We are building the infrastructure layer for upper airway dysfunction.

Sensing, scoring, routing, therapy, outcomes — one connected system that does not exist in the market today.

We power every decision with AI.

HYPNARA™ — THE PALATAL IMPLANT

88%	$2,500
HYPNARA™ GROSS MARGIN	ASP PER PROCEDURE

PATENT PORTFOLIO — FULL PLATFORM
hardware, software, and implant, across the flywheel

6	~136
U.S. PATENT APPLICATIONS FILED	PATENT CLAIMS FILED TO DATE

THE DE-RISKING STORY

FDA-classification de-risked on the software side: counsel review concludes the Somnus Sleep™ app, the BSA™ acoustic engine, and the Somnus Index™ fit within the FDA General Wellness Policy.

The Somnus Sleep™ app turns any smartphone into a sensor via BSA™, our on-device acoustic breathing and snoring engine — zero hardware, zero cost to enter the funnel. The Somnus Index™ is a composite wellness score that tracks progression across the platform. Both operate under the FDA General Wellness Policy and are positioned in wellness terms.

Somnus Index™ is a wellness metric under FDA General Wellness Policy. Not a medical device.

Not a device gap. It's an infrastructure gap. The market keeps shipping better open-loop products into a problem that only a closed loop can solve.

01 · Narrative

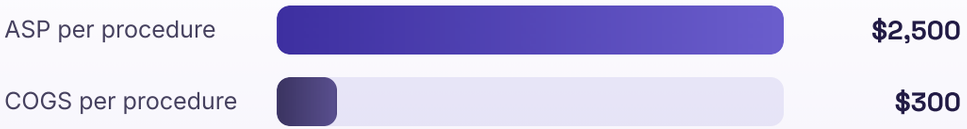
What we’re building, in our own words

We're building the infrastructure layer for upper airway dysfunction (UAD).

The clinical wedge is HYPNARA™, a palatal implant with strong unit economics: $2,500 ASP, $300 COGS, 88% gross margin, break-even at two thousand units. At its May 7, 2026 FDA Pre-Submission meeting, **FDA confirmed the 510(k) pathway and our predicate device. Clinical study is next, as planned.** A clinical study evaluating safety and effectiveness supports the change in implant material; design, sample size, and protocol are set in a supplemental Q-submission, and the 510(k) submission follows study completion. CRO partners are in final selection. That's the near-term commercial story.

