



Microdosed Ibogaine: A Novel Therapeutic Approach for PTSD and Complex PTSD

A strategic co-development program between DioMEDe Science and OctaGenix, with collaboration from the Wyatt Group, aiming to revolutionise PTSD treatment through innovative microdosing techniques.



Executive Summary

Our strategic co-development programme (Ibg-P001-DSO) is innovative microdosed ibogaine as a next-generation therapeutic intervention for Post-Traumatic Stress Disorder (PTSD) and Complex PTSD, two of the most urgent and underserved mental health challenges of our time.

Current treatment options for PTSD often fall short due to limited efficacy, poor patient compliance, and significant side-effect burdens are common.

Millions of patients remain trapped in cycles of relapse, chronic distress, and diminished quality of life.

This is where we are different.

Through a unique collaboration between DioMEDe Science and OctaGenix, we are building a novel treatment platform with the potential to set a new global standard in PTSD care.

Utalising cutting-edge neuroscience, AI-assisted clinical design, and precision dosing, our program aims to deliver:

- **Sustained therapeutic benefits:** promoting long-term symptom remission and emotional resilience.
- **Enhanced patient compliance:** optimised microdosing to improve tolerability and adherence.
- **A favourable safety profile:** reducing risks associated with current high-dose or polypharmacy approaches.

With our regulatory expertise and a world-class team, Ibg-P001-DSO is positioned to become the first approved prescription Psychedelic therapy.



Core Hypothesis and Therapeutic

Core Hypothesis

Microdosed ibogaine, at sub-perceptual or mildly perceptible doses, can modulate key neurobiological pathways implicated in PTSD, promoting neuroplasticity and facilitating trauma processing without causing intense psychoactive effects.

Microdosing Strategy

Our approach involves chronic, low-dose administration, distinct from single, high-dose protocols used for addiction. This minimises acute psychoactive effects and reduces cardiovascular risk while allowing for sustained neurobiological modulation that integrates well with psychotherapy.

Expected Outcomes

Enhanced emotional regulation, facilitated fear extinction, and improved cognitive processing of traumatic memories—all crucial for PTSD recovery. Recent Stanford research suggests promising improvements in veterans with traumatic brain injuries when combined with magnesium.

Ibogaine is a naturally occurring indole alkaloid derived from the *Tabernanthe iboga* plant native to Central Africa, historically used in traditional healing ceremonies.

Mechanism of Action

NMDA Receptor Modulation

Antagonism of NMDA receptors is hypothesised to be critical for ibogaine's neuroplastic effects, which are relevant to fear extinction and trauma memory reconsolidation.

