

LPCN 2201

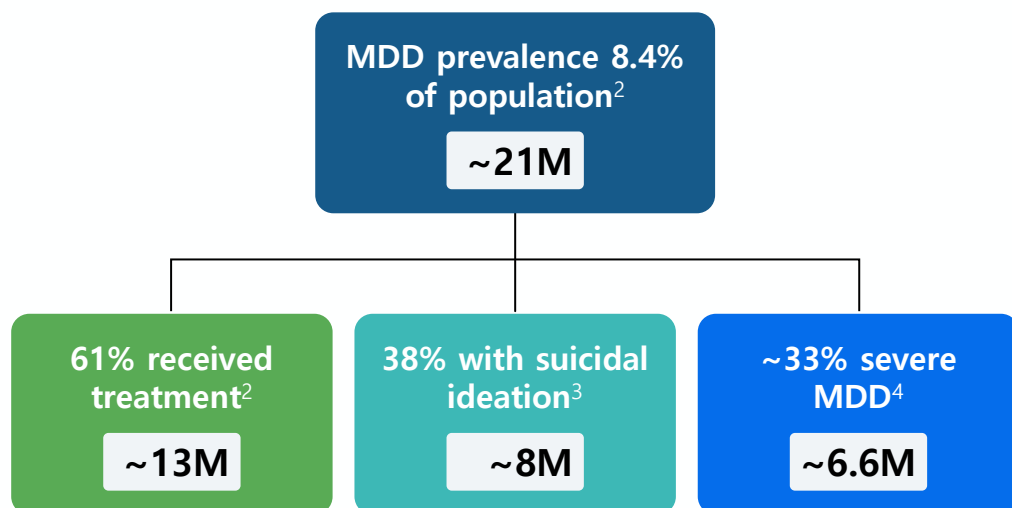
Oral Brexanolone for
Major Depressive Disorder (MDD)



MDD Market Potential

Total annual burden of medication-treated MDD among the US population was \$92.7 billion¹

Severe MDD is strongly linked to significant difficulty in work, social, and home activities



SPRAVATO® Rx cost: ~ \$15,000 annually*, \$405M in Q3 2025⁵

AUVELITY® Rx Cost: ~\$15,000 annually, \$136 M in Q3 2025⁶

Market expected to reach \$31B by 2030⁷

Significant Unmet Needs in Depression Disorders



Rapid Relief

Hours/Days, especially for severe MDD



Robust Efficacy

Adequate and durable remission/response; treat anxiety comorbidity



Good Tolerability

Minimal CNS depressant effects, no dissociation, no sexual dysfunction or weight gain side effects, no withdrawal side effects upon discontinuation



Unrestricted Access

Outpatient or at home use

LPCN 2201 – Targeted Attribute-Based Product Differentiation

Potential Rapid Acting Anti-depressant (RAAD)

Product Attribute*	LPCN 2201 (Neuroactive Steroid)	SPRAVATO (Esketamine) ¹	AUVELITY (Dextromethorphan + bupropion) ²	SSRI/SNRI
Mechanism of Action	Positive GABA _A modulator	NMDA receptor antagonist	NMDA receptor antagonist + norepinephrine/dopamine reuptake inhibitor	Serotonin reuptake inhibition (SSRI) or serotonin + norepinephrine reuptake inhibition (SNRI)
Route	Oral	Intranasal	Oral	Oral
Onset of Efficacy	Hours to days	Hours to days	1-2 weeks	4-8 weeks
Key AEs	TBD	Psychological effects (61-84%) including dissociation, dizziness (29%), nausea (28%), sedation (23%), vertigo (23%)	Dizziness (16%), nausea (13%), dry mouth, somnolence	Sexual dysfunction, weight gain, GI upset
Monitoring/ Administration Setting	Not expected/At home	REMS/In-clinic observation (≥2 hrs post-dose)	None required/At home	None required/At home

Psychedelic Drug Candidates

Issues and Challenges

- **Not appropriate for all patients**
 - Psychedelics can cause strong psychomimetic effects, sometimes overwhelming or distressing
 - May trigger anxiety, confusion, or panic in some individuals.
 - Patients with personal or family histories of certain mental health conditions (like psychosis) may be at higher risk of adverse effects
- **Side effect**
 - While generally mild to moderate, notable side effects include nausea and headache
- **Requires controlled clinical setting and 4 hours monitoring** Even short-acting psychedelics require: Medical supervision
Psychological support
Safety monitoring
This limits access and increases cost.
- **Emotional intensity of the psychedelic experience**
 - Even in a therapeutic setting, psychedelic sessions can be: Emotionally overwhelming, Anxiety-inducing, Unpredictable in psychological content. This may deter some patients.
- **Limited data on long-term infant and maternal outcomes**

LPCN 2201 – Oral RAAD for Major Depression Disorders

Potential to set rapid relief benchmark for MDD

- ✓ High unmet need for oral RAAD; large market potential
- ✓ Leverage expertise/credibility and investment/value in oral NAS created to date
- ✓ Streamlined development
- ✓ Issued and pending patent claims for MDD indication

Attributes

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Rapid Relief



Convenient Oral

At-Home Use



Favorable

Safety Profile

