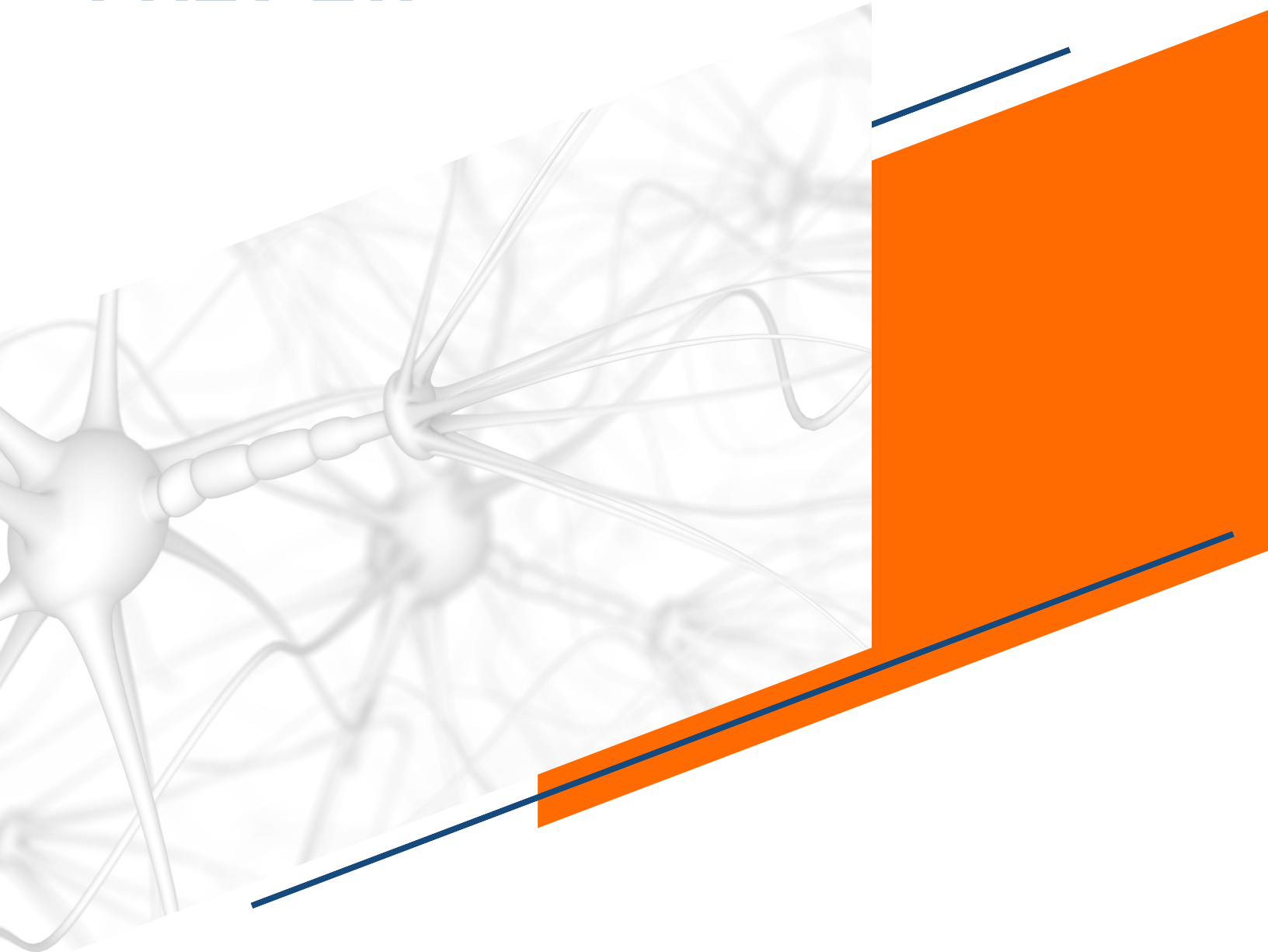
elevate ventures

LIFE SCIENCES & HEALTHCARE PORTFOLIO PREVIEW



JANUARY | 2024

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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 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 clinical stage lead assay in development targets early detection of undiagnosed pancreatic cancers.

Problem or Market Opportunity

Pancreatic cancer is the 3rd deadliest cancer with 74% of patients dying within 12 months of diagnosis. Early detection and treatment are key to improving patient outcomes. Incidental detection of pancreatic cysts discovered during imaging presents a window to early detection, presents challenges to the healthcare system, and has increased at a significant pace without a clear clinical pathway for decision-making on the diagnosis. Competitive tests are limited by low sensitivity and specificity and require large fluid volumes. There is a large unmet medical need for better diagnostics to manage these patients and detect pancreatic cancer earlier. Additional and improved in-vitro diagnostics are needed to help clinicians manage these patients and identify those whose lives could be saved with early intervention.

Technical & Competitive Advantage

PanCystPro™, is a clinical stage assay that provides a highly accurate in-vitro diagnostic solution for pancreatic cysts which will allow clinicians to better identify patients at risk for developing pancreatic cancer as well as reduce unnecessary surgeries and associated complications. This is a highly sensitive and specific test, and is a true first in class. The primary competitors are a molecular diagnostic assay, CEA with low accuracy 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 a $4,000/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 early Q1 2024. The company began processing clinical samples first for research use only in Q4 2021 and has published clinical data in two peer-reviewed journals. The technology is supported by a global suite of the composition of matter IP issued and exclusively licensed from Purdue.

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

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
2023	Series Seed Preferred	$2.3M of $3M closed in current open capital raise (OCA Ventures/Elevate Ventures leads)	$3.5M max
2023	Non-dilutive	SBIR Phase 1 ($450k), 2 Research Use Only projects ($400k), other State of Indiana Grants	$1M

Current Round, Terms, and Use of Proceeds

Current $3.5m open round is a Series Seed Preferred with $6.5M pre-money valuation, terms set by lead VCs, diligence sharing available, $.7M remaining open. Round enables CLIA regulatory milestone, fuels commercial stage, supports reimbursement clinical tudies, 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

Vince Wong, JD, MBA |BOD (Observer), Investor, Advisor
Chief Commercial Officer, Geneoscopy; former VP at Roche Diagnostics

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

NOVILYTIC
THE CANARY IN THE FERMENTOR

Company Overview

Novilytic is a molecular recognition company that utilizes nanotechnology to help pharmaceutical companies bring new medicines to market faster and far less expensively. Our 'secret sauce' is based on our multiple patents that replace existing 40-year-old instrumentation. Called the Protoemeter®, it allows scientists and engineers to monitor medicines in minutes versus the 8-24 hour burden they struggle with currently. The product is sold as a consumables kit that 'plugs and plays' into >253,000 instruments creating a $2.8 billion TAM (Total Addressable Market).

Market & Commercialization Strategy

Time is the biggest enemy of the pharmaceutical industry. It takes them 7-10 years to get a product developed, patented, and FDA-approved. Our marketing strategy is focused on saving time and ease of use. First, the Proteometer not only saves hours and days – it also has better accuracy. Secondly, it is a "plug and play" consumable that utilizes existing tools and software that are already owned and used daily in all stages of the pharmaceutical development process. The go-to-market strategy will utilize major instrument and distributor channels that can sell more of their products with our technology. All manufacturing will be completed at GMP and ISO-validated suppliers to complement our similar assembly strategy. Combined, this focus will ensure way-above-average profits and an expeditious expansion into the market.

Technical & Competitive Advantage

The utilization of our patented nanotechnology is not available from any other source. To ease its use, the Proteometer (a.k.a. Proteoform Meter) has been tested and approved for use by 4 of the top 5 instrument companies in the world. Then its utility was confirmed in pilots at multiple major (Top 10) pharmaceutical companies. Two of them (Pfizer and J&J) then published peer-reviewed articles and presentations on the Proteometer.

Regulatory Strategy & Intellectual Property

The Proteometer is first be adopted in pharma discovery, clone selection, and process R&D departments that do not have regulatory restrictions. If it is utilized in manufacturing, it will be part of the pharma company FDA submittal. As >90% of the target instruments are outside of manufacturing, regulatory approval is not a major part of our IP Go-to-Market strategy. Our IP includes multiple method and concept of matter patents which combine to create a protective mote from outside duplication. We currently have additional patents pending with similar strategies.

Key Milestones

Objective	Milestone	Date/Year
Industry-based pilots	Completed pilot testing, review, improvements, with instrument and pharma companies.	December 2022
Launch first product	Launched first product in our platform, the Proteometer-L	March 2023
First repeat sales	Obtained first orders and repeat orders totaling >$100,000 in first year of launch	December 2023
Launch second product	Launched second product, the Proteometer-UFT in December	December 2023

Capitalization History

Year	Grant Funding Round	Description	Amount
2014-2020	SBIR Phase I, II, and IIa	Non-dilutive Federal SBIR grants via the NIH (National Institute of Health)	$4,200,000
2014 - 2018		Founder Investment Capital	$186,000
2020-2021		Seed Round, includes $400,000 investment by founders	$1,810,000
2023		Bridge Round, includes $400,000 investment by founders	$1,300,000

Use of Proceeds

SBIR grant monies were utilized for the development, testing, and prototyping of the original designs. Seed round monies were employed for the commercialization, piloting, and early launch of the Proteometer platform. The Bridge Round funds are being invested into the launch of the first two products, including all marketing and sales efforts. A small portion is also being used to develop the next product releases.

Key Team Members

Paul C. Dreier, BSc., MBA | CEO

Dreier has been an equity holder and leader in four other analytical and software company start-ups (all successful exits). His background includes focuses in chemistry, math, product development/ management, and global sales/marketing. He also has lived in and managed teams in six countries.

Fred E. Regnier, Ph.D. | CTO

Dr. Regnier is also on his 5th analytical technology start-up. His most successful exit was with Perceptive Biosystems for >$384M. Dr. Regnier is a "Global Top-20" analytical chemist who taught at Purdue, Harvard, and MIT Universities. He holds >50 patents, with 1,000s of references to his papers.

