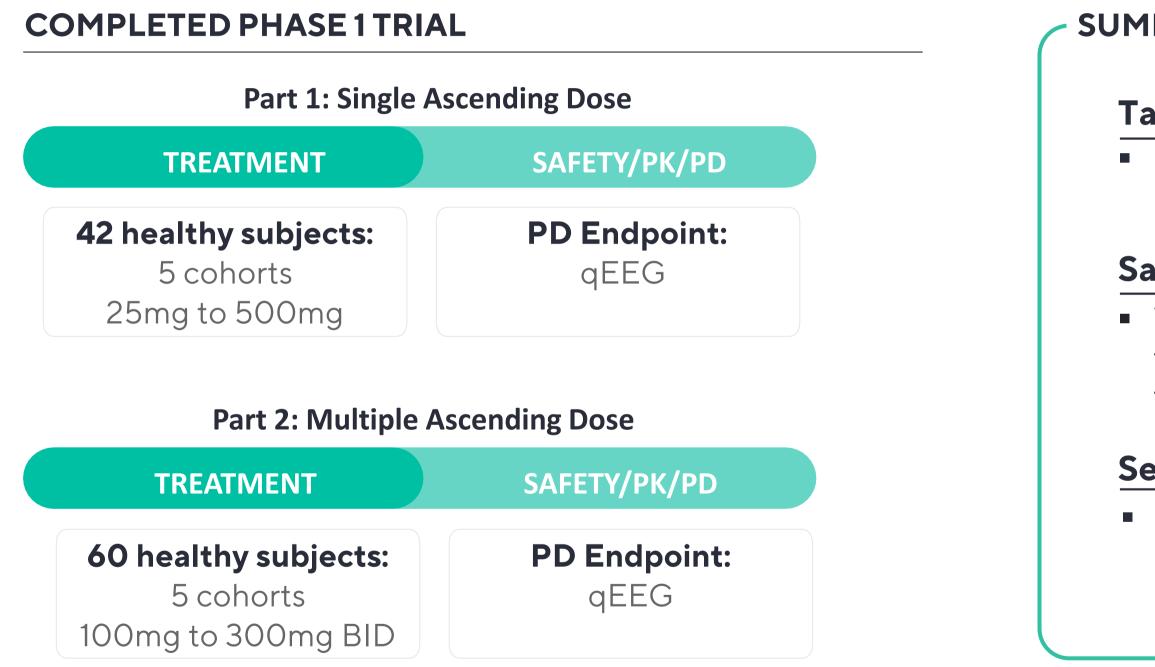
Most common mental health disorder<sup>1</sup>



<sup>1.</sup> World Health Organization

<sup>3.</sup> GlobalData (as of 6/1/2023) - All recent approvals by the FDA have been reformulations of long-standing antidepressant and benzodiazepine options

## Phase 1 Study: GRX-917 Trial Design & Results Summary Demonstrated a rapid and dose-dependent PK/PD effect along with a favourable safety profile



### SUMMARY OF PHASE 1 RESULTS

### Target engagement demonstrated

 Dose-dependent increases in qEEG beta power

### Safe & well-tolerated

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

### Sedation comparable to placebo

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



## Phase 1 Study: GRX-917 Detailed Safety Data

Safe and well-tolerated, with sedation comparable to placebo and consistent with the EEG results on alpha power

### GRX-917 Phase 1 MAD study safety data<sup>1</sup>

					GRX-917			<b>T</b> 111
Given every 12 hours for 7 days, GRX-917 was	<b>Placebo</b> N = 15	100 mg N=9	150 mg N=9	200 mg N=16	300 mg N=9	All doses N=43	<b>Total</b> N=58	
well-tolerated with no dose-limiting toxicities identified up to the highest dose of 300mg	Any TEAE <sup>2</sup>	9 (60%)	7 (78%)	4 (44%)	11 (69%)	4 (44%)	26 (61%)	35 (60%)
	Mild	9 (60%)	7 (78%)	4 (44%)	11 (69%)	4 (44%)	26 (60%)	35 (60%)
There were no corious adverse events reported	Moderate	2 (13%)	1 (11%)	1 (11%)	1 (6%)	0	3 (7%)	5 (9%)
2 There were <b>no serious adverse events reported</b> nor dose-related discontinuations due to adverse events	Severe	0	0	0	0	0	Ο	0
	Serious TEAE	0	Ο	0	0	0	0	0
	TEAEs leading to discontinuation	Ο	0	0	0	0	0	Ο
3 Adverse events in both single- and multiple- ascending dose (SAD and MAD) regimens were	Most common TEA	\Es <sup>3</sup>						
comparable to placebo-treated subjects	Headache	2 (13%)	4 (44%)	1 (11%)	3 (19%)	1 (11%)	9 (21%)	11 (19%)
	Ventricular tachycardia	1 (7%)	0	1 (11%)	2 (13%)	0	3 (7%)	4 (7%)

