2026–2027 | NCI SBIR

INVESTOR INITIATIVES

SHOWCASE COMPANIES



NATIONAL CANCER INSTITUTE | SBIR DEVELOPMENT CENTER

INVESTOR | INITIATIVES

CONTENTS

SHORT COMPANY SUMMARIES

Biopharmaceuticals **02**
Devices **09**
Diagnostics/Tools **12**
Digital Health **14**

ONE-PAGE COMPANY OVERVIEWS

BIOPHARMACEUTICALS

Alanis Therapeutics 18
Cloverleaf Bio 20
Allterum Therapeutics 22
Lumina Pharmaceuticals 24
March Biosciences 26
Metaclipse Therapeutics 28
Myosin Therapeutics 31
NomoCan Pharmaceuticals 33
NovoMedix 35
Orphagen Pharmaceuticals 37
Privo Technologies 39
TippingPoint Biosciences 42
Trethera Corporation 44

DEVICES

Cordance Medical 46
Gradient Medical 49
iSono Health 51
Leuko Labs 53
Lumicell 55
Navigation Sciences 57
SafeGuard Surgical 59
Syntr Health Technologies 61

DIAGNOSTICS/TOOLS

Early is Good 63
Eximius Diagnostics Corporation 65
ImCare Biotech 67
Orbit Genomics 69
Sus Clinicals 71

DIGITAL HEALTH

Gradient Health 73
Imvaria 74
mPath Health 76
Neuralrad LLC 79

On behalf of the National Cancer Institute SBIR Development Center (NCI SBIR), I am proud to introduce this showcase company portfolio to you, our community of investors and collaborators.

This cohort arrives at a pivotal moment, when a five-year runway has been secured for the SBIR/Small Business Technology Transfer (STTR) program. The recent reauthorization of SBIR marks a new chapter, one defined by renewed commitment to America's small businesses and the breakthrough technologies they are building. With this reauthorization comes an expanded collaboration between federal agencies and the investment community to support innovation. New multimillion dollar programs, including the **Phase IIB Strategic Breakthrough Award** and the Commercialization Readiness Pilot Program, are designed to accelerate promising technologies from early-stage research toward commercial readiness and mission impact. Both mechanisms are built on a simple idea: Government funding gets a company started and advances it to a key inflection point, but private capital is what carries it across the finish line.

With more than 300 active oncology-focused projects, our early-stage portfolio spans a variety of technology areas, including therapeutics, devices, diagnostics, research tools, and digital health. Every year, eligible companies from our portfolio can apply for our Investor Initiatives program, where they will be scored by private investors and strategic partners on their readiness to secure their next fundraise and/or partnership. **Out of a record-breaking 152 applicants this year, I am excited to share with you the top 30 companies selected for the 2026-2027 NCI SBIR Investor Initiatives Showcase Program.**

The companies featured in this book have been vetted not only through rigorous NIH peer review, but also by our review committee of experienced investors and industry partners who understand what it takes to succeed in oncology. They represent a diverse range of approaches to cancer care, and each is ready for the next stage of growth.

Each company will attend and pitch at industry events across the United States throughout FY27. I invite you to explore what they're building, learn about the science and the teams behind it, and consider the role your investment and partnership could play in shaping what comes next.

If you see any companies that fit your interests and would like to learn more, or if you will be attending one of the showcase events listed on our website, please email NCI SBIR Director of Investor Relations Brittany Connors at **brittany.connors@nih.gov**. She can gather a non-confidential slide deck or make direct introductions.

We're grateful to have you as part of this work.

Sincerely,

MICHAEL WEINGARTEN
DIRECTOR, NCI SBIR DEVELOPMENT CENTER

THANK YOU TO OUR 2026 NCI SBIR/STTR INVESTOR INITIATIVES REVIEW COMMITTEE

If you are an investor or strategic partner interested in oncology and would like to be a part of future review cycles, please contact Brittany Connors at brittany.connors@nih.gov.

Please note that these company summaries were updated as of mid-2026. Many companies have updates, so please either reach out to Brittany for more information or connect directly with the company.

BIOPHARMACEUTICALS

Company	Technology Type	Indication(s)
Alanis Therapeutics, Inc. (AvantGen, Inc.)	Biologics/Vaccine	MDS/AML
Cloverleaf Bio, Inc.	Biologics/Vaccine	Hepatocellular carcinoma, colorectal cancer
Allterum Therapeutics, Inc. (Fannin Partners, LLC)	Biologics/Vaccine	Relapsed or refractory T- or B-cell acute lymphoblastic leukemia and lymphoblastic lymphoma
Lumina Pharmaceuticals, Inc.	Radio Theranostics	Oncology (Solid Tumors)
March Biosciences, Inc.	Cell/Gene Therapy	T-cell lymphoma, hepatocellular carcinoma
Metaclipse Therapeutics Corporation	Biologics/Vaccine	Triple-negative breast cancer, head and neck cancer
Myosin Therapeutics, Inc.	Small Molecule	Glioblastoma (pan-cancer, AML next)
NomoCan Pharmaceuticals, LLC	Biologics/Vaccine	Pancreatic cancer, colorectal cancer, breast cancer
NovoMedix, LLC	Small Molecule	TNBC/advanced breast cancer, pediatric solid tumors
Orphagen Pharmaceuticals, Inc.	Small Molecule	Adrenocortical cancer pediatric and adult; the SF-1 (high) subset of HPV-negative HNSC
Privo Technologies, Inc.	Drug/Delivery Device	Oral cancer
TippingPoint Biosciences, Inc.	Small Molecule	Diffuse intrisic pontine glioma and diffuse midline gliomas
Trethera Corporation	Small Molecule	Prostate cancer, optic neuritis, Crohn's disease

DEVICES

Company	Technology Type	Indication(s)
Cordance Medical, Inc.	Diagnostic & drug delivery platform	Non-invasive liquid biopsy of brain cancers to aid in diagnosis
Gradient Medical, Inc.	Surgical/Ablative Device	Soft tissue ablation
iSono Health, Inc.	Imaging Device	Whole breast automated ultrasound for breast implant integrity and imaging
Leuko Labs, Inc.	Imaging Device	Cancer patients receiving antineoplastic therapy
Lumicell, Inc.	Surgical/Ablative Device	Breast cancer surgery (FDA-approved), GI cancer under investigation
Navigation Sciences, Inc.	Surgical/Ablative Device	Lung and other soft tissue tumors
SafeGuard Surgical, Inc.	Surgical/Ablative Device	Anastomotic protective device
Syntr Health Technologies, Inc.	Medical Device + Biologic	Breast reconstructive surgery

DIAGNOSTICS/TOOLS

Company	Technology Type	Indication(s)
Early is Good, Inc.	In Vitro Diagnostic	Bladder cancer surveillance
Eximius Diagnostics Corporation	In Vitro Diagnostic	HCC screening
ImCare Biotech. Inc.	In Vitro Diagnostic	Detection of liver cancer (HCC) in at-risk patients
Orbit Genomics, Inc.	AI-Enabled Genomics Platform	Non-invasive early-stage lung cancer diagnosis
Sus Clinicals, Inc.	Research Tool	Oncology

DIGITAL HEALTH

Company	Technology Type	Indication(s)
Gradient Health, Inc.	Bioinformatics/Health IT/ Digital Health	None
IMVARIA, Inc.	Bioinformatics/Health IT/ Digital Health	Lung disease
mPATH Health (Digital Health Navigation Solutions, Inc.)	Bioinformatics/Health IT/ Digital Health	Cancer screening and HEDIS care gap closure
NeuralRad LLC	Surgical/Ablative Device	Stereotactic radiosurgery workflow platform



SHORT COMPANY SUMMARIES

Take a glance at this year's featured companies and their promising cancer technologies



ALANIS THERAPEUTICS, INC. (AVANTGEN, INC.)

Biologics/Vaccine

LOCATION
San Diego, CA

STAGE
Preclinical development

Alanis, in collaboration with researchers at Columbia University, is developing an antibody therapeutic that inhibits oncogenic signaling in the bone marrow of MDS/AML patients that drives leukemogenesis and progression, especially in high-risk patients. The company is seeking a Series A to generate clinical grade antibody for a first-in-human clinical trial to assess safety and possible clinical signals to justify further development.

CLOVERLEAF BIO, INC.

Biologics/Vaccine

LOCATION
New Haven, CT

STAGE
Preclinical development

Cloverleaf Bio, Inc., is a Yale spinout that is developing a new class of tumor-selective ADC payloads, grounded in our discovery of an RNA-based mechanism that actually drives 5-flurouracil's activity. We've built a platform that directly leverages this biology to target tRNA pathways required for tumor survival and metastasis. Our lead program has shown compelling activity in both cell culture and CDX models, and we are now advancing toward a development candidate in our lead indication: colorectal cancer. While our initial focus is oncology, we see the technology having a broader platform with uses in neurological and fibrotic disease down the road. We are raising a $12M seed round and have commitments for more than 50% of the round, including from two top-five pharma venture arms.

ALLTERUM THERAPEUTICS, INC. (FANNIN PARTNERS, LLC)

Biologics/Vaccine

LOCATION
Houston, TX

STAGE
In clinical trials

Allterum Therapeutics, a Fannin portfolio company, is advancing 4A10, a first- and best-in-class, highly selective chimeric monoclonal antibody targeting the alpha chain of the IL-7 receptor (IL-7Rα, or CD127) for the treatment of CD127-expressing cancers. Our initial IND application, for patients with acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LL), cancers in which CD127 is highly expressed, has been cleared, and Allterum has transitioned into the clinic, where it is now enrolling patients in the "ALLIANCE" Phase 1 first-in-human trial. The program has received both Orphan Drug and Fast Track designations from the FDA. Because more than 80% of these patients are children, this rare pediatric disease also makes the program eligible for an FDA Rare Pediatric Disease Priority Review Voucher. The program is designed to support broader expansion into additional CD127-expressing hematologic malignancies, including other lymphomas, acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL), and non-Hodgkin lymphoma (NHL).

LUMINA PHARMACEUTICALS, INC.

Radio Theranostics

LOCATION
Boston, MA

STAGE
In clinical trials

Lumina Pharmaceuticals uses radioligand therapy (RLT) to target biomarkers that are abundantly present in various disease states yet largely absent in healthy humans. Lumina's RLT is a theranostic platform for precision medicine, combining a targeting vector that seeks out tumors with various radioisotopes that can either be used to see and treat the cancer. Lumina's lead asset targets fibrin, which is abundant in the microenvironment of solid tumors and absent in healthy tissue. Our fibrin targeting approach has been validated in human imaging and mouse studies.

MARCH BIOSCIENCES, INC.

Cell/Gene Therapy

LOCATION
Houston, TX

STAGE
In clinical trials

March Biosciences is a Houston-based clinical-stage cell therapy company developing MB-105, a first-in-class autologous CD5-directed CAR-T therapy for relapsed/relapsed/refractory (r/r) T-cell lymphoma, an aggressive cancer with no standard of care therapies in the r/r setting, no approved CAR-T options, and a median survival of roughly six months after relapse. MB-105 holds FDA Orphan Drug and Regenerative Medicine Advanced Therapy (RMAT) designations and, in its ongoing Phase 2 trial, achieved a 100% complete response rate in the safety run-in of the primary efficacy cohort. The company has raised over $54M across venture and non-dilutive sources with a deliberately lean, capital-efficient model.

METACLIPSE THERAPEUTICS CORPORATION

Biologics/Vaccine

LOCATION
Houston, TX

STAGE
In clinical trials

Invasive breast cancer, the second leading cause of death in women, occurs in 1 in 8 U.S. women with an estimated U.S. healthcare cost of over $20B annually. An aggressive, refractory form of the disease, classified as triple-negative breast cancer (TNBC), occurs in 15-20% of women with breast cancer who do not currently have effective targeted treatment options. TNBC is a highly heterogeneous disease, occurring more frequently in young African-American women. Heterogeneity within TNBC requires individualized treatment. Metaclipse is developing a novel immunotherapy tailored to treat each patient's specific tumor. Briefly, excised tumor tissue is processed with specific immunogenic molecules and injected back into the same patient with an 18-day turnaround. Our proprietary technology seeks to address TNBC heterogeneity and does not require tedious, costly methods such as gene sequencing or cell-surface protein characterization, making our approach simple and versatile. We demonstrated the effectiveness and feasibility of our approach in numerous murine cancer models, both alone and in combination with immune checkpoint inhibitors. Projected competitive advantages include niche focus on unmet market need, simplicity, fast turnaround, broad applicability, an attractive pricing strategy. The anticipated market potential of our vaccine is ~$1.2B, with estimated CAGR of 5.5% from 2025-2030. IND approval and IRB approval from Emory University were both received, and initiation of the Phase 1 clinical trial began in Q2 2026. Our commercialization strategy entails licensing to major pharma after Phase 2 clinical trials. The leadership team has domain expertise and seasoned entrepreneurial experience, including product development and commercialization. Metaclipse is seeking $2M bridge funding by end of Q4 2026 and closing a $10M Series A round by end of 2027. Funding will be applied towards matching an NIH Phase IIB bridge award and the CPRIT award to support Phase 2 clinical trials.

MYOSIN THERAPEUTICS, INC.

Small Molecule

LOCATION
Jupiter, FL

STAGE
In clinical trials

Myosin Therapeutics is a clinical-stage oncology and neuroscience company developing first-in-class therapies targeting cancer cell mechanics; the physical machinery tumors use to move, adapt, and divide under therapeutic stress; and maladaptive brain plasticity in substance use disorders.

NOMOCAN PHARMACEUTICALS, LLC

Biologics/Vaccine

LOCATION
New York, NY

STAGE
Preclinical development

At NomoCan, we are building a revolutionary oncology platform that integrates high-specificity diagnostics with first-in-class therapeutics (mAb/ADC) precisely engineered to target core cancer-driving pathways across multiple tumor types.

NOVOMEDIX, LLC

Small Molecule

LOCATION
San Diego, CA

STAGE
Preclinical development

NovoMedix is a San Diego–based biotechnology company developing orally available small molecules for oncology indications with high unmet need. Its lead candidate, NMX1, is an IND-stage asset addressing triple-negative breast cancer (TNBC) and advanced/metastatic breast cancers, relapsed/refractory pediatric solid tumors (sarcomas and neuroblastoma), and anthracycline-induced cardiotoxicity. Mechanism: NMX1 is an NKA-Src signalosome modulator that binds Na^+/K^+-ATPase α1 at a site distinct from cardiac glycosides, stabilizing the inactive NKA-Src complex. This single upstream action drives a coordinated downstream program (AMPK activation, mTOR suppression, and reduced IL-11 signaling) that induces selective metabolic stress in tumor cells and decreases inflammation and EMT in the tumor microenvironment while protecting cardiomyocytes. The result is a differentiated dual profile: direct anti-tumor activity plus protection against chemotherapy-induced cardiac injury. Differentiation: NMX1 enhances chemotherapy efficacy while simultaneously preventing cardiotoxicity, a combination no approved or clinical-stage oncology agent offers. Dexrazoxane, the only FDA-approved anthracycline cardioprotectant, carries safety and efficacy trade-offs. NMX1 is oral, improves rather than compromises anti-tumor activity, and is suited to long-term survivorship use. Preclinical data: NMX1 produces 65–80% tumor growth inhibition across TNBC and sarcoma models as monotherapy. Combined with doxorubicin, it achieves 98% tumor inhibition (vs. 36% for doxorubicin alone) while reducing cardiac troponin ~85% and preserving left-ventricular ejection fraction, in contrast to a decline with doxorubicin alone. In survival studies, NMX1-treated arms (monotherapy or combined with doxorubicin) achieved 80–100% survival versus 40% for doxorubicin alone. Beyond doxorubicin, NMX1 shows mechanism-based synergy across chemotherapy classes; topoisomerase inhibitors (irinotecan, topotecan, etoposide); vinca alkaloids (vincristine, vinorelbine); and cyclophosphamide; and with anti–PD-1/PD-L1 checkpoint inhibitors, a combination directly relevant to TNBC. Synergy with methotrexate is cell-line-dependent, and NMX1 shows rationally defined antagonism with platinum agents, enabling focused chemotherapy- and immunotherapy-combination development. Unmet need: Metastatic TNBC has a median overall survival of ~18 months with limited options after standard chemotherapy; relapsed/refractory pediatric sarcomas and neuroblastoma have 5-year survival under 30%; and anthracycline cardiotoxicity affects 20–30% of treated patients, constraining effective dosing. Market: TNBC represents a ~$5B drug market within a ~$25B metastatic breast cancer opportunity; relapsed/refractory pediatric sarcomas and neuroblastoma add a ~$3B market with orphan exclusivity and Priority Review Voucher potential (~$100M+). Broad anthracycline cardioprotection (>100,000 U.S. patients/year) is a major expansion opportunity across the ~$250B oncology market. Stage and regulatory: NMX1 is completing IND-enabling studies. The 28-day GLP rat toxicology study is complete (NOAEL 600 mg/kg, full reversibility), and the 28-day GLP dog study is in progress. A 2 kg cGMP API lot is available, and GMP drug product (capsules) is being manufactured; IND submission is targeted for Q4 2026. Phase 1 is a monotherapy dose-escalation in advanced/metastatic TNBC and other breast cancers using PD-biomarker-guided dosing to establish the recommended Phase 2 dose (RP2D); doxorubicin-combination cohorts, with co-primary efficacy and cardioprotection endpoints, follow once the RP2D is established. The regulatory path includes early Fast Track, Orphan Drug, and Rare Pediatric Disease designations (with Priority Review Voucher potential) in pediatric sarcoma and neuroblastoma, and Breakthrough Therapy designation as a post-Phase 1 opportunity contingent on clinical response and cardioprotection data. Team: NovoMedix is led by CEO Cathy Swindlehurst, PhD, and CSO Kyle Chan, PhD, with Board Chairman David Stirling, PhD (originator of the thalidomide/IMiD/CRBN program at Celgene), and discovery leadership experienced in lenalidomide, pomalidomide, and apremilast. Clinical advisors include pediatric- and cardio-oncology experts. Financing and partnering: NovoMedix is raising a $20M-$30M Series A to fund the Phase 1 TNBC trial through an initial efficacy/cardioprotection readout. The company is seeking oncology-focused investors and strategic partners, with particular fit to groups active in breast cancer, cardio-oncology, and immuno-oncology combinations.

ORPHAGEN PHARMACEUTICALS, INC.

Small Molecule

LOCATION
San Diego, CA

STAGE
Preclinical development

Orphagen translates fundamental biology into life-altering therapies for cancer and other serious diseases. Orphagen's lead program is a first-in-class precision oral small molecule, OR-449, intended to treat metastatic adrenocortical cancer (ACC), an aggressive malignancy with a median patient survival of 15 months. ACC is a rare cancer with high unmet need, no effective medical therapy, a defined population, and peak commercial potential of over $500M per year given premium pricing for comparable rare disease oncology drugs. OR-449 blocks a candidate driver of ACC tumor growth, steroidogenic factor-1 (SF-1 or NR5A1). OR-449 was discovered and developed with non-dilutive funding at Orphagen and is close to IND filing. Equity funding will unlock a $10.2M matching grant from CPRIT, the Texas state cancer institute, to support a Phase 1 clinical trial in adult ACC. The sole FDA-approved drug for ACC, mitotane, has uncertain efficacy, severe toxicity, and a non-specific mechanism of action. OR-449 is supported by target-specific inhibition of preclinical tumor growth. FDA approval is feasible as a once-daily first-line therapy in a single-arm trial within six years of IND filing. OR-449 expansion opportunities include pediatric ACC, supported by an RPD designation from the FDA, and approximately 10% of head and neck cancers where SF-1 is 1,000-fold more highly expressed above baseline in a unique genomic context. A second pipeline program has selected a first-in-class development candidate for treatment of inflammatory bowel disease, a highly selective antagonist to the retinoic acid receptor (RARA).

PRIVO TECHNOLOGIES, INC.

Drug/Delivery Device

LOCATION
Peabody, MA

STAGE
In clinical trials

Privo Technologies is a private company from MIT's Langer Lab at Koch Institute for Integrative Cancer Research. Privo's platform significantly improves the MoA of potent APIs by increasing safety via localized delivery, with a focus on rare oncology conditions with unmet medical needs. Privo is conducting a Phase 2/3 clinical study for its lead product, PRV111, in patients with oral carcinoma in situ (CIS), an early-stage oral cancer (OC) that is not yet invasive. PRV111 is a nanoparticle-based platform that delivers a "one-two punch" effect directly to the tumor, simultaneously killing tumor cells and activating nearby lymphocytes. To date, Phase 2 enrollment is complete, and Privo is currently conducting active patient follow-up, in addition to designing the pivotal portion of the trial. Ninety-two percent of patients treated achieved a pathologic complete response, and 100% avoided surgical resection. PRV111 was well-tolerated, with no treatment-related serious adverse events (SAEs) and negligible systemic exposure. Privo additionally has clinical assets PRV211 (intraoperative patch) and PRV131 (intratumoral injection) in an ongoing Phase 1/2 trial.

TIPPINGPOINT BIOSCIENCES, INC.

Small Molecule

LOCATION
San Francisco, CA

STAGE
Preclinical development

TippingPoint Biosciences is developing first-in-class therapeutics for DIPG, a fatal pediatric brain cancer, by targeting disease-specific epigenetic interfaces that other platforms cannot see or drug. Spun out of UCSF, the company is advancing toward in vivo proof-of-concept as it works to bring the first targeted therapy to patients with H3K27M-driven tumors. The platform is also applicable to other indications, including TNBC, which the company plans to advance through partnerships with pharma.

TRETHERA CORPORATION

Small Molecule

LOCATION
Sherman Oaks, CA

STAGE
In clinical trials

Trethera has a clinical-stage biotechnology company developing TRE-515, a first-in-class oral dCK inhibitor for cancer and autoimmune diseases. TRE-515 has completed Phase 1 dose escalation in more than 30 heavily pretreated solid tumor patients, demonstrating favorable safety, no dose-limiting toxicities, biomarker-confirmed target engagement, and encouraging clinical activity. Trethera is advancing TRE-515 as a pipeline-in-a-product, with lead oncology opportunities in mCRPC plus Pluvicto. TRE-515 has FDA Fast Track designation for prostate cancer and Orphan Drug designation for ADEM and optic neuritis, with UCLA-originated IP protection potentially through 2045.

CORDANCE MEDICAL, INC.

Diagnostic and drug delivery platform

LOCATION
Mountain View, CA

STAGE
Preclinical development

Prototype fully developed; in beta testing

Cordance Medical (C-Corp) is a privately held development-stage company headquartered in California. Cordance Medical is developing a platform solution that will bring about a momentous change in how brain diseases are diagnosed and treated. This solution temporarily opens the blood-brain barrier with patented and patent-pending, non-invasive techniques using focused ultrasound. The solution is realized with a compact, portable, and cost-efficient system deployable in outpatient settings like infusion centers and clinics. Cordance Medical is backed by various groups, including private investors and venture firms (lead Sonder Capital). Importantly, Cordance Medical has received two National Science Foundation and a National Institutes of Health award totaling about $1.75M. Cordance Medical's approach has received enthusiastic support from several prominent neurosurgeons and neuro-oncologists, the National Brain Tumor Society, and The Focused Ultrasound Foundation, as it has the potential to enable treatment options for patients with brain disease who often have few or no options. The team includes experienced medical technology executives, subject matter experts, and key opinion leaders.

GRADIENT MEDICAL, INC.

