



Next Generation Mental Health™

CORPORATE PRESENTATION Q1 2024



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Additional Information and Where to Find It

This communication contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements provide Enveric Biosciences, Inc.'s ("Enveric Biosciences") current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. You can find many (but not all) of these statements by looking for words such as "seeks," "believes," "hopes," "expects," "anticipates," "potential," "intends," "potential," "intends," "potential," "would," "should," "could," "may," "will" or other similar expressions. In particular, these include statements relating to future actions, Enveric Biosciences' prospective products, applications and customers, information about future performance and results of prospective products. These forward-looking statements are subject to certain risks and uncertainties that are outside Enveric Biosciences' control and could cause actual results to differ materially from Enveric Biosciences' historical experience and its present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- Enveric Biosciences' dependence on the success of its prospective product candidates, which are in preclinical stages of development and may not reach a particular stage in development, receive regulatory approval or be successfully commercialized;
- potential difficulties that may delay, suspend, or scale back Enveric Biosciences' efforts to advance additional early research programs through preclinical development and investigational new drug application filings and into clinical development;
- the limited study on the effects of medical psychedelics, and the chance that future clinical research studies may lead to conclusions that dispute or conflict with Enveric Biosciences' understanding and belief regarding the medical benefits, viability, safety, efficacy, dosing, and social acceptance of psychedelics;
- the expensive, time-consuming, and uncertain nature of clinical trials, which are susceptible to change, delays, termination, and differing interpretations;
- the ability to establish that potential products are efficacious or safe in preclinical or clinical trials;
- the fact that Enveric Biosciences' current and future preclinical and clinical studies may be conducted outside the United States, and the United States Food and Drug Administration may not accept data from such studies to support any new drug applications Enveric Biosciences may submit after completing the applicable developmental and regulatory prerequisites;
- Enveric Biosciences' ability to effectively and efficiently build, maintain and legally protect its molecular derivatives library so that it can be an essential building block from which those in the biotech industry can develop new patented products;
- Enveric Biosciences' ability to establish or maintain collaborations on the development of therapeutic candidates;
- Enveric Biosciences' ability to obtain appropriate or necessary governmental approvals to market potential products;
- Enveric Biosciences' ability to manufacture product candidates on a commercial scale or in collaborations with third parties;
- Enveric Biosciences' significant and increasing liquidity needs and potential requirements for additional funding;
- Enveric Biosciences' ability to obtain future funding for developing products and working capital and to obtain such funding on commercially reasonable terms;
- legislative changes related to and affecting the healthcare system, including, without limitation, changes and proposed changes to the Patient Protection and Affordable Care Act;
- the intense competition Enveric Biosciences' faces, often from companies with greater resources and experience than Enveric Biosciences;
- Enveric Biosciences' ability to retain key executives and scientists;
- the ability to secure and enforce legal rights related to Enveric Biosciences' products, including intellectual property rights and patent protection;
- Enveric Biosciences' success at managing the risks involved in the foregoing.

Additional information concerning these risks, uncertainties and assumptions can be found in Enveric Biosciences' filings with the SEC, including the risk factors discussed in Enveric Biosciences' most recent Annual Report on Form 10-K, as updated by its Quarterly Reports on Form 10-Q and future filings with the SEC.

Important risk factors could cause actual future results and other future events to differ materially from those currently estimated by management, including, but not limited to, the risks that: No assurances can be given that any of the events anticipated by the forward-looking statements will transpire or occur, or if any of them do occur, what impact they will have on the results of operations, financial condition or cash flows of Enveric Biosciences' forward-looking statements. These forward-looking statements are and will be based upon management's then current views and assumptions regarding future events and operating performance, and are applicable only as of the dates of such statements. Enveric Biosciences does not assume any duty to update or revise forward-looking statements, whether as a result of new information, future events or otherwise, as of any future date.