Meena Narsimhan, Ph.D. | Director of Analytical Chemistry

Dr. Narsimhan is recognized and cited in numerous scientific journals and covers for her discoveries in plant biochemistry, DNA, and now protein analytics (Analytical Chemistry October 2023). She holds numerous patents and is a key developer of the Proteometer and its patents.

Company Overview

GeniPhys is a preclinical stage medtech company poised to revolutionize the regenerative medicine field. GeniPhys is developing a first-in-class polymerizing collagen platform technology referred to as Collymer. Collymer materials address a massive unmet need in regenerative healing by supporting site-appropriate tissue regrowth without evoking an inflammatory response. Collymer retains the natural scaffold forming capability of collagen, and can be manufactured into various shapes and formats, and with differing mechanical properties. Due to this versatility, Collymer has the potential to impact multiple high-need medical areas, including wound healing and reconstruction, orthopedics, cardiovascular, aesthetics, and more. GeniPhys' initial product will be Collymer Self-Assembing Scaffold (SAS), an in-situ scaffold forming product intended for wound management. GeniPhys has an experienced leadership team and board of directors, an extensive IP portfolio, and a clear regulatory path to initial launch via 510(k).

Market & Commercialization Strategy

The wound care market is substantial and growing. It is also underserved and in dire need of innovation. Collymer represents a highly differentiated product that resonates with the medical community. Over 50 million people worldwide suffer from poor-healing wounds, and CMS spends over $30 billion annually to address this market. GeniPhys plans to engage a commercialization partner to assist in accelerating market penetration due to the diverse and broad customer base. Post-approval human data will demonstrate superiority to existing treatments and support additional indications for Collymer SAS. Development partnerships will drive the expansion of Collymer into new markets, such as aesthetics and orthopedics. Strategically, GeniPhys will retain it's core competency in manufacturing and development of novel presentations of Collymer materials.

Technical & Competitive Advantage

There are no products available today that possess the unique scaffold formation and immune tolerance of Collymer. Current collagen derived products are rapidly resorbed via inflammatory induced degradation. Collymer is naturally sourced and highly purified to remove all immunogenic components, yet it retains the innate chemical cross-linking. Collymer materials persist rather than resorb, supporting the ingress of surrounding tissue into the scaffold. This allows Collymer to be a single application product - reducing repeat visits and treatments for patients. GeniPhys has developed a robust and straightforward manufacturing process that results in low COGS and anticipated pricing on par to current standard of care, with substantial benefits and the promise of improved outcomes for patients. GeniPhys intends to pursue reimbursement based on Collyer SAS' unique value proposition and will benefit from bundled reimbursement initially at a competitive price point.

Regulatory Strategy & Intellectual Property

GeniPhys has already had multiple engagements with the FDA via the Q-sub process to refine and align on a regulatory strategy. Preclinical testing is underway to support an initial 510(k) for wound management (Product Code KGN) in 2024. No human clinical data will be required for this initial submission. GeniPhys plans to pursue indications as a soft tissue filler and for breast conserving surgery (lumpectomy) for breast cancer patients via the PMA pathway, supported by wound management revenue.

Collymer is protected by nine existing patents and seven pending patent applications, with protection extending to 2042. Patent coverage includes composition of matter, process, and methods of use patents.

Key Milestones

Objective	Milestone	Date/Year
Design freeze	Final verification of manufacturing process and test methods	Q3 2023
Test Devices	Production of test devices for submission enabling testing	Q4 2023
510(k) submission	Submission of 510(k) for wound management indications (KGN)	Q3 2024

Capitalization History

Year	Grant Funding Round	Description	Amount
2019	NSF SBIR	Phase I grant	$224,873
2022	NSF SBIR	Phase II grant	$974,349
2023	Initial Equity Funding	A Round equity investment	$6 million

Use of Proceeds

Current funds are focused on submission enabling activities and building manufacturing capabilities. A 6,000 square foot manufacturing facility is under construction in Indianapolis to support GMP production of bulk Collymer. GeniPhys is partnering with a fill/finish CMO to support production of Collymer SAS kits utilizing pre-filled syringes.

Key Team Members

Sherry Harbin, PhD | Founder and CTO

Dr. Harben has worked in the field of regenerative biomaterials for over 30 years and remains on faculty in the Weldon School of Biomedical Engineering at Purdue University. She has authored over XX publications and XX patents.

Andrew Eibling, MBA | President and CEO

Mr. Eibling has over 35 years of life science experience focused on business development and alliance management at companies including Eli Lilly & Co, Covance (Labcorp), and Enable Injections. He joined GeniPhys in 2021.

Michael Hoffa | COO

Mr. Hoffa has extensive medical device operations experience at both established companies as well as startups including Cook Medical, Suros Surgical (Hologic), and Probo Medical.

Company Overview

myBiometry empowers patients with asthma and COPD by identifying the risk of an attack/exacerbation up to 20 days before symptom onset. The core technology is a patented sensor and connected device (razor/razor blade) designed to measure lung inflammation via an established biomarker in exhaled breath (fractional exhaled nitric oxide [FeNO] breath test). The technology moves testing from the pulmonary lab to the home, creating a proprietary dataset for predictive models that drive proactive adjustments in therapy to prevent attacks. The diagnostic data is augmented by digital solutions and evidence-based education programs through an exclusive partnership with the American Lung Association.

Market & Commercialization Strategy

Asthma and COPD are two of the biggest healthcare problems in the world, impacting over 500 million patients. In the US alone, the cost to manage these diseases is over $132 billion annually. myBiometry partners with payors to remotely monitor patients, using its data to drive personalized and proactive interventions that prevent exacerbations, saving $4,700-$12,000 per event. Additional market opportunities exist for traditional point-of-care testing in physician offices and retail pharmacies for the diagnosis, stratification, and therapeutic monitoring of patients. Both markets, home and point-of-care, are reimbursed via existing CPT codes.

Technical & Competitive Advantage

myBiometry's core technology is a single-use, disposable gas sensor that measures airway inflammation through a simple, non-invasive breath test. The technology simplifies a complex, lab-based test and reduces the cost by more than 20 times, enabling daily home use. The digital solution tracks exposure to environmental asthma triggers, symptoms, and disease control. The combined data form a proprietary dataset used to identify disease deterioration as early as 20 days before symptom onset

Regulatory Strategy & Intellectual Property

myBiometry invented and developed its core sensing technology, which is 100% owned by the company. The company has 16 issued patents and maintains trade secrets in sensor manufacture and chemical formulation. The regulatory pathway is 510(k) Class II for point-of-care and De Novo for home use with predictive algorithms.

Key Milestones

Objective	Milestone	Date/Year
510(k)	Clearance	2024
Paid Pilots	2 paid pilots with payors insuring over 120,000 patients with asthma and COPD	2024

Capitalization History

Year	Funding Round	Description	Amount
2019	Pre-Seed	Technology Development, Intellectual Property	$3.5M
2023	Seed	Product Development, Regulatory Clearance, Early Commercialization	$7.0M

Use of Proceeds

510(k) clearance and execution of paid pilots with two large regional health insurers.

Key Team Members

Bryan Nolan | Founder/CEO

20 years of healthcare experience in sales, marketing, and strategy, including 10 new product launches. Previously with Johnson & Johnson (Ethicon Endo Surgery). Co-inventor of the technology.

Anmol Wassan, M.B.A. | Chief Operating Officer

20 years of healthcare experience. Co-founded Virtify (exited to Private Equity), which set the standard in solutions for structured content management for biopharma product labeling.

Devon Campbell, M.S. | Chief Product Officer

25 years of product development experience with over 10 cleared devices and diagnostic platforms. Previously led product development at Quanterix (IPO) and Ventana (acquired by Roche for $3.4B).

Mark Vreeke, Ph.D. | Chief Technology Officer, VP of R&D

30 years of IVD and biosensor product development experience with over 90 patents. Co-inventor of Therasense diabetes sensor technology (acquired by Abbott Diabetes for $1.3B).

NEURAVA

Company Overview

SUDEP (sudden unexpected death) is a terrible risk faced by 65M epilepsy patients globally and 3.5M Americans. There is no device currently available to monitor for this risk nor identify patients at highest risk of SUDEP. Neurava is developing novel wearables on the arm and neck for nighttime monitoring and alerting of seizures, cardiorespiratory dysfunctions and SUDEP risk in epilepsy patients. The recorded data will enable physicians to expedite formulation of treatment plans and to triage and further assess patients with the highest individual SUDEP risk. Neurava has completed a clinical study of its arm wearable and is currently conducting clinical testing of its full platform on people with epilepsy.

Market & Commercialization Strategy

Employing a bottom-up approach, the total available market consisting of 3.5M Americans with epilepsy is $8.1B. The serviceable available market consisting of 1.2M refractory patients is $2.8B. Neurava plans to enter the market by targeting the approximate 221,000 refractory patients waiting to enter an epilepsy monitoring unit (EMU) annually, giving a target market of $512M. Once a neurologist determines that an epilepsy patient needs to go to an EMU, we will sell our device to these patients through physician prescriptions. Our wearables will cost $1600. A smartphone app grants access to a patient database for $1/day, in addition to $1/day for replaceable adhesive patches. Neurava's platform technology can also be scaled to patients at risk of sudden infant death syndrome and sleep apnea.

Technical & Competitive Advantage

Currently, there are no devices on the market that specifically monitor SUDEP risk. Epilepsy patients instead use seizure monitoring devices like those by Empatica, NightWatch, and Neureka. However, seizure-based detection devices remain limited in their ability to mitigate SUDEP risk since they do not monitor for the cardiorespiratory dysfunctions leading up to SUDEP. By detecting cardiorespiratory dysfunctions in addition to seizures, our wearables can help mitigate the risk of SUDEP within the entire epilepsy community.

Regulatory Strategy & Intellectual Property

Neurava is pursuing the 510(k) premarket notification pathway for their wearables to monitor and alert for seizures and cardiorespiratory dysfunctions. Once approved, Neurava will apply for a breakthrough device designation for SUDEP risk monitoring and expand indications of its 510(k) approved devices. This strategy was validated in a pre-submission meeting with FDA. Neurava has secured an exclusive license to a patent portfolio consisting of three patents from Purdue. This portfolio provides a variety of coverages, including for a multi-modal wearable seizure sensor system (arm wearable). Neurava also converted and filed a non-provisional patent application (Neurava owned) for the neck wearable.