Surgical/Ablative Device

LOCATION
Raleigh, NC

STAGE
Preclinical development

Gradient Medical is a medical device company developing INSPIRE, a next-generation cancer ablation platform designed to destroy inoperable tumors while simultaneously activating the patient's immune system to fight metastatic disease. INSPIRE uses ultrashort, high-energy electrical pulses to selectively kill cancer cells, enabling rapid, uniform tumor destruction through a minimally invasive procedure as simple as a biopsy. By converting a local intervention into a systemic anti-tumor response, INSPIRE has the potential to transform ablation from a palliative tool into a curative cancer therapy.

ISONO HEALTH, INC.

Imaging Device

LOCATION
Sunnyvale, CA

STAGE
Commercially available

iSono Health is built the world's first wearable, autonomous breast imaging and longitudinal data platform, combining robotics, AI, and quantitative ultrasound to address one of the largest unmet needs in women's health. Its FDA-cleared platform automates whole-breast imaging in approximately two minutes per breast without requiring a sonographer, enabling scalable, accessible, standardized breast imaging at the point of care.

LEUKO LABS, INC.

Imaging Device

LOCATION
Cambridge, MA

STAGE
In clinical trials

Prototype fully developed; in beta testing

Leuko Labs is committed to improving quality of life and outcomes for cancer patients through the development of the first noninvasive white blood cell monitoring device.

LUMICELL, INC.

Surgical/Ablative Device

LOCATION
Waltham, MA

STAGE
Commercially available

Lumicell's FDA-approved imaging system (April 2024) is the first and only technology to detect residual tumor inside the lumpectomy cavity during breast cancer surgery, with reimbursement secured from CMS and private payers. The company is now raising capital to expand into GI cancers.

NAVIGATION SCIENCES, INC.

Surgical/Ablative Device

LOCATION
Brookline, MA

STAGE
Prototype fully developed; in beta testing

Navigation Sciences is developing a system to address the growing need to locate and remove lung and other soft-tissue cancers.

SAFEGUARD SURGICAL, INC.

Surgical/Ablative Device

LOCATION
Tampa, FL

STAGE
Preclinical development

SafeGuard Surgical is developing a preventive solution to one of surgery's most feared and costly complications: the anastomotic leak. Its flagship device, LeakGuard™, is a bioabsorbable implant that reinforces and protects a surgical connection (anastomosis) as it heals and is engineered to prevent leaks and eliminate the need for a temporary ostomy. LeakGuard™ has been granted FDA Breakthrough Device designation and is advancing through a De Novo (Class II) regulatory pathway, with a clear reimbursement route through established DRGs. Built on FDA-recognized biodegradable polymers, LeakGuard™ achieved 100% technical success in initial large-animal studies. It is the lead product of the broader Guard™ platform, which extends the same bioabsorbable, payload-capable technology across a $25B+ opportunity in oncology, radiation, wound, and infection management, beginning with a $4.5B colorectal market.

SYNTR HEALTH TECHNOLOGIES, INC.

Medical Device and Biologic

LOCATION
Irvine, CA

STAGE
Prototype fully developed; in beta testing

Commercially available

Syntr Health is redefining autologous breast reconstruction through an FDA-cleared automated tissue processing platform that delivers standardized, reproducible, high-quality regenerative fat grafts, enabling the next generation of biologic reconstructive surgery.

EARLY IS GOOD, INC.

In Vitro Diagnostic

LOCATION
Indianapolis, IN

STAGE
In clinical trials

Early is Good is a cancer diagnostics company developing non-invasive urine tests, starting with bladder and prostate. Our multi-omic platform reads DNA, RNA, and protein from a single sample in one workflow, capturing biology that single-analyte tests miss. Both tests show strong results; BCDx, our bladder surveillance test, is validating at Washington University and Indiana University, and PCDx, our prostate test, is co-developed with Mayo Clinic.

EXIMIUS DIAGNOSTICS CORPORATION

In Vitro Diagnostic

LOCATION
Los Angeles, CA

STAGE
Preclinical development

Prototype fully developed; in beta testing

Eximius Diagnostics is a UCLA spinoff company developing extracellular vesicle (EV)-based liquid biopsy tests for cancer diagnosis and treatment monitoring. Its first product is an in vitro diagnostic (IVD) liver cancer test that detects hepatocellular carcinoma (HCC) using human plasma samples collected from at-risk liver cirrhosis patients. Eximius' test uses qPCR technology to quantify HCC EVs, enabling more accurate, more accessible, and less expensive detection of early-stage (Stage 0-A) HCC.

IMCARE BIOTECH, INC.

In Vitro Diagnostic

LOCATION
Doylestown, PA

STAGE
Prototype fully developed; in beta testing

ImCare Biotech is a biotechnology company dedicated to transforming the detection and treatment of liver cancer, where current surveillance methods often miss early-stage disease. Our non-invasive, multi-analyte assay combines a proprietary algorithm with our novel LC-SPIK biomarker to accurately identify cancer in its earliest, most treatable stages. We are launching this high-precision screening commercially by 2027 as a laboratory-developed test (LDT) while concurrently pursuing full FDA approval to drastically improve patient survival rates.



ORBIT GENOMICS, INC.

AI-Enabled Genomics Platform

Location
Boulder, CO

STAGE
Preclinical development; FDA approval not applicable

Orbit Genomics is a precision healthcare company commercializing a first-in-class blood test for the non-invasive diagnosis of early-stage lung cancer while leveraging its patented, AI-enabled genomics platform to unlock a previously inaccessible layer of genomic biology for the development of products spanning the diagnosis, treatment, and prevention of multiple complex diseases and healthy aging.

SUS CLINICALS, INC.

Research Tool

LOCATION
Cincinnati, OH

STAGE
Commercially available

Sus Clinicals' technology enables healthcare clients to advance the most promising therapeutics to human clinicals more quickly, predictably, and efficiently. Our proprietary, FDA-cleared large-animal research platform is focused initially on oncology, but over time could extend more broadly to other therapeutics. It is the first and only solution that truly addresses the systemic lack of predictive preclinical models in life science research. Our porcine platform generates predictive data to help researchers accelerate those therapies most likely to work in humans, and shut down less promising paths prior to expensive human trials.

GRADIENT HEALTH, INC.

Bioinformatics/Health IT/Digital Health

LOCATION
Durham, NC

STAGE
Commercially available

Gradient Health deidentifies medical data and makes it available to train lifesaving AI.

IMVARIA, INC.

Bioinformatics/Health IT/Digital Health

LOCATION
Berkeley, CA

STAGE
Prototype fully developed; in beta testing

Commercially available

IMVARIA is an applied clinical AI company and Medicare-registered IDTF commercializing FDA-authorized AI technology in high-impact disease states. Its cleared products, Fibresolve (IPF/ILD diagnosis) and ScreenDx (lung nodule/ILD detection), plus pre-market Bronchosolve (nodule malignancy risk), use multimodal AI to improve patient outcomes.

MPATH HEALTH (DIGITAL HEALTH NAVIGATION SOLUTIONS, INC.)

Bioinformatics/Health IT/Digital Health

LOCATION
Winston-Salem, NC

STAGE
Commercially available

Founded in 2022, mPATH Health is a vertical SaaS company that closes cancer screening gaps for health systems and payers. Our direct-to-patient platform navigates patients from identification through completed screening automatically, and, for most patients, without involving clinical staff. mPATH reaches patients by text, email, or portal; verifies true screening eligibility; educates with behavioral science content designed for low-literacy populations; and lets patients self-order their screening test. AI agents manage follow-through to completion. mPATH was developed and validated with more than $8M in NCI funding, including a Fast Track STTR supporting commercialization, and is the only platform in its category proven in multiple randomized controlled trials: a 44% increase in lung cancer screening completion (*JAMA*, 2025) and a doubling of colorectal screening completion (*Annals of Internal Medicine*). The platform also identifies approximately three times as many screening-eligible patients compared to EHR data alone. To date, 26,000+ patients enrolled in clinical studies, 100,000+ patients served, 15 peer-reviewed publications, and 3 U.S. patents pending. Modules cover colorectal, lung, breast, and cervical cancer screening, deploying in 3–4 weeks with no EHR integration. Customers include Atrium Health, Kintegra Health, and UNC School of Medicine, with an active pipeline spanning health systems, statewide payers, FQHCs, NCI-designated cancer centers, and government health agencies. mPATH is completing a $1.5M seed extension, a priced round led by VentureSouth with Oncology Ventures participating above pro-rata that closes in September 2026. mPATH was founded by physician-informaticists David P. Miller, MD, MS (CEO) and Ajay Dharod, MD.

NEURALRAD LLC

Surgical/Ablative Device

LOCATION
Madison, WI

STAGE
Prototype fully developed; in beta testing

NeuralRad LLC is a medical technology company developing AI solutions for radiation oncology. Its platform supports brain tumor segmentation, stereotactic radiosurgery planning, lesion tracking, and clinical workflow automation, helping clinicians improve efficiency, consistency, and treatment precision.



COMPANY OVERVIEWS



ALANIS THERAPEUTICS, INC. (AVANTGEN, INC.)

Antagonist Anti-JAG1 Antibody

Robert Goodenow | robert.goodenow@alanistx.com | 949-291-9018 | Alanistx.com

COMPANY OVERVIEW

Current therapies for AML and MDS remain limited by relapse driven by leukemic stem cells (LSCs) and persistent minimum residual disease. Recent advances in AML treatment have largely relied on mutation-targeted small-molecule inhibitors, such as BCL2, IDH1/2, and FLT3 inhibitors. While clinically meaningful, these agents benefit only small molecularly defined patient subsets (approximately 5–10% for IDH1/2 and 20–30% for FLT3 mutations), elicit at best 50% response rates with less than 5 months progression-free survival and are prone to resistance and clonal evolution. Importantly, these therapies target leukemic blasts but do not address the bone marrow micro-environment, which plays a central role in disease persistence and relapse. Alanis Therapeutics, a subsidiary of AvantGen, is developing a first-in-class monoclonal antibody targeting Jagged-1, a key ligand of the Notch signaling pathway implicated in leukemic stem cell maintenance, disease progression, and therapeutic resistance in AML and MDS. Aberrant Jagged-1–mediated signaling within the bone marrow microenvironment contributes to self-renewal of leukemic stem cells and relapse, particularly in high-risk and elderly patient populations. The antibody preferentially binds Jagged-1 over Jagged-2 and without cross-reactivity DLL2 or DLL4—all ligands of Notch-1. This selectivity is designed to enable targeted inhibition of pathogenic Jagged-1 signaling while potentially preserving other Notch-dependent physiological functions, supporting a differentiated safety profile compared to pan-Notch pathway inhibition strategies. Mechanistically, the antibody is designed to disrupt Jagged-1–Notch interactions within the leukemic niche, thereby reducing stemness signaling, inducing apoptosis of malignant cells, and promoting restoration of normal hematopoiesis. By targeting a ligand rather than downstream signaling components, the approach offers a novel upstream modulation strategy with potential synergy in combination with existing AML therapies. The program arose from an ongoing collaboration with investigators at the Herbert Irving Cancer Center at Columbia University and includes licensed intellectual property from issued and pending patent applications. Preclinical development has progressed through master cell bank generation, scale-up production and formulation development. Nonhuman primate pharmacokinetic studies are underway to support IND-enabling activities. In late 2025, we entered into a collaboration with Blood Cancer United's BEAT AML program to evaluate Jagged-1 signaling across genetically defined AML subtypes using patient-derived samples from the BEAT AML Master Trial. This collaboration supports biomarker-driven patient stratification and clinical positioning. If successful, this targeted approach has the potential to address relapse-prone AML and MDS populations with high unmet need, particularly elderly and chemotherapy-ineligible patients for whom durable therapeutic options remain limited.

MARKET & COMMERCIALIZATION STRATEGY

The MDS/AML competitive landscape comprises mostly of drugs targeting clonal variants. Our approach uniquely targets resistant tumor stem cells harbored in the marrow with no apparent toxicity. The WW MDS/AML market is $10B. The addressable market is $5B for high-risk patients. We believe a drug that reduces relapse rates could reach $1B in WW annual sales and would be attractive to a pharma partner for global commercialization.

TECHNICAL & COMPETITIVE ADVANTAGE

Our Jagged-1 antibody program offers multiple differentiated advantages across biology, development strategy, and commercial positioning: (1) Selective Targeting of Jagged-1: The antibody preferentially binds Jagged-1 over Jagged-2 and without cross-reactivity to DLL2 or DLL4, all ligands of Notch-1. This selective inhibition is designed to modulate pathogenic Jagged-1 signaling while potentially preserving other Notch-dependent physiological functions, supporting a differentiated safety profile relative to broader Notch pathway inhibitors. (2) Biomarker-Driven Strategy: Jagged-1 signaling is enriched in high-risk AML subsets and associated with leukemic stem cell maintenance and relapse. Collaboration with the BEAT AML program enables evaluation of Jagged-1 signaling across genetically defined AML subtypes using patient-derived samples from the BEAT AML Master Trial. This provides access to clinically annotated samples and supports a precision-medicine positioning strategy.

(3) De-Risked Development Platform: Key CMC milestones have been completed, including master cell bank generation and banking, scale-up production, and formulation development. Nonhuman primate pharmacokinetic studies are underway. The program is advancing toward a pre-IND meeting in late 2026, with IND submission targeted for Q2 2027 and Phase 1 initiation in Q3 2027. (4) Strong Academic and Clinical Foundation: The program arose from an ongoing collaboration with Stavroula Kosteni, PhD, and Azra Raza, M.D., at the Herbert Irving Cancer Center at Columbia University, and includes licensed intellectual property from issued and pending patents. The BEAT AML collaboration further strengthens clinical validation and future trial network access. (5) Attractive Commercial Segment: Approximately 38% of AML/MDS patients are estimated to represent a Jagged-1–positive population. With the combined AML/MDS market projected to exceed $10B by 2030, a targeted biologic addressing relapse-prone elderly patients represents a meaningful commercial opportunity. Together, these attributes position AvantGen's Jagged-1 antibody as a differentiated, biomarker-informed therapeutic candidate with a clear regulatory path and defined value inflection at first-in-human data.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Our regulatory strategy is to focus on U.S. development in a path well-established for the FDA approval of drugs to treat chemo-ineligible patients with MDS/AML. We plan to establish safety in a Phase 1A trial of all comers with retrospective analysis of their Jagged-1 status. If we observe a clinical signal in the 3+3 dose escalation Phase 1A, we will expand cohorts of MDS and/or AML patients to correlate clinical responses with Jagged-1 status. This will serve to (1) establish the need for patient selection and (2) position the antibody therapeutic for a possible Phase 2 trial for accelerated approval. Two patents underpin our IP portfolio. The issued U.S. 10350216 patent covers "Methods of treating, preventing, and diagnosing leukemias and other blood disorders and diseases" (July 16, 2019), for which Alanis holds an exclusive license from Columbia University. We also have a pending composition of matter patent application covering our Jagged-1 antibody ATI-D1 63/695,239 entitled "Jagged-1 binding agents and uses thereof" (September 2024).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2026	Conduct pre-IND meeting with FDA
Q2 2027	IND submission to FDA
Q3 2027	Phase 1 clinical trial initiation (First Patient In)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2006-2025	Grants and Contracts	U.S. government and other awards	$10M
2006-2025	Grants and Contracts	Commercial services, biotech, pharma, etc.	$20M

USE OF PROCEEDS

We are currently seeking approximately $15M to support IND-enabling development and early clinical execution. Proceeds will fund GLP toxicology studies, final CMC activities and GMP manufacturing, regulatory submission (IND targeted Q2 2027), and initiation of a Phase 1 clinical trial (First Patient In targeted Q3 2027). This financing is expected to advance the program through IND clearance and into first-in-human clinical evaluation, representing a significant value inflection point. AvantGen is actively engaging institutional investors and strategic biopharma partners with the objective of securing funding within the next 6–12 months.

KEY TEAM MEMBERS

Dr. Robert Goodenow, CEO, brings over 30 years of oncology drug commercialization experience across senior operating and executive roles in both biotech and large pharmaceutical companies, beginning with the market launch and expansion of Taxotere. Most recently as president of HUYABIO International, he led the development, launch, and partnering of HIYASTA for non-Hodgkin lymphoma in Japan. He has deep expertise in regulatory and clinical development, business development, and financing relative to both large pharmaceutical organizations and emerging biotech companies.

Dr. Danielle James, CMO, led the global development of Imbruvica, the first BTK inhibitor, from first-in-human studies through 15 global regulatory approvals at Pharmacyclics and AbbVie following its $21B acquisition in 2015. At Summit Therapeutics, she advanced ivonescimab, a first-in-class VEGF–PD1 bispecific antibody, culminating in a $5B partnership. Dr. James received her M.D. from the Pennsylvania State College of Medicine and a master's of advanced studies in clinical research from UC San Diego.

Dr. Catherine Woods, Research Head, has more than 30 years of experience in pharmaceutical and biotechnology research and development. She has served as executive director of research at Targeted Molecules, director of clinical research and senior director of biological research at Alliance Pharmaceutical Corp., and research fellow at Merck Research Laboratories.

CLOVERLEAF BIO, INC.

Novel RNA Therapeutics Platform for Oncology

Austin Draycott | austin@cloverleafbio.com | 347-596-9754 | cloverleafbio.com

COMPANY OVERVIEW

Cloverleaf has radically improved upon current-generation chemotherapies by dramatically increasing potency and specificity. Our engineered RNA therapeutics specifically inhibit up to 25 factors required for cancer-selective protein synthesis from a single molecule—eradicating cancer cells without damaging healthy tissue. Our team has demonstrated proof-of-concept efficacy in multiple mouse models of cancer and has a partnership with a top-five pharmaceutical company.

MARKET & COMMERCIALIZATION STRATEGY

CRC and HCC represent complementary commercialization opportunities for Cloverleaf because both are large, high-unmet-need solid tumor markets where current standards remain limited by resistance, tolerability, and incomplete durability of response. In CRC, the opportunity is especially attractive because the disease remains highly prevalent, with an estimated 158,850 new U.S. cases and 55,230 deaths in 2026. Early-onset CRC also continues to rise, creating demand for more potent therapies that can initially enter in refractory disease and potentially move earlier into combination regimens if safety and efficacy are differentiated. HCC provides a second major opportunity in a biologically aligned indication with substantial global mortality and limited therapeutic windows; the American Cancer Society estimates about 42,340 new U.S. cases of primary liver/intrahepatic bile duct cancer in 2026 . Cloverleaf's platform is commercially compelling because a single engineered tRNA payload can be programmed against multiple tumor-relevant tRNA-modifying enzymes, supporting a differentiated product profile with potential for monotherapy, combination with standard-of-care agents, and expansion across multiple tumor types beyond the initial CRC and HCC beachheads.

TECHNICAL & COMPETITIVE ADVANTAGE

Cloverleaf's technical advantage is that we have a novel and experimentally grounded understanding of how one of the oldest chemotherapeutics actually works. While the traditional understanding of the MoA of 5-flurouracil (5-FU) is as a DNA-directed chemotherapy, Cloverleaf's academic roots give us the insight that 5-FU's cancer-relevant activity is mediated through RNA, specifically inhbiting a number of tRNA-modifying enzymes that tumors overexpress and depend on. We used that mechanistic insight to develop novel engineered RNAs that target the enzymes that matter, while avoiding the broad DNA damage, S-phase arrest, and dose-limiting toxicities associated with conventional chemotherapy. This gives Cloverleaf a competitive advantage over both conventional chemotherapy and standard single-target oncology approaches, because we are not simply making another cytotoxic payload; we are developing a selective, multi-enzyme, RNA-guided therapeutic platform.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Cloverleaf's regulatory strategy is to advance lead engineered tRNA candidates through a conventional preclinical development path, generating repeat-dose tolerability, PK/PD, biodistribution, efficacy, and GLP toxicology data to support FDA engagement and eventual IND submission. On intellectual property, Cloverleaf has built a defensible position around covering composition of matter and method of use of our inhibitory RNAs, and through our core IP, which is exclusively licensed from Yale.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2024	Cloverleaf spun out of Yale
2024	Key in vivo PoC for lead platform in mouse model of hepatocellular carcinoma
2025	Key NIH SBIR funding received

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2024	Seed Round		$1.05M
2025	Grant	NCI Small Buisness Transition Grant	$2.4M
2025	Award	NCI Concept Award	$350K

USE OF PROCEEDS

We are raising a $12M seed round to advance our lead program to a development candidate and expand our platform.

KEY TEAM MEMBERS

Austin Draycott, CEO and Co-Founder

Cole Lewis, CSO and Co-Founder

Wendy Gilbert, Academic Co-Founder



ALLTERUM THERAPEUTICS, INC. (FANNIN PARTNERS, LLC)

Chimerical Monoclonal Antibody Against CD127

Atul Varadhachary | atul@fannininnovation.com | 617-800-4959 | allterum.com

COMPANY OVERVIEW

Allterum Therapeutics, a Fannin portfolio company, is advancing 4A10, a first- and best-in-class, highly selective chimeric monoclonal antibody targeting the alpha chain of the IL-7 receptor (IL-7Rα, or CD127) for the treatment of CD127-expressing cancers. Our initial IND application, for patients with acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LL), cancers in which CD127 is highly expressed, has been cleared, and Allterum has transitioned into the clinic, where it is now enrolling patients in the "ALLIANCE" Phase 1 first-in-human trial. The program has received both Orphan Drug and Fast Track designations from the FDA. Because more than 80% of these patients are children, this rare pediatric disease also makes the program eligible for an FDA Rare Pediatric Disease Priority Review Voucher. The program is designed to support broader expansion into additional CD127-expressing hematologic malignancies, including other lymphomas, acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL), and non-Hodgkin lymphoma (NHL).

MARKET & COMMERCIALIZATION STRATEGY

4A10 is a best-in-class anti-CD127, highly selective, with no off-target toxicity, and funding through Phase 2a. The ALL market alone exceeds $1B annually, with a multibillion-dollar expansion potential across 5+ additional indications. Combined with our Pediatric Review Voucher eligibility, FDA Fast Track and Orphan designations, and a diversified first-in-class pipeline, Allterum Therapeutics represents a rare and de-risked clinical stage biotech company.

TECHNICAL & COMPETITIVE ADVANTAGE

CD127, the alpha chain of the IL-7 and TSLP receptors, is a validated target at the top of the JAK-STAT pathway, where over 20 cancer and inflammation drugs were approved. 4A10 achieves what prior IL-7 inhibitors could not: It binds CD127 with high affinity, without activating the toxicity-associated with the gamma chain. And it works through a unique triple mechanism of action, including signal inhibition, NK cell mediated ADCC, and macrophage mediated ADCP.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

4A10 is protected with a suite of patents through 2036. The regulatory strategy is to pursue an accelerated approval with a single arm Phase 2a clinical trial, then quickly follow on the ALL program and expand to other hematologic malignancies such as AML, CML, and NHL. In parallel, we are generating options for select major solid tumors and autoimmune indications. These proof-of-concept studies are already ongoing and generating data.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q1 2025	First close series SEED 2
Q3 2025	IND clearance; $3M (CPRIT), $1M (NCI SBIR) awarded
Q4 2025	FDA Orphan and Fast Track designations
Q2 2026	Initiate Phase 1 first-in-human (FPI); final close of SEED 2
Q4 2026	Initiate additional 4A10 clinical programs; initiate IND enabling studies for pipeline asset(s)
2027	Phase 1 in ALL data readout; initiate Phase 2a in ALL; potential FDA accelerated approval conversation; multiple Phase 2a trials for additional hematology-oncology programs; enter the clinic with pipeline assets

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	CPRIT Seed Grant		$2.9M
2020	SEED 1 equity financing		$1.8M
2022	NCI SBIR Grant		$2.2M
2023	CPRIT Grant		$11.7M
2024	NCI (NExT/PIVOT)		$3.2M
2025	CPRIT (Suppl.)		$3M
2025	NCI SBIR		$1M
2026	SEED 2 equity financing		$5.2M

USE OF PROCEEDS

To fund expansion to other hematologic malignancies and to solid tumors and autoimmune disorders, the company is seeking an additional $50M-$80M.