— Unit economics & IP trajectory

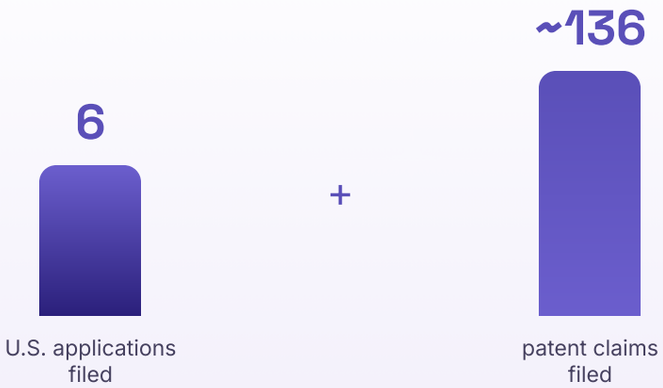
HYPNARA™ unit economics



88%
gross margin

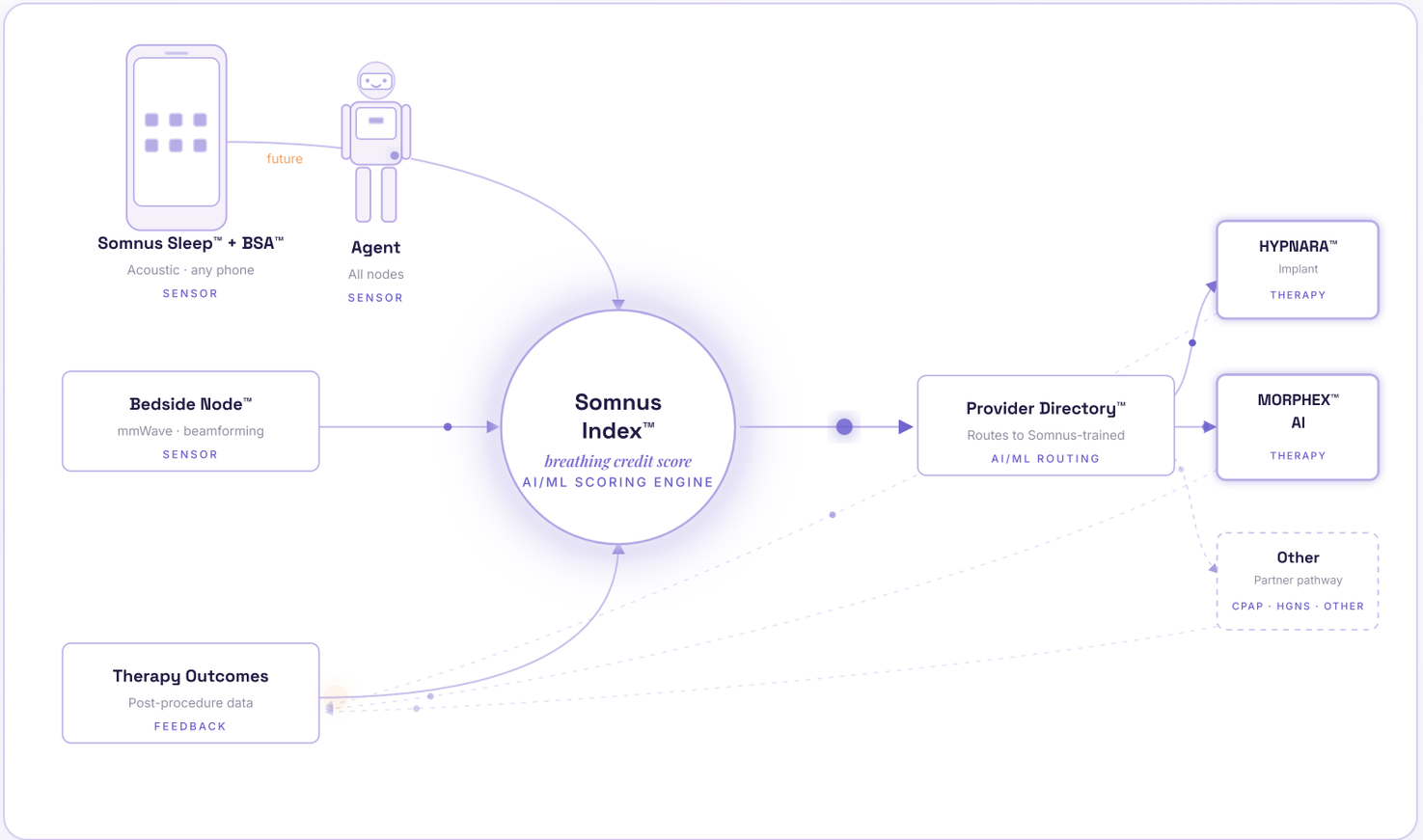
~2,000
units to break-even

IP portfolio — filed to date



02 · The Flywheel

Every product makes the others more valuable



Every treated patient sharpens routing for the next.

Sensors → Bedside Node → Somnus Index™ → Provider Directory → Therapy → Outcomes → Re-scoring & Re-routing → back to Sensors. **We are building the loop.**

03 · The Platform

Seven pieces, one flywheel

CLINICAL WEDGE

HYPNARA™

Palatal implant for snoring and mild-to-moderate OSA. 510(k) pathway via our predicate device; manufactured by Voltas Medical (ISO 13485). Passive structural device; AI/ML decision layer in the surrounding software. Pre-Sub complete (May 7) — FDA confirmed the pathway and predicate; safety-and-effectiveness clinical study is next, as planned; CRO selection in final evaluation; submission follows study.

$2,500 ASP · 88% GM · ~2,000 units

ORAL DEVICE ARM

MORPHEX™ AI

A smart oral device with on-device airway analytics, supported by an AI/ML clinical decision layer. Ships in three regulatory stages so each stage funds the next; supports clinical decision-making and does not diagnose independently.

V1 MAD → V2 wellness → V3 diagnostic

TOP OF FUNNEL

Somnus Sleep™ + BSA™

Turns any smartphone into a sensor via BSA™, our on-device acoustic breathing and snoring engine. Zero hardware, zero cost to enter the funnel. Machine-learned acoustic classification with per-patient calibration.

Pre-launch · FDA General Wellness Policy-aligned

THE SCORE

Somnus Index™

Composite wellness score that tracks progression across the platform. Patient-facing in the app, provider-facing in the Directory. Operates under the FDA General Wellness Policy and is positioned in wellness terms.

Core of the defensible moat

PROVIDER INTERFACE

Somnus Provider Directory™

Launch: patient-browsable directory of sleep-health providers from public registry data (NPPES). Neutral, informational — no credentialing claim, no selective routing — in the wellness context.

Roadmap (V3): predictive, selective routing layer and provider worklist is a roadmap capability on the device-software track; pathway under counsel review.

