Simulated Psychedelic Immersive Experience: Healthcare Intervention (Si-PHI)

Backed by Latest Mixed Reality Technology
EEG Biomarkers
Ongoing Rigorous Clinical Validation

Yale SCHOOL OF MEDICINE

Blavatnik Accelerator: 2024 Awardee

YNHHS Innovation: 2024 Awardee

Our Team

Mohini Ranganathan, MBBS
Associate Professor
Psychiatry

Interventional psychiatrist
- Ketamine
- Esketamine

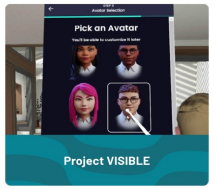
Psychedelic drug researcher
- *Ketamine*
- *DMT*
- *Psilocybin*
- *Salvinorin A*

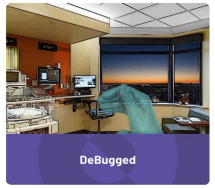
Kimberly Hieftje, PhD
Assistant Professor
Pediatrics

Asher Marks, MD
Associate Professor
Pediatrics

Jose Cortes-Briones, PhD
Assistant Professor
Psychiatry

Co-Directors: XRPeds and Yale Center for Immersive Technologies: Experts in Extended Reality and game technology





Neuro-imaging and EEG biomarker development
- Depression/ PTSD
- Psychedelic drug EEG Biomarkers

Software Development
- **Mark Grossnickle,** MindTrust Inc
- **Bradley Newman,** MindTrust Inc
- **Chris Errato,** MindTrust Inc

Business Development
- **Julia Rosander,** Yale Ventures
- **Shannon Anderson,** Yale Ventures
- **Jennifer Beecham,** Yale Ventures

Strategy and Growth Advisor
- **Nikhilesh Rao,** SpinQbe Consulting

Laboratory Team Members
- **Carly Hewes,** Research Assistant
- **Ella Miller,** Research Assistant
- **Robert Burde,** Research Assistant

Psychedelic drugs offer novel therapeutic options but have major operational challenges

- ~300 million adults globally have depression (MDD) of whom 21 million reside in the US
- ~13M seek treatment: 30% Treatment Resistant Depression (TRD)
- Psychedelic drugs hold promise as novel antidepressants: and are used for TRD
- Operational barriers, safety concerns and regulatory restrictions pose challenges to psychedelic treatments

FDA Approved	In Development
Esketamine	*LSD*
Ketamine	*MDMA*
	DMT
	Psilocybin

Re-envision psychedelic treatments by leveraging immersive technology without the challenges

Can the benefits of psychedelic treatments be harnessed without these challenges?

Psychedelic drug t

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Psychedelic Drug Treatment

PHI treatment

Li
Nc
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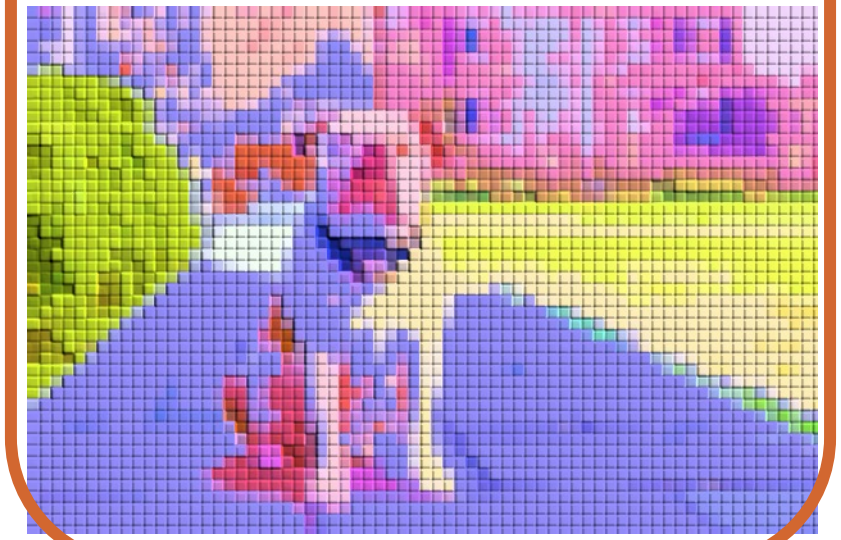
Si-PHI
Simulated (Non-Drug) Psychedelic immersive experience