KEY TEAM MEMBERS

Yan Moore, MD, MBA, CEO, board member (26 years of drug development experience, 56 INDs)

Atul Varadhachary, MD, PhD, President R&D, executive board chair (>20 years drug development exp.)

Philip Breitfeld, MD, CMO, (>20 years pharma exp., >20 years academic heme/onc. practice)

Jack Schaumberg, PhD, head of clinical operations (>20 years pharma development operations exp.)

Shibani Kudchadkar, MD, medical director (>5 years industry development experience)

Mike Hefferman, PhD, head of CMC/quality (>15 years development exp.)

Brian Wipke, PhD, VP R&D (>15 years pharma/ biotech exp.)

LUMINA PHARMACEUTICALS, INC.

Novel Potential Pan-Cancer Radioligand Therapy

Cara Ferreira | cara@luminapharma.com | 403-604-2326 | Luminapharma.com

COMPANY OVERVIEW

Lumina Pharmaceuticals is a clinical-stage radiopharmaceutical company distinguished by its innovative technology that targets novel biomarkers that are abundantly present in solid cancers yet largely absent in healthy humans. Lumina's lead asset is a potential pan-cancer radioligand therapy (RLT), targeting a hallmark of solid tumors. Over 10M patients are diagnosed with solid cancers each year worldwide. Many of these cancers lack effective treatment strategies, resulting in poor outcomes and high mortality rates. We seek to address this unmet need. Our lead asset, CM500/CM600, is an RLT that combines a tumor-seeking molecule combined with a radioactive atom (radionuclide) for the diagnosis and treatment of solid tumor cancer. CM500/CM600 targets fibrin, an abundant protein in the tumor microenvironment, well-known to be present in various solid tumors including head and neck, colorectal, breast, pancreatic, and gastric. We estimate the total addressable market for CM500/CM600 in the United States to be over 600K patients with as many as 110K being late-line patients who have exhausted standard treatment options, representing an important unmet medical need. Our approach has been validated in both animal models and humans. Human imaging studies using our tumor-seeking molecule with an imaging radionuclide were conducted in cancer patients, showing high uptake in all cancer lesions with no safety issues. Efficacy studies in two mouse tumor models using a therapeutic radionuclide showed doubling of overall survival at relatively low and tolerable doses. Currently, we are conducting a Phase 0 human imaging study and further preclinical studies to support translation to a Phase 1 therapeutic trial. We plan to leverage this data to conduct a Series A raise to fund the Phase 1/2 clinical trial to demonstrate the safety and efficacy of CM500/CM600 in a limited number of prioritized solid tumor indications. Led by a board and management team experienced in building successful start-ups and developing RLT assets, Lumina is committed to accelerating the advancement of its diagnostic and therapeutic radiopharmaceutical pipeline.

MARKET & COMMERCIALIZATION STRATEGY

Solid cancer tumors represent 90% of all adult cancers worldwide. RLT is recognized as an emerging pillar in cancer treatment. Current approved RLT agents are limited to prostate and neuroendocrine tumors, but the oncology community is excited for novel RLT candidates to address the unmet need in other cancer indications, and the pharmaceutical industry is investing heavily in the space. Lumina's CM500/CM600 has the potential to address unmet need in this patient population as it seeks and binds a novel protein abundant in solid tumor indications. Additionally, RLT has been shown to have application in earlier lines of cancer treatment indicating an even larger future market. For example, Pluvicto was approved in 2025 for use in patients before chemotherapy. Studies also suggest that RLT can have a beneficial synergistic effect with other established earlier-line cancer treatments. Representative high unmet need cancer indications with high vascular permeability in the tumor resulting in deposition of fibrin, the protein that CM500/CM600 binds, include triple negative breast, head and neck, as well as peritoneal metastases from CRC, gastric, and ovarian cancers. The initial annual addressable salvage patients (last line of therapy, or 50% or annual deaths from these indications) in the United States alone for just these indications is 43K patients, representing $7B market potential. Expansion via moving to earlier lines of therapy, into combinations, and to other indications would provide an addressable market of over $28B and 10% CAGR sustainably.

TECHNICAL & COMPETITIVE ADVANTAGE

RLT is recognized as an emerging pillar of cancer treatment. Lumina's lead asset is a novel potential pan-cancer RLT that combines a tumor-targeting molecule that binds to a protein abundant in solid tumors, fibrin, with either a radionuclide for imaging or a therapeutic radionuclide for treatment. The reliable abundance of fibrin in solid tumors including metastatic lesions and its absence in healthy tissue makes it an ideal target for RLT. Fibrin's presence has been extensively reported in solid cancers including lung, colorectal, kidney, breast, pancreatic, head and neck, ovarian, gastric, and others. Our approach has been validated in humans and mouse models and

published in a top tier journal (Esfahani et al. Sci Transl Med. 2024 Dec 11;16(777)). Human imaging studies using our tumor-seeking molecule with an imaging radionuclide were conducted in gastric cancer patients. Across 7 patients, all 52 tumor lesions showed high uptake of our radiopharmaceutical (7 primary and 45 metastases) confirming the reliable and homogeneous presence of fibrin across tumor lesions in these patients. No safety signals were observed, and the radiopharmaceutical was rapidly cleared from other non-target organs, indicating a positive safety profile. Efficacy studies in two mouse tumor models using a therapeutic radionuclide showed doubling of overall survival at relatively low and tolerable doses. As a potential pan-cancer therapy, CM500/CM600 could have substantial impact for cancer patients. The overwhelming majority of cancer deaths are related to solid cancers. High unmet need exists in solid tumor cancers, with many patients exhausting treatment options. RLT has already been shown to have good adoption in last-line patients in prostate cancer and neuroendocrine cancer with the FDA approved drugs Pluvicto and Lutathera, respectively. There is strong interest from the oncology community to have an RLT option for other indications. RLT also has potential to improve outcomes and quality of life for patients earlier in their cancer journey, and the precision medicine nature of RLT can translate to less side effects. Additionally, RLT has shown synergistic efficacy with other cancer therapies.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Lumina holds granted and filed patents covering multimodal imaging of fibrin and fibrin-binding compounds for imaging and treatment in multiple major geographies.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2026	Preclinical data with therapeutic isotopes
Q4 2026	Human imaging data in multiple solid tumor types
Q2 2027	Low dose dosimetry data with therapeutic isotope(s)
Late 2027	Advance the most promising indications for the theranostic

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2012-19	NIH SBIR grants		$10.35M
2020	NIH SBIR grant		$2.3M
2021	NIH SBIR grant		$800K
2023	NIH SBIR grant		$1.3M
2025	Seed investment	SAFE (simple agreement for equity)	$2M

USE OF PROCEEDS

Lumina Pharmaceuticals is looking to raise $35M-$50M Series A funds over the next 6-9 months to accelerate the clinical development of the CM500/CM600 technology and other undisclosed pipeline assets. Funds raised will be used to advance the theranostic RLT through Phase 1/2 in selected indications that are determined to have the highest probability of success and potential for early efficacy signals. Additionally, funds will be used to strengthen supply chain and manufacturing to support development and advance a second asset to first in human imaging.

KEY TEAM MEMBERS

Greg Sorensen, MD, Co-founder and Chair of Board
Successful healthcare technology executive and board-certified radiologist with over 30 years experience spanning academic medicine, corporate leadership and entrepreneurship. Currently, CSO at RadNet where he acquired his startup, DeepHealth, in 2020. Previously, president and CEO of Siemens Healthcare North America. Full professor at Harvard Medical School.

Peter Caravan, PhD, Co-founder and Board member
Full professor at Harvard Medical School. Co-director at the Center for Interdisciplinary Innovation in Imaging. Scientific expertise in RLT and medical imaging, with 200+ publications, 20+ patent applications, and numerous awards. Serial entrepreneur founding several startups based on innovative medical imaging technologies. At Lumina, scientific advisor and SBIR grant subaward holder supervising preclinical studies.

Cara Ferreira, PhD, MBA, Chief Executive Officer
Over 20 years experience in the radiopharmaceutical industry. Most recently, executive at Fusion Pharmaceuticals, a leader in the RLT space that was acquired by AstraZeneca in 2024. Previously, a consultant at McKinsey & Co. where she supported pharma clients on corporate strategy and M&A. Began professional career at Nordion (BWXT Medical) leading development and commercialization projects for radiopharmaceuticals.

MARCH BIOSCIENCES, INC.

CD5-Targeted CAR-T Cell Therapy

Sarah Hein | sarah@march.bio | 713-898-0838 | march.bio

COMPANY OVERVIEW

March Biosciences was launched in 2023 with initial seed financing and technology from the Center for Cell and Gene Therapy at Baylor College of Medicine, Houston Methodist Hospital, and Texas Children's Hospital by chief executive Sarah Hein, PhD, with scientific founders Maksim Mamonkin, PhD, and Malcolm Brenner, MD, PhD. The company's mission is to bring the curative potential of CAR-T therapy to difficult cancers that the first wave of immunotherapy has left behind, beginning with T-cell malignancies. In under three years, March advanced its lead asset, MB-105, from an academic construct to a national multicenter Phase 2 trial, earned Orphan Drug and RMAT designations, and reported best-in-class early clinical results, all via an efficient capital structure. The company is led by an experienced team of cell therapy scientists, clinicians, manufacturing specialists, and regulatory experts, and is backed by leading life sciences investors alongside non-dilutive support from CPRIT and the NIH SBIR program.

MARKET & COMMERCIALIZATION STRATEGY

T-cell lymphoma is an orphan indication of high unmet need: approximately 10,300 new U.S. cases per year, with only about one patient in 10 surviving beyond five years and a median survival of roughly six months after relapse. Standard care is chemotherapy and, for the minority eligible, allogeneic transplant; there is no standard of care in the relapsed/refractory setting. March's beachhead is CD5-positive relapsed/refractory T-cell lymphoma, affecting roughly 4,800 U.S. patients per year and representing an approximately $2.9B annual opportunity at CAR-T pricing benchmarks (~$600k per patient). CD5 is also expressed across T-ALL, chronic lymphocytic leukemia, and mantle cell lymphoma, expanding the U.S. addressable CD5-positive relapsed/refractory population to roughly 10,300 patients (~$6B). Movement to consolidative first-line therapy would expand the opportunity further. MB-105's RMAT designation enables a potential accelerated-approval path for a first-in-class, best-in-class asset in a category with no approved competition.

TECHNICAL & COMPETITIVE ADVANTAGE

The central obstacle to cell therapy for T-cell cancers is that malignant and healthy T cells share the same surface antigens, so a CAR-T built against a T-cell target attacks both the tumor and the patient's normal T cells, and the engineered cells destroy one another through fratricide. MB-105 is an optimized CD5 CAR which uniquely drives antigen downmodulation on the engineered cell, so CAR-T cells resist self-killing while CD5-positive malignant cells are efficiently eradicated. This downmodulation uniquely does not require additional gene editing prior to CAR integration. The result is a product with four key properties: (1) potent CD5-directed cytotoxicity, (2) avoidance of fratricide, (3) a favorable safety profile with minimal cytokine release syndrome and neurotoxicity across dose levels, and (4) a robust, editing-free manufacturing process that preserves the naive-like and effector-memory T cells associated with durable responses. Competitively, rival programs rely on gene or base editing that adds manufacturing complexity, cost, and regulatory risk, or pursue narrower antigens (CD7, CD70, TRBC1) that reach smaller populations and have shown target-negative relapse or poor CAR-T persistence. Of note, the single-modification architecture is the only clinically validated architecture that is potentially amenable to next-generation delivery, including a lentiviral, safety-switch-enabled construct and in vivo approaches. The company is further expanding into solid tumor strategies via the synapse-stabilizing receptor (SSR), an AND-enhancer platform which mitigates against CAR target downmodulation without adding to off-tumor toxicity. These programs extend March's mission to address difficult tumor indications via sophisticated engineering strategies.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

MB-105 has received FDA Orphan Drug designation and, in November 2025, RMAT designation for relapsed/refractory CD5-positive T-cell lymphoma. RMAT provides intensive, early FDA engagement and eligibility for expedited review mechanisms including rolling and priority review, and March intends to pursue an accelerated approval path following a single-arm registrational cohort which would be negotiated with the agency. The CD5 CAR design is protected by an issued U.S. and European patent family, with additional U.S. method claims allowed that provide broad indication protection of our strategy. Separate intellectual property covers the manufacturing process and the SSR platform. All technologies are exclusively licensed from Baylor College of Medicine and provide a broad, defensible foundation across its pipeline.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2021	March Biosciences incorporated
Sept. 2022	Exclusive license to the CD5 CAR-T technology secured from Baylor College of Medicine
Jan. 2023	~$9M seed round closed; company incubated by the CPRIT-supported TMC Accelerator for Cancer Therapeutics
2024	CPRIT product-development award (DP240073; $13.4M); $29.6M oversubscribed Series A closed, co-led by Mission BioCapital and 4BIO Capital
2024	NCI SBIR Phase II award (R44CA295245, ~$2.0M) supporting dual-specific (pipeline) CAR-T development
2025	NCI SBIR Direct to Phase II award (R44CA302357, ~$2.2M) supporting the MB-105 Phase 2 program
2025	Company-sponsored multicenter Phase 2 trial of MB-105 initiated (NCT06534060)
Nov. 2025	FDA RMAT designation granted for relapsed/refractory CD5-positive T-cell lymphoma
Dec. 2025	ASH 2025: 100% complete response rate reported in the Phase 2 run-in primary efficacy cohort (5/5 patients)
2026	+$2M CPRIT supplement awarded

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2023	Seed Round	Convertible notes co-led by TMC Venture Fund and Portal Innovations, with a Cancer Focus Fund clinical trial commitment	$9M
2024	Series A Preferred	Oversubscribed round co-led by Mission BioCapital and 4BIO Capital to fund MB-105 Phase 2 development. Participation from KdT Ventures, Modi Ventures, TMC Venture Fund, Alexandria Venture Investments, Mansueto Investments, and others.	$29.6M
2024	CPRIT Award (DP240073)	$13.4M Texas Therapeutics Company product-development grant supporting the MB-105 Phase 2 program; $2M supplement in 2026	$15.4M
2024–2026 (active)	NIH / NCI SBIR	Direct Phase II award (R44CA295245,~$2.0M) supporting dual-specific pipeline development and Direct to Phase II award (R44CA302357, ~$2.2M) supporting MB-105	$4.2M

USE OF PROCEEDS

March will raise a Series B of approximately $60M-75M to advance MB-105 towards approval. Proceeds will fund (i) continued MB-105 clinical execution, (ii) advancement of the next-generation CD5 program for in vivo targeting, (iii) the SSR solid-tumor platform lead asset in hepatocellular carcinoma, and (iv) secondary pipeline applications for the SSR in solid tumors. Key activities may be accelerated depending on investor appetite and fundraising.

KEY TEAM MEMBERS

Sarah Hein, PhD, Co-Founder and Chief Executive Officer Founding CEO of March Biosciences; previously co-founder and VP of Operations at Courier Therapeutics (acquired by Valo Health, $510M deal value) and founding entrepreneur in residence at the CPRIT-supported TMC Accelerator for Cancer Therapeutics.

Maksim Mamonkin, PhD, Co-Founder and Chief Scientific Advisor Lead inventor of the CD5 and CD7 CAR-T clinical-stage technologies, inventor of the synapse stabilizing receptor. 2023 ASGCT Outstanding New Investigator with 50+ publications and 9 patent families.

Alice Bexon, MD, Chief Medical Officer 30+ years of clinical and pharmaceutical development experience across cell therapy, biologics, and drug-device combinations; lead author/reviewer on numerous INDs, BLAs, and other global regulatory submissions.

METACLIPSE THERAPEUTICS

METACLIPSE THERAPEUTICS CORPORATION

Autologous Immunotherapy Platform

Shaker Reddy | sreddy@metaclipse.com | 678-358-8532 | linkedin.com/company/metaclipse-therapeutics/home/

COMPANY OVERVIEW

Metaclipse's first product is MTC-TNBC1, an individualized vaccine immunotherapy for TNBC. Metaclipse chose TNBC as its initial focus due to unmet medical need, lack of an efficacious therapy, and high tumor heterogeneity. TNBC tumors lack expression of estrogen, progesterone, and HER2 receptors, representing 15-20% of breast cancers. Currently used treatment regimens are not adequately effective for TNBC, as none are individually targeted regimens. Most patients initially respond well to current standard of care (SOC) therapy, but up to 50% relapse within 24 months. At this point, most additional SOC approaches are not effective in curtailing further tumor progression and metastasis to other organs, ultimately leading to death. Anti-PD-1 antibody (pembrolizumab) was approved for high-risk, early-stage TNBC in 2021, but is effective for only a small fraction of patients. Therefore, MTC-TNBC1 is expected to qualify for fast-track approval. MTC-TNBC1 is prepared by generating tumor membrane vesicles (TMVs) from patient tumor tissue, which are then covalently linked to immunostimulatory molecules (ISMs) using our patented protein-transfer technology. Metaclipse requires approximately 0.5-1 gram of excised patient tumor tissue to process the tumor material needed to generate the TMVs used for the vaccine preparation. These patient-specific TMVs, which capture the unique tumor antigen signature for each individual, are then combined with GPI-linked ISMs that allow membrane anchoring to TMVs to produce the vaccine. We anticipate its administration to the same patient 18 days after surgery, allowing time for patient recovery. The particulate nature of our vaccine, along with the concurrent presentation of our membrane-anchored adjuvant proteins, facilitates antigen uptake, enhances dendritic cell activation, and promotes an enhanced antitumor-immune response. In addition, the MTC-TNBC-1 can be administered following current SOC drugs and treatments, such as localized radiation and chemotherapy. We are confident that oncologists would not hesitate to prescribe an immunotherapy approach such as MTC-TNBC1 to alter the current disease course, since the Metaclipse approach would not interfere with the current SOC treatment regimens. Treatment with MTC-TNBC1 early in the disease course is projected to stimulate potent, multivalent CD4 and CD8 T-cell responses capable of eliminating metastatic colonies and leading to increases in rates of progression-free survival as well as overall survival. In addition, our approach works in synergy with a checkpoint blockade inhibitor (anti-CTLA-4 antibody) in the immune checkpoint resistant mouse 4T1 TNBC model, reducing metastasis to the lungs and significantly increasing overall survival rates in a therapeutic challenge setting. In addition, we have promising preclinical data in several head and neck cancer models, including MOC1 and MOC2, with a significant reduction in primary tumor growth, reduced metastasis, and increased TILs in both models either as a monotherapy or in combination with checkpoint inhibitors. In 2024-2025, we received both IND and IRB approval at Emory University for the head and neck cancer indication, and our Phase 1 trials at Emory University are currently open and recruiting patients for both indications.

MARKET & COMMERCIALIZATION STRATEGY

An independent market analysis of our technology and business model revealed concurrence among experts that if our therapy were to extend similar survival benefit to TNBC patients as Herceptin for HER2+ patients, then the clinical adoption and estimated price point would follow the Herceptin model. The price of Herceptin is reported to be $54,000 per patient-year of drug therapy. A recent study concluded that a $100,000 per quality-adjusted life year was justified. Based on current coverage range for breast cancer patients, Metaclipse estimates pricing of $75,000 per patient year is reasonable. Herceptin, despite losing significant market share (~$1.8B worldwide) to biosimilars, generated worldwide revenues of over $3.2B in 2024 (~$1.2B for U.S. market); the size of the patient segment qualifying for Herceptin treatment is similar to the size of the TNBC segment. Approximately 20% of newly diagnosed breast cancers are TNBC; and about one-third of TNBC patients respond to front-line therapy, leaving two-thirds who are likely candidates for Metaclipse products. Thus, it was estimated that the U.S. market

potential for Metaclipse's product line would be ~$1.2B, with a growth rate of 5.5% from 2025-2030. The scientific and technological basis and design principles that govern our product constitution are applicable beyond the initially targeted TNBC niche segment. Metaclipse plans to exploit the technology platform to develop a pipeline of products that are aligned with market demand, advancing next into head and neck cancer followed by lung cancer.