Nausea

Dizziness

Lethargy

1(7%)

0

0

No significant evidence of sedation or other benzodiazepine-like side effects<sup>4</sup> at any doses tested

Note: TEAE = Treatment-emergent Adverse Event, SAD = Single Ascending Dose, MAD = Multiple Ascending Dose

- 1. n = number of subjects reporting at least one TEAE in that category, % proportion of cohort total
- 2. Defined as an adverse event that began after the start of trial medication treatment

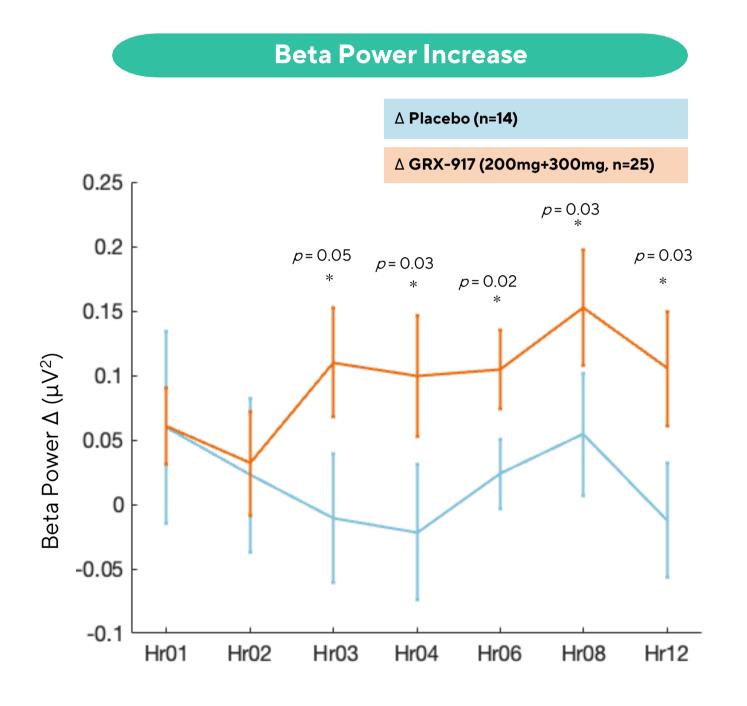
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- 3. Non-exhaustive. Other recorded TEAEs included Upper respiratory tract infection (3%), Rash erythematous (3%), Dysmenorrhoea (3%), Catheter site pain (3%)
- 4. Of the 565 patients given XANAX in Ph.3 placebo-controlled trials for anxiety disorders, 41% reported drowsiness versus 22% of those administered placebo (as reported in XANAX FDA label)

)	4 (44%)	1 (11%)	3 (19%)	1 (11%)	9 (21%)	11 (19%)
I	0	1 (11%)	2 (13%)	0	3 (7%)	4 (7%)
I	1 (11%)	1 (11%)	0	0	2 (5%)	3 (5%)
	0	0	2 (13%)	0	2 (5%)	2 (3%)
	0	1 (11%)	0	1 (11%)	2 (5%)	2 (3%)



## Phase 1 Study: GRX-917 Pharmacodynamic Evidence of Target Engagement Beta power increase is in line with pharmacodynamic efficacy of exogenous neurosteroids and benzodiazepines

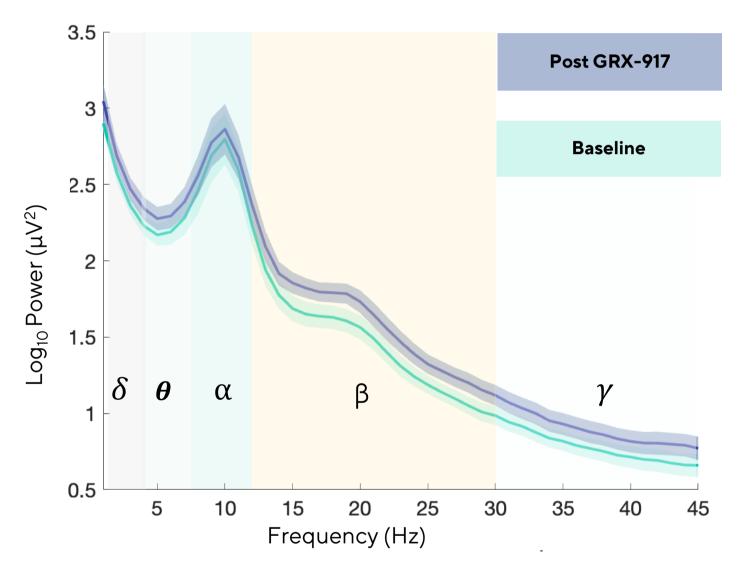


**Sensitivity Analysis:** Line plot showing Beta power  $\Delta$  (mean±SEM) at each hour for placebo and GRX-917 (combined 200mg and 300mg cohorts).

