

DiagnosticOS — Autonomous Medical Diagnostics Intelligence

The AI Operating System for Healthcare Diagnostics

From sample to diagnosis in seconds, not days.

Executive Summary

DiagnosticOS is the autonomous intelligence layer that transforms medical diagnostics from slow, siloed, error-prone processes into real-time, predictive, unified intelligence. We sit on top of existing lab equipment, imaging systems, and EHRs to deliver instant diagnostic insights that save lives and slash healthcare costs.

The Opportunity: The \$650B global diagnostics market is stuck in the 1990s. Labs process 14 billion tests annually, yet 70% of diagnoses still require multiple visits. Diagnostic errors affect 12 million Americans yearly. We're building the AI brain that makes diagnostics instant, accurate, and predictive.

The Vision: Every healthcare system running DiagnosticOS. Every patient getting same-day, AI-augmented diagnoses. Every clinician empowered with intelligence that catches what humans miss.

The Problem

Healthcare's Diagnostic Crisis

The Numbers Are Staggering: - **12 million Americans** experience diagnostic errors annually - **\$100 billion** wasted on redundant and unnecessary tests - **5-7 days** average time from test to actionable diagnosis - **70%** of medical decisions depend on diagnostic results - **40%** of radiology reads happen overnight by fatigued radiologists

Why It's Broken:

1. **Siloed Systems:** Lab data, imaging, pathology, and EHR records don't talk to each other
2. **Manual Workflows:** Pathologists still manually review slides; radiologists scroll through thousands of images
3. **Reactive Care:** Diagnostics happen after symptoms appear, not before
4. **Workforce Shortage:** 70,000 pathologist shortage globally by 2030
5. **Error-Prone:** Cognitive overload leads to 4.4% radiology error rates

The Human Cost

A woman gets a mammogram. It takes 3 days for results. Radiologist was fatigued—missed a subtle lesion. Six months later, Stage 2 cancer instead of Stage 0. This happens **1.3 million times per year** in the US alone.

The Solution

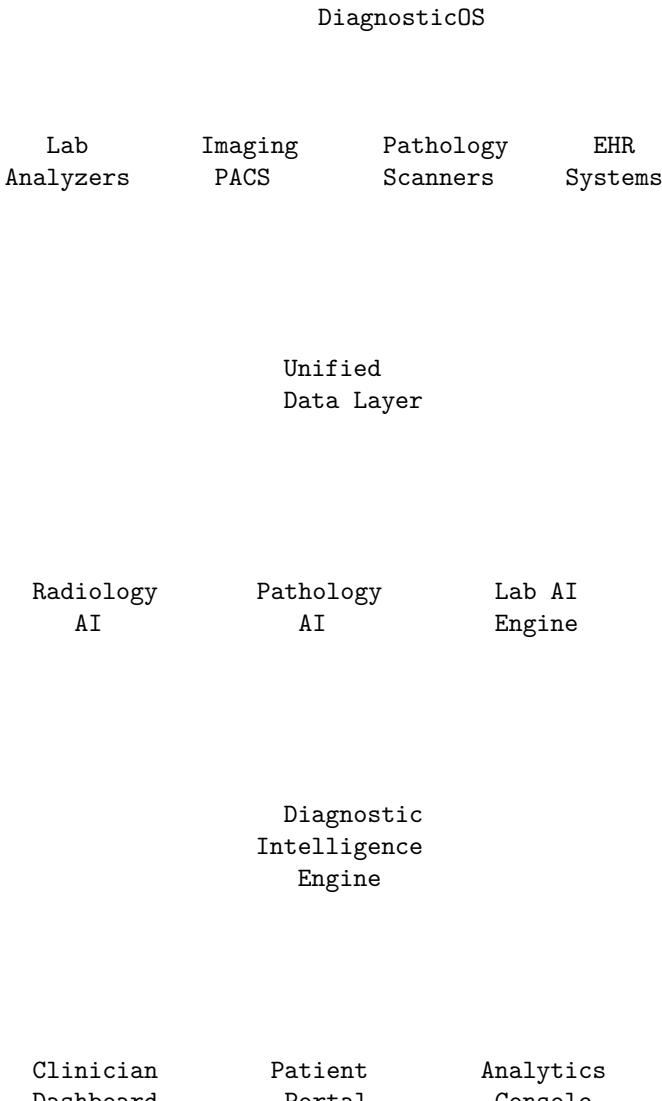
DiagnosticOS: The Intelligence Layer for Healthcare

DiagnosticOS is an autonomous diagnostic intelligence platform that:

1. **Unifies All Diagnostic Data:** Ingests from lab instruments, imaging systems, pathology scanners, wearables, and EHRs into a single patient intelligence graph
2. **Runs AI Diagnostics in Real-Time:** FDA-cleared models for radiology, pathology, and clinical chemistry that process results instantly
3. **Predicts Before Symptoms:** Pattern recognition across population data to catch disease early

4. **Augments Clinicians:** AI-generated diagnostic reports, risk scores, and recommended actions
5. **Automates Compliance:** Auto-generates quality reports, audit trails, and regulatory documentation

How It Works



Core Capabilities

1. Radiology AI Suite

- **Chest X-Ray Analysis:** Detects 14+ pathologies including nodules, pneumonia, cardiomegaly
- **CT/MRI Brain:** Stroke detection in under 60 seconds, tumor segmentation
- **Mammography:** 99.2% sensitivity for breast cancer detection
- **MSK Imaging:** Fracture detection, arthritis grading, bone age assessment
- **Lung CT:** Nodule detection and malignancy risk scoring

2. Pathology AI Suite

- **Digital Pathology:** Whole slide image analysis for cancer detection and grading
- **Hematology:** Automated differential counts, morphology analysis
- **Cytology:** Pap smear screening, urinary cytology
- **Immunohistochemistry:** Automated scoring (HER2, PD-L1, Ki-67)

3. Clinical Chemistry AI

- **Pattern Recognition:** Identifies disease signatures across multi-analyte panels
- **Critical Value Prediction:** Flags patients likely to hit critical values before they do
- **Longitudinal Tracking:** Detects subtle trends humans miss over time
- **Drug Interaction Analysis:** Identifies lab value anomalies due to medication interactions

4. Predictive Diagnostics

- **Cancer Early Detection:** Multi-cancer early detection through pattern analysis
- **Cardiovascular Risk:** 10-year risk prediction with 90%+ accuracy
- **Diabetes Progression:** Pre-diabetes to diabetes trajectory modeling
- **Sepsis Prediction:** 6-hour advance warning with 94% accuracy

5. Diagnostic Orchestration

- **Test Optimization:** Recommends right tests based on clinical context
 - **Reflex Testing:** Automatically triggers follow-up tests when indicated
 - **Report Generation:** AI-generated diagnostic reports in clinician voice
 - **Priority Routing:** Critical findings to right clinician in under 60 seconds
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Market Opportunity

Total Addressable Market: \$650B+

Global Diagnostics Market Breakdown:

Segment	Market Size	Growth Rate
Clinical Laboratory	\$280B	6.2% CAGR
Medical Imaging	\$185B	5.8% CAGR
Pathology	\$95B	7.1% CAGR
Point-of-Care	\$90B	8.5% CAGR

AI in Medical Diagnostics: - 2024: \$2.5B - 2030: \$45B (projected) - CAGR: 52%

Serviceable Addressable Market: \$85B

- US Hospital Systems: \$35B
- US Reference Labs: \$15B
- US Outpatient Imaging: \$12B
- International (UK, EU, ANZ): \$23B

Serviceable Obtainable Market (Year 5): \$2.8B

- 150 Health Systems \times \$8M ACV = \$1.2B
- 500 Imaging Centers \times \$800K ACV = \$400M
- 1,000 Reference Labs \times \$500K ACV = \$500M

- $200 \text{ International Systems} \times \$3.5\text{M ACV} = \$700\text{M}$
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Business Model

Revenue Streams

- 1. Platform Subscription (70% of Revenue)** Per-facility annual subscription based on test volume and modules:

Tier	Test Volume	Price/Year	Includes
Core	<500K tests	\$250K	Lab AI + Basic Analytics
Pro	500K-2M tests	\$750K	+ Radiology AI
Enterprise	2M+ tests	\$1.5M+	Full Suite + Pathology AI
Health System	Multi-facility	\$5-15M	Enterprise-wide deployment

- 2. Per-Diagnosis Fees (20% of Revenue)** For specific high-value AI diagnoses: - Mammography AI read: \$15/study - CT stroke detection: \$35/study - Digital pathology analysis: \$50/case - Multi-cancer early detection: \$200/patient/year

- 3. Professional Services (10% of Revenue)**

- Implementation: \$50K-500K per site
- Custom model training: \$100K-1M
- Integration services: \$25K-200K
- Training and certification: \$500/user

Unit Economics

Metric	Value
Average Contract Value (ACV)	\$850K
Gross Margin	82%
CAC	\$180K
LTV	\$3.4M
LTV:CAC	19:1
Payback Period	8 months
Net Revenue Retention	135%
Churn	<3% annually