TECHNICAL & COMPETITIVE ADVANTAGE

Metaclipse's immunotherapy confers several advantages over competitive approaches. First, the production of TMVs from a patient's tumor does not require establishment of cultured cell lines or use of viral vectors, making our process simple, reproducible, and clinic-friendly. Rapid manufacture of modified TMVs from excised tumor tissue allows delivery of the individualized vaccine product in as little as 18 days. The fast turnaround permits prompt and efficient therapy, allowing for the patient's immune system to regain capacity and potency for cancer battle before metastatic cells grow. The patient requires only 3 simple injections of the vaccine given every 14 days; all 3 doses are derived from their initially excised tissue. Thus, the full regimen is completed within 7-8 weeks after the initial excision, depending on patient recovery rate post-surgery. Further, most other immunotherapy approaches generate immunity against only one target protein or collection of predicted MHC Class-I-restricted antigens, which is a drawback as only CD8 T cells are stimulated. This single target approach may not be relevant for particular groups of patients, and even when it is, the tumors often escape from the limited immune response. This is in marked contrast to the Metaclipse approach, which relies on immunity generated against a wide array of tumor surface antigens. These antigens include both MHC Class I and Class-II-restricted epitopes present in that patient, priming both CD4 and CD8 T cells, potentially averting CD8 T cell exhaustion. Further, unlike neoantigen approaches, we also capture aberrantly glycosylated target proteins, overexpressed proteins, and altered expression proteins in addition to mutated proteins, further broadening the immune response. Projected competitive advantages include niche focus on unmet market need, simplicity, fast turnaround, broad applicability, and attractive pricing. Metaclipse possesses composition of matter, use patents, trademarks, and trademark secrets covering the protein transfer technology.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Metaclipse has completed preclinical work in mice, demonstrating the feasibility and effectiveness of our approach in mouse breast, head and neck, and lung cancer models, both alone and in combination with checkpoint inhibitors. In addition, we established reproducible protocols for generating our therapeutic vaccine from human breast tumor tissue specimens. We have also showed that our immunotherapy does not induce liver toxicity, even when administered with checkpoint inhibitors. An independent GLP toxicology study confirmed our preliminary observations and demonstrated the safety of our vaccine formulation in animal models. The toxicity study revealed a favorable safety profile with no significant adverse events or visible gross pathology in either high-dose TMV vaccine alone or in combination with checkpoint blockade inhibitors. We have already refined and standardized the purification of the membrane-anchored adjuvants (GPI-proteins) using immunoaffinity. Metaclipse has already established cGMP-compliant standard operating procedures for production and purification of membrane-anchored proteins, which will be transferred to a qualified CMO. The initial cGMP manufacturing campaign of the GPI-protein adjuvants was completed, but additional campaigns and scale-up studies are currently underway to support our multiple clinical efforts. Required QA/QC and stability studies on the manufactured proteins (drug substance) and final drug product (MTC-TNBC1) have also been completed. The TMV vaccine is stable for at least 6 months, and prepared test vaccine preparations were free of detectable bioburden. Extended GPI-protein stability studies demonstrated stability for over three years. Metaclipse received IND approval, and IRB approval at Emory University was received in 2025. We anticipate dosing of the first TNBC patient in our Phase 1 clinical trial in Q3 2026. Metaclipse is aware of ICD codes for immunotherapy, and guidelines for establishing CPT codes for cancer vaccine and its administration are available. Dr. Ira Kalfus, MD, (a clinical expert who has conducted numerous clinical trials) serves as our chief medical director. Metaclipse is working with Keerthi Gogineni, MD, for our TNBC Phase 1 clinical trial at Emory University. The company is collaborating with Dong Moon Shin, MD, a head and neck clinical oncologist at Emory University who is currently conducting an additional Phase 1 clinical trial to treat recurrent head and neck cancer. Metaclipse is also collaborating with Neal Akhave, MD, on a second head and neck cancer trial at MD Anderson Cancer Center to treat advanced metastatic disease. Intellectual Property: Metaclipse's technology is derived and developed from Emory University inventions. Rights to the patent estate have been exclusively licensed from Emory to Metaclipse for all applications and uses worldwide. 1. Patent US 12/023,379 B2 entitled: "Immunostimulatory Compositions, Particles, and Uses Related Thereto". Priority Date Dec 2020, jointly by Metaclipse and Emory University. 2. Patent CA 2863658 A1 entitled: "Immunostimulatory Compositions, Particles, and Uses Related Thereto". Priority date Feb 2012, jointly by Metaclipse and Emory University. 3. Patent application EP 3520809 A1 entitled: "Immunostimulatory Compositions, Particles, and Uses Related Thereto". Priority date Feb 2012, jointly by Metaclipse and Emory University. 4. PCT patent application US 17/925,179 entitled: "Compositions and Methods for Detecting and Treating a SARS-CoV-2 Infection". Priority date May 2020, jointly by Metaclipse and Emory University. 5. PCT patent application US 17/876,413 entitled: "Dendritic Cells Pulsed with Tumor Membrane Vesicles and Uses in Treating Cancer". Priority date Jul 2022, jointly by Metaclipse and Emory University Metaclipse intends to file 2 additional process patents in 2026 covering protein purification and an overall process patent covering vaccine preparation. In addition to the 20-year exclusivity offered by the Metaclipse patent portfolio, the Food and Drug Administration offers a 12-year commercial exclusivity for first-to-market biologics.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
8/2026	Launch Phase 1a dose escalation clinical trials in TNBC and HNSCC to determine safety, immune response
2/2028	Launch Phase 1b clinical trials (combination with ICI) in TNBC and HNSCC to determine safety, immune response
3/2028	Complete Phase 1a/b clinical trials in both TNBC and HNSCC and launch Phase 2 clinical trials in both indications

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
Prior to 2018	SBIR and CO state grants	Early-stage funding leading to publication (above) and corporate activities	$500K
2019	SPARK grant	Non-GMP manufacturing of potential lead compounds	$100K
2018-Present	SBIR Fast Track grant	Enabled lead optimization and will allow completion of IND-enabling studies	$2.3M

USE OF PROCEEDS

Metaclipse is seeking $2M bridge funding by end of 2026 and closing a $10M Series A round by end of 2027. Funding will be applied towards matching a future NIH Phase IIB bridge award in 2028 ($4M) and the current CPRIT award ($3M matching funds). These combined awards and funding will sponsor expanded GMP manufacturing campaigns and Phase 2 clinical trials.

Metaclipse is seeking $2M bridge funding by end of 2026 and closing a $10M Series A round by end of 2027. Funding will be applied towards matching a future NIH Phase IIB bridge award in 2028 ($4M) and the current CPRIT award ($3M matching funds). These combined awards and funding will sponsor expanded GMP manufacturing campaigns and Phase 2 clinical trials.

KEY TEAM MEMBERS

Shaker Reddy, MS, President, CEO, Co-Founder. Mr. Reddy has over 25 years entrepreneurial experience including several start-ups. He has successfully built and sold two previous companies. Mr. Reddy provides operational leadership.

Periasamy Selvaraj, PhD, CSO, Co-Founder. Professor, Emory University School of Medicine. He has more than 25 years of experience in tumor immunotherapy and immunology. He moved to Emory after completing postdoctoral training at Harvard. He has authored/co-authored 90+ articles in leading journals. Dr. Selvaraj provides advice and support for the foundational science leading to Metaclipse products.

Michael Coleman, PhD, Senior Vice President, Business Strategy. Dr. Coleman has over 25 years of experience in biologics, including gene therapy, cancer therapy, and medical device development. He also has extensive experience in business development, raising over $4M in funds for various biotechnology companies that supported CMC, IND filing, and clinical trial development efforts. Ira Kalfus, MD, Chief Medical Director. Dr. Kalfus has over 15 years of experience in clinical drug development including FDA approvals and 30 years of experience in medicine.

MYOSIN THERAPEUTICS, INC.

First-In-Class Therapies Targeting Molecular Nanomotors

Courtney Miller | courtney@myosintherapeutics.com | 713-385-9558 | myosintherapeutics.com

COMPANY OVERVIEW

Myosin Therapeutics is a privately held, clinical-stage biopharmaceutical company developing first-in-class small molecules that target molecular nanomotors, the physical machinery controlling cell movement, division, trafficking, and stress adaptation. The company's proprietary nMotor™ platform supports programs in oncology and neuroscience and is anchored by MT-125, a brain-penetrant dual inhibitor of the molecular nanomotor non-muscle myosin IIA and IIB (NMIIA/IIB). In partnership with Mayo Clinic, Myosin is currently evaluating MT-125 in the Phase 1/2 STAR-GBM trial for newly diagnosed, IDH wildtype, MGMT unmethylated glioblastoma (GBM). GBM serves as the initial clinical entry point for validating cancer cell mechanics as a therapeutic strategy, with MT-125 being developed as an oncology platform molecule with pan-cancer potential because it targets conserved mechanical dependencies across tumor types. A strong data package supports AML as the leading expansion opportunity. Myosin has raised over $34M, with more than 80% derived from competitive, peer-reviewed, non-dilutive government funding.

MARKET & COMMERCIALIZATION STRATEGY

Glioblastoma is a high-value orphan oncology market with approximately 14,000 new U.S. cases annually, median survival of 12-15 months, and nearly universal recurrence. Internal pricing and penetration models indicate a multibillion-dollar opportunity in GBM alone. MT-125 is designed to integrate directly into the existing treatment pathway as an adjunct to radiotherapy at diagnosis, facilitating adoption at the major neuro-oncology centers where GBM treatment is concentrated. Following establishment of human safety and pharmacokinetics, Myosin plans to expand MT-125 into AML, which has approximately 20,000 new U.S. cases annually, and subsequently into other mechanically dependent, treatment-refractory cancers. Commercialization may proceed through a strategic oncology partnership following Phase 2 clinical data in the ongoing STAR-GBM trial, supporting pivotal development, regulatory submission, and launch. Scalable, cost-efficient synthesis, kilogram-scale GMP drug substance manufacturing capability, clinical drug product supply, and an oral formulation program support commercial readiness.

TECHNICAL & COMPETITIVE ADVANTAGE

MT-125 introduces a fundamentally differentiated therapeutic strategy: targeting the physical mechanics of cancer cells rather than another potentially redundant signaling or immune pathway. By inhibiting both NMIIA and NMIIB, MT-125 simultaneously interferes with tumor cell invasion, cytokinesis, and the ability to withstand oxidative and genotoxic stress. Its strong brain penetration extends MT-125's pan-cancer potential to both primary CNS tumors and systemic cancers with CNS involvement. In preclinical studies, MT-125 demonstrates single agent activity in treatment-resistant GBM models, synergizes with radiotherapy and FDA approved receptor tyrosine kinase inhibitors, and extends survival across all five AML models tested to date, including treatment-resistant TP53 mutation. The platform and lead program are supported by two 2025 publications in *Cell*. This combination of a first-in-class mechanism, demonstrated combination synergy potential, CNS exposure, activity across solid and hematologic models, and a platform capable of generating follow-on nanomotor inhibitors differentiates Myosin from conventional kinase, cytotoxic, anti-angiogenic, and immunotherapy programs.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

MT-125 is being developed under active FDA IND 170975 and has received Orphan Drug designation for malignant gliomas and Fast Track designation for glioblastoma. An ODD application will be submitted in Q3 2026 for AML. STAR-GBM is a Phase 1 dose escalation followed by parallel, randomized Phase 2 dose expansion to characterize safety, pharmacokinetics, exposure-response relationships, and preliminary activity while selecting a recommended Phase 2/3 dose. The program was developed through FDA interaction to position the subsequent study for registrational development.

Myosin intends to pursue Breakthrough Therapy designation and discuss potential Accelerated Approval strategies with FDA. Myosin holds an exclusive worldwide license from the University of Florida to a layered patent estate covering NMII inhibitor composition of matter and therapeutic applications, with protection through 2040. Additional filings cover combination therapies, formulations, and polymorphic forms to extend lifecycle protection through 2046 and beyond. Issued and pending protection spans the United States and other major commercial markets.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Nov. 2016	Collaborative NMII medicinal chemistry and drug development program launched by Drs. Miller, Griffin, and Kamenecka at Scripps Research (Florida) with NIH support through the Blueprint Neurotherapeutics program.
Dec. 2020	Myosin Therapeutics founded to translate molecular nanomotor biology into therapeutics.
2023–2025	Completed two seed financings totaling $6M and completed MT-125 IND-enabling studies.
June 2025	FDA IND 170975 opened and MT-125 received Orphan Drug designation for malignant gliomas.
Aug. 2025	Two peer-reviewed *Cell* publications established the selective NMII inhibitor platform and MT-125's GBM mechanism and preclinical efficacy.
Aug. 2025	Awarded a $4.5M NCI Phase IIB Bridge Award to support STAR-GBM clinical development.
Oct. 2025	FDA granted Fast Track designation to MT-125 for glioblastoma.
March 2026	Awarded $2M from the Florida Cancer Innovation Fund to support MT-125 clinical development.
May 2026	First patient dosed in the Phase 1/2 STAR-GBM trial at Mayo Clinic.
July 2026	First dose level fully enrolled; six-week treatment complete or nearing completion, with no MT-125-attributed adverse events or dose-limiting toxicities reported.
April 2027	Complete STAR-GBM Phase 1 dose escalation and establish the recommended dose levels for expansion.
April 2027	Initiate clinical testing of MT-125 in AML, subject to financing, regulatory clearance, and protocol readiness.
Dec. 2027	Complete STAR-GBM randomized Phase 2 dose expansion.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2006-present	NIH/NINDS Blueprint Neurotherapeutics Award	Development of non-muscle myosin II small molecule inhibitors	$10M
2021-2024	NIH/NIDA R44DA055420	Development of a first-in-class nonmuscle myosin II inhibitor to prevent substance use disorder relapse	$1.6M
2022	Seed financing	Support the development of MT-110 and MT-125	$3M
2023-2026	NIH/NCI R42CA278293	MT-125 for the therapeutic treatment of glioblastoma	$2.6M
2025	Seed-1 financing	Support the development of MT-110 and MT-125	$3M
2025-2027	NIH/NIDA R44DA063266	Phase 0/1b clinical trial of novel therapeutic agent MT-110 for the reduction of methamphetamine use - Part 2	$1.4M
2025-2026	NIH/NCI SB1CA302068	Development of drug product to support a Phase 0/1b dose escalation trial of MT-125 in recurrent high-grade gliomas	$250K
2025-2027	NIH/NCI R44CA278293	Phase 0/I dose escalation trial of MT-125 monotherapy in recurrent high-grade gliomas	$4.4M
2026-2027	Florida Dept of Health 26C19	Phase 2 randomized parallel dose expansion trial of a first-in-class small molecule in newly diagnosed, MGMT methylated glioblastoma (GBM) with radiation	

USE OF PROCEEDS

Myosin is currently raising a $14M Series A to support three primary activities: (1) Addition of a combination arm (+ FDA approved sunitinib) to STAR-GBM Phase 2. Preclinical studies show the combination induces synthetic lethality through oncogene addiction, resulting in long-term remission and no sign of tumor in models totally resistant to current standard of care. (2) Initiation of ORION-GBM Phase 2 trial of MT-125 in relapsed/refractory AML. (3) MT-125 oral formulation development with a PK bridging study in healthy volunteers.

KEY TEAM MEMBERS

Courtney A. Miller, PhD, Co-Founder, Chair and Chief Executive Officer Neuroscientist with more than 25 years of experience in cytoskeletal biology and therapeutic development whose laboratory made the foundational discovery of NMII's therapeutic potential. She is a PECASE recipient, awarded by President Obama, and was named BioFlorida's Entrepreneur of the Year in 2022.

Karen Smith, MD, PhD, MBA, LLM, Chief Medical Officer Physician-executive with experience spanning more than 100 clinical trials, over 20 global regulatory approvals, senior biopharma leadership, early stage biotech builds, and more than $15B in corporate transactions. She leads MT-125 clinical development, safety governance, and FDA interactions.

Patrick R. Griffin, PhD, Co-Founder, Co-Chief Scientific Officer and Director Biophysical chemist with more than 35 years of academic and industry drug development experience. As a senior chemistry leader at Merck, his team contributed to the discovery of sitagliptin/Januvia, and he brings extensive expertise in protein druggability, translational discovery, and CMC strategy.

NOMOCAN PHARMACEUTICALS, LLC

First-In-Class, Tumor-Specific ADC for PDAC

Ehsan Yazdi | ehsan.yazdi@nomocan.com | 347-712-1635 | nomocan.com

COMPANY OVERVIEW

NomoCan Pharmaceuticals is a precision oncology company developing first-in-class targeted therapeutics for difficult-to-treat solid tumors. Its lead program, NMC-521, is a novel antibody-drug conjugate (ADC) directed against a highly differentiated, cancer-associated target with preferential expression on malignant cells. NMC-521 is designed to selectively deliver a potent cytotoxic payload to tumor cells while also leveraging the inherent therapeutic activity of its antibody component. NomoCan is initially focused on pancreatic ductal adenocarcinoma (PDAC), one of the deadliest and most treatment-resistant cancers, as part of a broader pan-cancer development strategy. Preclinical studies have demonstrated robust anti-tumor activity across patient-derived tumor models, ex vivo human tumor specimens, and in vivo models. The company is advancing NMC-521 toward IND-enabling studies and building a differentiated oncology platform around its novel target biology and ADC technology. NomoCan's target is novel and cancer-exclusive, independently validated and funded by NCI, and has driven complete tumor eradication in both animal models and real human tumor specimens. The ADC market is actively rewarding assets with exactly this profile. The company's Series A financing is designed to take NMC-521 to an IND, one of the most value-creating milestones in early-stage biotech. NomoCan's target biology, preclinical data, and experienced leadership team position the company to advance NMC-521 toward clinical development.

MARKET & COMMERCIALIZATION STRATEGY

Starting narrow: A biomarker-selected PDAC population offers the clearest path to a clean, efficient clinical signal. Broader opportunity: The target is expressed across multiple solid tumors, including CRC and breast cancer, among others. Initial indication: PDAC is a major area of unmet medical need with late diagnosis, aggressive progression, limited treatment options, and poor survival. Market: A multibillion-dollar global oncology opportunity, with significant need for more durable, higher-response therapies. Strategy: Establish clinical proof-of-concept in PDAC, then expand into additional solid tumor indications. Path forward: Pursue strategic partnerships, licensing, or co-development following clinical validation and/or compelling early data. First-in-class target with pan-cancer potential creates multiple avenues for future value creation.

TECHNICAL & COMPETITIVE ADVANTAGE

NomoCan's principal competitive advantage is its highly differentiated target biology and therapeutic approach. NMC-521 is directed against a novel cancer-associated target that offers the potential for selective tumor recognition and targeted delivery of a potent cytotoxic payload. Key technical advantages include: (1) A differentiated, potentially first-in-class target with broad applicability across solid tumors. (2) Demonstrated anti-tumor activity in multiple preclinical models, including patient-derived tumors and ex vivo human tumor specimens. (3) A therapeutic antibody component with inherent anti-tumor activity, offering the potential for dual mechanisms of action ADC optimization capabilities spanning antibody engineering, linker-payload selection, drug-to-antibody ratio (DAR), and conjugation chemistry. (4) Potential for tumor-selective payload delivery, which may improve the therapeutic index relative to conventional chemotherapy. (5) A development strategy initially focused on PDAC, with potential expansion into multiple additional tumor types. NomoCan's approach combines differentiated tumor biology with modern ADC engineering to address the limitations of existing therapies and build a potentially broad oncology platform.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

NomoCan is pursuing a staged regulatory strategy designed to advance NMC-521 through IND-enabling development and into first-in-human clinical studies. The near-term development plan includes optimization of the ADC construct; completion of CMC and GMP activities; pharmacology and pharmacokinetic characterization; GLP toxicology and safety studies; bioanalytical assay development; and preparation and submission of an IND application. The company intends to engage with regulatory authorities as appropriate throughout development to obtain guidance on the clinical and nonclinical development pathway for NMC-521. NomoCan is building a multi-layered intellectual property strategy covering the novel target, therapeutic antibodies, antibody-drug conjugates, linker-payload configurations, methods of treatment, and potential applications across multiple cancer indications; this provides broad composition-of-matter and use-based protection around the platform and lead therapeutic candidate.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2018–2023	Target discovery and validation. Conducted focused research along a cancer biology pathway, leading to the discovery and validation of a novel, cancer-exclusive therapeutic target on a cancer-driving surface antigen previously overlooked by the oncology field. Conducted multiple collaborations with leading institutions, including Harvard Medical School, Weill Cornell Medicine, and Roswell Park, for internal and external validation of the discovery.
2023–2026	First-in-class antibody generation, mechanistic discovery, and therapeutic validation. Generated proprietary first-in-class antibodies against the novel target and demonstrated target-specific binding and engagement. Conducted mechanistic studies revealing the antibody's anti-tumor mechanisms, including direct anti-tumor activity and recruitment of natural killer immune cells. Demonstrated substantial anti-tumor activity across multiple in vivo cancer models and complete ex vivo eradication of freshly excised human tumor tissue from a patient whose disease was refractory to standard-of-care chemotherapy. NomoCan was part of the inaugural cohort of the NIH/NCI Concept Award program and subsequently received peer-reviewed NIH/NCI funding twice through the program, enabling advancement of its target discovery, validation, and therapeutic development efforts.
2025–2026	ADC development and preclinical proof of concept. Developed NMC-521-ADC by arming the proprietary antibody with a cytotoxic payload. Demonstrated tumor-selective biodistribution and retention, followed by complete tumor eradication in human pancreatic cancer models with preliminary evidence of tolerability, establishing preclinical proof-of-concept for the ADC therapeutic approach.
2026–2028	IND-enabling development. Advancing clinical candidate selection and completing IND-enabling CMC, pharmacology, bioanalytical, GLP toxicology, and regulatory activities.
2028	IND submission and first-in-human development. Submit an IND and advance NMC-521-ADC toward first-in-human Phase 1 clinical development.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2023–2025	Non-Dilutive Grant Funding	Secured competitive non-dilutive grant funding to support the company's translational development programs	$1M
2022–2024	Institutional and Angel Investor Funding	Raised from institutional and angel investors to support development of NomoCan's oncology platform	$4M

USE OF PROCEEDS

NomoCan is currently raising $15M to advance NMC-521-ADC through IND-enabling development and submission. The initial $5M tranche is expected to complete the IND-enabling program, while the full $15M financing will position NomoCan to advance NMC-521-ADC through IND submission and clinical manufacturing readiness, establishing a strong foundation for first-in-human clinical development and potential strategic partnership or licensing opportunities.

KEY TEAM MEMBERS

Ehsan S. Yazdi, PhD, MPH Founder and Chief Executive Officer of NomoCan pharmaceuticals and adjunct faculty in the Department of Medicine at Weill Cornell Medicine. Dr. Yazdi founded the company, discovered the novel target, invented the parental monoclonal antibodies, led platform development, secured the company's core intellectual property, and raised venture and NIH/NCI non-dilutive funding. He brings approximately 18 years of experience in cancer research, translational oncology, and biotechnology development.

Bibhash Mukhopadhyay, PhD, Strategic Lead
Dr. Mukhopadhyay brings nearly two decades of experience across biotech investing, company building, strategic partnerships, and corporate transactions. He has served as a fund manager, investor, and board member of both private and public biotech companies. His experience includes founding the specialist biotech venture firm Sound Bioventures, investing with NEA, and holding business development and corporate strategy roles at Johnson & Johnson and AstraZeneca. He has managed investment funds and led numerous biotech M&A transactions, bringing extensive experience in strategic exits and partnerships that will be valuable to NomoCan.

Massimo Cristofanilli, MD, Associate Director Precision Medicine, Meyer Cancer Center at Weill Cornell Medicine, and a leading clinical trial expert and internationally recognized oncologist. Dr. Cristofanilli is a pioneer in liquid biopsy and brings extensive expertise in translational oncology, biomarker development, precision medicine, and clinical trial design. He serves as an advisor to Merck, AstraZeneca, and Celcuity. His expertise directly supports NomoCan's companion diagnostic strategy and clinical development pathway.

NOVOMEDIX, LLC

Novel Small Molecule Multi-Pathway Modulators

Cathy Swindlehurst | cswindlehurst@novomedix.com | 858-382-8200 | Novomedix.com

COMPANY OVERVIEW

NovoMedix is a San Diego–based biotechnology company developing NMX1, an orally available small molecule with potent single-agent anti-tumor activity for high-unmet-need cancers: triple-negative breast cancer (TNBC), advanced/metastatic breast cancers, and relapsed/refractory pediatric solid tumors (sarcomas and neuroblastoma). NMX1 is an NKA-Src signalosome modulator that, as a single agent, matches or exceeds approved agents in preclinical efficacy; it also sensitizes tumors to a broad range of chemo- and immunotherapies and uniquely protects the heart from anthracycline toxicity. IND submission is targeted for Q4 2026.

MARKET & COMMERCIALIZATION STRATEGY

Metastatic TNBC has a median overall survival of ~18 months with limited options after standard chemotherapy, and relapsed/refractory pediatric sarcomas and neuroblastoma have 5-year survival under 30%. TNBC represents a ~$5B drug market within a ~$25B metastatic breast cancer opportunity; relapsed/refractory pediatric sarcomas and neuroblastoma add a ~$3B market with orphan exclusivity and Priority Review Voucher potential (~$100M+). Anthracycline cardio-protection (>100,000 U.S. patients/year) and potential reversal are additional expansion opportunities within the ~$250B oncology market. NovoMedix plans to partner with a larger pharmaceutical company for commercialization.