PREMIUM TIER · ROADMAP

Somnus Bedside Node™

Premium-tier bedside hardware with mmWave radar and beamforming mics. Extends BSA™ and the Somnus Index™ beyond the phone, and pairs with the MORPHEX AI V3 diagnostic tier when that stage activates. Multi-modal sensor fusion with graceful degradation.

Roadmap — aligns with MORPHEX AI V3

— The Moat

The post-therapy outcome data nobody else captures is our training set.

The Long-Term Moat Is the Closed-Loop Data Network

The seven pieces are the components; the loop that connects them — sense, score, route, treat, re-score — is the durable asset. We are building the loop. As one connected system it does not exist in the market today, and it is the subject of multiple patent-pending applications across the closed-loop architecture, scoring, routing, and sensor-fusion claim families.

We're not selling a device. We're building the infrastructure layer for upper airway dysfunction.

Maturity reflects build status, not accumulated usage.

04 • Near-Term Milestones

What the round funds

Use of proceeds. First-close capital funds HYPNARA™ through the FDA-required clinical study and 510(k) submission, the Somnus Sleep™ launch, IP-portfolio expansion, and provider-network seeding. The full round adds the MORPHEX AI V1 MAD 510(k) workstream.

- HYPNARA™ clinical study initiated and progressed toward 510(k) submission.
- Somnus Sleep™ launched; early engagement traction.
- IP portfolio expanded from the filed base of 6 applications / ~136 claims.
- Provider network seeded (neutral, public-registry-sourced directory at launch).
- MORPHEX AI V1 MAD 510(k) workstream underway (full-round capital).

05 · The Ask

Terms & structure

$3–5M	$20–24M	Single entity	$2.5M	10–12 wk
TARGET RAISE	PRE-MONEY	STRUCTURE · SAFE	FIRST CLOSE	CLOSE TIMELINE

- **Round —** one round, one entity; $3M–$5M at $20M–$24M pre-money.
- **Option pool —** 10% reserved at close. **Board —** three seats: Founder/CEO, Lead Investor, Independent.
- **Issuer —** Somnus Technologies, Inc., a Wisconsin C-corporation, single entity through seed close.

USE OF FUNDS — FIRST CLOSE ($2.5M), 18-MONTH RUNWAY TO CLEARANCE & SERIES A READINESS

MILESTONE A

HYPNARA™ to clearance + first implants

- 510(k) pathway and predicate confirmed; clinical study planning underway → submission post-study → clearance.
- R&D, biocompatibility, and delivery-tool development; Voltas Medical scale-up under the existing ISO 13485 agreement.

MILESTONE B

Somnus Sleep™ launch

- Patient-acquisition funnel goes live; the BSA™ acoustic engine in production.
- Target 10K downloads, 1K engaged patients within the first-close window, at near-zero marginal CAC.

MILESTONE C

IP-moat deepening

- Additional provisional applications across the portfolio — porous-UHMWPE chemistry, delivery-tool variants, anchor geometries, and closed-loop data network extensions.
- Somnus Index™ validation study (Q2–Q3 2026) supports the closed-loop data network moat.

MILESTONE D

Provider-network seeding

- 25 Somnus-trained™ providers credentialed in the Somnus Provider Directory™.
- Anchored to palate-dominant anatomy workup; seeds the HYPNARA™ commercial pipeline.

Series A readiness at month 18: HYPNARA™ cleared, MORPHEX AI V1 in flight on full-round capital, the closed-loop data network moat validated, and a 25-provider network live.

An F-reorganization (IRC §368(a)(1)(F)) to a destination jurisdiction is planned pre-Series A and is investor-contingent; the destination is open. The HoldCo + two-subsidiary structure (Somnus Medical Devices, Inc. + Somnus Digital Health, Inc.) is a Phase-2, pre-Series A event.

06 · Advisors

The room we've built around this

John R. McDonald — Shareholder · Chair, Startups & VC · Godfrey & Kahn, S.C.

Amy Salmela — Partner · U.S. Patent Attorney · EIP

Jeffrey K. Shapiro — Partner · FDA & Life Sciences · King & Spalding LLP

Agustin J. Arrieta, MD — Otolaryngology / Sleep Medicine · Clinical advisor & HYPNARA™ candidate-evaluation reference.

Mike Kremkau — Strategic Advisor · Industry veteran.

Matthew Cronin · Founder & CEO
mcronin@somnustech.ai

Book a 10-minute call →

"On any full clinic day, I see three to five patients presenting with snoring concerns — sometimes more. The demand for a single-procedure palatal solution is steady and underserved by today's options." — Agustin J. Arrieta, MD

Website by Lavahopper AI