COAT™ by Evon Medics, Inc.

Computerized Olfactory Adaptive Training — An Intelligent, Closed-Loop Olfactory Neuromodulation Platform

Investor Executive Summary | 2026

The first intelligent, closed-loop olfactory neuromodulation therapy — engineered to restore brain structure and cognition in early Alzheimer's disease.

$11.5M	$300B+	5.7M+	$9.8M
Total Target Capital	Alzheimer's TAM by 2030	US Patients (AD & aMCI)	Over-cap R01 request approved (in peer review)

The Problem: A $1 Trillion Crisis Without a Structural Solution

Over 5.7 million Americans live with early Alzheimer's disease (AD) or amnestic mild cognitive impairment (aMCI) — a population projected to exceed 20 million worldwide by 2026. The new anti-amyloid antibodies (lecanemab, donanemab) are a genuine advance, yet they expose a hard truth: clearing amyloid does not stop neurodegeneration. Brain atrophy continues and cognition declines. These therapies also require lifelong IV infusions, carry ARIA (brain swelling and micro-hemorrhage) risk, and remain out of reach for most patients — disproportionately so for the underserved communities the disease burdens most. No approved therapy today restores brain structure or cognitive function in early AD.

The Solution: COAT™ — Intelligent, Closed-Loop Neuromodulation

COAT™ is the first intelligent, closed-loop olfactory neuromodulation platform for early Alzheimer's disease. It is not a scent dispenser. It is an adaptive therapeutic system that uses the one sensory pathway with a near-direct line into the brain's memory circuit — the olfactory route into the entorhinal cortex and hippocampus, the first regions AD attacks — to re-engage and rebalance the dysregulated medial temporal lobe (MTL) networks that drive early decline.

Delivered through a nasal cannula for 18 minutes a day at home, COAT's onboard telemetry reads each user's cognitive-sensorimotor response, and its adaptive engine re-computes the stimulus every session — sequence, timing, flow rate, and dilution — so no two sessions are alike. This closed-loop design is deliberate: the brain habituates to repetition, so COAT's proprietary Similarity–Dissimilarity Index (SDI) and Adaptive Randomization Algorithm engineer a novel neuroplastic stimulus every time, sustaining engagement of the very circuits the disease works to shut down.

The odorants are the actuator. The therapy is the adaptive intelligence driving them.

Why COAT Wins: A Defensible, Compounding Moat

COAT is the only therapy that simultaneously modifies disease, restores brain structure, and improves cognition — safely, at home. Its moat is built on five reinforcing pillars:

- **Adaptive-intelligence engine & data moat —** a closed-loop learning system whose telemetry compounds a proprietary dataset with every session, on top of a decade-built trade-secret database mapping 100+ neuroplastic scent molecules to 300+ brain regions. This is what a competitor cannot copy: not the device, but the intelligence and data driving it.

- **Intellectual property —** 3 global utility patents (2 issued, 1 pending) covering the closed-loop adaptive delivery mechanism and personalized scent algorithms.
- **Regulatory —** FDA Breakthrough Device Designation (in progress) and a De Novo pathway, which also unlocks the CMS Transitional Coverage for Emerging Technologies (TCET) reimbursement pathway.
- **Federal validation —** peer-reviewed feasibility results, an NIH research spotlight (2026), and NIA approval to submit an over-cap $9.8M R01 for the Phase 3 trial (currently in peer review).
- **Access by design —** non-invasive, home-based, no ARIA, no infusion suite, >90% adherence — reaching the populations amyloid therapies cannot.

Clinical Evidence: Peer-Reviewed, Multi-Level Results

In a randomized, sham-controlled feasibility trial (N=70; early AD and aMCI; NCT05122598), COAT produced consistent effects across every level measured — reducing excessive MTL connectivity, preserving and increasing gray-matter volume in memory-critical regions, and delivering clinically meaningful cognitive gains — with an excellent safety profile.

Outcome	Result
Cognition (PACC)	+2.34 units vs. control (p = 0.02)
Clinical decline (CDR-SB)	−0.466 units at Month 9 vs. +0.749 in control (between-group separation 1.2 pts; p < 0.001)
Brain volume — hippocampus	MRI-confirmed increase (p = 0.034)
Brain volume — entorhinal cortex	MRI-confirmed increase (p = 0.001)
Gray-matter volume	+2.6% in memory-critical regions
Network connectivity	Reduced excessive MTL coupling across 15 resting-state pathways
Adherence / Safety	92% adherence; zero serious adverse events; no ARIA

To our knowledge, this is the first evidence of structural restoration in critical memory regions paired with cognitive improvement from a non-invasive, at-home therapy (Hipólito M, et al., Alzheimer's & Dementia and Alzheimer's & Dementia: TRCI, 2026).

