

Two indications. One film. One pilot.

The first clinical program testing a sublingual esketamine film with PTSD as the primary indication and autoimmune disease as an adjunctive — from a single Phase 1/2 pilot. 505(b)(2) pathway confirmed. LTS Lohmann GMP manufacturing active. IRB-ready, Q4 2026 enrollment.

Sublingual Film • Flexible Dose 26—90mg • At-Home After First Dose • PTSD Primary • Autoimmune Adjunctive

\$3.5B+

PTSD therapeutics market by 2035 (primary indication)

\$120B+

Autoimmune therapeutics market (adjunctive opportunity)

2×

Higher autoimmune rate in PTSD patients (O'Donovan 2015, N=666K)

25+

Years since last novel PTSD mechanism was FDA-approved

Why now: the post-Lykos window is wide open.

FDA's rejection of MDMA-assisted therapy for PTSD (Aug 2024) eliminated the only other novel PTSD candidate with a home-adjacent delivery model — and re-prioritized clean, placebo-controlled evidence. Ketamine's RCT record is exactly that. No approved biologic holds the PTSD primary label. The same molecule now has transcriptomic proof (Wellington 2025) of modulating the cytokines targeted by Skyrizi, Cosentyx, Humira, and Actemra.

THE DUAL-INDICATION THESIS

One molecule. Two price points. One pilot to signal both.

PATH 1 Psychiatric — PTSD primary

Primary CAPS-5 endpoint. 505(b)(2) IND pathway confirmed by FDAMap. Phase 2 RCT → NDA. Positioned alongside Spravato at ~\$64K/year reimbursement.

Feder 2021 (d=1.13) • Feder 2025 (d=1.9)

PATH 2 Immunology — autoimmune adjunctive

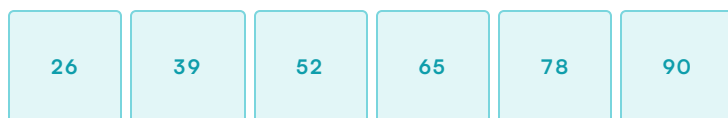
Exploratory disease-activity endpoints in same Phase 1/2 cohort. If signal → Phase 2b adjunctive to standard-of-care immunologics. Positioned on rheumatology shelf at ~\$250K/year reimbursement.

Wellington 2025 (IL-17, IFN- α/β , cytokine storm) • Lee 2017 (Th17 EAE)

FLEXIBLE DOSE DESIGN

Tile-based titration. Not a fixed dose.

13mg tiles combine to deliver 26, 39, 52, 65, 78, or 90mg per session within a single label — a differentiated, defensible Phase 3 label grounded in ketamine's inverted-U dose response.



AT-HOME REMS NON-INFERIORITY

Match Spravato's monitoring standard remotely.

- **HR/SpO₂ concordance** ≥ 0.70 vs. in-clinic
- **CADSS remote sensitivity** ≥ 90%
- **Automated escalation** within pre-specified vital-sign envelopes
- **FDA precedent**. MindMed/definium SMS pre-sub cleared at 126-patient scale

COMPETITIVE POSITIONING

Only dual-indication NMDA program in active development.

	PROJECT LUCID	SPRAVATO (J&J)	IV KETAMINE	COMPOUNDED SL	AUTOIMMUNE BIOLOGICS
PTSD indication	Phase 1/2 active	Not indicated	Off-label	Off-label	N/A
Autoimmune indication	Exploratory endpoints	None	None	None	Primary
Dual-indication design	Yes — only program	No	No	No	No
Route	Sublingual film	Intranasal	IV	Oral (unregulated)	IV / SC
At-home scalability	Designed for it	Blocked by REMS	Impossible	No FDA path	SC self-inject only
Digital monitoring	Wearable + app, patent-pending	Clinician only	None	None	None
Reimbursement target	\$64K (psych) or \$250K (immunology)	~\$64K (TRD)	\$5–10K (cash)	\$1–2K (cash)	\$64–250K
FDA pathway	505(b)(2) confirmed	Approved (TRD)	Off-label	None	BLA

MILESTONE ROADMAP

Four investor-catalyst events in 18 months.

Q3 2026

IRB approval

Protocol v3.0, 66pp, 4-member DSMB incl. rheumatologist.

Q4 2026

Enrollment N=12

CAPS-5 ≥26 + co-occurring autoimmune. Full biomarker panel.

Q1–Q3 2027

DSMB IA-1/IA-2 + final

Go/no-go across 4 domains: PTSD, autoimmune, safety, digital.

Q4 2027

IND + Series A

505(b)(2) IND filing, dual-indication Phase 2 design, \$15–25M Series A.

SEED ROUND TERMS

\$2.5M

SAFE raise

Post-money SAFE (YC standard form). Funds Phase 1/2 (N=12), biomarker panel, REMS concordance dataset, IND filing. Series A target \$15–25M post-Phase 1 (Q4 2027). Non-dilutive path in parallel: CDMRP TBIPHRP (up to \$2.1M), NIMH SBIR. Check size and subscription details on request.

\$12M

Pre-money cap

TEAM

- **Richard Idell, MD** — Founder/CEO/Sponsor-Investigator. Dallas psychiatrist, PTSD specialist.
- **Mukesh Kumar, PhD, RAC** — Regulatory. FDAMap, 150+ trials, 505(b)(2) path confirmed.
- **Steven Idell, MD, PhD** — Scientific. Temple Chair (Pulm Fibrosis), Lung Therapeutics (acquired).
- **EMMES** — CRO, full-service Phase I–IV.
- **LTS Lohmann** — GMP film manufacturing (active partnership).
- **Neurolivd** — Lived-experience partner (Wurzman, Nelson).

EXIT COMPARABLES

Transcend — methalone acquired ~\$1.2B • **Axsome (AXS-05)** — 505(b)(2), \$5B+ mkt cap • **Spravato (J&J)** — intranasal esketamine, TRD only, ~\$64K/yr • Generic esketamine COM patent expires 2027 (Teva). Clear strategic lane for acquirers in immunology or psychiatry.