TECHNICAL & COMPETITIVE ADVANTAGE

NMX1 is an NKA-Src signalosome modulator that binds Na^+/K^+-ATPase α1 at a site distinct from cardiac glycosides. Through this upstream action, it activates AMPK, suppresses mTOR, and reduces IL-11 signaling, inducing selective metabolic stress in tumor cells and decreasing inflammation and EMT in the tumor microenvironment. Single-agent activity: As monotherapy, NMX1 produces 65–80% tumor growth inhibition across TNBC and sarcoma models and, in survival studies, shows 100% survival versus 40% for doxorubicin, efficacy comparable to or better than approved agents, with a better short- and long-term safety profile. Combination and immunotherapy: NMX1 broadly sensitizes tumors to chemo- and immunotherapy. Combined with doxorubicin, it raises tumor inhibition to 98% (versus 36% for doxorubicin alone), and it shows mechanism-based synergy with topoisomerase inhibitors (irinotecan, topotecan, etoposide); vinca alkaloids (vincristine, vinorelbine); cyclophosphamide; and anti–PD-1/PD-L1 checkpoint inhibitors. Synergy is tumor-context-dependent (e.g., temozolomide additive in Ewing sarcoma, synergistic in neuroblastoma; methotrexate cell-line-dependent), with rationally defined antagonism limited to platinum agents. Cardio-protection differentiator: NMX1 additionally prevents anthracycline cardiotoxicity, reducing cardiac troponin ~85% and preserving left-ventricular ejection fraction (51% in combination compared to 49% for control) in contrast to a decline with doxorubicin alone (41%). This anti tumor plus cardio protection profile is not offered by existing approved or clinical-stage oncology agents; unlike dexrazoxane (the only approved cardio-protectant), NMX1 is oral and enhances rather than compromises anti-tumor activity, suiting long-term survivorship use.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

NMX1 is completing IND-enabling studies. The 28-day GLP rat toxicology study is complete (NOAEL 600 mg/kg, full reversibility), and the 28-day GLP dog study is in progress. A 2 kg cGMP API lot is available, and GMP drug product (capsules) is being manufactured; IND submission is targeted for Q4 2026. Phase 1 is a monotherapy dose escalation in advanced/metastatic TNBC and other breast cancers using PD-biomarker-guided dosing to establish the recommended Phase 2 dose (RP2D). Doxorubicin-combination cohorts, with co-primary efficacy and cardiac safety endpoints, follow once the RP2D is established. The regulatory path includes early Fast Track, Orphan Drug and Rare Pediatric Disease designations (with Priority Review Voucher potential) in pediatric sarcoma and neuroblastoma, and Breakthrough Therapy designation as a post–Phase 1 opportunity contingent on clinical response. Intellectual property: NMX1 composition-of-matter family (“Substituted Biaryl Sulfonamides,” priority

2012–2013) covers the compound and its use across all indications; term to ~2033, extendable via patent-term extension on approval. In the United States, NovoMedix has three patents issued (9,156,781; 9,604,924; 10,040,757) and numerous continuations pending. OUS patents include Europe (EP 2925718 granted, validated in 11 countries; divisional pending), Asia-Pacific (granted: Japan, China, Australia, Singapore, New Zealand; pending: India, Korea), and other markets (granted: Mexico, South Africa; pending: Canada).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2026	28-day GLP toxicity and toxicology
2026	IND (in progress)
2027	Phase 1 initiation (TNBC)
2027	Orphan, Rare Pediatric, and Fast Track submissions
2027	First Phase 1a interim readout 2028: RP2D/initial efficacy readout
2029	Phase 1b cardio-oncology readout

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2001–2010	Contract	Research revenue and founders' investment	$169K
2007	Investment	Phase I SBIR (1R43DK077285-01)	$1M
2010	Grant	Qualifying Therapeutic Discovery Project (IRS/HHS)	$160K
2010	Tax credit	Phase I SBIR (1R43CA144156-01A1)	$300K
2011	Grant	Qualifying Therapeutic Discovery Project (IRS/HHS)	$121K
2012–2014	Tax credit	Phase I SBIR (1R43CA165739)	$300K
2012–2015	Grant	Phase II SBIR (2R43CA144156	$2M
2015–2016	Grant	Seed A	$340K
2016–2017	Investment	Phase I SBIR (1R43HL131356)	$1M
2017–2019	Grant	Seed B	$775K
2019–2020	Investment	Phase I SBIR (1R43HL147726)	$375K
2021	Grant	Bridge loan (convertible debt)	$2.8M
2021–2022	Investment	Phase I SBIR (1R43HL160460)	$375K
2022–2023	Grant	Innovative New Concept Award (75N910022C00001)	$355K
2022–2024	Contract	Phase II SBIR (1R44HL164314)	$2M
2024–2026	Grant	Phase I SBIR (1R43HL176343)	$306K
2024–2026	Grant	NHLBI CRP (1SB1HL174247)	$500K
2025–2026	Grant	Phase II Innovative New Concept Award (75N91025C00051)	$2.9M
2025–2026	Grant	Phase 1 SBIR (1R43AR086064)	$314K

USE OF PROCEEDS

To date, NovoMedix has secured more than $12M in non-dilutive grant funding (NIH SBIR and related awards). NovoMedix is raising a $20M-$30M Series A to fund the Phase 1 TNBC trial through an initial efficacy readout. The company is seeking oncology-focused investors and strategic partners, with particular fit to groups active in breast cancer, cardio-oncology, and immuno-oncology combinations.

KEY TEAM MEMBERS

Cathy A. Swindlehurst, PhD, CEO. Over 30 years in drug discovery and development; CEO of NovoMedix since inception, with prior executive positions at several biotech companies. PhD in chemistry, and a post-doc in immunology from the University of Illinois, certificate in business management from UCSD.

Kyle W.H. Chan, PhD, CSO. Over 30 years in biotechnology spanning drug discovery and development through clinical and regulatory operations. Previously senior director of discovery research at Celgene and co-founder and former CTO of BioTheryX.

David I. Stirling, PhD, Board Chairman. A co-founder and former CSO of Celgene and the originator of the thalidomide and IMiD programs at Celgene that started the CRBN-mediated protein degradation franchise. Advisors.

Fadi Salloum, PhD, cardio-oncology expert. Senior associate dean for research, VCU School of Medicine, Congdon endowed chair in cardiology, and professor of medicine.

Aru Narendran, M.D., PhD, FAAP. Professor of pediatrics and oncology at the Alberta Children's Hospital and the University of Calgary and director of the Pediatric Oncology Experimental Therapeutic Investigator Consortium (POETIC) laboratory for preclinical and drug discovery studies and Phase 1 clinical trials.



ORPHAGEN PHARMACEUTICALS, INC.

First-in-Class Precision Small Molecule Therapy for Adrenal Cancer

Scott Thacher | SMT@orphagen.com | 858-527-5596 | orphagen.com

COMPANY OVERVIEW

Orphagen was founded in 2000 to identify small molecules targeting orphan or unexplored members of the nuclear receptor superfamily, a validated but underexploited class of drug targets. This platform, refined over more than two decades with academic collaborators and pharmaceutical partners, led to the discovery of OR-449, a first-in-class oral SF-1 (NR5A1) antagonist for adrenocortical carcinoma (ACC). Orphagen has advanced OR-449 from target discovery through IND-enabling studies almost entirely with non-dilutive funding, including over $12M in NIH/NCI grants and roughly $30M from pharmaceutical partnerships.

MARKET & COMMERCIALIZATION STRATEGY

ACC is a rare, lethal cancer, with an estimated 700 new U.S. patients diagnosed annually and a global mitotane-treated population of roughly 2,000. Mitotane, approved in 1970, remains the only FDA-approved therapy despite severe toxicity and no demonstrated survival benefit; NCCN guidelines direct advanced/metastatic patients toward a clinical trial rather than mitotane. This absence of an effective standard of care, combined with recent premium U.S. pricing for comparable rare-cancer small molecules—Ojemda (tovorafenib) at ~$440K/year and Korlym (mifepristone) at ~$500K–$600K/year—supports a peak U.S. pricing estimate of $500K-$750K/year for OR-449. At this pricing, first-line approval in adult ACC alone supports peak U.S. revenue of approximately $500M/year, with global peak potential of $500M–$1B/year as OR-449 expands the treated population through earlier, broader use. Two further opportunities extend this market: pediatric ACC, where OR-449 holds FDA Rare Pediatric Disease designation and Priority Review Voucher eligibility (historically valued at $50M-$100M+), and head and neck squamous cell carcinoma, where ~10% of tumors show markedly elevated SF-1 expression, a second indication that could double long-term revenue. Orphagen's commercial strategy is a B2B exit to a mid-sized oncology- or endocrine-focused pharmaceutical acquirer following Phase 1 data, consistent with recent comparables such as Jazz Pharmaceuticals' $935M acquisition of Chimerix and Servier's $2.5B acquisition of Day One Biopharmaceuticals.

TECHNICAL & COMPETITIVE ADVANTAGE

OR-449 is the only orally bioavailable SF-1 (NR5A1) antagonist in clinical development for ACC. Three independent lines of evidence identify SF-1 as a central ACC driver: (1) it is the most active transcription factor in adult ACC tumors, (2) its gene is somatically amplified in ~90% of pediatric ACC tumors, and (3) its expression correlates with disease severity in adults. OR-449 binds the SF-1 ligand-binding domain and blocks SF-1-driven transcription, producing complete growth inhibition of two preclinical tumor models, including an ACC xenograft, at oral doses translating to a 150–450 mg/day human range. In GLP toxicology studies in two species, OR-449 showed no evidence of adrenal suppression, no clinically relevant CYP inhibition, and no genotoxicity signal; this is a favorable profile relative to mitotane, whose mechanism remains poorly defined. Competing ACC programs rely on an intratumoral peptide against a non-validated target, an IV antibody-drug conjugate potentially active in only ~70% of tumors, or an immunotherapy/TKI combination with overlapping toxicity; none has reported clinical efficacy. OR-449 offers once-daily oral dosing and a mechanism supported by both genetic and functional evidence of an essential tumor-biology role, mirroring the precedent of other nuclear receptor antagonists that built multibillion-dollar oncology franchises (estrogen receptor antagonists in breast cancer, androgen receptor antagonists in prostate cancer). Drug substance and drug product manufacturing are complete through cGMP scale, and GLP safety studies are complete in two species, making the program IND-ready.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

OR-449 is protected by patents allowed in the United States and Japan, with applications pending in the EU, China, Australia, Canada, India, and Israel, providing exclusivity to 2042. Orphagen has completed a pre-IND meeting with the FDA, which responded favorably that the proposed CMC program and nonclinical package are adequate to support a first-in-human study in adult ACC. Because SF-1 is on the FDA's list of relevant pediatric oncology molecular targets and ACC also occurs in children, Orphagen holds a Rare Pediatric Disease designation for OR-449, making the program eligible for a Priority Review Voucher (historically valued at $100M+) upon first pediatric approval. The regulatory path is: (1) an initial Phase 1a/1b trial in adult ACC to establish safety, PK, and early efficacy signals; (2) a single-arm Phase 2 registrational trial supported by Breakthrough Therapy designation; and (3) a parallel Phase 1/2 pediatric trial to establish PRV eligibility. Given the lack of any therapy with demonstrated survival benefit in ACC and current NCCN guidance steering patients to clinical trials, Orphagen believes OR-449 is a strong candidate for accelerated approval as first-line therapy.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Nov. 2024	Notification of CPRIT matching funds $10.2M for a Phase 1 trial of OR-449 in adrenocortical cancer
Dec. 2026	IND filing for OR-449
May 2027	First patients enrolled in Phase 1 adult ACC trial of OR-449 at MD Anderson
June 2028	Dose escalation complete for OR-449 and Phase 1b expansion in adult ACC begins

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2001	Friends and Family	Company founding capital	$209K
2023	Early-stage bridge funding	Convertible notes	$706K
2025	Founder investment	SAFE notes and stock option exercise	$342K

USE OF PROCEEDS

Orphagen is raising an initial $2.5M note ($12.5M cap, 20% discount) to trigger first-year matching funds from its $10.2M CPRIT award, which requires a minimum $0.50 non-dilutive match per CPRIT dollar. These combined funds complete the final CMC step (cGMP tablet manufacturing) needed to trigger IND filing, support IND approval, and fund the first 12 months of Phase 1a/1b startup which will include CRO selection, clinical trial agreements, and site activation at MD Anderson and the University of Michigan. Proceeds also fund two key hires, a COO and VP of clinical development, to build the clinical operations team needed to run the trial. The goal is to enroll the first patient cohort within ~12 months, at which point Orphagen expects to raise a $12.5M Seed/Series A round — unlocking Years 2–3 of CPRIT matching (~$25M total non-dilutive plus equity capital) — to complete Phase 1a/1b dose escalation and generate the safety, PK, and efficacy signal needed for partnering or a Series B.

KEY TEAM MEMBERS

Scott Thacher, PhD, CEO and Founder 25-year veteran biotech entrepreneur with multiple partnerships developed in orphan nuclear receptor small molecule drug discovery.

Paul Crowe, PhD, VP of R&D Former senior director at Neurocrine Pharmaceuticals; pharmacologist with expertise in immunology, oncology, and preclinical development. 15-year team member at Orphagen.

Rick Hawkins, Board Member Serial entrepreneur in Austin, Texas; co-founder of Pharmaco (merged with PPD), Covance Biotechnology, and Sensus (developed Somavert, marketed by Pfizer); CEO of Lumos Pharma (2010–2024).

Andrew Dorr, M.D., CMO 30+-year veteran of oncology clinical trials with experience at NCI, Eli Lilly, Salmedix, and Ionis, with critical roles in the approval of several major oncology drugs.

PRIVO TECHNOLOGIES, INC.

First Non-Surgical Therapy for Early-Stage Oral Cancer

Manijeh Goldberg | mgoldberg@privotechnologies.com | 978-609-1465 | privotechnologies.com

COMPANY OVERVIEW

Privo Technologies, Inc. is a late-stage biotechnology company founded in 2015 and headquartered in Boston, MA, developing localized therapies for solid tumors using its proprietary nanoengineered delivery platform. Privo's mission is to redefine cancer treatment by delivering nanoengineered therapeutics directly to diseased tissue, achieving tumor eradication while preserving patients' health, function, and dignity. Its vision is to establish a new standard of care that eliminates early-stage cancer without surgery, systemic toxicity, or radiation. The company's PRV™ platform is an engineered nanotechnology system that enables locoregional delivery of highly concentrated treatments precisely where they are needed without damaging healthy tissue, offering advantages in versatility, enhanced efficacy, improved safety, validated technology, and multilayered IP. Privo has been recognized by the NCI, FDA, NIH, Forbes, and *Nature Communications*.

MARKET & COMMERCIALIZATION STRATEGY

Oral cancer represents a large, growing, and costly disease burden with significant unmet need. Current U.S. prevalence exceeds 400K, accounting for 3% of all cancers, with rates of oral cavity and pharyngeal cancers rising approximately 1% annually over the past two decades. It is also increasingly appearing in younger individuals under 40 who lack traditional risk factors. Oral cancer progresses through stages from mild dysplasia to high-grade dysplasia and carcinoma in situ (HGD/CIS, Stage 0) and ultimately invasive carcinoma, yet there are no FDA-approved therapies to prevent this transformation. The current standard of care is surgery, often combined with radiation or chemotherapy. It is invasive and debilitating, carrying a roughly 35% recurrence rate (over 85% within 12 months) along with speech and swallowing impairment, disfigurement, functional deficits, and a suicide rate up to 3.5x higher than the general population. Treatment costs range from about $50K for surgery alone to over $200K for combination regimens, before accounting for recurrence and long-term complications, and oral cancer is the most costly cancer in the U.S. on a per-patient basis. The market opportunity is substantial. U.S. HGD prevalence is 4.3M and CIS prevalence is 36.1K, with an additional 6.6M+ patients in the EU, 1.7M+ in Japan, and 1.7M+ in select rest-of-world markets. PRV111 has strong clinical and physician validation. KOLs at Cleveland Clinic and Baptist Health describe consistent, reliable, tissue-preserving results, and double-blinded physician market research found 95% positive perception, with 17 of 17 physicians viewing the safety profile favorably and 16 of 17 considering the preliminary data from CLN-001 clinically sufficient. Taken together, this positions PRV111 to potentially replace the standard of care by eliminating surgical reconstruction and minimizing recurrence across a multibillion-dollar opportunity.

TECHNICAL & COMPETITIVE ADVANTAGE

Privo's PRV™ platform is a versatile nanotechnology system that delivers highly concentrated treatments directly to tumors and draining lymph nodes while sparing healthy tissue and avoiding systemic exposure. The platform combines four components: (1) nanoparticles that encapsulate and protect active pharmaceutical ingredients while enabling rapid, sustained local release; (2) a matrix built from GRAS excipients that defines the dosage form across patches, injectables, hydrogels, foams, and pastes; (3) an adjuvant primer or activator that drives uniform drug distribution and penetration while limiting spread to surrounding tissue; and (4) a kitted system customized to the specific cancer being treated. This design allows the platform to encapsulate small molecules, proteins, mAbs, and combination therapies, and to be tuned for indication-specific needs like nanoparticle size, release profile, and depth of penetration. The platform is versatile across modalities and form factors, has an excellent safety profile that avoids healthy tissue and systemic circulation, and is fully biodegradable and biocompatible.

Its technology is validated across four clinical trials, with a breakthrough 94% pCR rate and 100% surgery elimination in Phase 2/3 HGD/CIS, and it is protected by 10 issued or allowed patents and 26 filed patents, plus trade secrets and no bioequivalence pathway for generics. Clinically, ICP-MS platinum quantification from the CLN-001 trial (published in *Nature Communications*) confirmed that PRV111 concentrates cisplatin at 259x higher levels in tumor and 80x higher in lymph nodes versus IV cisplatin, while delivering 182x lower blood levels, with zero systemic toxicity across more than 300 patch applications. Because HGD/CIS carries subclinical lymph node risk even in N0 patients, this lymphatic penetration addresses occult nodal spread preemptively, something no other non-surgical modality can do. The platform also amplifies cisplatin's validated mechanism of action by adding an immunomodulatory dimension, turning cold tumors hot through a 20x to 40x increase in tumor-infiltrating lymphocytes and driving both cytotoxic and immunologic responses. Beyond oncology, Privo has extended the nanoparticle technology into oral GI drug delivery, developing a gut-targeted treatment that delivers NAADP to regenerate damaged intestinal epithelium, with efficacy demonstrated across three preclinical studies in colitis and radiation-induced injury models. Together, these attributes position the PRV platform as a de-risked, broadly applicable foundation for treating a wide range of cancer and non-cancer diseases.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Privo's PRV™ platform is protected by multiple layers of intellectual property that create strong barriers to generic competition. The company holds 10 issued or allowed patents and has 26 additional patents filed, providing protection through the mid-2040s. Beyond patents, multiple trade secrets cover the proprietary nanoparticle formulation and GMP manufacturing processes. PRV111 also carries Orphan Drug designation with 7-year regulatory exclusivity for carcinoma in situ (CIS), with potential for additional products. Critically, as a local, topical non-systemic therapy, there is no bioequivalence pathway for generics; any competitor would have to conduct new clinical trials and overcome years of accumulated nanoparticle and manufacturing trade secrets.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
08/2018	NCI Bridge Award provided $3M in support of Privo's current clinical study. Only four companies in the United States received this prestigious award.
09/2019	FDA Orphan Division provided $2M in support of some of additional requests by the FDA
09/2020	Privo CEO and founder Dr. Goldberg is named the winner of AIM-HI Accelerator Fund's Women's Venture Competition
06/2021	Privo presents Phase II data for PRV111 at ASCO Annual Meeting 2021
08/2021	Privo awarded $3M NIDCR NIH Commercialization Readiness Pilot Grant as part of Phase 2b SBIR
02/2022	Presentation at the 24th Annual Bio CEO and Investor Conference
02/2022	NCI NOSI Award provided $2.5M in support of PRV211 intraoperative Phase 2 trial
08/2022	Privo announces publication in *Nature Communications*, https://www.nature.com/articles/s41467-022-31859-3
09/2022	NCI Direct to Phase 2 SBIR contract for $2M in support of development of PRV311 for treatment of cervical cancer in low-resource settings
12/2022	Privo receives IRB approval for CLN-004 study investigating PRV211 in solid tumors
02/2024	Privo selected by NCI as a Nanotechnology Characterization Laboratory for Collaboration
02/2024	Privo selected for presentation of PRV131-related abstracts at AACR Annual Meeting 2024
08/2024	NCI SBIR Phase IIB Bridge Award for $4.5M in support of pivotal trial for PRV111

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Grant	NCI Bridge Award	$3M
2021	Grant	NIDCR Phase 2b SBIR	$3M
2022	Grant	NCI NOSI SBIR	$2.5M
2022	Grant	NCI Direct to Phase II SBIR Contract	$2M
2024	Grant	NCI SBIR Phase IIB Bridge	$4.5M

USE OF PROCEEDS

$30M for Phase 3 operations and marketing registration for PRV111 in oral CIS.

KEY TEAM MEMBERS

Manijeh Goldberg, PhD, has over 25 years of industry experience. She has taken several healthcare products from concept to commercialization, including involvement in five separate start-ups, one of which was acquired for $475M. She has developed U.S. key opinion leader (KOL) relationships, successfully lobbied to get PRV111 into a large, NIH-funded clinical study, planned and executed training, and helped drive on-time trial enrollment. Following successful completion of the Phase 1/2 study examining PRV111, Dr. Goldberg has been focused on driving the execution of a second generation of Privo's products while simultaneously pushing PRV111 through a commercialization-enabling trial.

James Mackay, PhD, has over 30 years of industry experience, and notably led the sucecssful $1.2B acquisition and transition of Ardea Biosciences into AstraZeneca. Prior to Ardea, he held a number of senior roles in AstraZeneca's clinical development function including portfolio management of all of AstraZeneca's clinical resources and management of the global budget for building/maintaining drug development partnerships.

Albert Collinson, PhD, has over 30 years of experience in the pharmaceutical and biotechnology industries. He was the president and CEO at Theracos, Inc. from 2009 to 2024, during which the company successfully developed Brenzavvy, an SGLT-2 inhibitor, to FDA approval and market introduction. Prior to this, Dr. Collinson founded and served as president and chief executive officer of Opsonic Therapeutics from 2009 to June 2014, a privately held biotechnology company engaged in the development of the next generation of antibody therapeutics. Dr. Collinson also served as the CBO of Rib-X Pharmaceuticals from 2004 to 2009, the senior vice president of business development at Phylos, Inc. from 2000 to 2004, and the vice president of global research and development licensing at BASF Pharma from 1998 to 2000.

TIPPINGPOINT BIOSCIENCES, INC.

First-In-Class Small Molecule Therapeutic Targeting the Aberrant Chromatin State

Laura Hsieh | laura.hsieh@tippingpointbiosciences.com | 650-861-2300 | tippingpointbiosciences.com

COMPANY OVERVIEW

TippingPoint Biosciences is a UCSF spinout developing first-in-class epigenetic therapeutics that target disease-specific protein-protein interfaces previously considered undruggable. The company's platform enables detection of mesoscale, disease-specific conformational states within chromatin complexes, states that are invisible to static structural biology or PDB-trained AI models. TippingPoint's lead program targets a PRC2 conformation specific to the H3K27M oncohistone mutation, present in approximately 80% of diffuse intrinsic pontine glioma (DIPG) cases, a uniformly fatal pediatric brain cancer with no approved targeted therapies. The company's compounds show selective activity in patient-derived DIPG cells while sparing healthy cells. Beyond DIPG, TippingPoint is extending the platform to triple-negative breast cancer and additional indications. Founded by CEO Laura Hsieh, PhD, based on technology invented during her postdoctoral work in Geeta Narlikar's lab at UCSF, the company has raised nearly $7M in funding to date and is an NCI Concept Grant awardee. The company is working toward in vivo proof-of-concept in DIPG as the key milestone unlocking its Series A.