# Mental Health Epidemic

## **WIDESPREAD**

2222 1 in 4

experiences a mental illness in any given year

## **LOW EFFICACY**



40%

First line SSRIs treatments work for less than half of Source: AHRO patients

## **HIGH DISABILITY**



Mental illness and substance use disorders are the leading causes of disability

## **DIMINISHED LONGEVITY**

People with severe mental health conditions die

10 to 20 years

Earlier than the general population

Source: CAM

# TARGETED DISORDERS

- 1. ANXIETY DISORDERS
- 2. DEPRESSION
- 3. PTSD

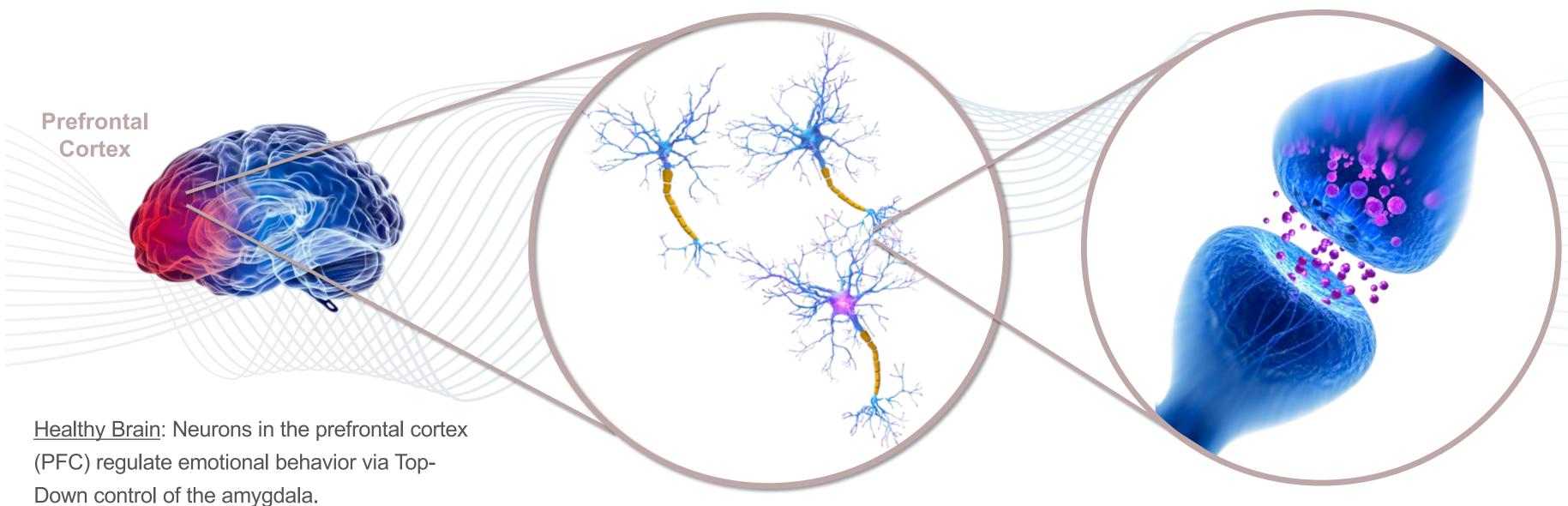
Patients with these conditions have been observed to suffer from <u>impaired</u> <u>neural connectivity</u> in certain regions of the brain







# Neuroplastogens: A new Class of Drugs



This modulates the fight-or-flight thoughts and emotions that originate in the amygdala

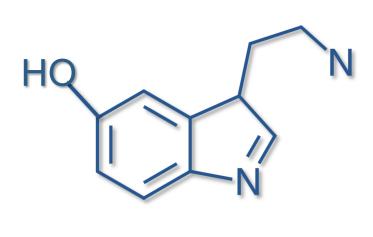
Neuropsychiatric Illness: Reduced neural connections in the PFC impairs the Top-Down control, resulting in the symptoms of anxiety, depression and PTSD

Neuroplastogens stimulate neuroplasticity in the PFC, which restores it to normal function and rescues the Top-Down control of the amygdala

