

AEVION QVenture — Investment Memo

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NeuroDx

Healthtech / Digital Health · seed · US · raising \$6,000,000

Score 69.5/100 — WATCH (conviction: medium)

Investment memo

We recommend a conditional lead—a "watch that leans in"—on NeuroDx: strong enough to anchor a term sheet, structured enough to survive a binary regulatory outcome. The single strongest reason to act is a genuine, time-boxed moat: a breakthrough-device-designated FDA clearance would turn any optometrist's chair into an Alzheimer's screening point, backed by 89% sensitivity, 22% MoM growth to \$55k MRR, and a 5.1x LTV/CAC that signals real execution. The single strongest reason against is reimbursement dependency—with no CPT code or payer coverage for pre-symptomatic screening, the multi-trillion TAM collapses to a cash-pay niche while FDA and prospective-validation timelines burn well past this \$6M. Entry plan: lead with ~\$2.28M for ~10% at a ~\$16.8M pre-money, hard-capped at \$3M, released in milestone tranches tied to disclosed specificity/PPV, prospective-cohort progress, and evidence of a coverage pathway, with IP warranties and pre-clearance marketing-claim reps. Reserve ~\$3.4M for pro-rata; size at ~2.2% of the portfolio.

Narrative engine: live model (anthropic)

Entry strategy

Ticket: \$2,275,500 target (range \$1,137,750–\$3,000,000)

Target ownership: 10%

Valuation band (pre-money): \$8,468,000 / \$16,755,000 / \$33,510,000

Return: 7.21x expected (16.8x base) · ~32.6% IRR over 7yr · loss prob 58%

Deployment schedule:

- 40% — Entry: On close, after founder + IP + cap-table diligence.
- 35% — Milestone: Product-market fit signal (retention cohort / first repeatable revenue).
- 25% — Pro-rata: Reserve for next priced round to defend ownership.

Portfolio: Size at ~2.2% of a diversified venture portfolio (fractional-Kelly, conviction-scaled). Reserve 3,413,250 USD for pro-rata follow-on.

Score breakdown

Market size & growth — 83/100 (weight 20%)

~\$11000B TAM, 18% CAGR (Healthtech / Digital Health).

Timing / tailwinds — 65/100 (weight 10%)

Sector growth 18% vs. 12% neutral baseline.

Moat / defensibility — 82/100 (weight 15%)

Dominant defensibility here: regulatory license.

Unit economics potential — 54/100 (weight 15%)

~60% mature gross margin, capital intensity 60%.

Team / execution signal — 92/100 (weight 12%)

revenue/customers cited; growth metric cited; unit-economics metric cited

Scientific / tech feasibility — 60/100 (weight 10%)

multimodal diagnostic models, FDA SaMD pathways, RWE evidence loops

Regulatory / legal headroom — 42/100 (weight 9%)

Regulatory intensity 90% (higher = more legal drag).

Competitive headroom — 58/100 (weight 9%)

Competitive intensity 60%. reimbursement dependency and long clinical validation cycles.

Analyst council

Research Scientist — Retinal-scan Alzheimer's screening is scientifically plausible but hinges on prospective validation and reimbursement, not seed-stage sensitivity claims

- + Retinal biomarkers for AD have genuine research backing: retinal amyloid imaging (NeuroVision), OCT-derived retinal nerve fiber layer thinning, and vascular changes correlate with brain amyloid/tau. UK Biobank and Duke oculomics work show DL can extract systemic disease signals from fundus images, so the mechanistic prior is credible, not hand-wavy.
- + 89% sensitivity vs PET in 1,200 patients is promising but the critical missing numbers are specificity, PPV in a low-prevalence screening population (~10-15% preclinical), and whether the cohort was retrospective/case-enriched. At screening prevalence, even 89% sens / 90% spec yields poor PPV and high false-positive burden — the standard failure mode for these claims.
- + Self-supervised vision models can overfit to site/scanner/demographic confounders (fundus camera model, image quality) rather than true pathology — the well-documented 'shortcut learning' problem in medical imaging. Needs multi-site, multi-device external validation and prospective enrollment to survive FDA and clinical scrutiny.
- + Breakthrough-device designation only *filed* (not granted); clearance likely requires a prospective pivotal study. De-risking event is a locked-model prospective trial hitting predefined spec/PPV against amyloid-PET or CSF ground truth, plus a defined intended-use (screen-to-refer, not diagnose).
- ! Regulatory + clinical validation timeline: prospective pivotal + FDA (De Novo/510k) plus longitudinal ground truth is likely 3-5 yrs and >\$6M; seed round unlikely to reach clearance without material dilution.
- ! Reimbursement: no CPT/coverage pathway for pre-symptomatic AD screening, and clinical utility is contested without disease-modifying therapy access — screening value undermined if positives can't act. Regulatory intensity scored 90/100 for good reason.
- ! Ground-truth and confounder risk: reported sensitivity may reflect case-enriched retrospective data and scanner-specific shortcuts; PPV could collapse in real optometry-chair screening, inviting overdiagnosis liability.