MARKET & COMMERCIALIZATION STRATEGY

TippingPoint's initial indication, DIPG, is a rare but high-value market. Approximately 2,000 patients per year in the United States are diagnosed with H3K27M-driven tumors. Annual pricing for rare pediatric oncology therapeutics of this kind is estimated at $500K-$1M per patient, supporting a $1B-$2B market opportunity in the United States. This is validated by two data points: Jazz Pharmaceuticals acquired Chimerix, developer of the first and only approved DIPG/DMG therapy (Modeyso), for $935M in 2025, and Modeyso generated $48M in net sales in its first partial year on the market (5 months), a strong result for a disease this rare. TippingPoint plans to retain and advance its DIPG asset independently given the high per-patient value and precedent for rare-disease biotechs to capture significant value through acquisition or commercialization on their own. Because the platform detects disease-specific conformational states rather than static binding pockets, it is extensible beyond DIPG to larger indications, including TNBC, a U.S. market estimated at approximately $3.1B. For TNBC and other larger-market programs, the company anticipates partnering with or co-developing alongside pharma, or out-licensing, to access the infrastructure needed to compete at scale.

TECHNICAL & COMPETITIVE ADVANTAGE

TippingPoint's platform is built on a proprietary chromatin reconstitution approach that captures mesoscale, disease-specific conformational states of protein complexes, states that are invisible to conventional structure-based drug discovery and to PDB-trained AI models, which rely on static, crystallizable structures. This allows the company to target protein-protein interfaces previously considered undruggable. Most competing epigenetic approaches rely on indirect biochemical proxies or static structural snapshots; TippingPoint's platform instead provides a direct, scalable, and reproducible functional readout of the disease-relevant conformational state itself, allowing it to identify compounds that other approaches would miss entirely.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

TippingPoint holds an exclusive license from UCSF to the core platform technology, with a priority date of January 2022. The company is pursuing additional composition-of-matter protection on its lead compound series as the program advances toward IND-enabling studies. TippingPoint's regulatory strategy for its lead DIPG program follows the standard oncology path, with in vivo proof-of-concept as the near-term milestone preceding IND-enabling toxicology and manufacturing work. The company anticipates leveraging FDA orphan drug and potentially rare pediatric disease designations given DIPG's status as a rare, fatal pediatric cancer with no approved targeted therapies.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2022	Priority date filed for methods patent at UCSF; Won Mission Bio Capital (MBC) Platinum Ticket
2023	Spun out of UCSF and raised pre-seed capital
2023-2024	Won 3 Golden Tickets sponsored by pharma
2025	Won NCI Concept Grant award; founding publication (Hsieh et al., *SLAS Discovery*)
2026	Raised $4.5M seed round; received term sheet from top 5 pharma for pilot collaboration
2027	In vivo proof-of-concept and mechanism of action determined
2028	Series A raise

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2023-2025	Pre-Seed	Initial pre-seed financing to support platform development and founding team	$2.2M
2026	Seed	Seed round to advance lead DIPG program toward in vivo proof-of-concept	$4.5M
2025	Non-Dilutive	NCI Concept Grant award to progress DIPG asset	$300K

USE OF PROCEEDS

TippingPoint is currently raising $5M in a Seed Plus round. Proceeds will be used to expand the platform to establish a lead compound in TNBC, a secondary indication, and to build out the company's AI capabilities to support platform development. Funds will also support the pilot collaboration with the pharma partner.

KEY TEAM MEMBERS

Laura Hsieh, PhD: CEO and Founder Invented the platform technology during her postdoctoral fellowship in Geeta Narlikar's lab at UCSF; leads scientific strategy, business development, and fundraising; has a strong track record securing grant funding.

Savi Ramurthy, PhD: Chief Technology Officer Drug hunter with a track record of delivering multiple drugs from screening through the clinic; background from FibroGen and Novartis.

Gary Li, PhD: Interim Chief Scientific Officer 3rd employee and venture advisor at RayzeBio; track record of successful exits across his start-ups, with experience fundraising, building teams, and running startup operations.

TRETHERA CORPORATION

Oral Small Molecule Inhibitor of Deoxycytidine Kinase (dCK)

Kenneth Schultz | KSchultz@trethera.com | 213-449-3248 | Trethera.com

COMPANY OVERVIEW

Trethera is a clinical-stage biotechnology company developing TRE-515, a first-in-class oral small molecule inhibitor of deoxycytidine kinase (dCK) for the treatment of cancer and autoimmune diseases. dCK is a rate-limiting enzyme in the nucleoside salvage pathway, which cancer cells and aberrantly activated immune cells use to support DNA synthesis, proliferation, and repair under therapeutic stress. TRE-515 has completed Phase 1 dose escalation in more than 30 heavily pretreated solid tumor patients, demonstrating a favorable safety profile with no dose-limiting toxicities and encouraging clinical activity. The program is supported by pathway-specific biomarkers, including [18F]CFA PET imaging and a plasma nucleoside index, which enable direct assessment of target engagement and may support future patient selection. Trethera is advancing TRE-515 as a pipeline-in-a-product, with opportunities in metastatic castration-resistant prostate cancer, KRAS-driven lung cancer combinations, and autoimmune/neuroinflammatory diseases. The program has received FDA Fast Track designation in prostate cancer and Orphan Drug designation for acute disseminated encephalomyelitis (ADEM) and optic neuritis. Trethera holds an exclusive UCLA license and robust intellectual property protection with potential exclusivity through 2045.

MARKET & COMMERCIALIZATION STRATEGY

Metastatic castration-resistant prostate cancer (mCRPC) remains a major unmet medical need, with approximately 34,000 prostate cancer deaths annually in the United States and 5-year survival of only ~30% for patients with distant metastatic disease. The global prostate cancer therapeutics market is approximately $12.9B today and projected to reach ~$29.2B by 2035, with the United States representing at least 35% of global sales. TRE-515 is being developed for PSMA-positive mCRPC patients receiving Pluvicto, an FDA-approved radioligand therapy. Although Pluvicto has changed clinical practice, its objective response rate remains approximately 30%, leaving most patients without meaningful tumor response. TRE-515 inhibits dCK and blocks the nucleoside salvage pathway, a DNA repair pathway upregulated after radiation, with the goal of improving response rates and durability when combined with Pluvicto. FDA has granted TRE-515 Fast Track designation for this combination strategy. Commercialization will focus on demonstrating improved clinical benefit, manageable safety, oral convenience, and seamless integration into existing mCRPC treatment pathways. Urologic oncologists will be key adopters, while payers will evaluate value based on response, survival, quality of life, and cost-effectiveness.

TECHNICAL & COMPETITIVE ADVANTAGE

TRE-515 is a first-in-class, orally administered small molecule inhibitor of dCK, the rate-limiting enzyme in the nucleoside salvage pathway. This pathway supports DNA synthesis and repair in proliferating cancer cells but appears largely dispensable for normal adult tissues, including major hematologic and immune cell populations. By selectively targeting this pathway, TRE-515 is designed to impair tumor growth and radiation-associated DNA repair while avoiding the broad cytotoxicity typical of many anticancer therapies. Clinically, TRE-515 has demonstrated a favorable tolerability profile in more than 30 heavily pretreated solid tumor patients, with no observed dose-limiting toxicities and only Grade 1 or 2 drug-related adverse events. Importantly for combination use with Pluvicto and other radiation-based therapies, TRE-515 has not shown pancytopenia or clinically meaningful myelosuppression. TRE-515 also offers practical commercial advantages as a convenient oral capsule intended for once-daily dosing. Its development is supported by three pathway-specific biomarkers: the plasma dC/dU nucleoside index and [18F]CFA PET imaging, enabling confirmation of target engagement, dose optimization, and potential patient selection. No leading prostate cancer therapy targets the nucleoside salvage pathway, giving TRE-515 a differentiated mechanism with broad combination potential.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Trethera is advancing TRE-515 under an open oncology IND, with an active Phase 1 solid tumor program and planned expansion into biomarker-guided combination studies. The lead regulatory strategy in oncology is focused on PSMA-positive mCRPC in combination with Pluvicto/radioligand therapy, supported by FDA Fast Track designation for TRE-515 in combination with radiation therapy. This pathway is intended to enable closer FDA interaction and potentially support expedited development if clinical data demonstrate meaningful benefit. Trethera has also secured FDA Orphan Drug designation for ADEM and optic neuritis, supporting broader development of TRE-515 across neuroinflammatory and autoimmune indications. In mCRPC, Trethera plans to use clinical response, safety, and biomarker evidence from the Pluvicto combination study to support a future Breakthrough Therapy designation filing if the data show substantial improvement over available therapy. Trethera holds an exclusive global license from UCLA to develop TRE-515 across all disease indications. The company's patent estate includes issued U.S. and international composition-of-matter and method-of-use patents, including the original UCLA composition-of-matter estate and second-generation structural patent U.S. #11,446,307, with additional filings that may extend protection and exclusivity through 2045.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2022	FDA granted Orphan Drug designations for TRE-515 in optic neuritis and ADEM, supporting development in rare neuroinflammatory autoimmune diseases.
2022	Strengthened TRE-515 patent estate with issued second-generation structural patent protection, extending key IP runway into the 2040s.
2023	NIH awarded Trethera grants for solid tumor oncology, lupus, ADEM, and Crohn's disease, with initial aims achieved.
2025	NIH awarded Trethera Phase 2 follow-on grants for prostate cancer, lupus, Crohn's disease, and lung cancer.
2025	FDA granted Fast Track designation for TRE-515 in combination with radiation therapy for metastatic castration-resistant prostate cancer.
2025	Reached the maximum tested dose in Phase 1 dose escalation, treating more than 30 heavily pretreated solid tumor patients with no dose-limiting toxicities observed.
2026	Opened Mass General ALS Expanded Access clinical collaboration to evaluate TRE-515 in up to six patients with advanced ALS.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2019–2025	Private	Seed and Seed Preferred financings from angels, founders, Board members, foundations, and patient advocates	$15M
2022–2025	NIH Grants	Non-dilutive SBIR funding across oncology, optic neuritis, ADEM, lupus, Crohn's, and lung cancer	$17M

USE OF PROCEEDS

Trethera is seeking up to $50M to build the company and advance TRE-515 into clinical expansion. Proceeds will fund the TRE-515 plus Pluvicto prostate cancer trial, the healthy volunteer biomarker study, continued CMC scale-up, and trial execution now that key sites are open and IRB approvals are in place.

KEY TEAM MEMBERS

Kenneth A. Schultz, MD, Chairman and CEO Former physician, McKinsey consultant, Halozyme VP of Innovation/Strategy/BD, and Medtronic Diabetes chief strategic officer. Led major pharma partnerships exceeding $5B in aggregate deal value and advanced TRE-515 from bench to clinic.

Cary Talbot, Chief Operating Officer Former Medtronic Diabetes leader with deep experience in product development, systems engineering, marketing, IP, and operations. Registered U.S. Patent Agent and inventor on 51 issued U.S. patents, including artificial pancreas technology.

CORDANCE MEDICAL, INC.

Non-Invasive, Focused Ultrasound System to Precisely Open the Blood-Brain Barrier

Bhaskar Ramamurthy | bhaskar.ram@cordancemedical.com | 650-383-0331 | Cordancemedical.com

COMPANY OVERVIEW

Founded in 2018, Cordance Medical develops technology to non-invasively open the blood-brain barrier (BBB), which is the tightly sealed lining of the brain's vasculature that blocks roughly 98% of molecules, including most drugs and diagnostic biomarkers, from crossing. The Platform: The company's platform, NeuroAccess, uses low-intensity focused ultrasound together with IV microbubbles to temporarily open the BBB at a targeted region of the brain. The microbubbles oscillate under the ultrasound beam, briefly opening the barrier for a few hours before it closes on its own. The system monitors the bubbles' reflected signals in real time to keep the opening within safe limits. This enables two applications: (1) liquid biopsy: Biomarkers (cell-free DNA, RNA, proteins, extracellular vesicles) pass from diseased tissue into the bloodstream, allowing brain tumor diagnosis from a simple blood draw. (2) Drug delivery: Large molecules—biologics, antibodies, gene therapies—reach targeted brain regions that they otherwise couldn't. Differentiation: While earlier focused-ultrasound devices established that the BBB opening is safe (across ~300 human subjects), they were large, costly, or invasive. Cordance's next-generation system is fully non-invasive, portable, and designed for community settings. Market and Roadmap: The initial indication is brain tumor diagnosis (glioblastoma and metastatic brain cancers; ~168,000–193,000 U.S. patients diagnosed annually), with a roadmap extending to Alzheimer's, Parkinson's, depression, and traumatic brain injury. Leadership: Michael Lesh (executive chairman) and Bhaskar Ramamurthy (co-founder, CEO). Scientific advisors include SonoBiopsy co-founders Eric Leuthardt and Hong Chen (Washington University in St. Louis) and Kirk Tanner (National Brain Tumor Society). IP and Funding: 8+ patents granted and ~15 pending. Funded through private and institutional investors and NSF/NIH grants; as of early 2026, Cordance has a signed term sheet from Sonder Capital to raise $10M at a $14M pre-money valuation.

MARKET & COMMERCIALIZATION STRATEGY

The initial opportunity is enabling liquid biopsy (LBx) for brain tumors. The device (Cordance/SonoBiopsy) uses focused ultrasound to release brain tumor biomarkers into the bloodstream so a routine blood draw can characterize tumors that current LBx can't reach. Total U.S. LBx oncology market: ~$9.3B (665K metastatic patients × ~$3.5K/test × ~4 tests/patient/year), growing ~25% annually. Currently serviced market: ~$1.7B in 2023 at ~18% penetration. Cordance's incremental market: Brain tumors are excluded from today's LBx market. By enabling blood-based characterization for the $168K–$193K newly diagnosed U.S. brain tumor patients per year, Cordance adds an estimated ~$455M–$475M to LBx manufacturers' serviceable market (a 25–30% increase). Cordance's own serviceable addressable market: ~$329M–$378M, based on 18% penetration × 168–193k patients × 4 procedures/patient/year × $2,720/procedure. Commercialization plan: Customer tiers (priority order): academic medical centers with NCI-designated cancer centers (top priority); hospital systems; community cancer centers. Decision-makers: Neuro-oncology department chairs, tumor board chairs, cancer center directors, and clinical trial office directors. Phased timeline: 2027–2028 (Phase 1, precommercial): hire commercialization lead, scientific outreach/publications, TCET Letter of Intent, place IDE-cleared devices in early-adopter sites, complete pilot study, submit IDE. Sales/marketing budget scales from ~$100K (0.5 FTE) to ~$3M (2→5 FTE). 2028–2029 (Phase 2, launch): PMA approval, expand commercial team, place approved devices in Tier 1 sites. 2030+ (expansion): roll out to Tier 2/Tier 3 community centers and pursue geographic expansion.

TECHNICAL & COMPETITIVE ADVANTAGE

Technical Advantages: Fully non-invasive, MRI-free guidance. NeuroAccess delivers low-power focused ultrasound accurately into the brain without a craniotomy, surgical implant, or live MRI guidance. When the cap is placed on a patient's head, the device calculates the cap's position relative to that patient's individual brain anatomy and steers the ultrasound to the physician-specified region of interest. This is protected by granted patents in the United States, Japan, Australia, and the EU (Family 1115). Competing systems (InSightec, Carthera) solve the skull-imaging problem with expensive MRI-guided or invasive craniotomy-based approaches. Patient movement is allowed with our device; there is no fixation frame or restraint. Using EM registration to the patient's MRI plus a forehead-mounted tracker, the device recalculates cap position in real time and selects which transducers to fire, so the patient's head is never tethered or immobilized. Competitors require fixation frames or physically restrain the patient. Closed-loop cavitation safety monitoring: The device reads harmonic, ultraharmonic, subharmonic and broadband noise content reflected from the microbubbles to confirm they are vibrating in a safe "stable cavitation" mode, and turns power down automatically if vibration becomes unsafe. Cordance has developed proprietary feedback loop algorithms on top of the published McDannold concept. Pre-opening focus confirmation: The device confirms the ultrasound focus is truly at the physician-specified location before the BBB is opened and can correct the focus in real time if it is off-target. Brain-wide access: The form factor is designed to reach targets across the whole brain, including a pipeline capability to open very large regions (whole lobes or hemispheres) for diffuse disease such as late-stage Alzheimer's. Defensible IP portfolio: 13 patents with patent families spanning non-invasive guidance, motion accommodation, safety, efficacy, and applications. Several have been deliberately reserved beyond the first product to sustain a long-term competitive edge. Only two underlying technologies come from expired/open-literature sources; the rest are Cordance-invented or licensed (BBB LBx concept licensed from WashU). Competitive advantages: The only portable, outpatient-capable BBB-opening platform. It can be used in clinics, infusion centers, and hospitals, whereas all major competitors are hospital-only and require some combination of fixation frames, live MRI, craniotomy, surgical implants, patient restraint, or a neurosurgeon. The device has a large cost advantage over standard of care. The non-invasive procedure runs in an infusion clinic setting (~$6,000 charge, 30–60 min outpatient, needing only an infusion chair and a nurse/operator) versus invasive surgical biopsy ($15,000–$51,000, 1+ inpatient days, MRI room, inpatient bed, three technicians, and a neurologist/neuro-oncologist). Payers save roughly $7,550–$43,550 per patient (a 50–85% reduction), with Medicare system-wide savings potential of $189M–$2B annually. FDA Breakthrough Device designation (granted Oct 23, 2023; Q232071), which recognizes substantial advantages over existing alternatives and provides strategic FDA engagement through the TAP program, de-risking the regulatory path. Enables serial, precision-medicine monitoring. Because it is non-invasive and repeatable, it enables serial LBx for tracking tumor mutations and recurrence over time, something surgical biopsy cannot practically offer, while creating aligned incentives across patients, physicians, hospitals, LBx partners, and pharma.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Device: NeuroAccess™ is a system that transiently opens the BBB to increase cell-free DNA (cfDNA) concentration in blood, facilitating noninvasive LBx for brain tumors. It is not intended to diagnose or treat tumors. Regulatory pathway: Likely Class III PMA due to the device's novelty. To accelerate review, Cordance proposes a Modular PMA approach, submitting non-clinical, clinical, and manufacturing modules independently for early FDA feedback, with modules starting in parallel with clinical studies. Key FDA engagements: Breakthrough Device designation accepted Oct 23, 2023 (Q232071), enabling close FDA interaction (sprint discussions, protocol agreements, pre-submission review). TAP Program (Total Product Lifecycle Advisory) admission, giving early/frequent strategic FDA communication plus payer, clinical, and market-access expertise. The current strategy was developed in consultation with FDA via TAP. Proposed initial indication: The NeuroAccess™ system is indicated for adults (age 22 and above) with known or highly suspected brain tumors, used by trained healthcare professionals to transiently open the BBB and increase the concentration of cfDNA in the blood circulation. This increased analyte concentration can then aid validated LBx tests in oncology. Development sequence: Non-clinical testing (non-GLP and GLP) include bench tests for electrical safety, biocompatibility, software validation, mechanical stress; animal studies. IDE submission targeted Q4 2026/Q1 2027. FDA clearance/clinical trial to begin Q3/Q4 2027 run under GCP; first site selected and aligned on protocol. Post-market surveillance: adverse-event reporting, post-market studies as needed, QSR compliance. Future indications (separate strategies): therapy delivery (drug + BBB opening): a new drug/device combination application per drug, beginning after first IDE clearance; Cordance or investigator-sponsored. Non-BBB applications: academic collaborations (e.g., Stanford) for glymphatic flow in stroke and chronic pain, handled case-by-case. Indication population: Adults 22+ with known or highly suspected brain tumors, used by trained healthcare professionals. Intellectual property: The following describes the IP across the different families of patents: S 11534630, Japan 7063882, Australia 2017305228, EU 17837489.8 "Ultrasound Guided Opening of Blood-Brain Barrier" The foundational patent for non-invasive guidance; when the Cordance cap is placed on a patient's head, the device calculates the cap's position relative to that patient's brain anatomy and steers low-power focused ultrasound to a physician-specified region of interest to open the BBB, without the MRI guidance or craniotomy that competing systems (InSightec, Carthera) require. (China 201780047574.6 pending.) US 11857812 B2, Australia 2022241580, Japan 7531542 "Ultrasound Guided Opening of Blood-Brain Barrier" A continuation of the US 11534630 invention describing a second, EM-based non-invasive method to locate the cap relative to the patient's internal anatomy: electromagnetic alignment of anatomical features to the patient's MRI, then a forehead-mounted tracker follows head motion in real time so the device selects which low-frequency

transducers to fire, allowing the patient to move freely rather than being tethered or immobilized. US 17/874166, Japan 2022-545376 “Coupling the cap to skull” A fillable water- or oil-filled jacket inserted between the rigid cap and the head that efficiently transfers ultrasound energy through the skull that conforms to each patient’s head shape to mechanically stabilize the cap (airbag-like), serves as a disposable revenue item, and adds a safety barrier between skin and device. (China 202180018631.4, Australia 2021212658, Europe 21747882.5 pending.) US 12017093 B2 “Methods and Systems for Confirming Focus of Ultrasound Beams” A method to verify, after the cap is placed but before the BBB is opened, that the ultrasound focus is truly at the physician-specified location, critical because acoustic pressure (and thus BBB opening) is highest at the focus; it processes signals from the monitoring transducers to calculate focal location and, if off-target, supports real-time correction. (PCT/US2023/028659 and CIP 18/671236 pending.) US 11667975, US 12054788, US 12310697 “Methods and Systems for Noninvasive and Localized Brain Liquid Biopsy Using Focused Ultrasound” Licensed from Washington University, this family covers the core SonoBiopsy concept: opening the BBB at a diseased site so biomarkers such as cell-free DNA cross into the bloodstream, where they can be drawn from a peripheral site (e.g., the arm) and analyzed for concentration and mutation profile, enabling non-invasive LBx (CON 18/750,459 and CIP 19/214,978 pending.)

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3/Q4 2027	Complete the early feasibility study demonstrating safe BBB opening in human
Q4 2029	Complete the PMA studies to support the initial indication of non-invasive liquid biopsy of the brain
2030	Initiate commercialization

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018-2024		Investments accepted via SAFE notes	
2024		All SAFES converted plus new money	$10M
2026		Completed a Sonder Capital-led round of $10M.	$10M

USE OF PROCEEDS

Cordance Medical seeks $25M-$30M to complete the PMA registration study for the first indication and accelerate commercialization.

KEY TEAM MEMBERS

Bhaskar S. Ramamurthy, PhD — Founder & CTO, Bhaskar Ramamurthy is the founder and CTO of Cordance Medical, based in Mountain View, California. He is an engineering leader with over 18 years of experience in the medical device field (other profiles cite 25+ years in the design and development of medical devices), with deep specialization in ultrasound engineering. He has held roles at SRI International (Executive Director, Ventures), Innervision (CTO), Siemens, and Acuson. At SRI International he worked on intellectual property strategy, commercialization, and the creation of spin-offs; at Innervision he developed a diagnostic imaging system for imaging obese patients; and at Siemens and Acuson he led the development of several widely adopted diagnostic ultrasound technologies. He is also President of Pacific Science Consulting.