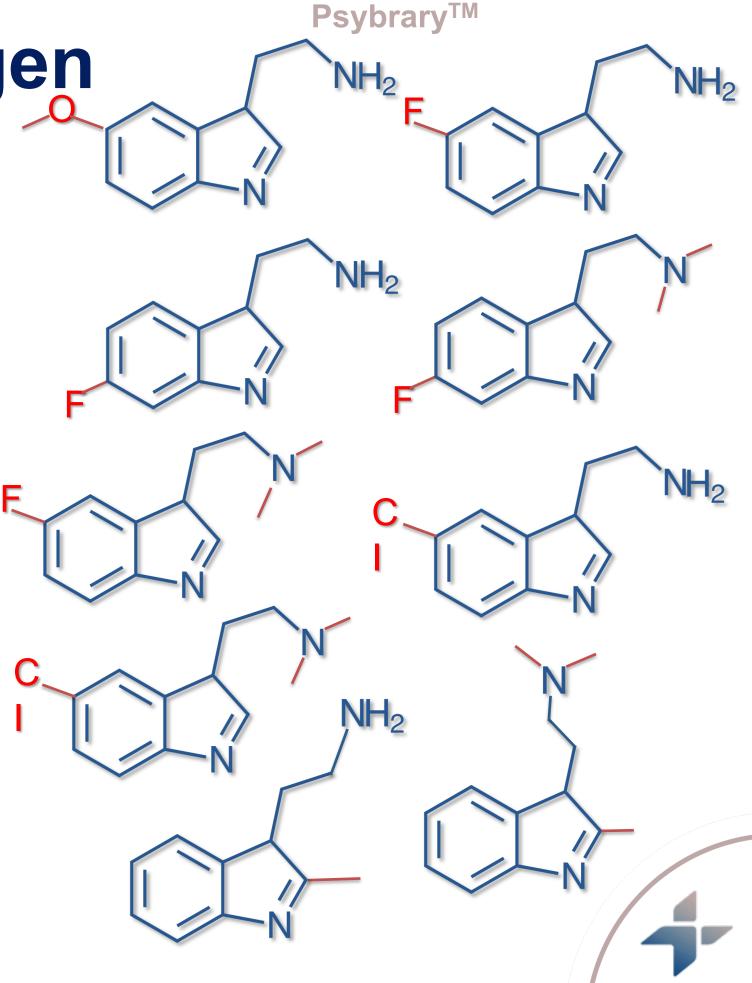
Our Portfolio of Neuroplastogen

Molecules

- The Psybrary<sup>TM :</sup> Our library of 500+ potential neuroplastogen drug candidates
- We combined synthetic biology and chemistry technologies to create a highly diverse portfolio for drug discovery
- Molecules are designed based on structures of known serotonin (5HT) receptor ligands, including tryptamines and others
- Psybrary<sup>TM</sup> candidates demonstrated to bind to numerous serotonin receptors