Key Milestones

Objective	Milestone	Date/Year
Clinical	Validate full system in both adult and children epilepsy patients	Q3 2024
Regulatory	Arm wearable 510(k) submission	Q2 2024
Regulatory	Neck wearable 510(k) submission	Q1 2025
Commercialization	Go-to market	Q4 2025

Capitalization History

Year	Grant, Funding Round	Description	Amount
2019-21	Pre-Seed	Pitch competitions and early convertible note	$87,500
2021	Seed – Convertible Note	Syndicate round led by Elevate Ventures, including strategic investor UCB	$656,250
2022-23	Series Seed – Equity	Syndicate round led by Life Science Angels with follow-on investments from all major previous investors, incl. UCB	$2.26M
2023	Cash Prize	Grand Prize Finalist – MedTech Innovator 2023 Program	$25,000

Use of Proceeds

The milestones of the Series Seed equity round include validation of the full system in both adults and pediatric epilepsy patients and a 510(k) submission to FDA for the arm wearable. Prior to Series A, Neurava plans to raise more capital to submit a 510(k) to FDA for the neck wearable.

Key Team Members

Jay Shah, PhD | CEO, Co-Founder

Jay has over 5 years of experience in medical device development. He previously worked at Cyberonics (now LivaNova) and a medical device startup on product development & clinical trial management/execution.

Vivek Ganesh, PhD | CTO, Co-Founder

Vivek has over 5 years of experience in medical device development. He previously worked at a startup designing medical equipment and at Apple designing new features of the Apple Watch.

Clinical Advisors

Dr. George Richerson, MD, PhD (Univ. of Iowa), Dr. William Nobis, MD, PhD (Vanderbilt Univ.), Dr. Samden Lhatoo, MD, FRCP (UT Health – Houston), and Dr. Michael Privitera, MD (Univ. of Cincinnati). They are leading experts in epilepsy and SUDEP and partners for Neurava's clinical studies.

UCB Biopharma

UCB is a strategic investor who brings epilepsy related business experience to the team. They are global leaders in epilepsy as producers of the most commonly used anti-seizure medications.

Company Overview

Recovery Force Health is an all-encompassing digital health organization focused on the application of data-driven solutions through wearable medical technology. Our mission is to be a leader in providing devices and solutions that alleviate unnecessary barriers for healthcare professionals to improve patient outcomes. While the company started solely with the idea of creating a solution to the current standard of care compression devices, we have ventured into other aspects of healthcare products that will enhance patient mobility and patient comfort.

Market & Commercialization Strategy

Our clinical trials and implementation results demonstrate that patients are spending significantly less time in bed and achieving remarkably higher compliance to DVT prophylaxis, as opposed to the current standard of care IPCs. These significant outcomes have been celebrated during poster presentations at national critical care conferences and within multiple peer-reviewed journals. Our product features, along with our trial results, promote how game-changing and innovative the MAC System is for patient safety not only for patients, but also caregivers. The benefits of our products & outcomes of our trials are showcased at numerous nursing & healthcare conferences across the United States.

Technical & Competitive Advantage

Current IPC products on the market are built for bedrest, tethering the patient to the bed while in use and only provide sequential compression to the patients legs. These devices often lead to refusals due to discomfort, noise levels, complaints of hot/sweaty, and a number of other limitations that come along with being tethered to the bed. MAC is the world's first cordless, tubeless therapeutic compression device that also generates mobility data in real-time. Patients wearing MAC have a more comfortable and lightweight means of compression therapy. Unlike the current standard of care, MAC takes a mobility-first approach allowing patients to receive the needed compression therapy while providing freedom to be mobile without having the MAC System removed from their legs each and every time they need to get out of bed.

Regulatory Strategy & Intellectual Property

The MAC System has issued intellectural property with Patent #11173095 (Issued 11/16/2021) and Patent #11179291 (Issued 11/23/2021) with multiple other patents pending. The MAC System has received FDA Class II 510(k) Clearance – K203052 (March 21, 2021) with upcoming enhancements for EMR Integration in Q1 of 2024. This will be a significant advancement in patient care and communication, which will allow the caregiver to automatically have patient mobility and adherence to mechanical prophylaxis charted into EPIC and Cerner. The advancement of EMR integration ensures that the accuracy of the chart is improved to optimize communication and achieve patient outcomes, while saving the nursing staff time and enhancing efficiencies in a healthcare environment struggling with nursing time and staff shortages.

Key Milestones

Objective	Milestone	Date/Year
EMR Integration	Complete EMR integration and connectivity with the MAC System	Q2/2024
Build Clinical Evidence	Design and execute clinical studies demonstrating reduction in non-reimbursable events	2024
Technology Awards	Pursue Innovative Technology designation on the MAC System with targeted GPOs	2024

Capitalization History

Year	Grant Funding Round	Description	Amount
2019	Seed Round	Foglia Family (Sage Products Founders) + Indiana Spine Ventures + Angel Investors	$10.3M
2021	Capital Raise Equity	Foglia Family + Indiana Spine Ventures	$3.0M
2022	Capital Raise Equity	Foglia Family + Indiana Spine Ventures + $1.25M Elevate Ventures match + Angel Investors	$7.7M
2023	Capital Raise Equity	Foglia Family + Indiana Spine Ventures	$4.1M

Use of Proceeds

Latest $10M round of funding will be used to further enhance product development initiatives focused on connectivity and EMR integration with Epic and Cerner with our flagship MAC System device. Funds will also be utilized for capex purchases related to our Elevate Patient Positioner, inventory, and salesforce expansion in key healthcare markets across the country.

Key Team Members

Matthew Wyatt | CEO

20+ years of executive management and entrepreneurial expertise specialized in building companies from the ground up with a proven track record of multiple exits to strategic partners.

Jason Bobay, MBA | President

15+ years in medical device specializing in sales, business development, product development, and clinical research with extensive knowledge on recurring revenue business models and commercialization of new products.

Tim Yohler | Chief Financial Officer

25+ years in private industry as CEO, CFO, and COO experience including 12+ years in Big Four Public Accounting Firm with several M&A transactions in both the public and private sectors.

Jeff Schwegman | Executive Vice President of Engineering

25+ years in design, development, manufacturing, and commercialization of medical devices, diagnostics, and drug delivery devices. Leads the day-to-day product development and design effort within the organization.

Company Overview

Incorporated in 2021 and headquartered in South Bend, Indiana, Vital View Technologies (VVT), is a medical IoT company, on a mission to change the short and long-term treatment of the chronically ill by developing non-contact connected solutions for hospitals and the hospital-at-home. Our beachhead market is in Congestive Heart Failure (CHF) long-term condition management. The platform utilizes a proprietary Radio Frequency (RF) Polarization Mode Dispersion (PMD) which enables a new contactless modality allowing a sensor to be installed seamlessly in the home-care setting. The VVT monitoring platform is a non-contact, noninvasive at-home medical monitor that tracks fluid change over time and provides care teams with actionable insights and enables early interventions designed to improve patient outcomes and reduce the risk of hospital readmission.

Market & Commercialization Strategy

Approximately 7 million Americans are suffering from heart failure in 2020, growing to 8.5 million by 2030, additionally, the heart failure readmission rate in the US is a staggering 25% within 1 month and reaches 50% within 6 months. There is an unmet need for improving patient adherence and better treatment solutions thus VVT's early detection platform is an at-home remote monitor which provides direct fluid change measurements, heart rate, and respiratory rate to clinicians. Within healthcare VVT has potential applications for heart failure (HF), chronic kidney disease (CKD), chronic liver disease (CLD) and fluid monitoring in ICU units of hospitals and ambulatory surgery centers (ASCs). Specifically, the initial CHF application has a TAM of USD $42.1 billion in the US. Targeting Accountable Care Organizations (ACOs) that represent a SOM of USD $1.2 billion for Vital View.

Technical & Competitive Advantage

Products on the market today are often imprecise, inconsistent, or invasive. Devices, such as weight scales, and wearables, suffer from inconsistency, surrogate data, discomfort, and patient adherence issues. Another category of existing solutions, such as pulmonary arterial implants are invasive, as they require surgery and are among the most expensive solutions. Vital View's solution is truly contactless, provides a direct measurement of fluid volume changes, utilizes wireless monitoring with vital signs capabilities and the potential for respiratory monitoring.

Regulatory Strategy & Intellectual Property

Vital View Technologies' proprietary polarization mode dispersion (PMD) technology is protected by significant IP, making it extremely difficult for competitors to develop a solution that enables contactless measurements of fluid balance. VVT currently has an exclusive, worldwide license to 7+ Issued Utility Patents (+ CIP) and 4+ Patents Pending. VVT has completed a pre-submission meeting with the FDA in June 2022 and anticipates another pre-submission meeting furthering the relationship with the FDA and confirming testing strategy. The company will then submit a 510(k) application in Q1 2025 with an intended use for fluid management in a variety of medically accepted clinical applications.

Key Milestones

Objective	Milestone	Date/Year
Development	2nd Generation Prototype (Valencia)	Q1 2023
Clinical	Pivotal Clinical Study	Q3 2024
Regulatory	510(k) Submission	Q1 2025

Capitalization History

Year	Grant Funding Round	Description	Amount
2020	Pre-Seed	Proof of Concept, Pit Road Fund	$200,000
2021	Seed	Priced Round led by ND Pit Road Fund	$1,670,000
2022-2023	Grant	Elevate Ventures/ARI Innovative Research Matching Grant	$100,000
2023	Seed Extension	Priced Round Co-Led by ND Pit Road Fund & Pier 70 Ventures	$5,500,000

Use of Proceeds

In Q4 2023 Vital View Technologies raised $5.5M Seed Extension round to complete its next gen prototype (Valencia), begin its pilot customer program, and conduct a pivotal clinical study, which upon successful completion, will be followed by 510(k) submission to the FDA.