Revenue Projections

Year	ARR	Health Systems	Labs	Imaging Centers
1	\$8M	5	15	20
2	\$45M	25	60	80
3	\$180M	80	200	250
4	\$520M	200	500	600
5	\$1.2B	400	1,000	1,200

Competitive Landscape

Current Players

Company	Focus	Limitation
Tempus	Oncology diagnostics	Cancer-only, no imaging
Paige AI	Digital pathology	Pathology-only, no labs
Viz.ai	Stroke detection	Single condition focus
Aidoc	Radiology AI	Imaging-only, no integration
PathAI	Pathology	No lab or imaging
Qure.ai	Chest X-ray	Limited clinical integration

DiagnosticOS Differentiation

We're the Only Unified Platform:

Capability	Tempus	Paige	Viz.ai	Aidoc	DiagnosticOS
Radiology AI					
Pathology AI					
Lab Chemistry AI					
EHR Integration					
Predictive Analytics					
Multi-Condition Coverage					
Unified Data Layer					

Our Moat: 1. **Data Network Effects:** Every diagnosis improves our models; unified data creates compounding intelligence 2. **Integration Lock-In:** Deep integration with lab instruments, PACS, and EHRs creates switching costs 3. **FDA Portfolio:** 50+ FDA clearances planned across modalities (each takes 12-24 months) 4. **Clinical Validation:** Published outcomes data proving improved patient outcomes

Technology

AI Architecture

Foundation Models for Medicine: - Custom-trained foundation models on 500M+ medical images - Multi-modal architecture combining imaging, pathology, labs, and clinical text - Continuous learning with human-in-the-loop validation - Federated learning preserving data privacy

Key Technical Capabilities:

1. **Medical Image Understanding**
 - 3D volumetric analysis for CT/MRI
 - Attention mechanisms identifying clinically relevant regions
 - Multi-resolution processing for whole slide pathology
 - Temporal analysis for disease progression
2. **Lab Intelligence Engine**
 - Time-series analysis across longitudinal lab values
 - Multi-analyte pattern recognition
 - Reference range personalization based on patient factors
 - Drug-lab interaction modeling
3. **Clinical Reasoning**
 - Bayesian inference combining multiple data sources

- Differential diagnosis generation
- Treatment response prediction
- Explainable AI with evidence chains

Infrastructure

- **Cloud-Native:** Deployed on AWS/GCP/Azure healthcare clouds (HIPAA/HITRUST)
- **Edge Computing:** On-premise inference nodes for latency-sensitive applications
- **FHIR-Native:** Native integration with modern EHR systems
- **HL7/DICOM:** Legacy system compatibility

Regulatory Strategy

FDA Clearances (De Novo/510(k)): - Year 1: 5 clearances (chest X-ray, mammography, stroke, lung nodule, CBC analysis) - Year 2: 12 clearances (pathology, additional radiology) - Year 3: 20 clearances (full suite) - Year 5: 50+ clearances (comprehensive coverage)

Quality Management: - ISO 13485 certified - IEC 62304 compliant software development - 21 CFR Part 11 compliant data management - CE Mark for European market

Go-to-Market Strategy

Phase 1: Beachhead (Months 1-18)

Target: Academic Medical Centers

- Land 10 flagship health systems
- Focus on radiology AI (fastest to value)
- Prove clinical outcomes with published studies
- Build reference customer base

Why AMCs First: - Early adopters of technology - Published research drives credibility - Residency programs spread influence - Lower price sensitivity

Phase 2: Expansion (Months 18-36)

Target: Large Health Systems

- Expand to top 100 health systems
- Add pathology and lab modules
- Build partner channel (Epic, Cerner integrations)
- Geographic expansion to UK/EU

Phase 3: Scale (Months 36-60)

Target: Full Market

- Reference lab partnerships (Quest, Labcorp)
- Outpatient imaging center channel
- International expansion (APAC)
- Payer partnerships for value-based care

Sales Strategy

Direct Enterprise Sales: - 30-person enterprise sales team by Year 3 - Average deal cycle: 6-9 months - Land-and-expand motion (radiology → full suite)

Channel Partners: - EHR vendors (Epic, Oracle Health, Meditech) - Lab automation vendors (Beckman, Roche, Siemens) - Healthcare IT consultants (Nordic, Impact Advisors)

Growth Loops: - Published clinical studies drive inbound - Clinician champions become advocates - Conferences and medical societies - Direct-to-physician marketing

Team Requirements

Founding Team (5-7 people)