Normal Visual Experience

Drug-Induced Psychedelic Experience

Virtual Reality Psychedelic Experience

Si-PHI Mixed Reality Psychedelic Experience



Si-PHI's Immersive Mixed Reality simulation sets it apart from other players in the market

Comparison Factors	TRIPP	Enosis	MindMed	Si-PHI
Patient and Biomarker-Informed	✗	✗	✗	✓
Simulation Type	Generic Visuals, Soothing audio	Environment for psychedelic therapy	Environment for psychedelic therapy	**Realistic Psychedelic Experience**
Technology Type	Virtual reality	Virtual reality	Virtual reality	**Mixed reality**
Data Type	2D	2D	2D	**3D, Immersive, Stereoscopic**
Sensory Type	Audio-visual	Uni-sensory	Uni-sensory	**Multi-sensory**

User Journey and Business Model

1

Patient is evaluated approved for treatment with Si-PHI

2

Si-PHI Treatment initiated. Metrics of simulation noted.

3

Si-PHI's cloud software captures EEG and other key treatment metrics

4

Si-PHI data analytics provide summarized insights into treatment parameters

5

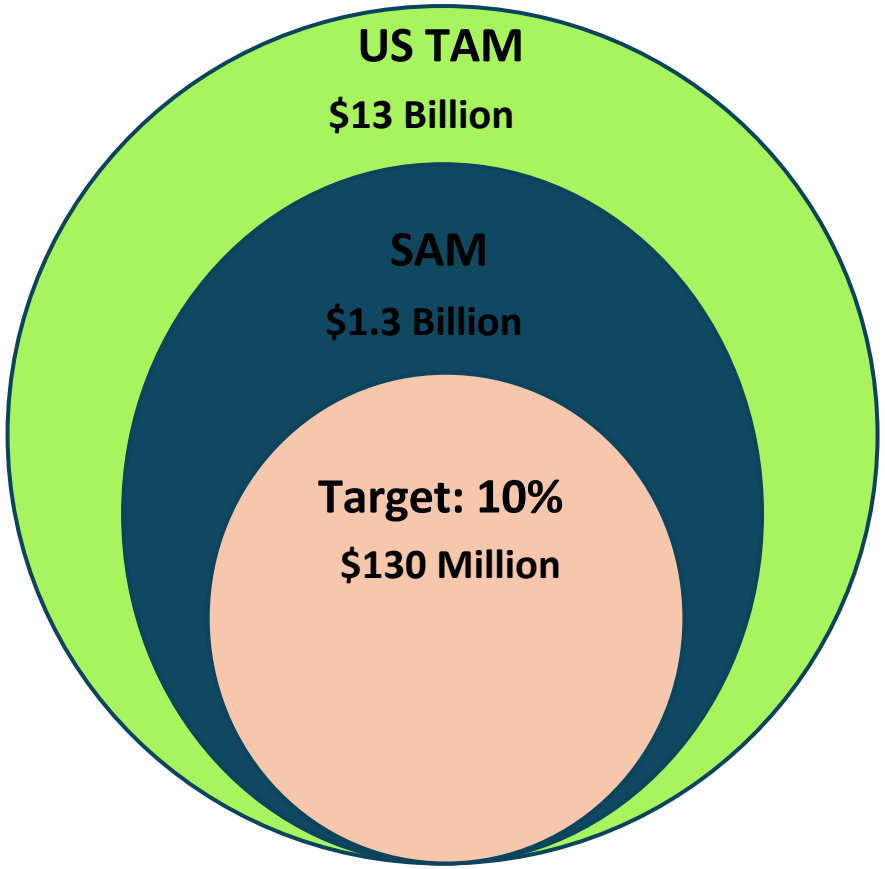
Providers receive reports to support clinical assessments

6

Providers can adjust settings to optimize care

Providers will be charged per patient and per treatment. Providers will seek insurance reimbursement or self-pay, similar to the current payment structure for Ketamine/Esketamine treatments.