Key Team Members

Raymond Fraser, MBA | Co-Founder & Chief Executive Officer

Focused on setting and executing the vision for Vital View Technologies, along with fundraising, allocating capital, and building and overseeing the executive team. Mr. Fraser is leveraging his 10+ years in the startup ecosystem as a serial entrepreneur which includes co-founding 3 startups (1 exit), and early employee at 2 startups.

Casandra Adams, M.S.| Co-Founder & Chief Operating Officer

Ms. Adams has 10+ years of Development and Commercialization experience within all phases of the Pharma and MedTech industries and drives operation efforts of key partners, including product development, regulatory/compliance, clinical strategy, and internal coordination of investor relations.

Chris Rauh | Co-Founder & Chief Technology Officer

Mr. Rauh comes from 35+ years of wireless technology experience and is leading VVT's engineering and design strategy as well as overseeing the device development from prototype to design freeze and its integration with the EMRs of health system providers.

Dr. Rick Snyder, MD, FACC | Co-Founder & Chief Medical Officer

Dr. Snyder leads the strategic direction and execution of the Company's medical safety & effectiveness program. Dr. Snyder is board certified in cardiovascular disease, interventional cardiology, and advanced heart failure and transplant.

Company Overview

Nanovis is a technology-driven company committed to bring science driven technology to enable our partners to engage health care and patients to engage life with improved clinical outcomes. Founded in 2008 with licensed intellectual property from Purdue Research Foundation, Nanovis has become the market leader in nanotechnology used to improve the biological response of implanted orthopedic devices. Since 2015, the company has obtained 7 FDA clearances for spinal implants with a nanotechnology designation

Market & Commercialization Strategy

Our strategy is to discover unmet clinical needs, innovate through collaboration to develop science driven technology platforms, and validate the commercialization of the innovation. Through it's wholly owned commercial distribution entity, the company is able to obtain and establish a relationship with the FDA, clear new technologies, and engage physician users with the product to demonstrate clinical efficacy. The company plans to build out the resources required to manufacture the surface technologies it develops. Innovations are monetized by capturing manufacturing margins, commercial product sales, licensing fees, and product royalties.

Technical & Competitive Advantage

Nanovis' core competency is the ability to quickly innovate and determine the commercial path of their developed and licensed technologies. The flagship technology, nanoVIS Ti Surface Technology, is a manufactured, permanent, nano surface on titanium orthopedic and spinal implants. The surface continually promotes osseointegration, increases vascularization, and reduces bacterial attachment and colonization. Our success of the surface technology in spine has generated new nanotechnology innovations with any implantable alloy. Our research team, located at NC State, provides the expertise to solve problems with medical device integration paired with science driven surface technology.

Regulatory Strategy & Intellectual Property

Nanovis has built a robust IP portfolio around its surface technology. With the combination of intellectual property protection, both licensed and owned, and utilizing protection under manufacturing trade secrets, the company is protected in both nano surface design and the process of creating the surface on a medical device. Our 510k, with a master file regulatory strategy, has been proven with the clearance of 7 spinal implant systems.

Key Milestones

Objective	Milestone	Date/Year
Micron Porous Spinal Interbody	Commercialize PEEK Spinal Interbody with porous titanium endplates (FortiCore)	2015
nanoVIS Ti Surface Technology	Commercialize nanoVIS Ti Surface Technology on Spinal Interbodies (Nano FortiCore)	2019
Nano Surface Commercialization	Commercialize nanoVIS Ti Surface Technology on Pedicle Screws (Nano FortiFix)	2021
Business Development	Close on strategic partnership with major OEM to further commercialize Nano FortiCore	2022
Business Development	Commercial Launch of First OEM Partner Product (Nano FortiCore)	2024

Capitalization History

Year	Grant Funding Round	Description	Amount
2008-2017	Common Units	Multiple Rounds of Common Units	$12.0M
2017	Class A Preferred	1 Round of Class A Preferred Units	$ 5.9M
2017-2021	Class B Preferred	2 Rounds of Class B Preferred Units	$14.7M

Use of Proceeds

Current 2023 Offering is for $5.5M convertible notes. Proceeds from this round will be used in three areas; i) $2.75M to fund startup cost of our OEM partnership to fully commercialize the Nano FortiCore product line, ii) $1.75M to fund new and ongoing technology development projects, and iii) $1.00M in general working capital.

Key Team Members

Brian More | President and Chief Executive Officer

With 27 years of experience in accounting, finance, operations, and corporate governance, Brian has been instrumental in the startup of six medical device related businesses as well as a leveraged buyout and other significant merger and acquisition related events. Prior to serving as CEO of Nanovis, he served many years as Chief Financial Officer for Micropulse, Nanovis, and Restoration Medical Polymers.

Jeff Shepherd | Chief Commercial Officer

Jeff Shepherd is a purpose-driven servant leader who holds his relationships with others at the forefront. He has extensive experience in medical device sales and strategic account management in medical devices. This is ultimately demonstrated by his values and teamwork modeled in his personal and professional life.

Joe Roth | Director of Operations

Joe Roth has over 15 years' experience in medical device manufacturing serving in processing, manufacturing, and quality engineering roles. Joe supports a team of seasoned engineering, manufacturing, and project management professionals focused on advancing Nanovis' products and services to market by partnering with critical suppliers, validating manufacturing processes, and ensuring high standards of quality and customer service.

Kreigh Williams | Director of Technology

Kreigh has over 12 years' experience as an engineer, leader, and innovator in medical devices. He has a proven track record of leading teams, scaling supply chains, and developing key relationships with coworkers, customers, and suppliers alike. Prior to Nanovis, Kreigh's leadership at Sites Medical was instrumental in collaborating with Nanovis to launch our Nano FortiCore product line.

Authenticx

Company Overview

Authenticx is the new standard for humanizing conversational intelligence in healthcare. Authenticx AI unlocks insights from 100% of customer conversations happening every day inside contact centers. These insights reveal hidden barriers, motivators, and strategies so healthcare organizations can make confident, data-backed decisions. In 2023, Authenticx was ranked No. 349 on the Inc. 5000, recognized as one of America and Indiana's fastest-growing private companies.

Market & Commercialization Strategy

The Authenticx market sits at the interection of a $43Bn healthcare analytics market and a $29.8 Bn coversation intelligence market. Authenticx serves enterprises within pharma, health insurance and healthcare provider verticals. The types of problems Authenticx helps this industry identify and solve friction in their customers' journey, thereby improving company profitability, customer rention and overall customer experience.

Technical & Competitive Advantage

Authenticx is a vertically specific AI company who has developed proprietary Machine Learning models, including generative AI models, based upon its own curated training data. The competitive advantage is that the product helps solve healthcare-specific business problems using more accurate and useful AI, as well as a proprietary methodology for leveraging insights from the data. Simply put, they deliver a 10x higher speed to value than its competitors.

Regulatory Strategy & Intellectual Property

Authenticx is a cloud-based SaaS company whose intellectual property is derived through a unique data set, proprietary machine learning models, and insights-mining methodology. Authenticx is licensed by the health care and life sciences industries who must comply with their regulating authorities. Authenticx helps the health care industry monitor and maintain regulatory compliance by identifying evidence noncompliance within conversation data.

Key Milestones

Objective	Milestone	Date/Year
First Revenue	Achieve paying customers with recurring revenue.	1.1.2019
Traction	Achieve >$5M in recurring revenue	6.1.22
Traction	Achieve >10M in recurring revenue	6.1.23

Capitalization History

Year	Grant Funding Round	Description	Amount
2020	Seed	Series seed led by Chicago-based M25	$1.2M
2021	Series A	Series A led by Salt Lake City based Signal Peak Ventures	$7.5M
2022	Series B	Series B led by Richmond, VA based Blue Heron Ventures	$20M

Use of Proceeds

Authenticx use of proceeds from Series B has included doubling the size of our sales team, broadening marketing efforts, and investing in a new Product Management functional team including a Chief Product Officer.

Key Team Members

Amy, Brown, MSW | Founder & CEO

Prior to founding Authenticx, Amy spent over 20 years working in the business of healthcare. She brings that experience daily as she leads a company of over 100 employees and consults with clients from the biggest healthcare companies in the country. Amy's passion for leveraging conversation data to improve healthcare was born from the trenches of working in it directly.

Michael, Armstrong, MBA | CTO

Nominated as a top honoree in 2022 for IBJ and Tech Point's CTO of the Year, Michael Armstrong has built the Authenticx platform and its proprietary AI from the ground up. Michael leads the Authenticx team of software and machine learning engineers, as well as the data science team.

Kip, Zurcher, MBA | CFO

Kip Zurcher has been recognized as a Top CFO in 2023 by the Indianapolis Business Journal. Kip is a strategic operational CFO, bringing decades of experience in large industry and tech startup to bear. Kip's leadership includes finance and accounting, pricing, legal and regulatory compliance.

Sam, Estes| CRO

Sam's sales tenure has been rooted in enterprise SaaS and his success is highlighted by his effectiveness at building and developing full stack sales teams. Sam is responsible for the growth function at Authenticx including sales development, account executives, account management and marketing.

Company Overview

3aware minimizes the cost, time and risk of MedTech regulatory compliance. Its aiSurveillance solution enables manufacturers to achieve PMCF-based compliance with active surveillance at less than 50% of the cost and one-tenth of the time of chart reviews and registries; and provides deeper, patient-level understanding with less bias, compared to traditional methods.

Market & Commercialization Strategy

Leveraging its dataset, which contains over 10.3M patients and over 60,000 medical devices, 3Aware is selling its unique value proposition directly to MedTech manufacturers to enable them to modernize and automate their compliance and product portfolio optimization processes.

Technical & Competitive Advantage

3Aware data content currently covers tens of thousands of devices explicitly tied to the experience of millions of patients; and is consistently growing. Proven AI capabilities facilitate the mining, interpretation and structuring of critical information buried in unstructured provider notes. The 3Aware platform enables analysts to immediately and directly access the distilled content they need to apply their expertise—in a clinical workbench optimized for Post-Market Clinical Follow-up.

