AMPLIFIED SCIENCES

Company Overview

Amplified Sciences is a clinical stage life science diagnostics company focused on accurately detecting and pre-empting the risks of debilitating diseases, with R&D operations in Purdue Research Park, a CLIA lab in Irvine, California, and key alliances in San Francisco and Boston. The company is developing a portfolio of diagnostic assays for early detection of some of the most challenging diseases. BioMatraTM, an ultra- sensitive universal optical reporter platform technology licensed from Purdue University enables a new class of multi-omics diagnostic tests demonstrating limits of detection 10,000x over comparable technologies utilizing 50x less volume of samples. The lead assay in development targets early detection of undiagnosed pancreatic cancers.

Problem or Market Opportunity

Pancreatic cystic lesions are detected in 3M patients each year, but the relative risks of those being benign vs. potentially malignant are not accurately diagnosed leading to potential missed malignancies (high false negatives), overtreatment (high false positives), and significant cost burdens. The total pancreatic cancer diagnostic market is over $2.9B. The customers include Gastroenterologists and pancreatic surgeons (decision maker), hospitals/clinics (influencer), and payer (buyer). PancystProTM will be launched as a Lab Developed test in 2024 initially to a small group of "early access" thought leaders and high-volume Advanced Endoscopist Gastroenterologists. The proprietary technology is a platform play enabling cost effective and quick scale to multiple assays which can be quickly launched in the commercial CLIA lab. The company has two additional assays in the pipeline.

Technical & Competitive Advantage

PanCystPro™, is a clinical stage assay that provides a highly accurate (+95% negative predictive value and +90% sensitivity) diagnostic solution for pancreatic cyst lesion risk stratification which allows clinicians to better identify patients at risk for developing pancreatic cancer as well as reduce unnecessary surgeries and costly imaging. The primary competitors are a molecular diagnostic assay, CEA with low accuracy and PancraGEN® offered by Interpace Diagnostics. Interpace's DNA based tests have limitations including large sample volume required, false negative rates particularly in high grade dysplasia, and long lab processing times. Amplified Sciences' PanCystPro is a superior solution that rules out disease with a high negative predictive value (crucial for early disease management decision making), requires a significantly smaller amount of cyst fluid, overcomes the competitor's performance features and can cross walk to a $2,500/test reimbursement rate.

Regulatory Strategy & Intellectual Property

Market entry begins through a CLIA laboratory model processing their lead assay PanCystPr0 as a Lab Developed Test (LDT). The company received CLIA regulatory approval of their California CLIA lab in November 2023. This enables commercial availability and ability to process patient samples in the lab with a launch in 2024. The company began processing clinical samples first for research use only in Q4 2021, and has published clinical data in three peer reviewed journals. The technology is supported by a global suite of composition of matter IP issued and exclusively licensed from Purdue for their reagent platform, as well as a IP filed by the company for their lead assay.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q2 2022	Clinical Evidence	ASCO poster yielding two pier reviewed articles showing superior accuracy vs. standard of care
Q3 2023	Regulatory	Regulatory CLIA approval of PanCystPro – secured 11/2023
Q1 2024	Launch	Early access targeted commercial launch and launch of clinical utility study for reimbursement
Q3 2024	Clinical Utility Trial	Initiate 3 site study to gather test results and clinical utility demonstration (value and cost savings) supporting reimbursement strategy

Capitalization History

Year	Grant or Equity Type	Description	Amount
2021	Series Seed – CN	Series Seed Convertible Note - $3.5M pre-money valuation cap	$1.78M
2024	Series Seed Preferred	$6.5M Pre-Monet with OCA Ventures/Elevate Ventures co-leads	$2.6M
2024	Non-dilutive	NIH-NCI SBIR Phase 1 ($450k), NSF SBIR Phase 1 ($325k), 2 Research Use Only projects ($400k), other State of Indiana Grant	$1.4M

Current Round, Terms, and Use of Proceeds

Closed Series Seed Preferred ($2.6M) secured CLIA regulatory milestone, fuels commercial stage, supports reimbursement clinical studies, and funds two additional assays.

Key Team Members and Advisors

V. Jo. Davisson, PhD | Founder and CSO
Purdue University biochemistry inventor with track record of industry collaboration and technology translation; $30M of grants earned

Diana Caldwell, MBA | Co-founder and CEO
Serial life science entrepreneur, sold first startup in Regulatory/Clinical trials services sector, former Eli Lilly Executive

Daniel Sheik, PhD |Director, Research and Technology
Leads scientific team (4 PhDs) and outside collaborators, PI on SBIR grant, third stent in startup

John Ridge | Director of Commercial and Market Access
Former VP Market Access, Lucid Diagnostics and Roche Diagnostics/Ventana; secured Cologuard reimbursement at Exact Sciences

Amplified Sciences | 3000 Kent Avenue, West Lafayette, IN 47906
Diana Caldwell | (317) 490-0511 | diana.caldwell@amplifiedsci.com