The Opportunity

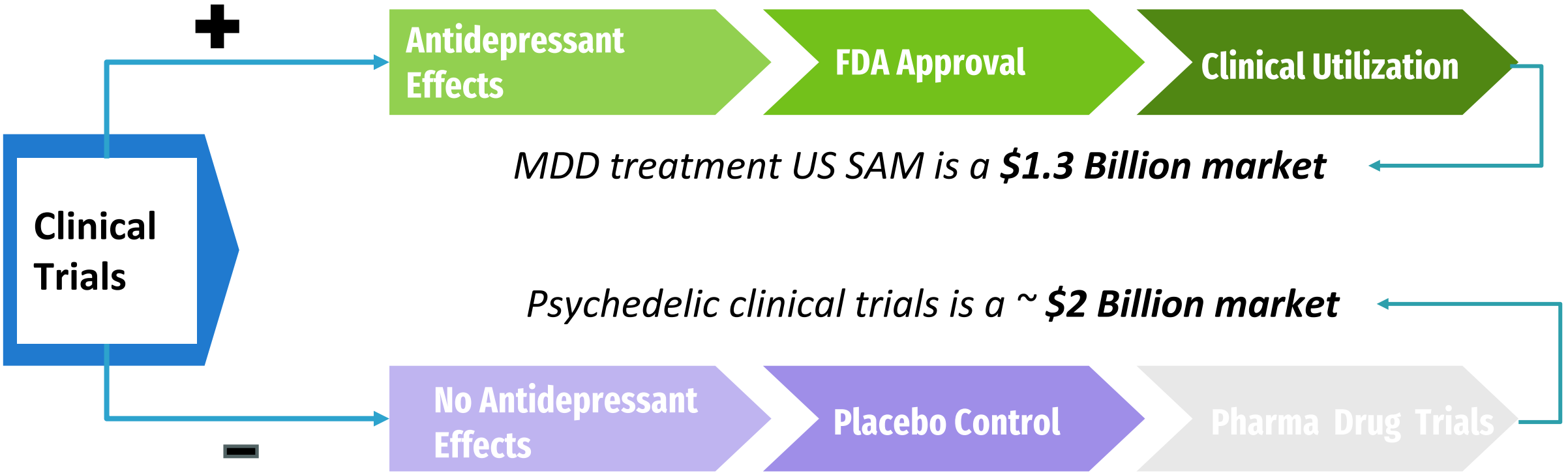


Si-PHI will focus on the US MDD market, concentrating on drug-based treatments, with the potential to expand to similar markets worldwide in the future.

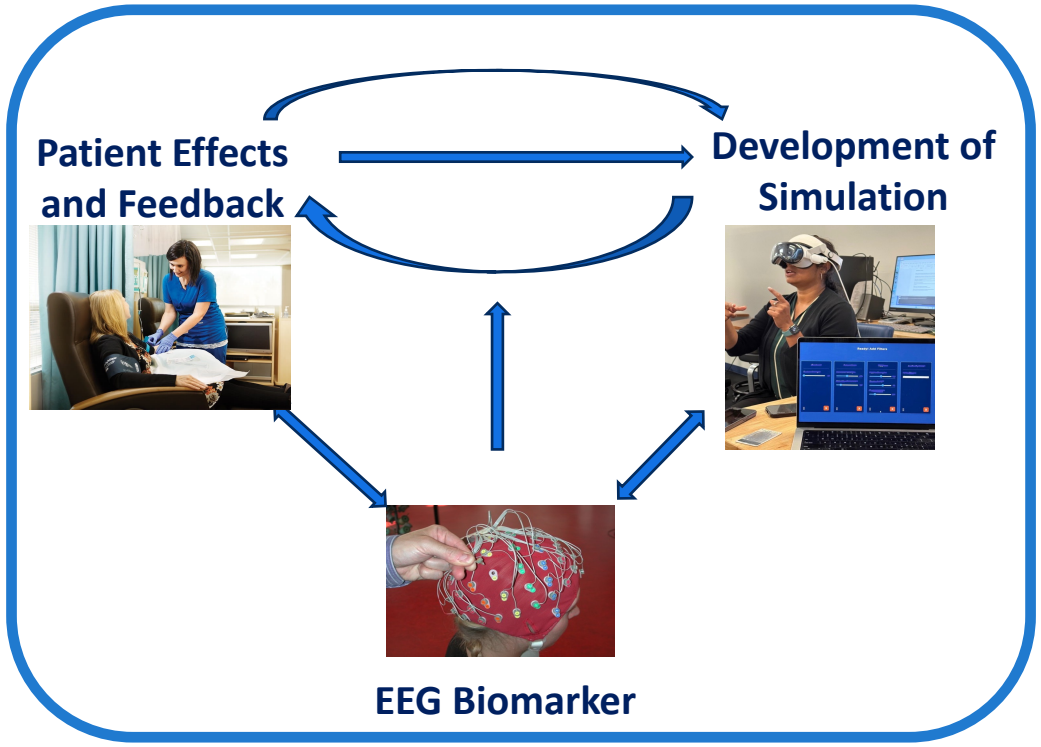
While we aim for a 10% share, we see the potential to significantly expand further based on product efficacy, service quality, sales and account management, and patent-driven exclusivity.