Regulatory Strategy & Intellectual Property

3Aware has filed a patent application on *Managing, Storing, Organizing, and Classifying Clinicial Health Data Associated with Medical Devices*. In addition, 3Aware has a perpetual license to the HiTrust certified core healthcare data ingestion and management platform developed by hc1 for the diagnostic industry and built to scale securely in the cloud. hc1 has used this platform for real-time data ingestion, organization, and enhancement for over 40 billion clinical results.

Key Milestones

Objective	Milestone	Date/Year
Company founded	Company founded and product design and development started	March 2022
Commercial Launch	3Aware commercial launch	June 2023
Expansion of Data	Partnership with Mayo Clinic Platform Announced	December 2023

Capitalization History

Year	Grant Funding Round	Description	Amount
2022	Seed	Founders Health Cloud Capital and Cook Ventures started company	$3M
2023	Bridge debt	In lead up to launch this debt was provided as a bridge to the current round	$2M
2023	Seed Extension	In process of raising additional round focused on commercial growth in the next 2 years	$8M

Use of Proceeds

Expand business development and clinical expertise. Expand data network. Increase marketing spending, including website upgrades, to drive growth.

Key Team Members

Bill Moss |CEO

Bill is a veteran life sciences entrepreneur who has built and led companies through successful exits in the genomics, insurance and pharmacy verticals, and was most recently the CEO of Seven Bridges Genomics.

Chris Brown | President & COO

Chris was one of the leaders who built HC1 Insights, a leader in precision diagnostics. Chris has a successful track record of scaling high-growth technology companies in the wireless and SaaS software industries.

Amelia Hufford PhD | SVP Clinical & Regulatory Science Operations

Amelia's clinical expertise is the catalyst of the clinical science and data science marriage that is a key differentiator for 3Aware's products.

David Kates | Chief Data Officer

David's extensive experience with health data from both a standards and practical perspective enable him to build the linkage and analysis of healthcare care data to drive actionable insights.

Company Overview

Harnessing the power of Brown Fat to advance the treatment of Obesity and Type Diabetes (T2D), Adipo Therapeutics is developing a new technology platform that acts by converting energy-storing white fat to metabolically beneficial, energy-burning brown fat. Given the growth of the Obesity and T2D treatment markets, Adipo forecasts a $8 billion annual revenue opportunity. Adipo is in late preclinical development. Proof of concept in animals has demonstrated weekly treatment with the lead product, ADPO-002, results in weight loss and improved glucose control, with no change in calorie intake. Studies of ADPO-002 treatment of human fat (in vivo and ex vivo) have induced increases in mitochondrial biogenesis. Adipo is seeking to raise $35 million in Series A to fund Investigative New Drug (IND) studies through Phase 1 Clinical trials.

Problem or Market Opportunity

By 2025, 140 million people in the US will have obesity and 37 million T2D. Despite available treatments, the majority of patients are not reaching therapeutic goals, resulting in an 8-year reduction in life expectancy. Driven by the GLP category of treatments (Ozempic/Wegovy, Mounjaro/ Zepbound) and investments by Eli Lilly and Novo Nordisk, the obesity market is forecast to reach $100 billion in the next decade (Barclays, April 2023). Obesity is driven by an imbalance of calories consumed and expended. The GLP treatments have demonstrated strong efficacy by decreasing calories consumed but are associated with side effects including nausea and vomiting and require long-term use. In addition, studies have demonstrated weight loss through decreased calorie intake triggers the body's metabolic adaptation, leading to decreases in core energy expenditure and rebound weight gain. There is a need in the market for a treatment with lower side effects that acts by increasing energy expenditure and can be used as a complementary treatment with the GLPs.

Technical & Competitive Advantage

Adipo Therapeutics is developing a unique treatment to increase energy-burning, metabolically beneficial brown fat by converting energy- storing white fat into brown fat, providing weight loss and improved glucose control with no change in calorie consumption. In addition, higher levels of Brown fat are correlated with lower rates of T2D, dyslipidemia, coronary artery disease, cerebrovascular disease, and hypertension. The Adipo treatment is being developed as a weekly, subcutaneous injection of Notch-inhibiting nanoparticles. Notch-inhibition in white fat induces an increase in mitochondria, converting the white fat to brown, increasing the total amount of lipid burning brown fat in the body. Nanoparticle administration provides rapid uptake in the targeted fat with very limited biodistribution, limiting safety concerns and side effect risks. By increasing energy expenditure, the Adipo treatment has the potential to provide a treatment for obesity and T2D that is an effective stand-alone treatment and a complementary treatment to the leading GLP treatments without the limiting side effects of nausea and vomiting.

Regulatory Strategy & Intellectual Property

Adipo will seek FDA approval for the treatment of Obesity and T2D, following a well-established and well understood path for injectable treatments. Adipo has recruited and retained a team of experts in all aspects of this approval plan to establish and guide the process. Adipo Therapeutics had a Type C meeting with the FDA in 2022, providing guidance which informed Adipo's IND and Phase 1 planning. Adipo is currently executing pre-clinical and manufacturing plans in preparation for a pre-IND meeting in 2024 and IND filing in 2025. Adipo has a composition of matter patent approved in EU and China and pending in the US, US 15/771,312; US63/055,410; U.S. 15/621,627; International: PCT/US16/58997. Adipo is partnering with Ivor Elrifi, JD at Cooley LLP to complete the patent application process.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q1 2022	FDA Guidance	Type C meeting
Q4 2024	FDA Guidance	Pre-IND meeting
Q2 2025	IND approval	Approval for first human dose

Capitalization History

Year	Grant or Equity Type	Description	Amount
2021	Equity	Seed	$1.9 million
2022	Local Grants	Indiana Innovation Grants	$82 K
2023	Convertible Note	Seed Bridge	$1.2 million

Current Round, Terms, and Use of Proceeds

Adipo is seeking $35 million Series A to fund IND enabling studies, IND submission, and Phase 1 clinical trials.

Key Team Members and Advisors

Karen Wurster, MBA | CEO

Pharmaceutical executive with over 25 years in developing, launching and commercializing blockbuster diabetes products. MBA from Kelley School of Business; BS in Biochemistry

Meng Deng, Ph.D. | Founder

Scientific expert in biomaterials technologies for drug delivery, cell and tissue engineering applications including post-doc work in the MIT Langer lab. Associate Professor at Purdue University with Ph.D. in Chemical Engineering, Postdoctoral in Bioengineering at University of Connecticut Health.

Roger Miller | VP of Operations

Pharmaceutical manufacturing expert with over 40 FDA submissions, and 50 corporate due diligence through his experience at big pharma and 6 biotech startups. MBA in operations, MA in Physical Chemistry

Keith Johns | Chief Strategy Officer

Pharmaceutical executive with over 25 years' experience. Former Sr. VP of Diabetes and Obesity at Eli Lilly, where experience included leading the launches of blockbusters Truclicity and Mounjaro and New Product Planning

Company Overview

Confluence is a clinical-stage company developing first-in-class medications for the rare orphan disease, Fragile X Syndrome, and a similarly anchored disorder, Autism Spectrum Disorder. Our lead therapy is Phase 2 ready and has received orphan drug designations, ensuring a faster route to approval along with commercial market exclusivities.

Problem or Market Opportunity

Confluence is solving a major health problem for a rare orphan disease called Fragile X Syndrome and a similarly anchored disorder, Autism. Our novel candidate has clinically demonstrated the ability to rescue social, behavioral and cognitive deficits. The Company is positioned to mirror these clinical findings in a Phase 2 clinical trial. The US/EU/JP addressable market represents a USD$25B a year unmet medical need. Today, there are no approved medications that mitigate these core impairments. Confluence has a defined regulatory path, Orphan Drug Designations, completed Phase 1 clinical trial and defensible IP.

Technical & Competitive Advantage

Fragile X Syndrome is caused by an X chromosome mutation. This alteration causes a neurosystem imbalance resulting in too much glutamate and not enough GABA being produced. A neurotranmitter imbalance either way impacts learning, language and social behavior. Our medication's dual action reduces glutamate while promoting GABA. This re-alignment results in a reduction of these core impairments. 50% of Fragile X patients have Autism, so proof in Fragile X is foundational to a larger market opportunity in Autism. Our medication will be a chronic care therapy and exploits a competitive therapeutic gap as the only one-drug solution in development that modulates receptors for both Glutamate and GABA.

Regulatory Strategy & Intellectual Property

Confluence completed a pre-IND meeting and has a confirmed regulatory path. The Company conducted a successful Phase 1 regulatory trial demonstrating safety and superior pharmacokinetics. Three critical elements needed for a successful Phase 2 regulatory trial have been determined through five academic clinical studies in Fragile X patients: patient selection, dosing and outcome measures. Confluence's Phase 2 IND has been drafted and awaits results of a final juvenile rat toxicology study before agency submission. A planned Phase 2 will be a double-blind, placebo-controlled trial pediatric/adolescent Fragile X patients to evaluate improvements in communications, social engagement, anxiety and hyperactivity.

Confluence has a robust portfolio covering multiple disorders, compounds, molecular biomarkers and formulation technologies all interconnected to extend patent life cycle out to 2036. Confluence has received Orphan Drug Designations (US, EU) providing additional layers of post-approval market exclusivity for up to 7 years in the US or 12 years in Europe. This exclusivity prevents any drug with a similar mechanism of action to be approved during this time. Our product has been successfully GMP manufactured and is commercially ready for production. Early discovery efforts are being conducted to improve the lead asset's active ingredient creating a new chemical entity to further improve and extend the product's life cycle.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q2 2024	Toxicology Study	Adult toxicology complete. Final juvenile rat toxicology study is to expand toxicology profile to include younger patients
Q3 2024	File IND	Finalize and file IND with the FDA for a pediatric/adolescent/adult Phase 2 clinical trial

Capitalization History

Year	Grant or Equity Type	Description	Amount
2011-14	Series A1	Series A1 preferred equity offering at $2.70 per unit	$2,600,000
2015-17	Dev Program	Non-dilutive development program payments	$2,100,000
2016	Series A2	Series A2 preferred equity offering at $4.42 per unit	$1,600,000
2019-20	Bridge	Bridge finacing: 2 yr. convertible notes with 8% interest	$1,400,000
2023-24	Exp Bridge (ongoing)	Expanded Bridge financing: 2 yr convertible notes with 10% interest, converts into Series B	$1,170,000

Current Round, Terms, and Use of Proceeds

Confluence is offering up to $2,000,000 in an expanded bridge round consisting of a convertible note carrying a 10% interest rate with a maturity of 2 years. Other terms include a conversion to Series B price at a 20% discount to lowest Series B price, 2x liquidation preference if the Company is sold. The funds will be used to conduct a final juvenile rat toxicology study, preparation/filing of Phase 2 IND and produce additional clinical product.