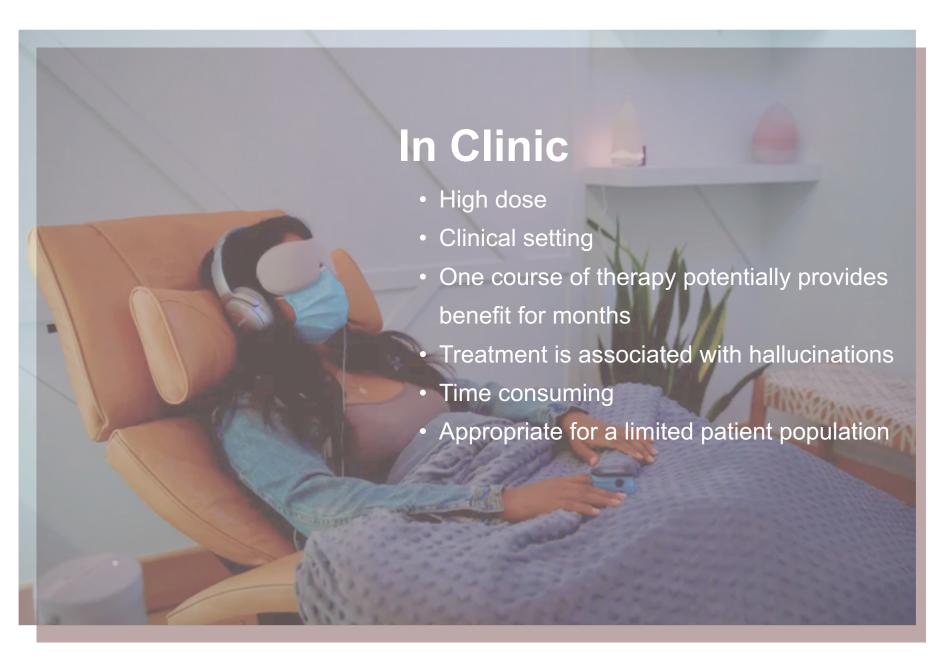


**SEROTONIN** 





# Distinct Neuroplastogen Treatment Paradigms







# Pipeline Programs

PROGRAM	INDICATION	PERFORMANCE	DISCOVERY	PRE-CLINICAL	PHASE I	NEXT MILESTONE
In Clinic: EB-002	Anxiety	5HT2AR ligand, brain- targeted, faster-acting, shorter duration, reduced GI upset				Initiate FIH in Australia
Prescription: EB-003	Anxiety, Depression, other Disorders	5HT2AR ligand, sub-clinical /non-hallucinogenic, improved cardiac safety profile, orally bioavailable, chronic administration, reduced abuse potential				Pre-Clinical



# In Clinic Program: EB-002

## **Synopsis of Target Benefits**

- Altered metabolic and pharmacokinetic properties relative to psilocybin to achieve improved risk/benefit profile
- Flexible delivery route potential for oral, intra-nasal, buccal or intravenous route for
  - Faster access to target receptor and target location
  - Therapeutic benefit at lower dose
  - Reduced GI Upset
- Faster-acting, shorter duration

## **Proprietary Protection**

 Received two patents and three Notices of Allowance from the USPTO protecting composition of matter of EB-002 and similar molecules



**INDICATION** 

DISCOVERY

PRE-CLINICAL

PHASE I

NEXT MILESTONE

PARTNER

**Anxiety Disorders** 

Initiation of FIH study

In discussions





# **EB-002 Development**



Developed an improved formulation of EB-002 designed to enhance the drug product's scalability, stability, and delivery for ongoing preclinical studies and planned clinical development.



Established Enveric
Therapeutics Pty. Ltd., an
Australia-based subsidiary, to
support the Company's plans
to advance its EVM201
Series, including lead
candidate EB-002, towards
the clinic.



Agreement with Avance Clinical, an Australiabased CRO, for its planned Phase 1 clinical trial of EB-002.



Repeat dose toxicology studies have been completed. Cardiac, respiratory, CNS safety pharmacology studies, an *in vitro* hERG current study, and genotoxicity studies have been completed and are undergoing analyses. Enveric expects to finalize all preclinical activities involving EB-002 in Q1 of 2024 in preparation for a first-in-human clinical trial.





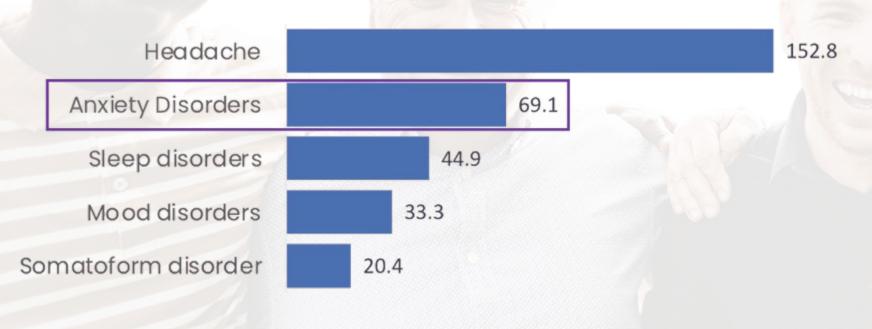
# **EB-002 Development**

- GLP toxicology studies in orally dosed rats and dogs are in advanced stages, with all in-life activities completed.
  - A broad margin of safety and tolerability is maintained with repeat dose testing.
  - Complete analysis and final reporting are expected by the end of Q1 2024.
- Safety pharmacology studies in rats and dogs, employing the core battery of respiratory, CNS and cardiovascular (CV) assessments, are completed.
  - Demonstrated an acceptable range of safety for each of these vital organ systems in orally dosed animals.
  - Complete analysis and final reporting are expected shortly.
- In vitro assessment of cardiotoxicity potential, involving assays targeting key CV targets including hERG, Cav 1.2 and Nav 1.5 have been completed.
  - Results suggest an acceptable range of cardiovascular safety well above the proposed clinical dose range.
- Non-GLP in vivo dose range finding (DRF) studies conducted in rats and dogs, completed, demonstrated effective oral bioavailability with dose-dependent increase in psilocin blood concentration detected in both species.
  - Results strongly suggest a broad range of tolerance, with a potential for reduced gastrointestinal (GI) upset and vomiting, as well as a rapid onset of action and systemic clearance, improving on PK characteristics of psilocybin.
- In vitro absorption, distribution, metabolism and excretion toxicology (ADME-tox) studies and a metabolic identification evaluation have been completed and confirmed minimal potential for adverse drug reactions (ADR), with no toxic metabolites identified, and no indication of any significant drug-drug interactions.
  - Results from this study also demonstrated rapid conversion of EB-373 to the active metabolite psilocin, consistent with previously reported pharmacokinetic (PK) studies.