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

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

**Beta Power Increase + No Alpha Decrease** 





COMPASS PATHWAYS)

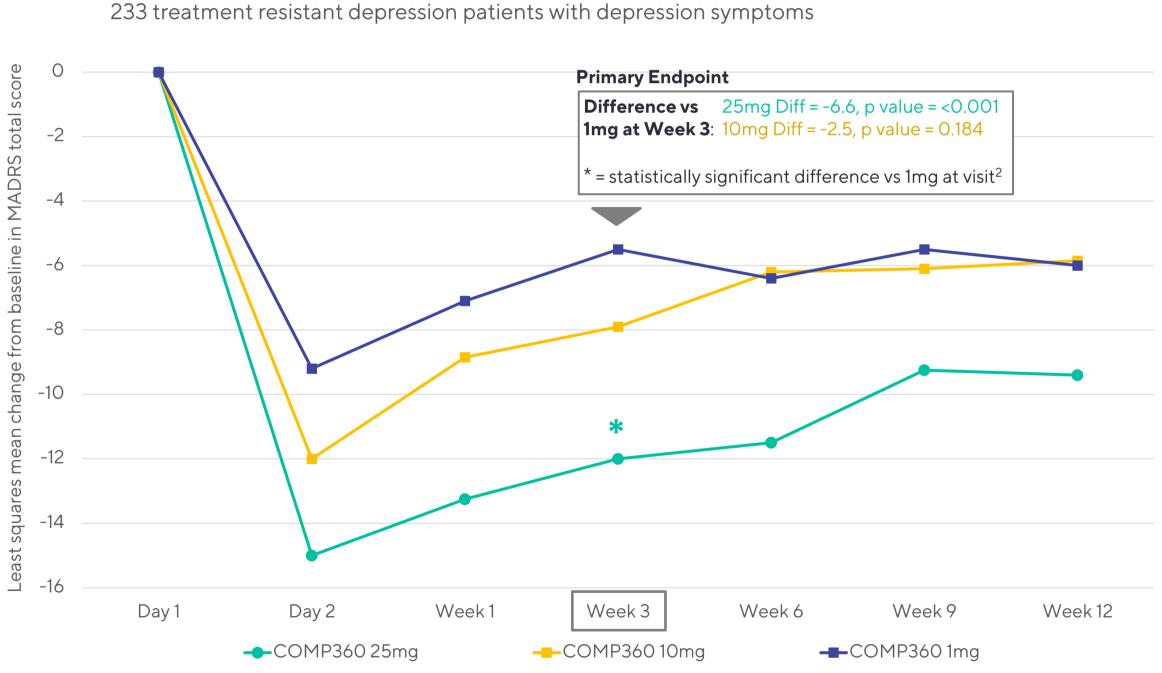


## SUMMARY: COMP360

OWNERSHIP	20.9% <sup>1</sup>
PRODUCT	Oral Psilocybin (COMP360)
PHARMA- COLOGY	5-HT2A-R agonist
PRODUCT FEATURES	Rapid onset, potential for sustained efficacy after single dose
INDICATIONS	Primary: Treatment Resistant Depression, Anorexia Nervosa, PTSD Potential: Major Depressive Disorder, Autism Bipolar Disorder, Chronic Cluster Headache
CURRENT STATUS	Phase 3 pivotal trial 1 data expected summer Phase 3 pivotal trial 2 data expected mid-25
INTELLECTUAL PROPERTY	Proprietary formulation of synthetic psilocyb COMP360
HIGHLIGHT	COMP360 demonstrated efficacy in reducin depressive symptom severity with rapid and durable response in Phase 2b study

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

### **PRIOR EVIDENCE IN HUMANS** (COMP360 PHASE 2b)



Source: Schedule 13D filed with the SEC as of November 29<sup>th</sup>, 2021, as amended Note: MADRS = Montgomery-Åsberg Depression Rating Scale; COMP360 = a proprietary high-purity, polymorphic crystalline formulation of psilocybin; In COMPASS's model of psilocybin therapy, COMP360 is administered in conjunction with psychological support from specially trained therapists.

