AEVION QVenture — Investment Memo

Generated 2026-07-10 · AEVION AI Investment Analyst · not investment advice

RetinaScan

Healthtech / Digital Health · seed · US · raising $5,500,000

Score 64.5/100 — WATCH (conviction: medium)

Investment memo

Verdict: watch, with a conditional lead—advance only against explicit regulatory milestones rather than passing outright. The single strongest reason for is a genuine regulatory-license moat paired with rare early traction ($40k MRR across 18 clinics and 91% sensitivity), a combination most seed diagnostics lack. The single strongest reason against is that the thesis is entirely gated by FDA clearance and reimbursement: breakthrough designation is only filed, cleared incumbents (Digital Diagnostics, EyeArt) already hold payer contracts and EHR integrations, and a $3–8M pivotal trial likely outruns a $5.5M round, forcing a dilutive down-bridge. Enter staged, not all-at-once: commit an initial $1.1M tranche at the ~$16.3M pre-money anchor for a first position, releasing the balance toward our ~10% target ($2.18M ticket, hard cap $2.75M) only upon breakthrough grant, verified specificity/prospective data, and evidence that MRR is reimbursement-backed rather than pilot fees. Reserve $3.27M for pro-rata. Size at ~2% of the venture book.

Narrative engine: live model (anthropic)

Entry strategy

Ticket: $2,180,500 target (range $1,090,250–$2,750,000)
Target ownership: 10%
Valuation band (pre-money): $8,348,000 / $16,305,000 / $32,610,000
Return: 6.79x expected (16.3x base) · ~31.5% IRR over 7yr · loss prob 59%

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% of a diversified venture portfolio (fractional-Kelly, conviction-scaled). Reserve 3,270,750 USD for pro-rata follow-on.

Score breakdown

Market size & growth — 63/100 (weight 20%)
~$200B TAM, 22% CAGR (Healthtech / Digital Health).

Timing / tailwinds — 75/100 (weight 10%)
Sector growth 22% 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 — 68/100 (weight 12%)
revenue/customers cited

Scientific / tech feasibility — 68/100 (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 — Feasibility rests on: multimodal diagnostic models, FDA SaMD pathways, RWE evidence loops.

+ Live frontier: multimodal diagnostic models, FDA SaMD pathways, RWE evidence loops.
+ Tech feasibility score 68/100 — driven by 22% sector innovation rate.
+ Capital intensity 60% sets the R&D burn profile.
! Scientific claims unverified without a technical deep-dive / reference customers.
! reimbursement dependency and long clinical validation cycles.

Data Analyst — RetinaScan: regulatory moat + real traction, but reimbursement and FDA clearance gate the thesis

+ TAM/SAM discipline: $200B digital-health TAM is irrelevant; the real anchor is US diabetic retinopathy screening — ~38M diabetics, ~60% under-screened, at ~$25-60 reimbursed (CPT 92229 autonomous AI screen ~$45-55). SAM "H 20M unscreened patients x ~$50 = ~$1B annual screening revenue, SOM far smaller. Frame the pitch on this, not the $200B number.
+ Unit economics look attractive IF reimbursement holds: SaMD gross margins should exceed the modeled 60% (closer to 75-85% at scale since marginal cost is inference + minimal hardware). $40k MRR / 18 clinics = ~$2.2k/clinic/mo — need CAC, payback, and net revenue retention; none disclosed. Clinic-level LTV depends entirely on screening volume per clinic and CPT reimbursement durability.
+ Comparable benchmark exists: IDx-DR/Digital Diagnostics (LumineticsCore) and EyeArt are De Novo/510(k)-cleared, autonomously reimbursed competitors — meaning the market is validated but RetinaScan is a late entrant still pre-clearance. Breakthrough designation only 'filed,' not granted; 91% sensitivity is below the ~87-96% sens / high-spec bar competitors already cleared. Missing: specificity numb
+ Score 64.5 'watch' is fair — strong moat (82) and timing (75) offset by regulatory drag (42) and unit-economics uncertainty (54). $5.5M seed must be explicitly bridged to FDA clearance + reimbursement traction, or it funds only more validation with no revenue inflection.
! Regulatory/clinical gate: no FDA clearance yet and only 91% sensitivity in a single 900-patient study; a pivotal trial for autonomous SaMD costs $3-8M and 18-24 months — the $5.5M raise may not clear the regulatory + commercial milestone, risking a down-round bridge.
! Reimbursement dependency: revenue collapses if CPT 92229 payment shrinks or payers restrict to specific AI vendors; incumbents (Digital Diagnostics, EyeArt) already hold cleared, reimbursed positions and payer relationships — RetinaScan risks being a me-too without differentiated sens/spec or workflow.
! Missing data kills confidence: no CAC, LTV, payback, churn, specificity, revenue concentration across the 18 clinics, or evidence the $40k MRR is reimbursement-backed vs. pilot fees. Traction may be non-recurring pilots, not durable ARR.