Michael D. Lesh, MD, FACC — Executive Chairman, Michael Lesh is a cardiologist, inventor, and serial medical-device entrepreneur who serves as Executive Chairman of Cordance Medical. He holds degrees in computer science, electrical engineering, and biomedical engineering from MIT, with medical training at UCSF and the University of Pennsylvania, and is a Professor of Medicine and former Chief of Cardiac Electrophysiology at UCSF. He is the author of over 200 scientific papers, book chapters, and books, and an inventor on over 250 patents. His research at UCSF produced an early atrial-fibrillation ablation method commercialized by Atrionix, which was acquired by Biosense/Webster in 1999. He went on to found, chair, and lead Appriva Medical, which developed the first trans-catheter left-atrial-appendage occlusion device (PLAATO) to prevent stroke—patents that form the basis of the Watchman device—as well as Mitralife (acquired by Medtronic), Evera Medical, and Middle Peak Medical (acquired by Symetis).

GRADIENT MEDICAL

Next-Generation Cancer Ablation Platform

Jordan Fong | jordan.fong@gradient-medical.com | Gradient-medical.com

COMPANY OVERVIEW

Gradient Medical is developing the INSPIRE System, a next-generation pulsed electric field (PEF) ablation platform designed to treat inoperable solid tumors while simultaneously stimulating a systemic anti-tumor immune response. Unlike conventional thermal ablation technologies, INSPIRE uses ultrashort, high-energy electrical pulses to selectively destroy cancer cells without damaging surrounding critical structures such as blood vessels and bile ducts. The company is initially focused on liver, lung, and pancreatic cancers, where existing treatment options are limited and patient outcomes remain poor. Since its founding in 2020, Gradient Medical has secured more than $2.5M in NIH funding, leveraged over $10M in supporting academic research, and generated extensive preclinical evidence demonstrating safety and efficacy in both large animal models and veterinary cancer patients.

MARKET & COMMERCIALIZATION STRATEGY

Gradient Medical is targeting the rapidly expanding interventional oncology market, where the global tissue ablation market is projected to exceed $15B, with the oncology ablation segment alone expected to surpass $4B over the next decade. INSPIRE is positioned to address major limitations of existing thermal and pulsed field technologies by enabling rapid treatment of tumors located near critical anatomy while reducing procedure complexity and operating room time. The commercialization strategy begins with a 510(k)-cleared system for soft tissue ablation before expanding into additional oncology indications, bronchoscopic lung applications, benign prostatic hyperplasia, and other soft tissue diseases. The platform's capital equipment model, combined with recurring disposable applicator sales, creates a scalable revenue model, while future opportunities include combination therapies with immuno-oncology drugs and strategic partnerships with established medical device companies.

TECHNICAL & COMPETITIVE ADVANTAGE

INSPIRE combines several technical advantages that differentiate it from both thermal ablation systems and competing pulsed field platforms such as NanoKnife and the Aliya System. The technology produces large, spherical ablation zones up to 4 cm in diameter using a single applicator in less than five minutes, dramatically reducing procedure time while simplifying physician workflow. Proprietary waveform algorithms minimize cardiac stimulation, preserve critical anatomy, eliminate heat sink effects, and allow real-time visualization of treatment zones using ultrasound and CT imaging. Preclinical studies involving more than 100 large animal safety procedures and 200 veterinary oncology patients have demonstrated reproducible safety, efficacy, and durable tumor control, including treatment adjacent to major blood vessels where conventional thermal ablation often fails. These capabilities position INSPIRE as a platform that improves speed, precision, safety, and immune activation while reducing procedural complexity.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Gradient Medical has established a well-defined regulatory strategy centered on the FDA's 510(k) pathway for soft tissue ablation following a successful pre-submission meeting that confirmed this regulatory route. The company is developing an IEC 60601-compliant clinical system with Blur Product Development while simultaneously preparing GLP animal studies and verification and validation testing prior to FDA submission. Existing reimbursement pathways are expected to support early commercialization through established CPT codes for soft tissue ablation procedures. Gradient's intellectual property portfolio includes two issued U.S. patents and multiple international patent applications covering proprietary pulse waveforms, treatment volume control, thermal management, immune modulation, and arcing mitigation. Together, these patents create substantial barriers to entry while protecting the core technology underlying the INSPIRE platform.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
March 2025	INSPIRE System Isolation Diagram Designed
May 2025	Industrial /GUI Design
July 2025	FDA Pre-Submission Meeting #1 Completed Sep. 2025
Sep. 2025	Phase II STTR Awarded for INSPIRE System Commercialization
Feb. 2026	Executive Advisor engaged with plans to transition to CEO
April 2026	Commencement of Commercial Development with Blur Product Development
May 2026	GLP Preclinical Animal Study Developed
June 2026	Freedom to Operate-like analysis by Wilson Sonsini Patent Group
Sep. 2026	FDA Pre-Submission Meeting #2
Jan. 2027	$5M raised
April 2027	Regulatory Device manufacturing
Sep. 2027	GLP Animal Study
Feb. 2028	510(k) submission packet
Oct. 2028	Clinical Trial Initiation

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	NIH Grant	Feasibility of a multi-phase algorithmic non-thermal ablation technology for inoperable tumors	$259K
2021	NSF Grant	Pulsed electric field mediated intradermal vaccine delivery	$255K
2022	NIH Grant	Feasibility of INSPIRE technology to enhance CRISPR mediated genome editors in vivo	$251K
2025	NCBC Loan	North Carolina Biotech Loan for commercial/business activities	$650K
2025	NIH Grant	Commercialization of algorithmic non-thermal ablation technology for inoperable tumors	$2.3M

USE OF PROCEEDS

Gradient Medical is seeking $5M to complete the final stages of product development and regulatory preparation over the next 18–24 months. The investment will support development of a production-ready, regulatory-compliant INSPIRE generator and disposable applicator, completion of GLP safety studies, required bench testing, verification and validation activities, manufacturing readiness, and preparation and submission of the FDA 510(k) application. These milestones are intended to position the company for market clearance, clinical adoption, and strategic commercialization partnerships while significantly reducing technical and regulatory risk.

KEY TEAM MEMBERS

Ken Coffey — Executive Advisor Will transition to CEO once funding is secured. He has experience bringing PFA devices through the FDA and raising money.

Michael Sano — Inventor and IRE/PFA expert Has been working in the IRE space for the past 15 years and has designed the technology from the ground up to create large ablations.

Darren Dasburg — Business Advisor Previous experience in scaling biotech companies and was brought on in 2021 as an executive in residence.

Jordan Fong — Co-founder and Engineer Specializes in MedTech and entrepreneurship and is the project manager for both the generator and applicator.

ISONO HEALTH, INC.

AI-Powered, Hands-Free Wearable and Automated Breast Ultrasound Imaging System

Neda Razavi | neda@isonohealth.com | 650-507-6601 | isonohealth.com

COMPANY OVERVIEW

iSono Health is building the world's first longitudinal breast imaging data platform: a wearable, robotic, AI-powered 3D quantitative ultrasound that compounds in diagnostic intelligence with every scan. We commercialized our FDA-cleared platform, which operates outside the radiology suite in clinics, with no sonographer needed. Now we're turning that hardware into a data engine, entering through the sharpest wedge in women's health, breast implant surveillance, one of many applications this platform unlocks. The problem: Breast imaging today is episodic, isolated moments stored in disconnected systems; no serial record exists of how tissue changes across a woman's lifetime before disease becomes visible. The result is a structurally underserved population, where one in three women skip mammography, and breast cancer, when caught late, costs lives that early detection could have saved. Our platform, ATUSA™, is the first wearable, automated, FDA-cleared, 3D breast quantitative ultrasound system, manufactured under ISO 13485 certification, built to make imaging as simple as a blood pressure check. It closes three gaps at once: mammography's technology falls short in dense tissue (36% sensitivity), sonographer shortages and thin radiology coverage delay screening, and no turnkey solution tool exists at the point-of-care, resulting in patients dropping out between visits and cancers surfacing late.

MARKET & COMMERCIALIZATION STRATEGY

We are pursuing three large, sequential markets, entering through the sharpest wedge first, breast implant surveillance, while our clinical validation study completes in preparation for our cancer detection application. Phase 1, breast implant surveillance, is a $1.6B opportunity across 10M women with breast implants in the United States. Today, 38% of implant ruptures are silent, with no pain or symptoms, yet only 20% of patients receive the MRI the FDA recommends for surveillance. Mammography is not part of that FDA-recommended pathway at all; MRI is, but it's not scalable, costs $3M-$5M in equipment, and requires ~45-minute exams that are confined to specialized facilities. Manual ultrasound is more accessible but operator-dependent, with no standardized way to track a patient over time. ATUSA closes that gap with a point-of-care, standardized scan that physician champions have already adopted for implant patients. Phase 2 expands into dense breast imaging, a $9.5B market across 38M women with dense breast tissue who need supplemental screening as density-notification mandates expand nationwide. Phase 3 is breast cancer detection, a $14.5B market across 50M women who lack adequate access today, positioning ATUSA as front-line detection alongside the standard of care. Every phase leads to Phase 4: iSono's proprietary longitudinal breast health platform, a recurring imaging record for every woman that builds over time. Implants generate revenue. Screening creates scale. Data create the moat. iSono Health employs a mix of direct sales and distributors within and outside of the United States. Our initial focus is the U.S. market, while we build international clinical foundations in the Gulf region for future entry. Our commercial model is B2B, selling to clinics and community hospitals, primarily breast surgeons, OB-GYNs, and longevity clinics. Revenue comes through CapEx purchase, lease/per-scan (ultrasound as a service), and software, teleradiology, and service packages.

TECHNICAL & COMPETITIVE ADVANTAGE

ATUSA processes raw radiofrequency ultrasound signal, not the compressed B-mode image most systems output, capturing over 2,000 frames of quantitative ultrasound data per scan. That raw signal is the foundation for our AI. We are training a foundational model with the explicit goal of outperforming handheld ultrasound's diagnostic accuracy, not just automating its acquisition. Our current classification AUC is 94%, 8% higher than the 86% industry average for the best-performing classification models on the market. Our primary competitors fall into two categories: automated whole-breast ultrasound (ABUS) systems like GE's Invenia ABUS, and traditional handheld ultrasound used as an adjunct to mammography. ABUS systems don't require a sonographer, but they still require registered technicians and are large, capital-intensive, and confined to specialized imaging centers. Handheld ultrasound solves for access but is operator-dependent, requiring a trained sonographer and having high false-positive rates. ATUSA closes the gaps neither modality solves by addressing mammography's blind spot

in dense breast tissue, MRI's reliance on contrast injection, and the access constraints created by facility-bound, capital-intensive systems. Our device is a wearable, hands-free, FDA-cleared platform that captures the full breast volume in minutes, with no injection required. No radiation, superior patient experience, small, and portable.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

iSono Health's ATUSA is FDA-cleared (K213620) as a whole breast ultrasound imaging device, manufactured under ISO 13485 certification. We have seven AI products in the works. Our AI features breast implant surveillance, auto-detection, classification, and 3D segmentation. Additional products are currently investigational and not yet FDA-cleared. We're pursuing a phased regulatory strategy: an FDA presubmission planned for October 2026, our first AI-specific FDA submission targeted for Q3 2027, and pursuit of Breakthrough Device designation to accelerate that pathway. Our IP protects both the hardware and the data engine behind it. iSono holds three granted patents, one pending, and one newly filed provisional. Our patents are five deep across two device generations, filed in our three largest markets, covering the wearable scanning mechanism, image reconstruction, and RF-to-QUS processing pipeline that our competitors don't have.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2016	Founded; raised pre-seed funding from Y Combinator
2019	Won J&J Grant, Texas Medical Center Accelerator, and Philips Health XL award
2020	Raised Seed-1 and won NSF non-dilutive grant ($1.6M); began UCSF Rosenman-Rise partnership
2022	Received FDA clearance
2023	Progressed next-generation ATUSA hardware to human testing; onboarded new CEO and refocused strategy on commercialization
2024	Closed Seed-2 and won NIH Clinical Validation Study grant ($2M); launched 4-site, 800-patient AUDIBLE clinical validation study
2024	Won WISH2024, awarded by Lord Drasi
2025	Won HLTH FInalist Diagnostic Award
2026	Entered early commercialization, sold to multiple customers across multiple segments; launched U.S. sales with a ready-to-purchase pipeline

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016	Pre-Seed	Founding capital from Y Combinator and friends & family	$265K
2019	Seed-1	Round to fund hardware development toward FDA clearance	$7.7M
2024	Seed-2 (last seed raise)	Extension to fund early clinical validation and early access commercial launch	$3.1M
2020–2026	Non-Dilutive Grants (NSF, J&J, NIH/NCI)	Federal and corporate grants funding R&D, clinical validation, and commercialization	$8M
2026	Series A-1 (current raise)	Raising to scale commercial deployment and advance the AI regulatory roadmap	$15M

USE OF PROCEEDS

We are raising $15M in 2026 to scale commercial deployment in the United States and our first international market, the Gulf region, and to advance our AI regulatory roadmap. Proceeds fund three priorities: scaling commercial operations across both markets; advancing our pipeline of seven AI products implant integrity surveillance, classification, segmentation, detection, and density evaluation and risk scoring-toward FDA submission; and training our foundational models on what will be the largest longitudinal breast imaging dataset in development today.

KEY TEAM MEMBERS

Neda Razavi, CEO: 26-year MedTech operator with 65 product launches across Illumina, Roche, Abbott, Medtronic, Baxter, and Natera; leads iSono's commercial and regulatory strategy.

Shadi Saberi, Co-Founder & CTO: Founding CTO driving hardware, software, and FDA strategy; background in electrical and computer engineering with prior roles at Intel and Broadcom. Carnegie Melon PhD.

Elmira Ghahramani, AI and Imaging Scientist: PhD in Bioengineering (University of Cincinnati) with postdoctoral research in quantitative ultrasound and AI at Weill Cornell Imaging; leads iSono's RF-to-QUS and 3D imaging AI pipelines.

Brittany Kimble, Clinical Application Specialist: 20+ years in medical imaging across GE Healthcare, Philips, and Mindray; RDMS/RVT-credentialed across radiography, mammography, and CT, focused on breast imaging application and clinical training.

LEUKO LABS, INC.

Non-Invasive White Blood Cell Monitoring Device

Carlos Castro Gonzalez | carlos@leuko.com | 781-954-0250 | Leuko.com

COMPANY OVERVIEW

Leuko is an MIT spinout developing PointCheck, the world's first medical device to monitor white blood cells (WBC) non-invasively. By enabling frequent at-home monitoring, Leuko aims to improve outcomes for over 1M U.S. cancer patients receiving antineoplastic therapies, reduce therapy-related hospitalizations by up to 50%, and save $4.6B annually in healthcare costs. The company is completing its pivotal clinical trial for regulatory approval and preparing for commercial launch. Leuko plans to raise a Series B to support manufacturing scale-up, go-to-market execution, and its 2027 product launch, and is seeking strategic and institutional investors.

MARKET & COMMERCIALIZATION STRATEGY

By preventing 50% of febrile neutropenia (FN)-related hospitalizations, Leuko addresses a $4.6B annual U.S. market (200K hospitalizations × $46K/case × 50%). Based on insights from over 200 customer interviews, our initial commercialization strategy targets integrated delivery networks (IDNs) and accountable care organizations (ACOs), which are incentivized to reduce healthcare costs. Following FDA approval, we will deploy a value-based leasing model, followed by expansion into fee-for-service providers through durable medical equipment (DME) reimbursement and remote patient monitoring (RPM) CPT codes. Longer term, we plan geographic expansion and additional clinical applications beyond oncology.

TECHNICAL & COMPETITIVE ADVANTAGE

PointCheckTM is the first non-invasive, portable self-test to monitor WBC levels at home. All existing technologies require visits to the clinic, blood draws, healthcare staff, reagents, and biohazard disposal, and thus cannot be easily performed at home and daily. Our technology is protected by six issued patents.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Working with regulatory counsel (Hogan Lovells), we submitted a 513(g) request to the FDA, confirming a Class II De Novo pathway. We subsequently completed an FDA pre-submission meeting, aligning on the intended use, pivotal trial design, sample size, and performance targets. To date, we have successfully completed proof-of-concept (n=45), usability (n=145), and feasibility (n=278) studies, and are currently conducting a multicenter pivotal trial for FDA clearance, expected in 2027. Leuko has an ISO 13485-compliant quality management system and six issued patents covering the United States, Europe, China, Japan, Canada, and Australia, including three exclusively licensed from MIT.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	First-in-human proof-of-concept completed (44 patients).
2022	Patient usability validated (154 patients).
2023	FDA De Novo pathway and pivotal trial design agreed.
2024	Feasibility study met performance goals (278 patients).
2025	Commercial manufacturing established under ISO 13485.
2026	Multicenter pivotal trial underway for FDA clearance.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	NIH SBIR Phase I grant		$250K
2019	Seed Financing	Led by Good Growth Capital	$2M
2020	NIH SBIR Phase II grant	Led by HTH VC	$2M
2022	Series A financing	Led by HTH VC	$5M
2024	NIH SBIR Phase IIB grant		$4.5M
2018-2024	non-dilutive awards	MassChallenge HealthTech, MIT $100K, MassVentures, M2D2, etc.	$500K

USE OF PROCEEDS

Leuko is raising a $15M Series B to support manufacturing scale-up, go-to-market execution, U.S. product launch in 2027, FDA label expansion, and commercialization. We are seeking both strategic and institutional investors to support this next phase of growth.

KEY TEAM MEMBERS

Carlos Castro-Gonzalez, PhD (CEO): Leads strategy, fundraising, and operations; MIT-trained entrepreneur with prior MedTech start-up experience.

Ian Butterworth, MSc (CTO): Leads hardware and product development; former MIT research engineer with prior MedTech start-up experience.

Alvaro Sánchez-Ferro, MD, PhD (CMO): Leads clinical strategy and regulatory studies; neurologist and clinical trial expert with prior MedTech start-up experience.

Aurelien Bourquard, PhD (Chief Data Scientist): Leads AI and software development; EPFL- and MIT-trained computer vision scientist.

Peter Soltani (Head of Commercialization): Former Siemens and Danaher executive with 25+ years leading commercialization and business development.

LUMICELL, INC.

Real-Time Fluorescence-Guided Imaging for More Precise Cancer Surgery

Jorge Ferrer | jmferrer@lumicell.com | 617-571-0592 | Lumicell.com

COMPANY OVERVIEW

Founded in 2008 and based in Waltham, MA, Lumicell develops fluorescence-guided imaging systems that let physicians see cancer in real time. Its founders started the company after losing loved ones to post-surgical cancer recurrence. Lumicell's first product, LUMISIGHT (pegulicianine) paired with the Lumicell direct visualization system, was FDA-approved on April 17, 2024 (NDA 214511; PMA P230014) as the first and only technology to image inside the lumpectomy cavity for residual tumor during breast-conserving surgery. Now commercial with reimbursement secured from launch, Lumicell (42 employees) is extending the platform to gastrointestinal cancers.

MARKET & COMMERCIALIZATION STRATEGY

Lumicell's GI platform targets high-risk esophageal and gastric cancer surveillance at referral and tertiary centers. Barrett's esophagus surveillance represents ~1.2M U.S. procedures annually (5% CAGR); gastric surveillance adds ~400K (7% CAGR), a combined addressable market exceeding 1.6M procedures, with a serviceable market of ~720K per year. At ~$3,685 revenue per case and a 9% five-year share, this supports a ~$295M 5-year business case (~$210M esophageal, ~$85M gastric). Commercialization leverages Lumicell's existing platform: ~95% of LUMISIGHT breast claims are reimbursed today, and the same infrastructure and payer playbook transfer directly to GI.

TECHNICAL & COMPETITIVE ADVANTAGE

LUMISIGHT is a protease-activated agent that stays dark until cleaved by cathepsins overexpressed in GI tumors, producing tumor-specific fluorescence in real time detected with a novel clip-on module fitting existing endoscopes; no new capital equipment is required. White-light standard of care misses up to 40% of patients with additional cancer foci. Competing modalities force a trade-off: chromoendoscopy is easy and low-cost but dye-dependent, while confocal microscopy and volumetric laser endomicroscopy reach 76–90% sensitivity yet remain constrained by cost and ease-of-use. Lumicell uniquely combines high performance with workflow simplicity and favorable economics.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The breast program is fully FDA-approved (NDA 214511; PMA P230014). For GI, Lumicell will pursue an IDE/510(k) pathway for the endoscopic imaging device and an NDA supplement to expand pegulicianine's label to gastrointestinal cancers, leveraging the existing safety and CMC package. An IDE submission is planned for Q3 2026, with a feasibility study starting Q1 2027. Intellectual property includes six issued U.S. patents (9,763,577; 11,793,594; 11,771,324; 10,813,554; 9,532,835; 12,163,887) spanning the activatable imaging agent, residual-cancer detection methods, and imaging device. Reimbursement follows the proven breast playbook: CPT pathway plus HCPCS J-code and transitional pass-through.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Aug. 2008	Lumicell founded to improve cancer surgery through real-time tumor visualization
March 5, 2024	FDA advisory committee (MIDAC) votes 16–2 in favor of LUMISIGHT benefit–risk
April 17, 2024	FDA approval of LumiSystem for breast-conserving surgery (NDA 214511; PMA P230014). First and only drug–device combination product of its kind approved in over a decade.
Jan. 2025	U.S. commercial launch with CMS assigned codes; ~92% of claims reimbursed across CMS and private payers
2025	Ex vivo GI feasibility: 12 esophageal + 18 gastric patients; optimal dose 1 mg/kg
Q3/Q4 2026	Secure funding to continue development of GI device and feasibility study
2027	IDE submission and approval; planned GI feasibility dose-escalation study start (esophageal, gastric)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2011, 2013, 2016	Series A, B, C	Funded drug and device development and breast clinical studies	$39.42M
2018–2023	Series D (multiple closings)	Priced round funding clinical studies and regulatory submissions through FDA approval	$40.88M
2025	Series BB Preferred	Priced round supporting post-approval commercialization	$24.79M
Multiple years	Convertible Notes (converted to equity)	Bridge financing between priced rounds, later converted into Series A–D/BB	$72.76M

USE OF PROCEEDS

Lumicell is raising $18M–$25M to expand its platform into GI cancers, deployed across three milestone-gated tranches: technology de-risk ($3.8M), clinical de-risk ($9.8M, feasibility through pivotal), and regulatory de-risk ($7.8M, through FDA submission and approval). Funds cover clinical trials, drug and device manufacturing, regulatory submissions, and a dedicated program team.

KEY TEAM MEMBERS

Jorge Ferrer, PhD — Chief Scientific Officer; led LUMISIGHT development through FDA approval, now directs the GI program.

Andrew Chan, MD — Principal Investigator; MGB gastroenterologist, former AGA Institute research chair.

Brian Schlossberg — VP of Innovation; leads development of the clip-on imaging hardware.

Kate Smith — VP of Clinical Affairs & Pharmacovigilance; leads GI clinical trial operations and execution.

David Drew, PhD — Investigator, MGB; Assistant professor, Harvard Medical School; runs trial execution at MGB.

NAVIGATION SCIENCES, INC.

GPS Navigation for Precise Margin Control During Surgical Resection

Alan Lucas | alan.lucas@navigationsci.com | 617-834-2829 | Navigationsci.com

COMPANY OVERVIEW

Navigation Sciences™ is a clinical-stage company developing the NaviSci™ System for the tissue-conserving removal of lung cancer and other tumors. The system integrates augmented reality and advanced software with surgical instruments to guide precise surgical resection by enabling real-time in vivo measurement for the first time. The system aims to improve surgical outcomes with cutting-edge technologies that reduce recurrence risk, conserve lung function, shorten hospital length of stay, and enhance surgical workflow.