# **Anxiety Market: New Treatments Needed**

- Anxiety disorders are among the most common CNS Disorders, ranking second.
- Anxiety disorders are chronic conditions that remain poorly controlled despite available treatments.
- The last FDA-approved drug to treat Generalized Anxiety Disorder was Cymbalta (Duloxetine) approved nearly 20 years ago (2004).

## **Top 5 CNS Disorders Prevalence Per Million**





Percent of Adults Ages 18-64 in the General Population Who Meet
Diagnostic Criteria for Anxiety Disorders in the Past Year and in Their
Lifetime

ANXIETY DISORDER	12 Month Prevalence %	Lifetime Prevalence %	
Specific Phobia	10.1	13.8	
Social Anxiety Disorder	8	13	
Generalized Anxiety Disorder	2.9	6.2	
Panic Disorder	3.1	5.2	
Agoraphobia	1.7	2.6	

Adapted from: Kessler et al. Twelve-month and lifetime prevalence and lifetime morbid risk of anxiety and mood disorders in the United States. Int J Methods Psych Res. 21(3): 169–184 (2012). Copyright © John Wiley & Sons, Inc. All Rights Reserved



# Prescription Model Program: EB-003

## **Synopsis of Target Benefits**

- Reduced hallucination profile
- Improved cardiac safety
- Orally bioavailable, chronic administration
- Treatment in clinic not required
- Drug intended to be prescribed for regular maintenance and taken at times and in settings more convenient to patient

## **Proprietary Protection**

 Received one Patent and six Notices of Allowance from USPTO for composition of matter of numerous EB-003 drug candidates



INDICATION	DISCOVERY	PRE-CLINICAL	PHASE I	NEXT MILESTONE	PARTNER
Anxiety, Depression,				File IND	In discussions