Economist — Regulatory-moat diabetic retinopathy screener with real traction, gated by reimbursement economics and incumbent autonomous-AI competition

+ Demand is structurally strong: ~40% of the 38M US diabetics go unscreened annually, and CMS reimburses autonomous retinal screening (CPT 92229, ~$45-55/scan) — creating an existing payment rail rather than requiring market creation.
+ Moat is the FDA clearance + breakthrough designation, but it is a licensing moat, not a data or network moat; 91% sensitivity trails the incumbent bar (IDx-DR/LumineTis cleared at ~87-96%) so the regulatory edge is replicable by better-capitalized rivals.
+ Traction is early-stage credible but thin: $40k MRR ($480k ARR) at 18 clinics implies ~$2.2k/clinic/mo; the model scales on per-scan reimbursement pull-through, so land-and-expand within each clinic's diabetic panel matters more than logo count.
+ Unit economics face a capital-intensity drag (60%) from hardware (smartphone lens) plus clinical validation spend; 60% gross margin is software-diluted-by-hardware — pure-SaMD comps run 75-85%, so a hardware-attach model caps the multiple.
! Reimbursement dependency: economics collapse if payers bundle screening into capitation or cut the CPT rate; primary-care adoption is entirely gated by whether the clinic captures the reimbursement spread net of the RetinaScan fee.
! Competitive displacement by cleared autonomous-AI incumbents (Digital Diagnostics/IDx-DR, EyeArt) that already have FDA clearance, payer contracts, and EHR integrations — RetinaScan's breakthrough designation is only *filed*, not granted, leaving a validation-cycle gap of 18-36 months.
! Long clinical/regulatory timeline vs. $5.5M seed: FDA De Novo/510(k) plus RWE loops likely burn the round before durable revenue inflection, forcing a dilutive Series A at an unproven ARR base.

Corporate & Regulatory Lawyer — FDA clearance is the moat and the gate: SaMD diagnostic with real regulatory drag and reimbursement dependency

+ Regulatory posture is central: as a diagnostic making disease-detection claims, RetinaScan is Class II SaMD requiring De Novo or 510(k) clearance; 'breakthrough-device designation filed' is not granted and does not shortcut clearance. Existing autonomous DR AI (IDx-DR/LumineticsCore De Novo 2018, EyeArt) sets the predicate but also shows the bar and 2-4yr validation timelines.
+ Reimbursement is the true revenue unlock: CPT 92229 (autonomous AI retinal imaging) exists and is the target

code, but current $40k MRR likely reflects per-clinic SaaS/cash pay, not payer coverage — coverage and adequate rates across CMS/commercial payers are unproven and gate scaling.

+ IP posture is thin as described — smartphone-lens diagnostics face crowded prior art (IDx, EyeArt, Google/Verily DR work); the durable asset is the FDA clearance + labeled indication + clinical dataset, not patents. Data/privacy exposure is high: HIPAA BAAs with every clinic, retinal images are biometric identifiers (BIPA/CCPA/CPRA), and training-data consent for RWE loops.

+ Deal protections to demand: milestone-based tranching tied to FDA submission/clearance, use-of-proceeds ring-fenced to the pivotal study, reps on IP ownership + no off-label marketing, clinical/regulatory diligence on the 900-patient study design (was it pre-registered, prospective, specialist-graded ground truth?), and info/board rights over regulatory strategy.

! Marketing a diagnostic pre-clearance or on off-label claims across 18 clinics risks FDA enforcement (warning letter/injunction) and unwinds current traction — verify current claims and whether any device is being sold as cleared.

! 91% sensitivity is below the ~87-97% sensitivity AND specificity envelope of cleared competitors; if specificity is weak or the study wasn't prospective/pre-registered, the pivotal trial fails or FDA demands a larger costly study, blowing past the $5.5M runway.

! Reimbursement dependency: without broad CPT 92229 payer coverage, unit economics (54/100, 60% capital intensity) don't clear — clinics won't sustain cash-pay at scale, capping the model regardless of clearance.

Market data sources

- Grand View Research (2025) — Digital health to reach $946.0B by 2030 at 22.2% CAGR
  https://www.grandviewresearch.com/industry-analysis/digital-health-market
- MarketsandMarkets (2025) — $199.1B in 2025 !' $573.5B by 2030 at 23.6% CAGR
  https://www.marketsandmarkets.com/Market-Reports/digital-health-market-45458752.html

Assumptions & limitations

- Market size / growth for Healthtech / Digital Health is anchored to Grand View Research (2025): Digital health to reach $946.0B by 2030 at 22.2% CAGR. Full citations are listed under "Market data sources".
- 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.