Reimbursement Strategy: Predicate-Backed, Not Aspirational

Reimbursement is the question sophisticated MedTech investors probe first — and our position traces to real precedent. Every non-invasive, at-home neuromodulation device that reached Medicare did so through a unique Level II HCPCS code obtained via the CMS coding cycle: electroCore's gammaCore (K1020) and, closest to us, Cala Health's Cala Trio (K1018 device + K1019 supplies). Cala is our direct analog — a durable console plus a recurring consumable, coded as a device code and a separate supply code — mapping onto COAT's $5,000 console and $1,000/yr cartridges. Our strategy runs on two parallel tracks:

- **Revenue today —** Remote Therapeutic Monitoring management (CPT 98975 set-up; 98980/98981 and the new 2026 code 98979) captures COAT's closed-loop telemetry and adherence data, alongside the clinician cognitive-care-plan visit (CPT 99483) and Medicare IDE trial-coverage during the pivotal study.
- **Durable coverage —** a Cala-style unique HCPCS device-plus-cartridge code, positioned for the Durable Medical Equipment (DME) benefit category — with COAT's console engineered to clear the 3-year useful-life bar that decided coverage for our predecessors — accelerated by a TCET letter of intent enabled by our Breakthrough designation.

We present this to investors plainly: reimbursement is a managed, lifelong risk for any therapeutic. Our edge is a multi-code strategy in which every element traces to a real precedent — RTM revenue now, a unique device-plus-supply code in progress, and a TCET-accelerated DME path ahead.

Market Opportunity & Economics

Evon Medics targets the early-stage, at-home segment of the Alzheimer's market — where need is greatest and intervention is most impactful. The global Alzheimer's market is projected to exceed $300 billion by 2030 (~7% CAGR), with devices and digital therapeutics representing a $60B+ opportunity alone. The economics are compelling: against a standard-of-care cost of $234K–$288K per patient over nine years, COAT's total cost is roughly $13K per patient — up to ~$600K in combined medical and caregiver savings.

Revenue Model

- **Hardware —** $5,000 one-time device sale (COGS < $1,000 at scale).
- **Consumables —** $1,000/year per patient in adaptive odorant-cartridge replacements (recurring, high-margin).
- **Reimbursement —** RTM management today; a unique HCPCS device + cartridge code in progress; a TCET-accelerated DME coverage pathway ahead.

Non-Dilutive Traction & De-Risking

COAT is among the most de-risked assets at its stage — validated by the world's most rigorous non-dilutive funder:

- **$15M+** in cumulative non-dilutive federal funding secured to date (NIH / NIA / NINDS / NIDA, 2018–2025).
- **NEW — NIA approval to exceed the R01 direct-cost cap.** NIH's standard R01 limit is $500K in direct costs per year (~$2.5M over five years). NIA's Division of Neuroscience has approved our request to submit above that cap, permitting a $9.8M budget request for the Phase 3 COAT-vs-Sham trial (PAR-25-332). The application is pending peer review; if funded, the award would begin April 1, 2027 — a potential non-dilutive source for the long-term pivotal trial.
- **Peer-reviewed publications** and an NIH research spotlight (2026).
- **124 memory-clinic partners** identified for pivotal launch; deep collaborations with Howard University, Johns Hopkins, and Georgetown.

The Ask: A Financing Sequenced to Program Milestones

Evon Medics is raising $11.5M across two tranches, timed to the program's clinical and regulatory inflection points:

Tranche	Purpose
Seed — $1.5M (H2 2026)	Finalize device manufacturing, initiate pivotal-trial operations, and engage key clinical sites.
Series A — $10M (H1 2027)	Raised as the pivotal program launches: scale ISO 13485 manufacturing, pursue FDA De Novo clearance, advance the HCPCS/TCET reimbursement strategy, and prepare commercial launch.

Milestone Timeline

H2 2026	Q1 2027	Apr 2027	H1 2027

Seed close	Global pivotal studies begin	R01 award start, if funded ($9.8M request)	Series A

The Series A is timed to the program's strongest inflection — pivotal studies underway and the R01 decision in hand. If the pending $9.8M R01 is funded from April 2027, it would carry the core long-term trial, concentrating investor capital further toward manufacturing, regulatory clearance, reimbursement, and commercialization. The financing plan does not depend on that outcome. Illustrative Series A allocation: 60% clinical & pivotal-trial operations · 20% manufacturing scale-up · 12% regulatory, IP & reimbursement · 8% working capital.

Leadership Team

- **Evaristus Nwulia, MD, MHS —** Co-Founder & CEO; Director, Blueprint NeuroTech Incubator; pioneer of olfactory Alzheimer's research.
- **Charles Nwaokobia, MBA —** COO & President; operations and growth leadership.
- **Sumeet Seth, MBA —** Chief Commercialization Officer; CEO of Trulogik; deep medtech go-to-market experience.
- **Thomas Obisesan, MD, MPH —** Chief Medical Officer; Professor & Director, Memory Center, Howard University.
- **Bryant Moore, Ph.D.** – Senior Advisor of Strategic Partnership, Evon Medics Inc; Previously 10-year VP Medtronic; Chair of Innovation, Natus Inc. (facilitated 2022 acquisition of Natus Inc. by Archimed)
- **Vamsi Reddy, MSE —** Global Head of Product Development.
- **Holly Cotter, RAC —** Lead Regulatory Advisor; Founder, White Lamb Regulatory Services.
- **Sebastian Seiguer, JD, MBA —** Chief Legal & Business Advisor; CEO of Scene Health; SBIR-to-market experience.

COAT is not a better version of an old idea. It is a new category — intelligent, closed-loop neuromodulation that restores brain structure while improving cognition, delivered at home, and validated by federal peer review. We invite you to build it with us.

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Financial projections are approximate and subject to change. Clinical results from Hipólito M, et al., Alzheimer's & Dementia: TRCI, 2026. Reimbursement pathways are strategy in development and not a guarantee of coverage.