Key Team Members and Advisors

Craig Erickson, MD| Scientific Founder and Lead Scientific Advisor
Director, Fragile X Research & Treatment Center, Director of Research, The Kelly O'Leary Center for Autism, Cincinnati Children's Hospital
Steven L. Johns, MBA | President & Founder
Work career includes 15+ years in Banking / Financial Management and 15 years in own business ventures
Boyd Sturdevant, Jr. | Chairman & Founder
Brings a depth of working knowledge in the areas of commercializing mental health services, engaging mental health advocate/consumer groups
Timothy Parshall | Vice President of Corporate Affairs
25+ years experience in global healthcare strategy, marketing and business development; Director of Strategic Marketing at both Guidant and Eli Lilly
Kenneth Payie, PhD | Director of CM&C
15+ years experience developing large and small molecule CM&C programs (Chorus Europe– Vanthys Pharmaceutical– Eli Lilly)
Jeffery Paul, PhD | Clinical Pharmacology Advisor
25+ years pharmaceutical experience in designing and executing clinical development programs for central nervous system drugs (Astellas, Pfizer)

Grannus Therapeutics

Company Overview

Grannus is an early-stage oncology drug development company, with a unique approach to a well-validated target, the chaperone protein Hsp90, that has demonstrated efficacy in clinical studies but known limitations that have prevented previous drugs from being approved. By selectively inhibiting the β isoform, or version, of Hsp90, Grannus has overcome the limitations of the previous failed programs, and unlocked opportunity across multiple tumor types (triple negative breast cancer, ovarian cancer, and others) as a single agent therapy and in combination with other approved drugs. The Grannus team has decades of experience developing and commercializing therapeutics in academia and at leading pharmaceutical and biotechnology companies of various sizes. The company has received ~$700K in Federal and State grants, and raised $1.8M in outside capital from venture funds and angel investors.

Problem or Market Opportunity

Triple negative breast (TNBC) and ovarian cancers are both large and growing markets (2028 forecasted market size of $5.3B and $3.7B for TNBC and ovarian cancer respectively) with significant unmet medical need, especially in late line therapy. Although new product launches are anticipated, forecasts indicate that chemotherapy will maintain a significant market share in late line therapy over the next ten years (>60%). This creates an opportunity to position Hsp90β-selective inhibitors as an attractive option vs chemotherapy alone. There is also potential to expand via other indications, earlier lines of therapy, and/or combination with immunotherapies. Grannus plans to progress the program through Ph 1 clinical trials, and then enter a co-development deal, license the program, or be acquired by a large pharma/biotech to support approval and commercialization.

Technical & Competitive Advantage

Hsp90 inhibition is a well-known therapeutic approach, with more than 17 Hsp90-targeted drugs investigated in clinical trials, all of which target multiple isoforms with similar affinity (pan-Hsp90 inhibitors). Unfortunately, most have failed in clinical trials due to ocular / cardiac toxicities and dosing / efficacy limitations. Research, pioneered by Grannus co-founders, indicates that the toxicity and dosing / efficacy limitations of previous pan-inhibitors are NOT related to the inhibition of Hsp90β. By selectively inhibiting Hsp90β, Grannus can deliver strong efficacy results without the toxicity and dosing / efficacy limitations of previous pan inhibitors.

Regulatory Strategy & Intellectual Property

The regulatory pathway for small molecule inhibitors in oncology is well established and defined. Based on feedback during Pre-IND meetings, Grannus will explore the potential for regulatory designations such as orphan and breakthrough status as well as potential accelerated approval pathways. Initial assessments performed by the NIH TABA Assessment Program confirm that Grannus has freedom to operate based on a worldwide exclusive license from the University of Notre Dame for a Composition of Matter Patent for Hsp90β-selective inhibitors.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q3 2024	In Vivo Studies	Confirmatory in vivo efficacy and Hsp90 specific toxicity (i.e., ocular and cardiac) studies
Q4 2025	Pre-IND Meeting	Conduct a pre-IND meeting with the FDA
Q2 2026	IND Filing	Complete IND filing with the FDA or other regulatory body to support FIH phase 1 study

Capitalization History

Year	Grant or Equity Type	Description	Amount
2020	Grant	STTR Phase 1 Grant NIH/NCI	$233,195
2021	Grant	Matching grant from Elevate Ventures / Indiana Economic Development Corporation	$100,000
2021	Grant	STTR Phase 1 Grant NIH/NEI	$346,562
2022	Equity	Priced seed round (Pit Road Fund and Angel Investors)	$1,000,000
2023	Equity	Convertible note (Pit Road Fund, Elevate Ventures, and Angel Investors)	$800,000

Current Round, Terms, and Use of Proceeds

Grannus is planning to raise $3M-$5M via a priced equity round in 2H 2024. Procedues from this round will fund IND-Enabling studies, support regulatory interactions with the FDA, develop a oral formulation suitible for clinical studies, and complete an IND filing with the FDA.

Key Team Members and Advisors

John Foglesong, MBA | President & CEO

Mr. Foglesong is responsible for day-to-day operations. He is a 20-year industry veteran with deep oncology expertise from his time at Genentech and Atara, where he focused on late-stage development and commercialization of multiple oncology and other biotechnology products.

Dr. Sanket Mishra, PhD | Vice President Preclinical Research and Development

Dr. Mishra leads Grannus scientific activities in collaboration with our Scientific Advisory Board and expert consultants. He is an expert in Hsp90 isoform-selective inhibitors and a co-inventor of the Grannus technologies.

Dr. Brian Blagg, PhD | Consultant & Scientific Advisory Board Chair

Dr. Blagg is an expert consultant and Chair of the Grannus Scientific advisory board and co-inventor of the Grannus technology. He is a world leading expert on isoform-selective inhibitors of the Hsp90 chaparone protein, with over 45 issued patents and 250 publications.

Radyus Research, Inc. | Expert Consultants and R&D Execution Partner

Radyus is Grannus's R&D operating partner supplementing our team and supporting R&D operations. RADYUS's team of 4 expert consultants brings over 75 years of combined work experience providing scientific expertise, strategic guidance, and operational implantation

KOVINA THERAPEUTICS, INC.

Company Overview

Kovina Therapeutics is an early-stage drug discovery company focused on **stopping HPV premalignant infections before cancer develops and treating HPV cancers after detection**. The company's proprietary science includes novel small molecule antiviral compounds which bind to and inactivate a key HPV protein always expressed in early, premalignant, and cancerous pathologies. With $5.2 million in financing, the company assembled a team of experts in HPV and drug development to advance its programs.

Market & Commercialization Strategy

Kovina's target US market is ~$4 billion annually across multiple indications including cervical and oropharyngeal (head and neck) cancers and cervical/anal dysplasia. OUS opportunities represent an even larger market with cervical cancer rates equal to 35-40x US rates. Globally, **HPV causes ~5% of all cancers** and nearly 630,000 HPV-related cancers occur each year. In addition, 300,000 US women are diagnosed with HPV16 premalignant cervical infections annually. While the existing HPV vaccine is effective, it has not been widely adopted and has no impact on existing HPV infections or malignancies which develop over years or decades. Competitive therapeutics in development include immunogens and non-specific antivirals that have not been effective in clinical trials. Kovina's compounds are the **only specific antiviral** compounds that induce death of HPV16 infected cells.

Competitive Advantage

HPV premalignant infections are currently treated with invasive procedures including lasers, electrocautery, or cryotherapy that may result in serious side effects such as infertility, miscarriage, and cervical stenosis. Kovina's first-in-class therapeutic replaces existing surgical interventions. Treatments for HPV induced cancers include surgery, radiation, and chemotherapy with high morbidity and challenging side effects. Oropharyngeal (head/neck) cancer patients have the second highest suicide rate among cancer survivors due to serious complications from the current standard of care. Kovina's compounds are designed to specifically kill HPV infected cells and reduce the side effects from intense chemo/radiation and surgical regimens by shrinking tumors prior to resection.

Regulatory Strategy & Intellectual Property

Kovina's intellectual property is protected by a patent portfolio the company co-owns with Indiana University and licensed to secure exclusive rights. Kovina will request a pre-IND meeting in 2024 to seek regulatory guidance for its first-in-class premalignant infection program. While oncology small molecule regulatory pathways are well defined, the company intends to explore accelerated approval for HPV induced head and neck cancers.

Key Milestones

Q/YYYY	Objective	Milestone Description
Ongoing	**Cervical/Oropharyngeal cancer program –** lead candidate screening and preclinical studies to nominate a clinical candidate	ADME characterization, pharmacology and tox studies, GLP Tox and formulation development
Q4 2025	**Cervical/Oropharyngeal cancer program** - IND filing	Complete IND filing to enter Phase Ib/2 human trials
Ongoing (pending financing)	**Premalignant infection program** – dose range studies, GLP tox and formulation development	Maximum tolerable dose/dose range finding studies. Formulation development work scheduled to assess optimal forms for cervical and anal delivery
Q3 2025	**Premalignant infection program** – IND filing	Complete IND filing to enter Phase I/1b human trials

Capitalization History

Year	Grant or Equity Type	Description	Amount
June 2021	Seed round	Local venture funds and angel investors	$2,050,000
March 2022	NCI grant	Fast track grant *(includes ICORPS)* - HPV cancer therapeutics	$2,337,191
July 2022	NIAID grant	Phase I SBIR – HPV premalignant infections	$298,527
Sept 2022	NIDCR grant	Phase I SBIR – HPV oropharyngeal cancers	$275,766
2022	Grants/Convertible note	Elevate Ventures – matching grants ($200k) and convertible note ($75k)	$275,000

Use of Proceeds:

Kovina is raising a $500k bridge to supplement grant funding and accelerate its oncology program, including completion of an MTD/DRF dog study.

