Revolutionizing Pancreatic Cancer Detection

Company Summary: Amplified Sciences is a clinical stage life science diagnostics company focused on accurately detecting and pre-empting the risks of debilitating diseases, including lethal cancers and organ loss with R&D operations in Purdue Research Park and key alliances in San Francisco and Boston. The company is developing a portfolio of fully-integrated diagnostic assays for early detection of disease. An ultra- sensitive molecular sensing technology licensed from Purdue Research Foundation operates with novel test-strips that combine with portable instrumentation and chemometric tools to form a highly versatile clinical assay platform that can scale to point of care. The lead assay in development targets early detection of undiagnosed pancreatic cancers.

Problem: Incidental detection of pancreatic cysts is significantly rising. Pancreatic cysts are incidentally detected in 13%-45% of cases undergoing abdominal imaging for other reasons. The clinical management of these cases is a major challenge for clinicians as there is no reliable risk stratification for malignancy of pancreatic cysts and the surgery to resect cysts is associated with 40% morbidity. Mucinous cyst neoplasms harboring high-grade dysplasia or invasive cancer represent precursor lesions to pancreatic cancer and should be surgically resected. However, retrospective analyses indicate a significant portion of mucinous cysts, serous cystadenomas, and pseudocysts are low grade or benign. Preoperative classification of these cyst types is challenging resulting in unwarranted surgeries, significant cost burdens, and high morbidity.

Solution: This problem is being addressed by the Amplified Sciences' ultrasensitive detection of biomarker activities in minute volumes of fluid obtained from these cysts. These biomarkers have been clinically validated using non-portable and difficult to commercialize methodologies. Our initial "rule-out" Laboratory Diagnostic Test (LDT) is more sensitive than standard of care (clinical data presented at ASCO June 2022 Annual Meeting), effectively stratifies patients into low risk vs. potential malignancy, and will provide significant cost savings to payers by reducing unneeded surgeries hence avoiding co-morbidities associated with invasive surgery and/or loss of organ function. This enables healthcare providers to define low risk and/or benign pancreatic cysts resulting in significant cost savings and patient peace of mind.

Market: Pancreatic cysts 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 $2.2B. The customers include Gastroenterologists and pancreatic surgeons (decision maker), hospitals/clinics (influencer), and payer (buyer).

Competition: The primary competitors are a molecular diagnostic assay, CEA with low accuracy demonstrating both low sensitivity and low specificity; and PancraGEN® / PanDNA® offered by Interpace Diagnostics Group. Interpace's DNA based tests have limitations including larger sample volume required, false negative rates particularly in high grade dysplasia, and long lab processing times. The Amplified Sciences' PanCystPro™ is a superior solution that rules out disease (crucial for early disease management decision making), requires a small amount of cyst fluid, overcomes the competitor's performance features and can model their precedent of $4,000/test reimbursement rate.

Business Model: In 2022, the test was offered to researchers for Investigational Use Only (IUO/RUO) to build awareness with thought leaders. In 2023, the lead assay, PancystPro will be launched as a Laboratory Diagnostic Test (LDT) in our CLIA laboratory. The sample access and core platform will provide revenue for follow on development of a 510K approved product. PanCystPro™ will initially target Gastroenterologists who perform EUS-FNA procedure to collect the pancyst fluid sample. The proprietary technology is a platform play; therefore, enabling quick scale to multiple assays serving the gastro suite and then expanding to other cancers, cardiovascular markers, and kidney diseases.

Strategy and Progress to Date: Company has raised total of $3.3M of funding, clinical testing data were presented at ASCO 2022 and published in a peer reviewed journal, earned an NCI SBIR Phase 1 grant, and $400k of RUO revenue secured. The lead assay is optimized and technically validated, global IP issued, and thought leader clinicians have been secured at UCSF, UPMC, and IU Simon Cancer Center. Past Seed round (closed in early 2021) enabled technical validation and clinical testing of the PanCystPro product and positions the company for entry into a commercializable LDT. Closure of a capital raise (led by OCA Ventures and Elevate Ventures) in 2023 will enable regulatory CLIA approval and launch in 2023, and the scale of a suite of LDT and 510k assays.

Business and Development Team; Founders V. Jo Davisson, PhD (CSO), Diana Caldwell, MBA (CEO) and lab scientist staff led by Daniel A. Sheik, PhD work with a seasoned team of advisors including Linda O'Keefe (CFO), Charles Craik, PhD, Kim Kirkwood, MD, Mohammad Al-Haddad, MD, Andy Cothrel (Board member, former Roche Diagnostics; serial life science entrepreneur), Patti Connolly (CLIA operations/MiraVista/Renalytic AI, Verici Dx), John Ridge (reimbursement/Roche/Exact Sciences/Lucid Diagnostics), Vince Wong (CCO Geneoscopy) and Tom Tague, PhD (Bruker). A series of consultants with commercial *in vitro* diagnostic experience have also been recruited to the team to develop operations for product launch.

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