Sources: Statista data on US mental health centers, physician input on MDD patient and drug spend, online research on psychedelic drug pricing

Si-PHI has potential regardless of its anti-depressant efficacy



Development, Validation and Prototype testing is presently underway



Si-PHI induces Robust Psychedelic Effects

"Having used psychedelics, that is the closest I've felt to being inside that headspace. Other apps try to show it visually, but I've never actually "felt" it before."

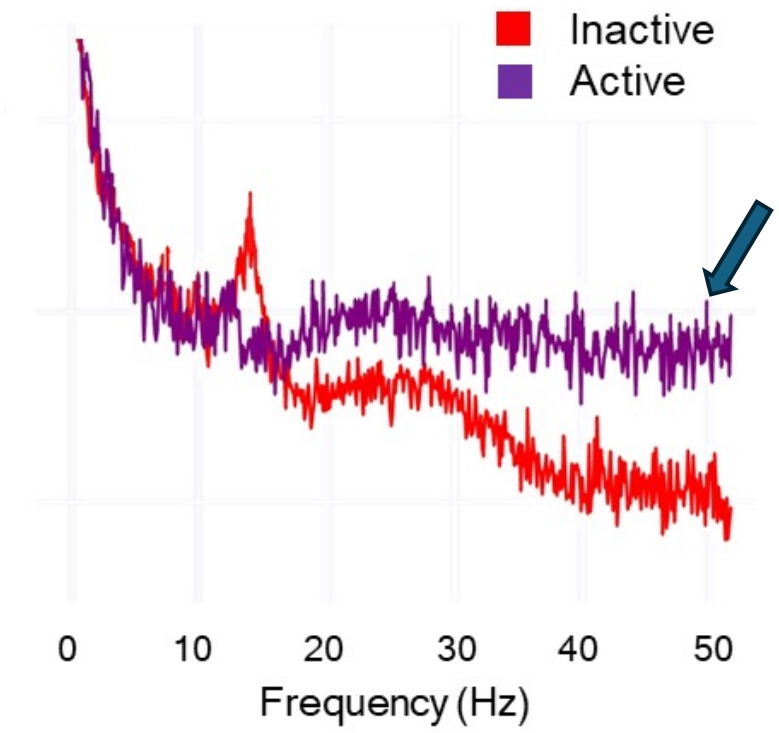
"While startling at first, it was ultimately oddly relaxing, and I can best describe it as being in two places at once. The audio changes made my thinking feel slowed in a good, relaxing way."

"As someone who has never done psychedelics, it was relaxing. I found over time it got me into a unique mindset."

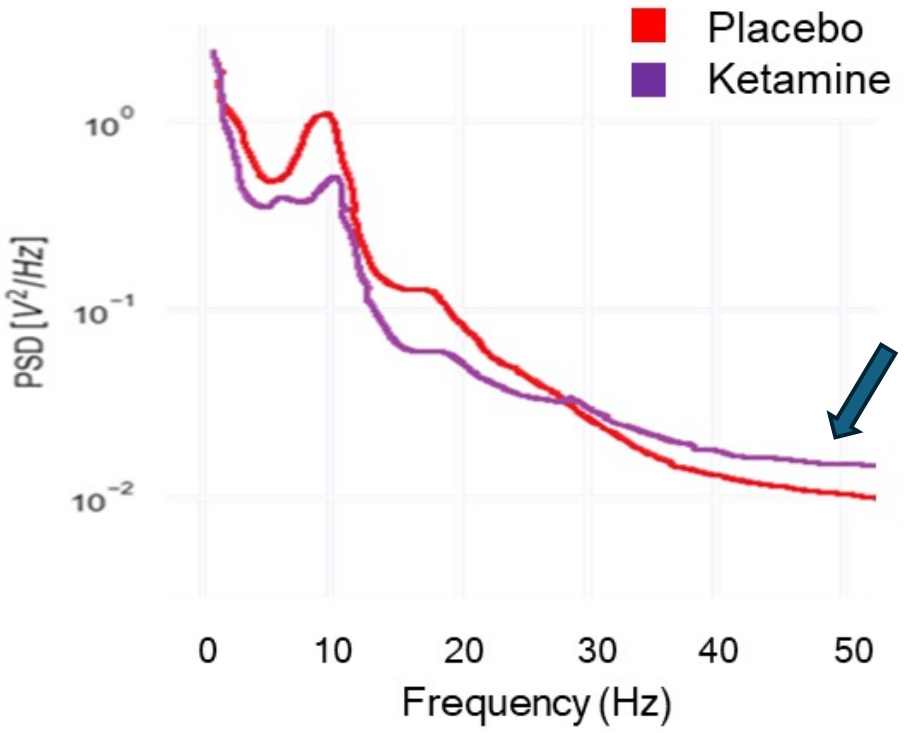
"When I adjusted the settings to a specific combination …. I felt like I was floating and somehow also sinking."