Key Team Members

Kristin Sherman, MBA | Chief Executive Officer

Leads the organization with 30 years of broad experience in drug and device development including large pharma (Eli Lilly), medical devices (Guidant Corporation), and CFO roles in three prior biotech start-up companies, two with successful exits to Roche and Novo Nordisk.

Elliot Androphy M.D. | Chief Scientific Officer and Co-founder

Directs all research efforts leveraging background as a practicing dermatologist, HPV key opinion leader, former department chair and active researcher at Indiana University. Dr. Androphy's labs have received continuous NIH and other grant funding for 35 years to conduct HPV research.

W. Garrett Nichols, M.D., M.Sc. | Chief Medical Officer

Responsible for clinical strategy and oversight. Dr. Nichols led antiviral programs for Glaxo Smith Kline and ViiV Healthcare resulting in approval of dolutegravir for HIV. Dr. Nichols also served as CMO for Chimerix (antivirals) and Istari Oncology (immunotherapeutics for solid tumors.)

Paddy Shivanand M.S., Ph.D. | VP Preclinical Development and CMC

Leads preclinical development leveraging more than 20 years of development experience with Alza Corporation, Johnson & Johnson and various biotech companies. During her career, Dr. Shivanand has advanced more than 25 molecules through various routes of administration.

MONUMENT BIOSCIENCES

Company Overview

Monument Biosciences is a next generation Alzheimer's and Related Dementia (ADRD) company focused on reducing **neuroinflammation** and enhancing synaptic/cognitive function for millions of patients in need. Our initial programs are anchored in a deep understanding of **human patient genetics**, recent discoveries around tau homeostasis and **tau seeding**, and the role of **microglia** in neuroinflammation. We have a robust **translational biomarker program** designed to offer **precision medicine** opportunities to treat the right patients and follow their disease progress in response to therapy. Based in Indianapolis, Indiana, the company has exclusive license to a pipeline of novel targets from globally recognized NIH/NIA consortiums called TREAT-AD and MODEL-AD. These organizations have been awarded over $100M to date to establish a fully integrated drug discovery program in ADRD. Our founding team is comprised of leading neuro focused scientists, clinicians, and entrepreneurs from Eli Lilly, Stark Neuroscience Research Institute, and Luson Bioventures with a proven track record in venture creation & drug development.

Problem or Market Opportunity

Alzheimer's Disease is a progressive neurological disorder that affects memory, thinking, and behavior. Disease progression significantly impacts daily task performance and can eventually lead to total dependence on caregivers. The US has over six (6) million people living with AD and this number is expected to double by 2050. There are also many forms of related dementia pathologies that add significantly to this burden. The economic impact of ADRD is substantial, with the cost of care estimated to be over $1 trillion globally. The burden of dementia underscores the urgent need for effective prevention, treatment earlier in the course of disease, and care strategies to mitigate its impact on patients, caregivers, and society.

Technical & Competitive Advantage

Eisai and Biogen won the first new approval in Alzheimer's in 20 years with their monoclonal antibody targeting Abeta called lecanemab. Lecanemab showed a reduction in disease progression by 27% over two years of therapy, which is a clinically meaningful advance for patients. However, with significant side effects, the drugs are far from a cure. Our approach to next generation ADRD programs incorporates the learnings from these Abeta agents, and we have potential advantages over all programs currently in development. Our initial programs target toxic **tau seeding** and microglia-driven **neuroinflammation** – now considered the hallmark biologies toward curing these diseases. Monument has exclusive rights through the leading institution in these major NIH-funded programs (Indiana University, top 3 in the world).

Regulatory Strategy & Intellectual Property

Our regulatory strategy employs a custom approach for each program to maximize clinical trial design efficiency. Using Monument's translational biomarker platform, we focus on fluid-based biomarkers of neuroinflammation to assess target engagement in early stage clinical trials (healthy volunteers). This strategy allows us to move into early proof of concept (POC) trials in genetically driven patient populations of Alzheimer's Disease with an informed dose selection. After achieving POC, we will broaden development into stratified ADRD populations.

Key Milestones

Milestone Description	Objective
Expected Seed Milestones	Establishment of expanded scientific R&D team and supporting infrastructure, completion of Candidate Selection (CS) with start of IND enabling studies for neuroinflammation program 1 (INPP5D, siRNA), and completion of CS for the first tau seeding program Bassoon (BSN, siRNA) and second NI program (PLCG2, small molecule)
Expected Series A Milestones	One-to-two IND candidates from internal pipeline; clinical readiness for one-to-two in-licensed programs; biomarker and clinical strategies detailed for lead programs – this would be a leading position in the field

Capitalization History

Year	Grant or Equity Type	Description	Amount
2016 & 2022	NIH/NIA U54	MODEL-AD 1 ($38M) 2016 & MODEL-AD 2 ($49M) 2022	$87M
2019	NIH/NIA U54	TREAT-AD 1 (TREAT-AD 2 in process)	$38M
2024	Seed Preferred	Founding Seed Round	$10-$15M

Current Round, Terms, and Use of Proceeds

Monument has been incubated by Luson Bioventures since 2022, and we are now initiating a $10-$15M founding Seed Financing to advance multiple programs into clinical-ready phase of development. This round is being initiated by pre-seed investments from Luson Bioventures and Dolby Family Ventures, with participation from Elevate Ventures and IU Ventures. Luson has founded and launched several new biotech ventures since 2007 and Dolby is a globally recognized life science investor with deep expertise in Alzheimer's and related dementia.

Key Team Members and Advisors

The founding team has deep industry, academia, and biotech drug discovery experience, alongside science founders who are leaders in their fields. **Derek A. Small | CEO and Chairman** - Experienced CEO executive with 20+ years in the industry, drug development, and venture capital roles; Founding managing director of Luson Bioventures

Alan Palkowitz, PhD | Director and SAB Co-Chair - President & CEO of Indiana Bioscience Research Institute (IBRI); TREAT-AD Lead PI and Co-Director; with 25+ years leading the discovery chemistry program at Eli Lilly and Company

Timothy Richardson, PhD | Chief Scientific Officer - Scientific Director Molecular Innovation of IBRI; Medicinal Chemistry and Chemical Biology Core Leader at TREAT-AD IUSM-Purdue; with 20+ year of discovery chemistry research from Eli Lilly and Company

Bruce Lamb, PhD | SAB Co-Chair - Executive Director of Stark Neuroscience Research Institute; Professor of Psychiatry, Medical & Molecular Genetics, & Alzheimer's Disease Research, IU School of Medicine; MODEL-AD – Director and TREAT-AD Center – Co-Director

Jeff Dage, PhD | Head of Translational R&D – Head of biomarkers and translation research at Stark Neuroscience Research Institute; TREAT-AD PI; with 20+ years at Eli Lilly and Company as Research Fellow and Group Leader of Translational Research

NĒRx Bio Sciences

Company Overview

NĒRx Biosciences is a pre-clinical stage biotechnology company focused on the discovery and development of biopharmaceutical compounds targeting the DNA Damage Response (DDR) pathway. The company's primary goal is to develop a new generation of anticancer therapeutics that are directed against novel protein targets for the treatment of lung and ovarian cancer.

Problem or Market Opportunity

Despite recent advances in targeted therapeutics, immune-oncology, and personalized medicine, the clinical reality of many common and aggressive cancers remains bleak. Lung cancer continues to be the number one cancer killer of men and women. Ovarian cancer continues to account for more deaths than any other cancer of the female reproductive system. Limited single agent activity and resistance remain major obstacles with molecularly targeted drugs and the low response rate for immune-oncology agents limits their widespread use in lung and ovarian cancer and there are *limited therapeutic options* for these patients.

Technical & Competitive Advantage

NERx Biosciences has developed a novel, first in class innovative cancer therapeutic agent that targets the validated DNA damage response pathway. The most successful DDR targeted therapy targets a DNA damage sensor, PARP. NERx capitalizes on this breakthrough to target the other crucial DNA damage sensors in the DDR pathway, for therapeutic intervention in the treatment of cancer. This differentiated strategy avoids redundancy and positions us to be more effective therapeutically. Our lead program is a novel target in the DNA damage response path-way, Replication Protein A (RPA). We are positioned to lead first in class and first in human trials targeting RPA for cancer therapy. The lead asset, NERx-329, demonstrates a robust mechanism of action as a competitive inhibitor of DNA binding as well as showing excellent solubility and stability. We have also found robust single agent anti-cancer activity, as exhibited in multiple animal models, and in vivo efficacy in combination with other DDR targeted thera-peutics. Right behind RPA, we have a robust discovery pipeline of first-in-class DDR pro-grams, the most advanced being a class of small molecule inhibitors that impair NHEJ through a completely novel mechanism of inhibiting DNA-PK, by inhibition of the DNA damage sensor Ku.

Regulatory Strategy & Intellectual Property

We have developed a combined Phase I/1b trial that will allow us to establish safety parameters as well as begin to examine preliminary efficacy of NĒRx RPA clinical candidate as single agents in patients with advanced solid malignancies. NERx has an exclusive license to develop their DDR targeted agents and therapeutics protected by multiple US and international patents with additional patents pending.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q4 2025	IND submission	Obtain authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.
Q1 2026	Initiate Phase 1/1b trial	Identify MTD that can be given safely, while simultaneously gathering preliminary data regarding efficacy.