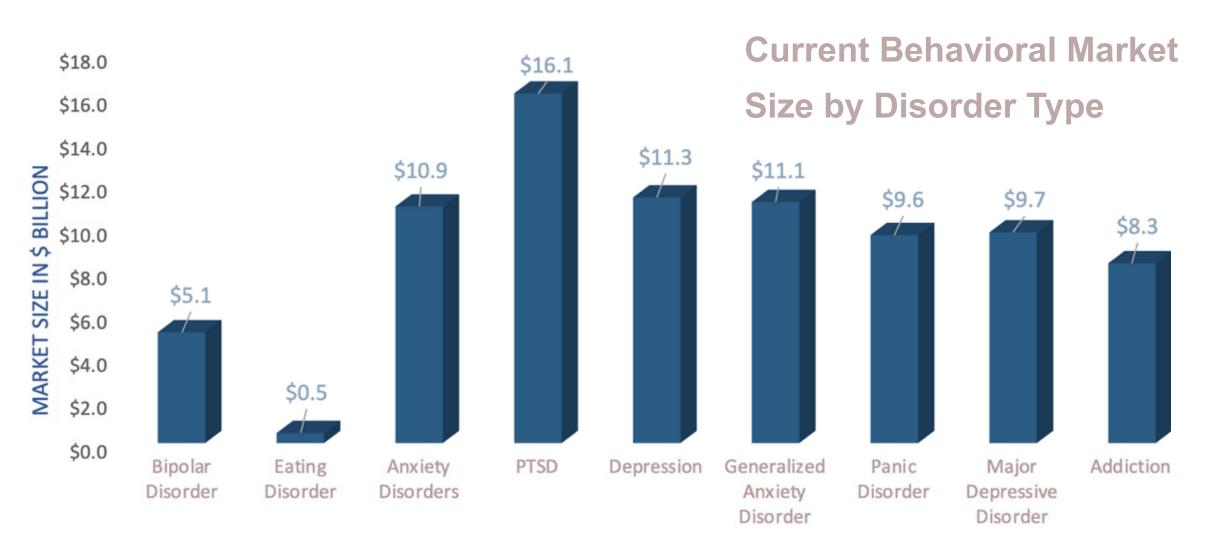


other Disorders

4-

# Neuropsychiatric Market Rapidly Growing

- Neuropsychiatric disorders continue to be a tremendous unmet need with limited innovation.
- The last FDA-approved drug to treat Neurpsychiatric disorders was Esketamine (2019) and Brexpiprazole (2015) both as an adjunctive therapy.
- The most widely used drug- Sertraline, best known by the brand name Zoloft (Pfizer, New York City), is a venerable antidepressant that was approved by the US Food and Drug Administration in 1991.







DISORDER	12 Month Prevalence %
Anxiety	19.1
Depression	8.3
PTSD	3.6
Panic Disorder	3.1
Addiction	1.7



# Intellectual Property

Psybrary<sup>™</sup>: Portfolio of 500+ drug candidates

#### Patents

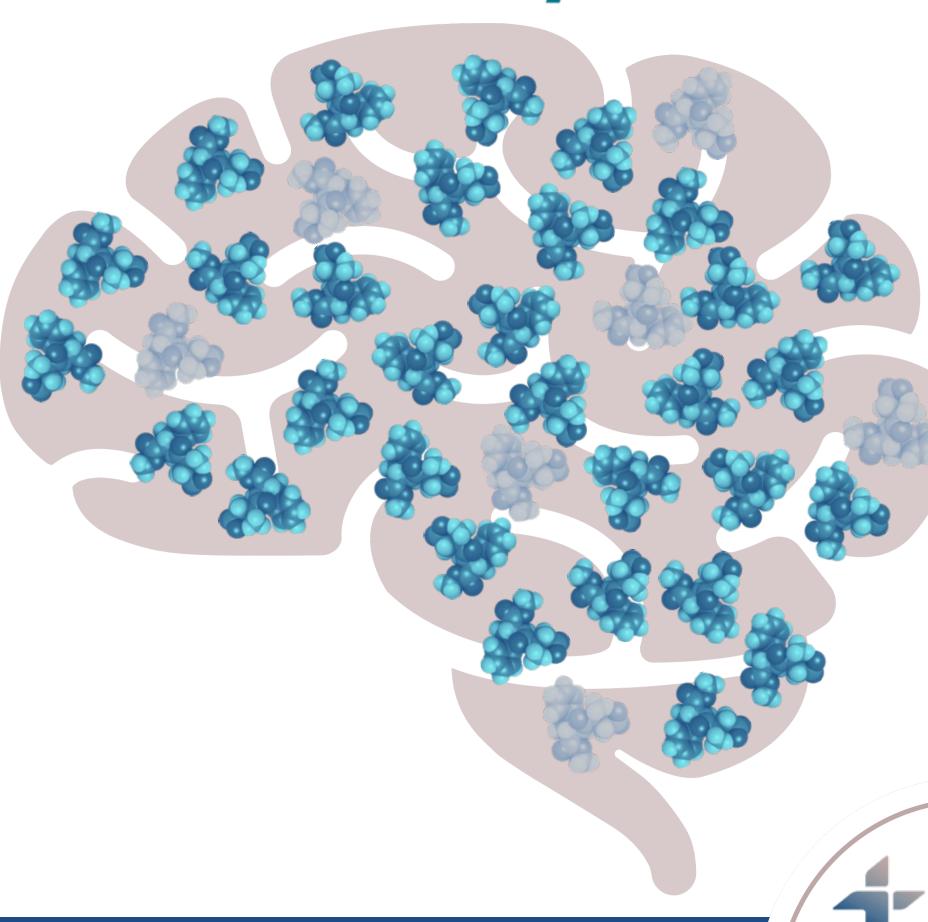
- EB-002:
  - US Patent 11,707,447; and US Patent 11,845,726; one more US application and one PCT application – compositions of numerous EB-002 molecules
  - Prodrug molecules other than EB-002
    - US Patent 11,746,087; two more US applications and three more PCT applications – compositions of numerous prodrug molecules other than EB-002
- EB-003:
  - US Patent 11,752,130; and US Patent 11,845,727; six Notices of Allowance – composition of numerous molecules
  - Five more US applications pending and multiple foreign applications in three patent families