Data Analyst — NeuroDx: compelling retinal-AD screening traction, but TAM inflated and reimbursement/FDA path unproven

- + TAM of \$11T is nonsensical for this use case — the real SAM is US eye-exam volume (~40M comprehensive exams/yr) x realistic AD-screening penetration. At even \$50/test on 10M screens, SAM"~\$500M; SOM at seed is low single-digit millions. The 83/100 market score rests on a category-level, not addressable, figure.
- + Unit economics are asserted (LTV/CAC 5.1x, 60% mature GM) but unverifiable at \$55k MRR/14 clinics (~\$3.9k MRR/clinic). 22% MoM is real but off a tiny base; need cohort retention, per-scan pricing, and who pays (clinic, patient cash, or CMS) — LTV is meaningless without reimbursement clarity.
- + Clinical claim (89% sensitivity vs PET, n=1,200) is promising but specificity is conspicuously omitted — for a screening tool false-positive rate drives clinical utility and liability. 'Breakthrough designation filed' "" granted; no PMA/De Novo clearance means no billing code and no defensible moat yet.
- + Comparable diagnostic-AI multiples (IDx/Digital Diagnostics, Viz.ai) show revenue only scales after FDA clearance + CPT reimbursement — a 3-5yr, \$20-50M+ capital path. \$6M seed is thin vs 60% capital intensity and regulatory drag (42/100).
- ! Reimbursement dependency: without a dedicated CPT code and payer coverage, adoption stalls at cash-pay early adopters — the single biggest thesis-killer, and no evidence of coverage progress is provided.
- ! Regulatory timeline/binary outcome: FDA SaMD clearance for an AD screen is high-scrutiny; a rejection or demand for prospective trials could extend runway beyond the raise and reset valuation.
- ! Clinical validity gap: undisclosed specificity + PET (not autopsy) as ground truth risks over-diagnosis; a screen with high false positives for an unactionable disease faces adoption and ethical resistance.

Economist — Retinal AI for early Alzheimer's: regulatory moat is real, but reimbursement + emerging anti-amyloid therapy demand define the terminal value.

- + Economic rent accrues to the FDA clearance + validated cohort, not the vision model per se — self-supervised architectures are increasingly commoditized (foundation models, big pharma/device incumbents). The 1,200-patient cohort and breakthrough-device filing are the durable moat, buying ~2-4 year lead.
- + Demand is derived, not intrinsic: screening value is a function of actionable downstream therapy. Anti-amyloids (lecanemab/donanemab) create a real treat-the-early-stage market, making cheap retinal triage a rational gatekeeper vs. \$5k+ PET/CSF. This is the core bull case and the reason 89% sensitivity matters.
- + \$55k MRR / 14 clinics = ~\$3.9k/clinic/mo at 22% MoM is a strong seed signal, but LTV/CAC 5.1x is pre-reimbursement — self-pay/cash-pay optometry demand is elastic and thin. The step-change is a CPT code / payer coverage, which converts screening from discretionary to standard-of-care and collapses CAC.
- + 60% gross margin with 60% capital intensity is mediocre for software-flavored diagnostics — this is a services/regulatory business, not pure SaaS. Network effects are weak (RWE data flywheel is the only real one); competitive equilibrium favors whoever locks payers + guideline inclusion first.
- ! Reimbursement dependency (structural, 90% regulatory intensity): without a CPT code and payer coverage, TAM shrinks from the cited multi-trillion to a discretionary cash-pay niche. Coverage decisions can lag clearance by 2-3 years, extending the cash-burn runway well past \$6M.
- ! Clinical validation risk: 89% sensitivity vs PET is promising but single-cohort; specificity/PPV in a low-prevalence asymptomatic screening population could produce high false-positive rates, triggering FDA/guideline pushback and eroding clinician trust. Over-screening without therapy access is an ethical/liability landmine.

! Incumbent + platform risk: retinal imaging OEMs (Topcon, Zeiss, Optos) and foundation-model labs can fast-follow once the pathway is de-risked; the moat is time-boxed to the exclusivity of the regulatory clearance, not the algorithm.

Corporate & Regulatory Lawyer — FDA SaMD diagnostic with strong moat but heavy regulatory drag; de-risk via milestone-tranched, IP-warranted seed terms

+ Regulatory pathway is the core asset and risk: as a Class II/III SaMD, likely De Novo or PMA. Breakthrough designation is only 'filed' (not granted) — clearance realistically 18-36 months out. The current 14-clinic revenue may be pre-market/LDT-style deployment carrying enforcement risk absent cleared labeling.

+ Data/privacy exposure is significant: HIPAA (PHI from retinal scans + Alzheimer's risk), plus GINA-adjacent discrimination concerns since pre-symptomatic Alzheimer's status affects insurability/employment. Need BAAs with all 14 clinics, and training-data provenance/consent for the self-supervised model to avoid IP/privacy taint.

+ Reimbursement is the true bottleneck (structural risk correct): no CPT code = out-of-pocket ceiling. CMS/AMA CPT and coverage determinations can take 2-4 years post-clearance; the 60% capital intensity and \$55k MRR imply runway pressure before reimbursement lands.

+ Moat is genuinely regulatory-license-based (82/100): a cleared indication plus RWE evidence loop is durable and hard to replicate — the strongest counter-argument to the 42/100 regulatory score, since the same drag that hurts also becomes the barrier competitors must clear.

! Clinical/liability: 89% sensitivity vs PET in one 1,200-patient cohort is promising but single-cohort; false negatives on a dementia dx invite malpractice/product-liability claims and could sink FDA clearance if not replicated prospectively. Specificity/PPV not disclosed — the honest gap.

! Enforcement risk on current commercialization: if diagnostic claims are being made pre-clearance, FDA warning-letter / marketing-restriction exposure could halt the \$55k MRR overnight and impair the traction narrative.

! Reimbursement failure: even with clearance, absence of Medicare coverage (aging Alzheimer's population is Medicare-heavy) caps TAM realization and prolongs cash burn against 60% capital intensity.

Assumptions & limitations

- Sector reference data (Healthtech / Digital Health) is directional, 2024–2026 public-consensus ranges — override with primary diligence.
- Stage norms reflect US-market seed deals; adjust for geography "US".
- Score is a screening signal, not a substitute for legal, financial, and technical due diligence.

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