1. Ownership percentage as of June 30<sup>th</sup>, 2023

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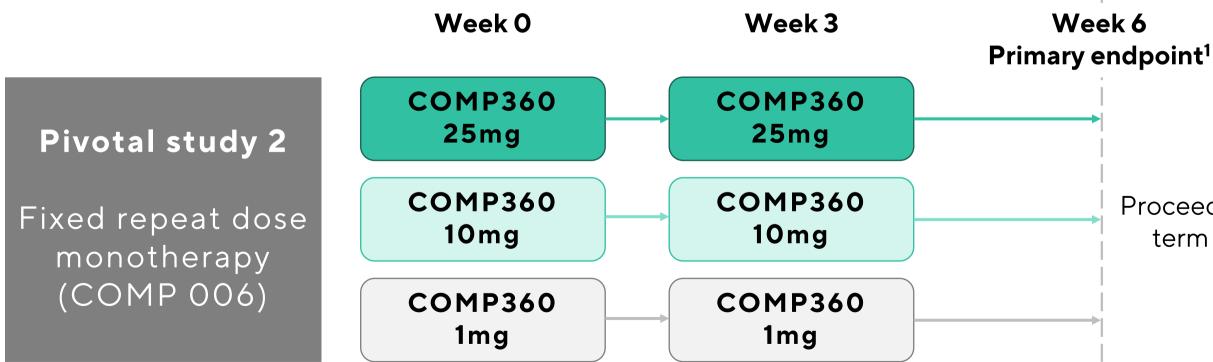
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2. Post-hoc analysis showed results were also positive at the other time points listed for 25mg dose, however, the nonsignificant finding for the comparison between the 10mg group and the 1mg group terminated significance testing based on the prespecified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

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

### **Pivotal Phase 3 Trial Designs**





Source: Compass Pathways Capital Markets Day presentation as of May 11<sup>th</sup>, 2023

1. Primary endpoint = Change from baseline in MADRS total score at week 6

2. The participant population (TRD definition and core inclusion / exclusion criteria) remains unchanged compared to Phase 2b

Proceeded by longterm follow up

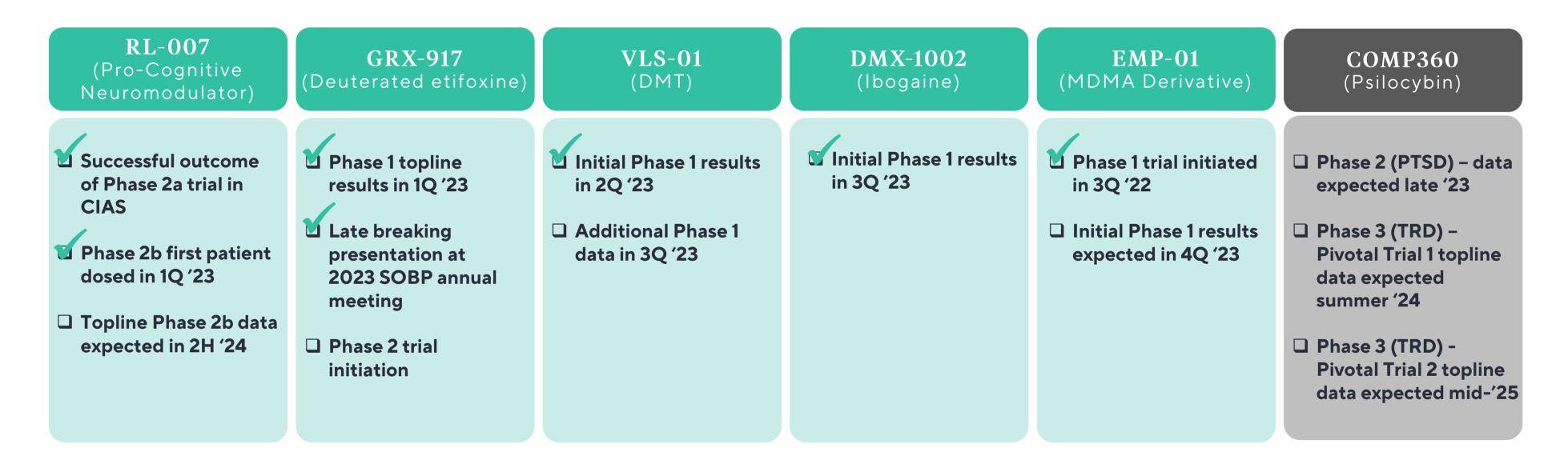
Randomization = 2:1Target  $N^2 = 255$ 

### **Topline data expected:** summer-2024

Randomization = 2:1:1Target  $N^2 = 568$ 

**Topline data expected:** mid-2025

## atai Life Sciences: Operational Focus & Program Guidance We expect to deliver several meaningful R&D milestones anticipated across our key programs through 2024



## **\$227M** in cash as of 6/30/23 provides expected runway into **1H 2026**

Nasdaq: ATAI