## Regulatory Exclusivity

- US: 5 years New Chemical Entity (NCE)
- Europe: 8-year Data Exclusivity

PsyAI<sup>TM</sup>: Artificial Intelligence tool that identifies promising candidates





Potential for Strategic Drug Development

Deals

## **Example Partnership:**

# SAGE THERAPEUTICS CONTRACT

Collaboration and License Agreement

Partners: Biogen, Sage Jurisdiction: Global

Products: Sage-217, Sage-324

Stage: Phase 3

Indications: PPD, MDD, essential tremor, other

Upfront: \$875M

Equity Investment: \$650M at 40% premium

Milestones: Sage-217, up to \$475M; Sage-324 up to \$520M;

plus up to \$525M per class

Profit Share: US - 50:50; Asia – SAGE;

ex-US, ex-Asia - ~20%



Upfront Cash and/or Equity

Purchase

Milestone Payments

PHASE I PHASE II

PHASE III

FDA

COMMERCIALIZATION

Share responsibility and costs for development as well as profits and losses for commercialization globally.

Profit Share / Royalties



Company	Program	Status	Ticker	Market Cap	Progress
Enverie Riccoionece	Gen 2	Public	c NASDAQ:ENVB	\$3.06M	Pre-Clinical
Enveric Biosciences	Gen 3	Public			Pre-Clinical
Compass Pathways	Gen 1		NASDAQ:CMPS	\$594.82M	Phase 3
	Gen 2	Public			Pre-Clinical
Cybin Inc.	Gen 2	Public	NYSE:CYBN	\$162.61M	Phase 2
Cybiii iiic.	Gen 3				Pre-Clinical
Gilgamesh Pharmaceuticals	Gen 2 Gen 3	Private	-	\$73.6 Total funding – Pitchbook  Most recent raise (May 2022)  \$39M Series B, \$149.5M PreMoney	Phase 1 Phase 1
Delix Therapeutics	Gen 2 Gen 3	Private	-	\$102.75 Total funding - Pitchbook  Most recent raise (Jan 2022), \$30M	Phase 1 Pre-Clinical

\*as of Jan 4, 2024

# Competitive Landscape





# Management

# Management Team



Joseph Tucker, Ph.D. CEO & Director



Kevin Coveney, CPA CFO



Peter Facchini, Ph.D. CIO



Jillian Hagel, Ph.D. VP Innovation

## **Board of Directors**

Michael D. Webb

**Board Chair** 

### **George Kegler**

Director, Chair of the Audit Committee

## Frank Pasqualone

Director, Chair of the Compensation and Nominating Committee

Marcus Schabacker, M.D., Ph.D.

Director, Chair of Science and Technology Committee

Joseph Tucker, Ph.D.

Director

## Scientific Advisors

Maurizio Fava, M.D,

Scientific Advisor

Stephen M. Stahl, M.D.,

Scientific Advisor

Sheila DeWitt, Ph.D.

Scientific Advisor

John Krystal, M.D.

Scientific Advisor

Michael Leibowitz, M.D.

Scientific Advisor





# **Value Inflection Points**

### EB-002

- File HREC for EB-002 in Australia
- First patient dosed in Phase 1 clinical trial EB-002
- O Positive results from initial Phase 1 clinical trial for EB-002
- File IND for EB=002 in US

### EB-003

- Additional Notices of Allowance for EB-003
- Manufacturing- optimized formulation EB-003
- File IND for EB-003 lead candidate
- O Positive results from initial Phase 1 clinical trial EB-003





# The Future of Neuroplastogen Medicine

### Pipeline provides multiple shots on goal

• Patented molecules can address multiple psychological indications

### Strong IP Portfolio

- Five patents and nine patent Notices of Allowance with 10+ more anticipated
- Large number of molecules expected to act as neuroplastogens
- Regulatory exclusivity
- PsyAI<sup>TM</sup>: Artificial Intelligence tool that identifies promising candidates

### Separate Indications & Targets

• Unique partnerships opportunities for each program

#### Market demand

 Significant pharma demand for neuroplastogens anticipated, yet only a small number of companies developing viable neuroplastogen medicines



# Nasdaq:ENVB