Neurotrophic Factor Upregulation

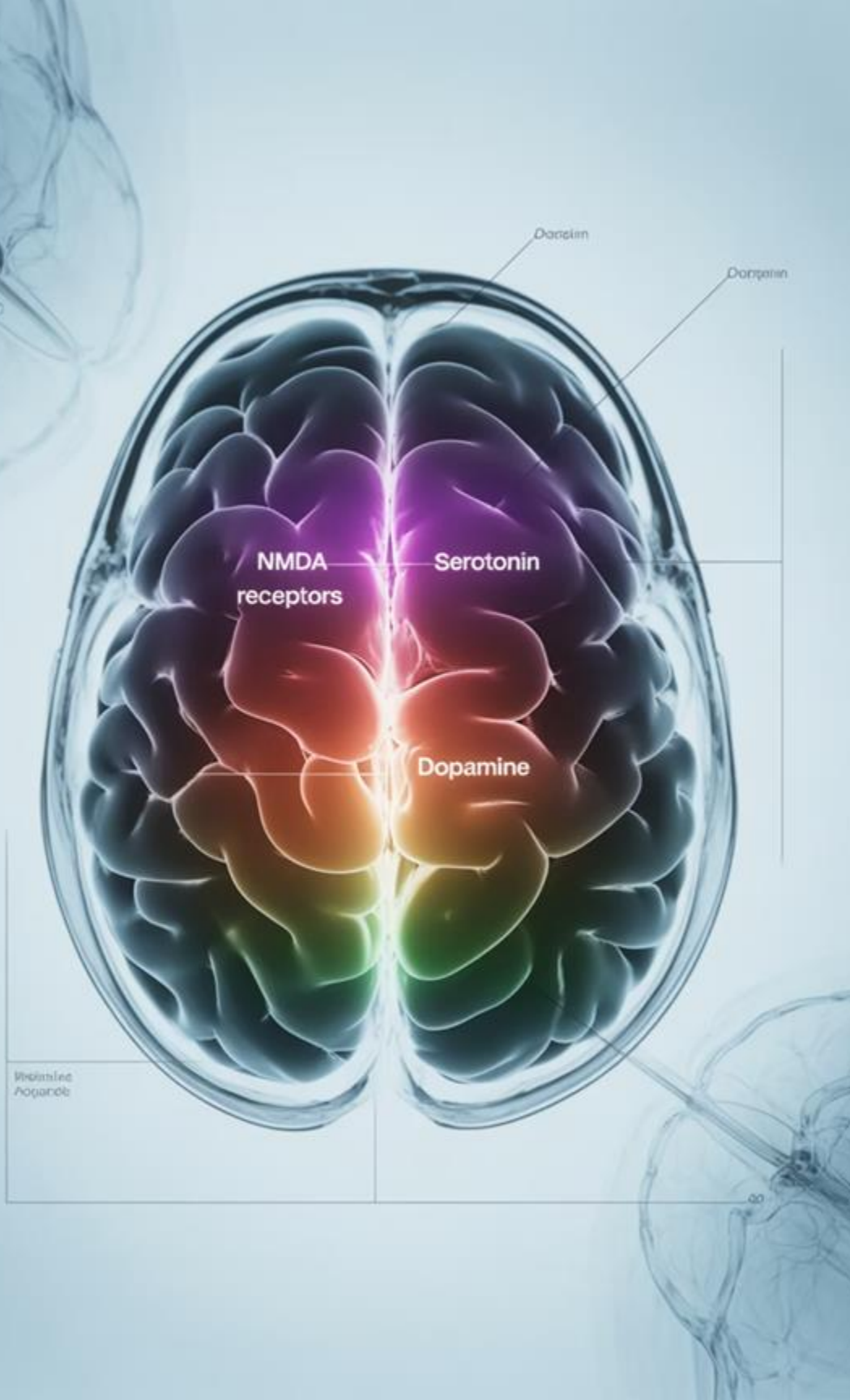
Ibogaine promotes the upregulation of GDNF and BDNF, which are vital for neuronal survival and growth in brain regions associated with PTSD.

Serotonergic and Dopaminergic Modulation

Subtle modulation of these systems may help improve mood, anxiety, and motivation in PTSD patients.

Default Mode Network Modulation

Microdosing may cause subtle shifts in DMN activity, which could improve cognitive flexibility and decrease rumination, addressing core cognitive symptoms of PTSD.



Manufacturing Excellence

In-House Manufacturing Advantages

DioMEDe Science and OctaGenix will conduct all manufacturing in-house in the UK, adhering to regulatory guidelines from the Medicines and Healthcare products Regulatory Agency (MHRA). This strategic decision ensures complete quality control and intellectual property protection throughout the development process.

Phased Manufacturing Approach

R&D Batches: Initial formulation development and stability testing

GLP Batches: Non-clinical studies requiring Good Laboratory Practice standards

GMP Batches: Human clinical trials and future commercial use under Good Manufacturing Practice



Comprehensive Preclinical Package



Pharmacology Studies

Confirm target engagement and efficacy in animal models of PTSD, examining behavioral, cognitive, and neurobiological effects of microdosed ibogaine.



Pharmacokinetics

Assess how ibogaine is absorbed, distributed, metabolised, and excreted at microdoses, with special attention to bioavailability and half-life.



Toxicology Studies

Single- and repeat-dose toxicity in multiple species, with special focus on cardiovascular safety due to known cardiac risks with full doses.

All preclinical studies will adhere to the highest standards of scientific rigor and ethical animal treatment, following ARRIVE guidelines and seeking to minimise animal use through careful study design.





Phase 1/2 Clinical Trial Design

Phase 1 Component (Healthy Volunteers)

- 30-50 healthy adults in single and multiple ascending dose studies
- Primary objective: Assess safety and tolerability of microdosed ibogaine
- Intensive safety monitoring including ECGs, vital signs, and neurological assessments
- Characterisation of pharmacokinetic profile at microdoses

Phase 2 Component (PTSD Patients)

- Randomised, double-blind, placebo-controlled trial with 80-150 patients per arm
- Chronic microdosing for 8-12 weeks with standardised psychotherapy
- Primary efficacy endpoint: Change from baseline on CAPS-5 or PSS-I
- Secondary endpoints: Anxiety, depression, sleep, and functional measures

All trials will adhere to Good Clinical Practice (GCP) guidelines and be conducted under oversight from ethical review boards.