Si-PHI induces EEG changes similar to Ketamine

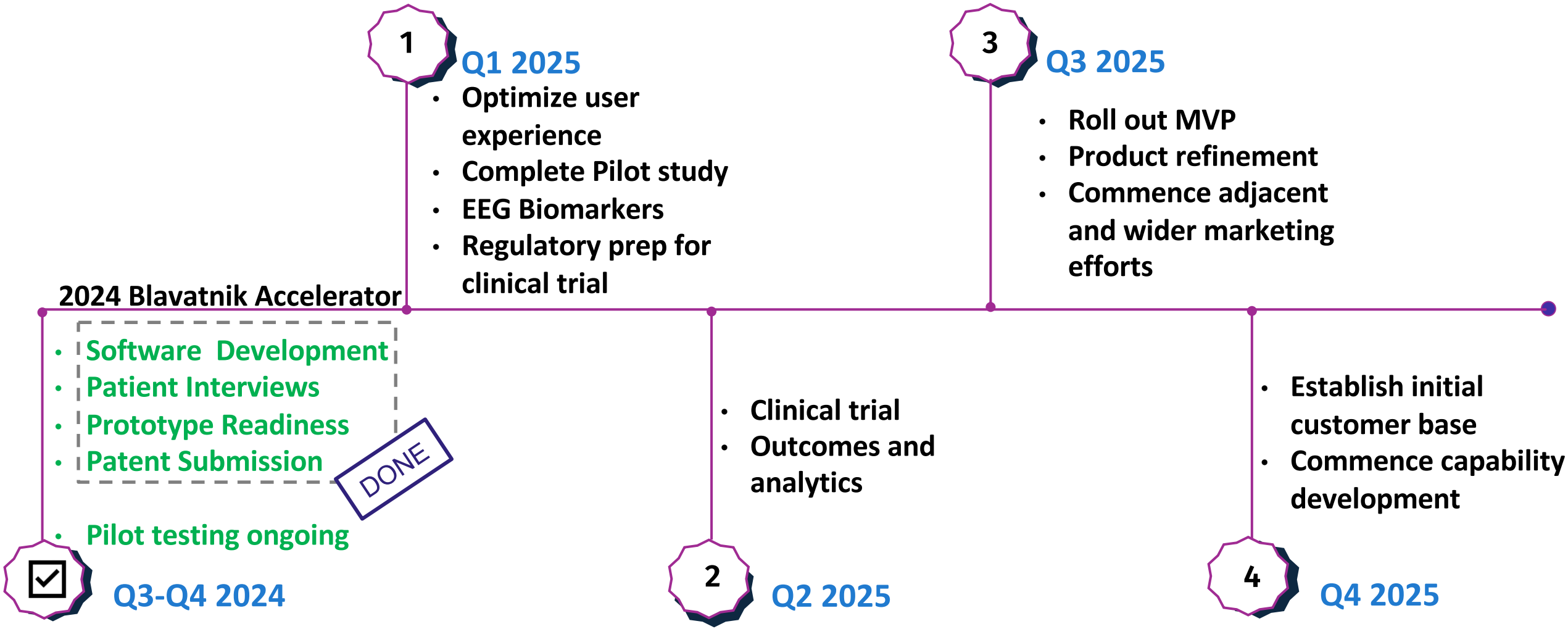
Si-PHI



Ketamine Effects



Roadmap for next 12 months



Proposed utilization of Blavatnik Funds

40%

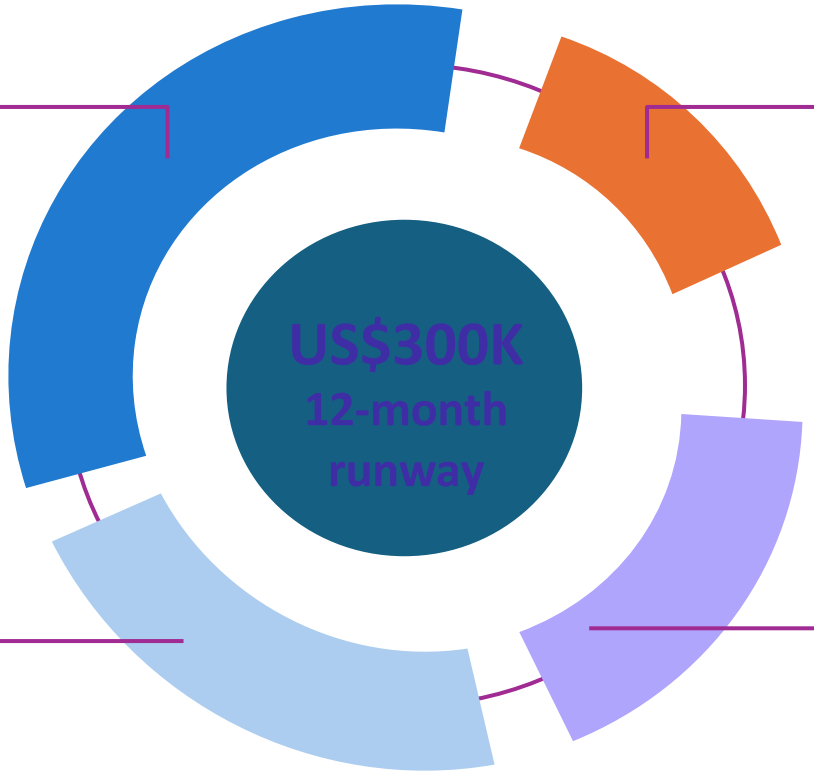
Research & Development

$120K: Clinical Trial for Efficacy in Depression

10%

Strategy & Marketing

$10K: Advisory board
$20K: Market research and Business development



30%

Product Development and Optimization

$30K: Software refinement
$60K: Analytics and Algorithm optimization using Clinical/simulation metrics/EEG data

20%

Team & Admin

$30K: Regulatory and clinical trial support
$30K: Clinical and safety data analysis, report generation

Thank You!

Si-PHI per patient per session revenue model

Antidepressant treatment replaced/ augmented with Si-PHI

Charge per patient, per treatment as per provider prescription*

- Providers approve patients
- Replace/Augment existing treatment with Si-PHI
- EEG and clinical metrics analytics report provided
- A fixed charge per session – lower than existing psychedelic treatments
- Optional features at an additional charge for advanced software and service features such as customized analytics and visualization, and personalized patient recommendations.

excludes the one-time software installation and training costs and hardware procurement fee.

Alternate Opportunity

Cost of Psychedelic Clinical Trials:

200-300 Psychedelic Trials annually*
$2M to $20M: $10M X 200→ **~$2B**
Phase III trials can cost $41,000 to $100,000 per patient*

Importance of a Placebo:

FDA requirement
Derisking costly Trial Failure due to lack of blinding

Financial Incentives for Pharma:

Successful Psychedelic Trial → Billions in revenue
Cost of a failed Phase III trial can → > **$100M.**
Derisking by **5%** represents a significant financial incentive.

Potential Revenue for SiPHI:

Dividing the cost of failure by by number of subjects (~500):
Estimated revenue → **$5K-$10K per patient per trial.**

Si-PHI: A perfect placebo for Psychedelic Drug Development

- Mimics psychedelic effects
- No therapeutic action
- Supports Blinding
- Satisfies FDA requirements
- Increases trial success probability

*NIH/ Clinicaltrials.gov
**Moore TJ et al., JAMA Internal Medicine, 2018.; DiMasi JA et al., Journal of Health Economics, 2016