Capitalization History

Year	Grant or Equity Type	Description	Amount
2023	Bridge Fund	Advance the clinical candiate, NERx 329, towards IND enabling studies.	$250,000
2019	Bridge Fund	Support studies to further enhance the POC data with RPA inhibitors that directly led to the identification of our clinical candidate, NERx-329.	$1,745,000
2012-2019	SBIR funding NIH/NCI	Funded projects devoted to developing novel lung cancer and ovarian cancer therapeutics that target the DNA damage response	$1,500,000

Current Round, Terms, and Use of Proceeds

We are seeking a strong partner with proven success in the Oncology space with pre-clinical and clinical capacity to accelerate NERx 329 through IND to the Clinic for first-in-human studies. Additionally, we are pursing a Series A round of financing to to support the further development of Ku targeted inhibitors for use as anti-cancer therapeutics as well as to advance our rapidly expanding pipeline of novel therapeutics targeting DDR sensors.

Key Team Members and Advisors

John Turchi, Ph.D. | Chief Scientific Officer, President

25 years in cancer research and the study of DNA repair and drug development. His work is recognized internationally and has impacted the molecular mechanisms of recognition and repair of DNA.

Katherine Pawelczak, Ph.D. | Chief Operating Officer

10+ years in scientific research and business development in academia and industry. Her expertise in DNA repair mechanisms and drug development combined with her industry experience are instrumental to her role at NERx.

Trent Carrier, Ph.D. | Chair, Board of Directors

Expert in drug development and has 20 years' experience in corporate development within the pharmaceutical industry. He has xtensive experience raising capital and leading a pre-clinical stage company that has successfully maneuvered the IND process.

Katherine Moynihan, Ph.D. | Member, Board of Directors

a breadth of scientific and business development experiences, including contractual and intellectual property expertise, due diligence and early-stage investment experience, business development

Company Overview

Neurodon is a preclinical pharmaceutical company leveraging their novel ER stress platform to develop first-in-class, disease-modifying small molecules for major diseases such as diabetes and Alzheimer's diseases as well as several rare diseases. Their diabetes program is currently undergoing IND enabling studies with a clinical trial planned for late 2024. Their Alzheimer's disease (AD) program is funded by the NIA/NIH through IND. Neurodon has raised over $11M with most (~70%) being non-dilutive grant-type funding. The company is currently raising a $30M Series A to fund Phase 1 and 2 clinical trials for their diabetes program.

Market & Commercialization Strategy

Type 1 Diabetes is projected to be a $2.8B market by 2026, with a CAGR of 7.20% (2022-2030). Many therapies are focused on targeting insulin, with mixed success, allowing Neurodon to be an emerging player with a novel, curative mechanism of action (MOA). Other markets also hold promise: Type 2 diabetes is expected to become a $57B market by 2029; Parkinson's an $11.5B market by 2029; Alzheimer's a $9.6B market by 2027; and DMD a $14.9B market by 2027 with a 43.70% CAGR. Neurodon currently has funding secured to complete INDs for both their diabetes and AD programs and will most likely partner with a large pharmaceutical company to take these products to market.

Technical & Competitive Advantage

Neurodon is the only company that has demonstrated disease-modifying effects in several preclinical disease models using their patented small molecules that restore cellular intracellular calcium homeostasis. Neurodon's compounds have undergone extensive proof-of-concept and de-risking preclinical studies in animal models. There are no competitors in market targeting disease using Neurodon's MOA and industry-leading ER stress platform technology.

Regulatory Strategy & Intellectual Property

All of Neurodon's IP is protected by an extensive global patent portfolio which Neurodon is 100% owner of. Neurodon currently has 13 granted patents and several pending patents in which Neurodon is the sole inventor, applicant, and assignee. These patents cover development candidates, backup compounds, uses, formulations, crystal forms, salts, etc. Neurodon has the only patented, drug-like compounds that target our unique, drug-modifying MOA. Neurodon is working with several regulatory and clinical consulting firms to complete and file 2 IND applications to the FDA within the next 12-18 months for their diabetes and AD indications. We plan to hold a pre-IND meeting with the FDA in Q2 of 2024 and submit the first IND in Q4 of 2024.

Key Milestones

Objective	Milestone	Date/Year
Diabetes IND-enabling Studies	Pivotal toxicology, formulation, CMC, and drug manufacturing	ongoing
IND Filing	Diabetes IND filing with FDA	Q4 2024
Initiate Clinical Trials	Diabetes Phase 1 clinical trial	Q1 2025
Alzheimer's IND-enabling Studies	Pivotal toxicology, formulation studies, and CMC	ongoing
IND Filing	Alzheimer's IND filing with FDA	Q2 2025

Capitalization History

Year	Grant Funding Round	Description	Amount
2018-2023	Grant	STTR/SBIR Phase 1, 2, and 2B Grants NIH/NIA	$6M
2019-2023	Equity	Angel Investments	$3.5M
2019-2023	Grant	Elevate Ventures Matching Grants	$250K
2022	Grant	JDRF IDDP Grant	$1M
2023	Grant	SBIR Phase 1 Grant NIH/NIDDK	$290K

Use of Proceeds

Neurodon is currently raising a Series A round of $30M to fund clinical trials for their diabetes candidate and submission of their AD IND application. The clinical trial funds will support a 30-person phase 1 study and a 60-patient phase 2 study. This will provide a demonstration of human efficacy which will enable an exit event such as IPO or acquisition of the asset(s).

Key Team Members

Russell Dahl, Ph.D. | CEO
20+ years of leadership experience in biopharma (BMS, Vertex, DuPont Pharma) with several successful NDAs and INDs filed
Colleen Mauger, R.N. | Vice President of Operations
Nearly 20 years of clinical, legal, and operations experience including management of large research collaborations and funded projects
Brunde Broady, MBA | Head of Outreach and Board Member
Partner in family investment firm managing investments up to $80M in startups, growth, and established companies
John Amatruda, M.D. | Lead Medical Advisor and SAB Member
Former Head of Diabetes and Obesity, Merck & Co.
Ilya Bezprozvanny, Ph.D. | SAB Chair and Advisor
UT Southwestern, Chair of Alzheimer's Research
Steve Davis, Ph.D., J.D. (McCarter & English) | IP Counsel
Partner and former in-house patent counsel for Lilly & Co.
Marty Waters, J.D. (Wilson Sonsini) | Corporate Counsel
Partner with 25 years of biotech experience in IPOs and strategic partnerships

TORALGEN

Company Overview

Toralgen is a preclinical stage biopharmaceutical company focused on oral delivery of biologics. The company is currently in active research collaborations with several global phramaceutical leaders to improve treatments for diabetes and autoimmune disorders. We seek to create a cost- effective oral solution addressing diabetes, autoimmune diseases, and cancer through our proprietary polybile nanopill delivery technology that closely mimics the natural enterohepatic process in the body.

Problem or Market Opportunity

Biologics represent over half of top selling pharmaceuticals, with the global market of biologic drugs estimated to be between $150-200 billion in annual sales. Although protein-based "biologic" drugs represent a major advancement in healthcare, they require administration through injection or infusion due to poor bioavailability or to avoid degradation from digestion through the oral route. Most patients prefer to take drugs orally because it is more convenient, less invasive, and does not require intervention by health professionals in an in-clinic setting. Despite the high level of interest amoung patients and their doctors, there are currently no effective commercial products available for oral bioavailability.

Technical & Competitive Advantage

To date, oral delivery approaches for biologics have been unsuccessful. Toralgen's solution is nanoparticles formulated using polymerized ursodeoxycholic acid, pUDCA. These particles have shown improved GI transport, stomach protection, and enhanced intestinal permeation. Under acidic conditions in the digestive tract pUDCA becomes more hydrophobic, limiting water permeability, a protective mechanism which reverses when distributed into blood and tissues with increased pH conditions. The nanoparticle ferries the API through the stomach and intestine before releasing into the body where it is needed.

Regulatory Strategy & Intellectual Property

Toralgen's business model is that of a biotech platform technology company. The company's goal is partner early with major pharmaceutical companies and develop an oral formulation of their proprietary API and work together to bring oral formulations to patients. The company currently has four ongoing early-stage collaborations with large pharmaceutical companies. Each has the potential to convert into individually crafted IP and significant licensing deals. Toralgen's platform is covered by US patent 10864170B2. Three other provisionals patents have been filed. New developments are leading to IP beyond the scope of Toralgen's core patents.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q3 2018	Company Formation	IP licensed from Yale university
Q4 2020	Research Collaboration	Toralgen enters into an initial research collaboration with a pharmaceutical company for two API
Q3 2022	Research Collaboration	Toralgen enters a fourth major pharamceutical collaboration, seven API total

Capitalization History

Year	Grant or Equity Type	Description	Amount
Q3 2019	Seed Funding 1	Initial phase of funding to transfer technology into company labs and conduct initial POC	$1.9M
Q4 2020	Seed Funding 2	Establishment of development lab, safety testing, scaling path and hiring of team	$6.4M

Current Round, Terms, and Use of Proceeds

If necessary, the company plans to close a $15M Series A round in Q4 of 2023. This will allow the company to complete platform development, expand formulation lab capacity, scale-up production and allow the company to pursue to additional collaborations.

Key Team Members and Advisors

Gerald Rea | CEO

Gerald is co-founder and CEO of Toralgen. He brings over 15 years of experience in early-stage technology development to the team.

Dave Moore | COO

Over 30 years of experience in drug development, business development, commercialization, and operations experience. At Eli Lilly & Co, Dave held a variety of leadership roles that resulted in several in-licensing deals and billion-dollar brand launches in diabetes and neurosciences

Ed Bastyr MD | CMO

Clinical endocrinologist, academic (Indiana University) and industry (Eli Lilly & Co, MB2) researcher 25+ years of experience

Andy Glasebrook, PhD | Vice President, Autoimmune Drug Development

40 years+ of experience in immunology and drug development, Past-President of the Inflammation Research Association, a named inventor on 9 issued US patents and co-author of 100 scientific publications.

John Lee, PhD | Director of Development

Over 15 years of nanomedicine development for treating autoimmune diseases and cancer. Former Yale lab manager. Co-inventor at Yale Labs **Dod Micheal, PhD | Advisor, Metabolic Research**

President Thermalin Inc, former head of insulin research at Eli Lilly and Joslin Diabetes Center fellow

Henry Havel, PhD | Advisor, Nanoparticles

Former Inaugural Chair of Nanomedicine Alliance and Senior Research Fellow at Eli Lilly

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