Phase 3 Pivotal Studies

Study Design

Multicenter, randomised, double-blind, placebo-controlled trials with hundreds to thousands of patients across diverse demographics and PTSD subtypes. Studies will assess the durability of response and impact on functional outcomes over 6-12 months.

Primary Efficacy Endpoints

- Change from baseline in CAPS-5 total symptom severity score at specified timepoint
- Response rate ($\geq 30\%$ or $\geq 50\%$ reduction in CAPS-5 score)
- Remission rate at primary endpoint timepoint

Secondary Endpoints

- Functional improvement (work, social, family domains)
- Quality of life measures
- Healthcare resource utilisation
- Long-term safety and tolerability

Market Opportunity and Differentiation

8.3M

US Adults with PTSD

Approximately 3.6% of the US adult population experiences PTSD in a given year, with higher rates among veterans and first responders.

40%

Treatment Resistance

A significant percentage of PTSD patients show limited response to current first-line treatments, including SSRIs and psychotherapy.

\$4.2B

PTSD Market by 2028

The global PTSD therapeutics market is projected to grow substantially as novel mechanisms are validated and awareness increases.

Our microdosed ibogaine approach offers several key advantages over existing treatments, including potentially faster onset of action, improved neuroplasticity support, and a novel mechanism that may benefit treatment-resistant populations without the risks associated with full psychedelic doses.

Conclusion and Investment Opportunity

The co-development of microdosed ibogaine for PTSD by DioMEDe Science and OctaGenix, with collaboration from the Wyatt Group, presents a promising new therapeutic avenue with significant market potential. By leveraging ibogaine's unique neurobiological mechanisms at sub-perceptual doses, our program aims to deliver:

- A safe, well-tolerated adjunctive treatment to psychotherapy
- Effective symptom relief for patients with PTSD and Complex PTSD
- A clear regulatory pathway through our structured manufacturing and clinical plans
- Strong commitment to patient safety and data integrity throughout development

We invite strategic partners and investors to join us in developing this innovative treatment that has the potential to transform the lives of millions suffering from PTSD worldwide.



Case Study – We’ve Been Here, and We Know the Way

BY: Dr Zulfiqar Khan

Cannabis to Sativex: The \$7.2 Billion Prescription Product

In the late 1990s, **Geoffrey Guy, Brian Whittle, Tom Chapman**, and I interviewed MS patients using high-THC cannabis.

The subjects reported reduced muscle spasticity and remarkable pain relief.

That insight led to the **first cannabis-based “specials” medicine** in Dr. Chapman’s lab in Brough (UK).

- While Tom Chapman and I could not secure funding for trials, Geoffrey Guy and Brian Whittle raised **\$5M**.
- Result: Sativex, launched in 2010, the world’s first and still only prescription THC-based medicine.
- In May 2021, Jazz Pharmaceuticals acquired GW Pharmaceuticals (makers of Sativex) for **\$7.2 billion**.

Main Lesson:

- We spotted a huge unmet medical need before anyone else.
- We proved it with real patient feedback and solid lab data.
- That proof sparked a multi-billion-dollar global success story.
- We missed out due to funding gaps.
- Early investors seized the moment and turned millions into billions.

The Next Sativex is Here: Psychedelics

The Multi-Billion-Dollar Opportunity Investors Can't Miss!

Today, Psychedelics are **exactly where Medical Cannabis was 15 years ago**, on the brink of disrupting; Mental health, Addiction, and PTSD treatment worldwide.

We already have:

- ✓ Preliminary clinical data showing strong potential
- ✓ Laboratories & protocols ready to initiate trials
- ✓ A proven regulatory pathway based on the Medical Cannabis and Sativex model
- ✓ A world-class team of renowned scientists
- ✓ Artificial Intelligence tools to accelerate trials
- ✓ Regulatory expertise to fast-track a licensed product to market in record time

The Market:

- Massive unmet need; PTSD, Addiction, Mental Health Disorders
- Potential market size: **In Excess of \$10B**
- Early-mover advantage and global category leader

WE TURNED INSIGHT INTO BILLIONS ONCE, IMAGINE WHAT IS NEXT!