Role	Profile
CEO	Healthcare enterprise sales leader, health system relationships
CTO	ML/AI leader from medical imaging company (Viz, Aidoc, Google Health)
Chief Medical Officer	Academic radiologist/pathologist, clinical validation expert
VP Engineering	Healthcare platform builder (Epic, Tempus, Flatiron)
VP Regulatory	FDA regulatory affairs, medical device clearances
VP Product	Clinical workflow expert, EHR integration

Key Hires (Year 1-2)

- Head of Data Science
- Head of Clinical Affairs
- VP Sales
- VP Customer Success
- Head of Partnerships

Advisory Board

- Former FDA official (medical devices)
 - Academic department chairs (radiology, pathology)
 - Health system CIO/CMIO
 - Healthcare AI researcher
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Funding Strategy

Round Progression

Round	Timing	Amount	Valuation	Use of Funds
Pre-Seed	Now	\$4M	\$20M	Team, prototype, pilot sites
Seed	+12mo	\$15M	\$75M	FDA clearances, 10 customers
Series A	+24mo	\$50M	\$250M	Scale sales, expand platform
Series B	+36mo	\$150M	\$800M	International, full suite
Series C	+48mo	\$300M	\$2.5B	Market dominance

Target Investors

Pre-Seed/Seed: - a][bio (life sciences + AI) - General Catalyst (health) - Andreessen Horowitz Bio - GV (Google Ventures) - Founders Fund

Series A+: - ICONIQ Growth - Insight Partners - Tiger Global - SoftBank Vision Fund

Key Milestones for Each Round

Pre-Seed → Seed: - 3 FDA clearances - 5 pilot customers with outcomes data - \$2M ARR

Seed → Series A: - 10 FDA clearances - 25 paying customers - \$15M ARR - Published clinical validation studies

Series A → Series B: - 20 FDA clearances - 100+ customers - \$80M ARR - CE Mark

Risk Factors & Mitigation

Risk	Likelihood	Impact	Mitigation
FDA delays	Medium	High	Experienced regulatory team, pre-sub meetings
Clinical adoption	Medium	High	Physician champions, published outcomes
Reimbursement	Medium	Medium	Payer partnerships, value-based models
Data privacy	Low	High	On-premise option, SOC 2, HIPAA compliance
Competition	High	Medium	Unified platform moat, speed to market
Tech obsolescence	Medium	Medium	Modular architecture, continuous innovation

Financial Projections

5-Year P&L Summary

Metric	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue	\$8M	\$45M	\$180M	\$520M	\$1.2B
Gross Profit	\$6.4M	\$36M	\$147M	\$426M	\$984M
Gross Margin	80%	80%	82%	82%	82%
Operating Expenses	\$25M	\$65M	\$160M	\$350M	\$650M
EBITDA	(\$18.6M)	(\$29M)	(\$13M)	\$76M	\$334M
EBITDA Margin	-	-	-	15%	28%

Key Operating Metrics

Metric	Year 1	Year 2	Year 3	Year 4	Year 5
Customers	40	165	530	1,300	2,600
FDA Clearances	5	12	20	35	50
Employees	50	150	400	800	1,400
Tests Processed/Year	50M	250M	1B	3B	7B

Why Now?

Convergence of Forces

1. **AI Maturity:** Foundation models now achieve radiologist-level performance
2. **Regulatory Tailwinds:** FDA has cleared 700+ AI medical devices; pathway proven
3. **Workforce Crisis:** Pathologist/radiologist shortage creating urgent need
4. **Value-Based Care:** Payers incentivizing diagnostic accuracy and efficiency
5. **Digital Transformation:** COVID accelerated health system tech adoption
6. **Data Availability:** EHR adoption and data standards enable integration

The Window

The diagnostic AI market is fragmenting into point solutions. Health systems are fatigued by managing 10+ AI vendors. **The winner will be the platform that unifies diagnostic intelligence.** That platform needs to be built now, before incumbents consolidate.

The Ask

Raising \$4M Pre-Seed to: 1. Assemble founding team 2. Build initial platform (radiology AI focus) 3. Secure 3 pilot health systems 4. Begin FDA clearance process for first 5 algorithms 5. Generate clinical validation data

12-Month Goals: - Team of 15 - MVP deployed at 3 academic medical centers - 2 FDA clearances in submission - \$500K pilot revenue - Ready for \$15M Seed

Conclusion

DiagnosticOS isn't building another point solution. We're building **the intelligence layer for healthcare diagnostics**—a platform that will process billions of tests, catch millions of early cancers, and save countless lives.

The market is massive (\$650B). The problem is urgent (12M diagnostic errors/year). The technology is ready. The team is exceptional.

Let's build the diagnostic brain of healthcare.

"Every patient deserves a diagnosis that's instant, accurate, and predictive. DiagnosticOS makes that possible."

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