MARKET & COMMERCIALIZATION STRATEGY

There are approximately 450K soft tissue cancer cases per year in the United States, where Navigation's technology may provide benefit. These cancers include lung, liver, head and neck, thyroid, brain, and breast cancer. The addressable U.S. market for Navigation's technology, including both systems and consumables, is estimated at approximately $1.26B. The company's lead application is lung cancer, where the potential to improve outcomes with early-stage detection and removal is particularly high. The impact of delayed treatment on morbidity and mortality is severe. There are more than 76K cases of early-stage lung cancer in the U.S. annually. Although the total number of lung cancer patients has been decreasing, the number of early-stage diagnoses is growing annually. It is expected to increase further due to expanded use of CT X-ray screening and favorable CMS reimbursement coverage for high-risk patients.

TECHNICAL & COMPETITIVE ADVANTAGE

The NaviSci System is fundamentally novel in several respects. It includes novel components that enable lung tumor resections with optimal oncological margins, thereby preventing recurrence. The NaviSci system is the only navigation platform that can accurately track lung nodules despite tissue deformation.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The company completed a clinical feasibility study with the NaviSci System under an FDA-approved Investigational Device Exemption (IDE) in patients with early-stage lung cancer. The 25-patient trial was conducted at Brigham & Women's Hospital to evaluate the system's safety and its ability to identify and remove tumors with appropriate margins using minimally invasive techniques. The trial is also designed to provide an initial opportunity to assess the technology's economic value proposition, namely improved surgical workflow and reduced hospital length of stay. We had a Pre-Sub meeting with the FDA in 2023 to affirm our planned regulatory pathway for the NaviSci System, including the 510(k) primary predicate device. We have 11 US and OUS issued patents and several pending applications.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2018	Founding
2023	IDE clinical feasibility study with 25 patients at the Brigham and Women's Hospital, Boston, MA
2025	Publication of clinical study

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Pre-Seed and founding		$75K
2019	Series A		$2.5M
2022	Series B		$3M
2026	Series B-1		$711K

USE OF PROCEEDS

$2M-$4M will be used toward complete verification and validation for the 510(k) application and rollout to key clinical advisors.

KEY TEAM MEMBERS

Alan D. Lucas, Co-founder, CEO, Director

Raphael Bueno, M.D., Co-founder, Director, SAB, chief, thoracic surgery, Brigham & Women's Hospital; professor of surgery, Harvard Medical School

Jayender Jagadeesan, PhD, Co-founder, SAB, Research interests include image-guided therapy, surgical navigation, robotics

Larry Roth, VP Product Development, Development of innovative Class II and III medical devices

SafeGuard Surgical

SAFEGUARD SURGICAL, INC.

Biodegradable Intraluminal Barrier Device Platform to Prevent Anastomotic Leakage Following Cancer Resection Surgery

Scott Kelley | drscottkelley@drscottkelley.com | 813-431-7702 | safeguardsurgical.com

COMPANY OVERVIEW

SafeGuard Surgical is developing a preventive solution to one of surgery's most feared and costly complications: the anastomotic leak. Its flagship device, LeakGuard™, is a bioabsorbable implant that reinforces and protects a surgical connection (anastomosis) as it heals; it is engineered to prevent leaks and eliminate the need for a temporary ostomy. LeakGuard™ has been granted FDA Breakthrough Device designation and is advancing through a De Novo (Class II) regulatory pathway, with a clear reimbursement route through established DRGs. Built on FDA-recognized biodegradable polymers, LeakGuard™ achieved 100% technical success in initial large-animal studies. It is the lead product of the broader Guard™ platform, which extends the same bioabsorbable, payload-capable technology across a $25B+ opportunity in oncology, radiation, wound, and infection management, beginning with a $4.5B colorectal market.

MARKET & COMMERCIALIZATION STRATEGY

Anastomotic leak is a serious, common failure point in gastrointestinal cancer surgery, associated with reoperation, permanent ostomy, prolonged hospitalization, higher mortality, and worse oncologic outcomes. SafeGuard's initial beachhead is colorectal surgery, a total addressable market of approximately $4.5B. The Guard™ platform then expands into adjacent high-value indications, including esophageal, gastric, and other GI resections, growing the opportunity to a $25B+ platform across oncology, radiation, wound healing, and infection-management applications. Commercialization is de-risked by a clear reimbursement pathway: leak-prevention maps to existing DRGs, and preventing a single leak avoids the substantial downstream cost of reoperation, ICU days, and ostomy management, all of which is a compelling hospital value proposition. Physician adoption is expected to be strong given the device's procedural simplicity and fit within the existing surgical workflow. The commercial model targets high-volume colorectal and surgical-oncology centers, with the platform architecture supporting a staged, indication-by-indication rollout and multiple strategic-acquirer exit paths.

TECHNICAL & COMPETITIVE ADVANTAGE

LeakGuard™ is engineered from FDA-recognized biodegradable polymers, including PDO, PLGA, and PCL (RESOMER®-grade materials from Evonik), which materially reduces material and biocompatibility risk. The device is designed to protect and reinforce the anastomosis during the critical healing window, then safely resorb, avoiding any secondary removal procedure. In initial large-animal (porcine) studies, LeakGuard™ achieved 100% technical success. Competitive position: SafeGuard is, to reviewers' knowledge, the only device pursuing true prevention of anastomotic leak rather than detection or downstream management. This preventive-first approach directly addresses the failure point and eliminates the need for a secondary removal procedure; this represents a clear differentiator over sealants, buttressing materials, and monitoring approaches. The Guard™ architecture (a resorbable scaffold capable of delivering therapeutic payloads) is broadly extensible, creating a multi-product moat rather than a single-device story.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

LeakGuard™ has been granted FDA Breakthrough Device designation (pre-submission Q-Sub Q253681), and SafeGuard is pursuing market authorization via the De Novo pathway, which will establish a new Class II classification. Breakthrough status provides prioritized, interactive FDA engagement that compresses the path to clearance. Use of well-characterized, FDA-recognized polymers further streamlines the biocompatibility and testing burden. Testing is being executed with established medical device CRO partners (NAMSA; Endolab GmbH). Intellectual property: SafeGuard's IP strategy spans device design, delivery systems, and leak prevention methods, with additional coverage anticipated across the Guard™ platform's payload delivery applications. The company is building a defensible, layered portfolio intended to be important and attractive to strategic acquirers.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
	Achieved Company founded; Guard™ platform and LeakGuard™ lead device defined Achieved 100% technical success in initial large-animal (porcine) proof-of-concept studies Achieved FDA Breakthrough Device Designation granted (De Novo, Class II; Q-Sub Q253681) Achieved Selected as 2026–2027 NCI SBIR Investor Initiatives Showcase Company
	Next GLP biocompatibility & design verification/validation testing (NAMSA, Endolab)
	Next First-in-human clinical study of LeakGuard™
	Next FDA De Novo submission for LeakGuard™
	Next Initiate second Guard™ indication (platform expansion)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2022	Founders	F&F Founder and early capital to establish company and IP	$800K
2024-2026	Non-dilutive	Non-dilutive SBIR/STTR and/or grant funding	$2.4M
2025	Seed / Notes	Convertible instruments to fund preclinical program	$3.2M
2026-2027	Series A (target)	Priced round to fund first-in-human and De Novo	$10M

USE OF PROCEEDS

SafeGuard Surgical is raising a $10M Series A to advance LeakGuard™ from large-animal proof-of-concept through first-in-human data and FDA De Novo submission.

Proceeds fund:

- First-in-human clinical study of LeakGuard™ through primary endpoint.
- GLP biocompatibility, design verification/validation, and pilot manufacturing with RESOMER®-grade polymers (Evonik) and CRO partners (NAMSA, Endolab GmbH).
- FDA De Novo submission and Breakthrough-track regulatory engagement.
- IP prosecution and freedom-to-operate across device, delivery, and platform methods.
- Initiation of the second Guard™ indication to validate platform expansion.

KEY TEAM MEMBERS

Scott T. Kelley, MD, FACS — Co-Founder & CEO. Surgical oncologist and associate professor of surgery; among fewer than 60 cancer surgeons globally to receive an FDA Breakthrough Device designation. Trained at Dartmouth, Columbia, the University of Pennsylvania, and Moffitt Cancer Center.

Jill Kelley — Co-Founder & Chief Development Officer. Leads development, regulatory, fundraising, and strategic-partnership workstreams.

Dean Hu — Chief Financial Officer. Leads finance, capital strategy, and investor relations.

Larry Robert Scott, PhD — Biomedical Engineer. Leads polymer engineering and device development across the Guard™ platform. Advisory Board. Co-inventor of the EpiPen and former senior FDA leadership, supporting device commercialization and regulatory strategy.

SYNTR HEALTH TECHNOLOGIES, INC.

Point-of-Care Technologies for Safer, More Effective, and More Accessible Tissue Reconstruction

Ahmed Zobi | azobi@syntrtech.com | 562-688-9335 | Syntrtech.com

COMPANY OVERVIEW

Syntr Health is a regenerative medicine company commercializing an FDA-cleared automated tissue processing platform for autologous breast reconstruction. Our technology transforms a patient's own adipose tissue into standardized, high-quality regenerative fat grafts at the point of care, improving consistency, workflow efficiency, and tissue viability. Protected by a portfolio of 25 granted patents and backed by more than $4M in NIH funding, Syntr is advancing a new standard for autologous reconstructive surgery.

MARKET & COMMERCIALIZATION STRATEGY

Approximately 300K women undergo a mastectomy or lumpectomy each year in the United States, yet only about 150K elect to undergo breast reconstruction. Many women remain untreated because they are not candidates for current reconstructive options, are concerned about the complexity and invasiveness of existing procedures, or are unaware that breast reconstruction is covered by insurance. Syntr Health is commercializing an FDA-cleared automated tissue processing platform for the $492M U.S. autologous body reconstruction market, enabling standardized, high-quality fat grafting for breast reconstruction. Our commercialization strategy targets leading plastic surgeons, academic medical centers, and comprehensive cancer centers through a capital equipment sale and high-margin recurring consumable business model, with future expansion into additional autologous reconstructive procedures.

TECHNICAL & COMPETITIVE ADVANTAGE

Syntr Health has demonstrated meaningful technical and economic advantages over conventional fat processing systems through published comparisons, proprietary performance data, and early clinical outcomes. Our FDA-cleared platform processes up to 1,200 mL of lipoaspirate in just 2–5 minutes, compared with approximately 27 minutes for Revolve and up to 70 minutes for PureGraft, while achieving an average 93% cell viability, compared with published values of approximately 81.5% for Revolve and 60–77.5% for PureGraft. Unlike existing systems, Syntr also microsizes purified fat, enabling injection through smaller cannulas without additional processing. By reducing operating room time by approximately 1 hour, Syntr has the potential to increase facility profitability by approximately $2,220 per procedure while improving surgeon economics by $144–$1,738 per case. Early clinical experience has demonstrated approximately 80% fat retention in reconstructive procedures, while our wound reconstructive surgery study achieved 85% wound closure within one week with no ulcer recurrence over more than 1 year of follow-up. Together, these technical, clinical, and economic advantages position Syntr as a differentiated platform for autologous breast reconstruction and regenerative surgery.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Syntr Health has established a strong regulatory and intellectual property foundation to support commercialization. Our platform has received two FDA 510(k) clearances for the harvesting, processing, and transfer of autologous adipose tissue across a broad range of surgical specialties, including plastic and reconstructive surgery. The technology is protected by 25 issued patents with 11 additional patent applications pending, covering automated tissue processing, microfluidic technologies, disposable processing systems, and regenerative tissue preparation workflows. As we continue to expand the capabilities of our platform and introduce new clinical applications, we expect to pursue additional regulatory clearances and strengthen our intellectual property portfolio through new patent filings. This combination of regulatory clearance and a robust IP portfolio creates significant barriers to entry while supporting the long-term expansion of our reconstructive and regenerative surgery platform.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2017	Syntr Health founded to develop an automated regenerative tissue processing platform.
2017	Awarded first NIH SBIR funding, validating the technology through non-dilutive federal support.
2019	Closed $750K Pre-Seed financing to advance product development, intellectual property, and regulatory activities.
2021	Received first FDA 510(k) clearance for the SyntrFuge® tissue processing platform.
2021–2023	Closed $2.75M Seed financing to support engineering, manufacturing, clinical validation, and commercialization readiness.
2023	Received second FDA 510(k) clearance (BK220723), expanding the platform's regulatory indications and commercial capabilities.
2023–2025	Generated promising early clinical outcomes in wound reconstruction, demonstrating rapid healing and supporting expansion into breast reconstruction and other reconstructive applications.
2026	Awarded a Federal Supply Schedule (FSS) contract, enabling commercialization across the U.S. Department of Veterans Affairs.
2026	Surpassed $3.75M in cumulative NIH non-dilutive funding while expanding the intellectual property portfolio to 25 issued patents and 11 pending patent applications.
2026	Initiated a $20M Series A financing to accelerate manufacturing scale-up, commercial expansion, and clinical adoption, with eligibility to apply for up to $20M in additional NIH Strategic Breakthrough matching funds.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018–2019	Pre-Seed Financing	Initial financing to advance prototype development, intellectual property, and early regulatory activities.	$750K
2021–2023	Seed Financing	Seed financing to support product development, FDA clearances, clinical validation, manufacturing scale-up, and commercialization readiness.	$2.75M
2017–2026	Non-Dilutive Funding	NIH SBIR/STTR grants supporting technology development, regulatory advancement, clinical research, and commercialization of Syntr's regenerative tissue processing platform.	$3.75M+

USE OF PROCEEDS

Syntr Health is raising a $20M Series A financing to accelerate the commercialization of its FDA-cleared regenerative tissue processing platform. The proceeds will be used to expand U.S. manufacturing, scale commercial operations, grow our sales and clinical support organization, execute post-market clinical studies in breast reconstruction and additional reconstructive applications, advance regulatory and product expansion initiatives, and strengthen our working capital. A key commercialization focus is the U.S. Department of Veterans Affairs, where a significant unmet need exists for breast reconstruction and other reconstructive procedures. Through our established Federal Supply Schedule (FSS) contract and preferential federal pricing, Syntr is well-positioned to accelerate adoption across the VA healthcare system while establishing a commercial foundation for broader expansion into academic medical centers, community hospitals, and private plastic surgery practices throughout the United States, where the unmet need for autologous breast reconstruction remains substantial. In parallel, we are pursuing the NIH Strategic Breakthrough Award, which could provide up to an additional $20M in non-dilutive matching capital to further accelerate commercialization and expand our clinical and product development roadmap.

KEY TEAM MEMBERS

Ahmed Zobi, EMBA — Chief Executive Officer & Co-Founder Biomedical engineer, inventor, and entrepreneur with over eight years of experience in microfluidics, biomechanics, medical device development, and regenerative medicine. As founder and CEO, he has led Syntr's technology development, intellectual property strategy, NIH funding efforts, FDA 510(k) clearances, strategic partnerships, and commercialization of the SyntrFuge® platform.

Hugo Salas — Vice President, Business Development & Co-Founder Biomedical engineer with expertise in business strategy, commercialization, and market development. He leads strategic partnerships, sales and marketing initiatives, customer engagement, and technical product documentation, helping position Syntr for adoption across the VA healthcare system and the broader reconstructive surgery market.

Justin Stovner, MSc — Vice President, Engineering & Co-Founder Biomedical engineer specializing in microfluidics, biomechanics, and medical device automation. As lead engineer and designer of the SyntrFuge® platform, he oversees product development, manufacturing, engineering validation, quality systems, and the expansion of Syntr's next-generation tissue processing technologies.

Dane Shackleford — Board Member and Commercial Advisor Medical device executive with more than 25 years of commercial leadership experience. Former vice president of sales at KCI/Acelity and former VP of sales and marketing at Spiracur, where he helped commercialize advanced wound care technologies and build sales organizations generating over $250M in annual revenue. He advises Syntr on commercialization strategy, sales execution, and market expansion.

Early is Good

EARLY IS GOOD, INC.

Multi-Omics Liquid Biopsy Platform

Thakshila Liyanage | thakshila@earlyisgood.com | 317-941-6953 | Earlyisgood.com

COMPANY OVERVIEW

Cancer tests today rely on a single analyte, either DNA, RNA, or protein, which makes them clinically suboptimal. No one has combined all three because the underlying science for each is fundamentally different. Early Is Good solved this. Our multi-omic platform reads DNA, RNA, and protein from a single urine sample, on one instrument, in a single workflow. We are advancing two lead assets toward major milestones: a bladder cancer monitoring test validating at Washington University and Indiana University with strong prospective data, and a prostate diagnostic co-developed with Mayo Clinic. The same core technology also supports a near-term revenue opportunity through commercial partnerships. Founded in 2021, Early Is Good is headquartered in Indianapolis.

MARKET & COMMERCIALIZATION STRATEGY

Our customer is the urologist, and both tests sell into the same call point: the 12,500 practicing urologists in the United States. Bladder is the beachhead, with 800K Americans under active surveillance who are scoped every 3-6 months for life. Prostate follows, with 3.75M elevated PSA results per year, of which roughly 1.3M lead to a biopsy to identify the 45K men who actually need treatment. Guidelines already call for molecular testing in both settings, and payers already reimburse it. At $900 for bladder and $750 for prostate, the first two products represent approximately $3.5B of annual U.S. revenue opportunity. That works out to $268,800 of addressable market per physician, compared with $111,774 for Guardant360 and $10,909 for Cologuard; thus, a small salesforce covers the entire market. Commercialization runs in two phases. Phase 1 is a centralized laboratory model through a CLIA reference laboratory partner, which provides national ordering, logistics, and billing infrastructure and establishes coverage evidence. Phase 2 licenses the tests to IVD manufacturers as kits for decentralized labs and global reach. Separately, our core technology supports a near-term licensing revenue opportunity with IVD manufacturers that begins ahead of clinical test launch.

TECHNICAL & COMPETITIVE ADVANTAGE

Every other test in this space reads one analyte class, which forces a tradeoff between catching cancers and avoiding false alarms. Reading all three, at sensitivity levels single-analyte methods cannot reach, removes that tradeoff and lets us develop multi-marker signatures that hold both sensitivity and specificity at once. The performance follows. In bladder cancer, prospective multi-site data show 92% sensitivity and 97% specificity with a 99% negative predictive value, against a standard-of-care urine test that misses roughly half of cancers. With our prostate cancer test, co-developed with Mayo Clinic, our discovery cohort reached an AUC of 0.91. The platform is the durable asset, not any single test. Each new indication is an application of the same technology rather than a new science problem, and the same core capability licenses directly to IVD manufacturers as a revenue stream independent of our clinical products.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Both tests will be offered as laboratory-developed tests from a CLIA certified laboratory, which allows commercial availability on the strength of validated analytical and clinical performance data. Reimbursement is pursued through the established Medicare coverage and coding pathway for molecular diagnostics, supported by evidence from our prospective multi-site studies. Our intellectual property portfolio includes issued U.S. patents and pending applications spanning composition of matter, method of use, and system and device claims across both core technologies, with international protection in national phase across major markets worldwide.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2021	Company founded in Indianapolis
2025	NIH SBIR Direct-to-Phase II award received
2025	Prospective multi-site clinical validation launched for bladder cancer test
2025	Prostate cancer test initiated with Mayo Clinic; analytical completed at AUC 0.91
2026	Bladder cancer interim readout: 92% sensitivity, 97% specificity, 99% NPV

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021-2024	Seed (Equity)	Founding institutional rounds funding platform development and initial clinical validation	$4.4M
2025	Non-Dilutive (NIH SBIR Direct-to-Phase II)	Federal award supporting bladder cancer test validation	$1.6M
2026	Series A (Equity, in progress)	Priced round to fund clinical validation, commercial launch preparation, and licensing execution	$11M

USE OF PROCEEDS

Early Is Good is raising $11M in a priced equity round with approximately $9M committed to date. Proceeds fund five areas: (1) Launch of our reagent licensing program with IVD manufacturers, generating revenue beginning in late 2026. (2) Clinical validation of the prostate test co-developed with Mayo Clinic. (3) Clinical utility study for the bladder cancer test. (4) CLIA laboratory operations and the reference laboratory launch partnership. (5) Bladder and prostate test commercial launch. The round is sized to carry the company through prostate clinical validation and initial commercial revenue.

KEY TEAM MEMBERS

Thakshila Liyanage, PhD, Chief Executive Officer and Co-Founder: Inventor of the multi-omic platform. PhD, Purdue University.

Asel Ananda, Chief Technology Officer and Co-Founder: Leads assay and platform development.

HL Ananda, Chief Operating Officer and Co-Founder: Leads commercial strategy, fundraising, and business development.

EXIMIUS DIAGNOSTICS CORPORATION

Extracellular Vesicle-Based Liquid Biopsy Tests

Matthew Smalley | msmalley@eximiusdx.com | 310-592-5071
linkedin.com/company/eximius-diagnostics-corporation/home/

COMPANY OVERVIEW

Eximius Diagnostics is a UCLA spinoff company developing extracellular vesicle (EV)-based liquid biopsy tests for cancer diagnosis and treatment monitoring. It was founded by Drs. Tseng and Zhu, co-directors of the UCLA liquid biopsy laboratory, and is supported by a Phase II SBIR from the National Cancer Institute. It is currently located in the Magnify Incubator space at UCLA. Eximius' first product is an in vitro diagnostic (IVD) liver cancer test that detects hepatocellular carcinoma (HCC) using human plasma samples collected from at-risk liver cirrhotic patients. Eximius' liver cancer test is intended to act as an alternative to ultrasound in the screening of at-risk populations for HCC. Eximius' test uses qPCR technology to quantify HCC EVs, enabling early-stage (Stage 0-A) HCC detection, and allowing it to tap into the widespread PCR capacity built up by diagnostic labs during the COVID-19 pandemic. It was the subject of a ~170-patient Phase 2 Biomarker study conducted at UCLA and Cedars-Sinai Medical Center. These results were published in the journal *Hepatology* and earned the test Breakthrough Device designation from the FDA, expediting its pathway to FDA clearance.

MARKET & COMMERCIALIZATION STRATEGY

There are ~4.5M patients in the United States at high risk for HCC, and for whom the American Association for the Study of Liver Diseases (AASLD) recommends biannual liver ultrasound screenings. Noninvasive HCC laboratory tests currently represent a $1.5B market, despite a current compliance rate of only 25% among these patients. More effective and convenient HCC surveillance solutions could improve patient compliance, leading to a projected market of $4.0B by 2032. While Eximius has yet to fully commercialize any products, it is progressing well on its HCC EV SP test for liver cancer screening, which was granted Breakthrough Device designation by the U.S. FDA in December 2022. Eximius' has brought in team members and advisors with CLIA and commercialization experience and plans to expand its commercialization team once we have a product transitioned to LDT use in a CLIA lab. We have mapped out a hiring plan with the help of advisors from the California Life Sciences' FAST Advisory Program. Furthermore, Han-Yu Chuang (PI) has joined our team, who was formerly VP of technology for Guardant's oncology division and has significant experience successfully commercializing cancer diagnostics.

TECHNICAL & COMPETITIVE ADVANTAGE

Most notably, this assay addresses two of the most critical practical issues in current HCC diagnosis: accuracy and patient usability. While HCC is curable when caught early, most patients are diagnosed at later stages because of a combination of a lack of screening compliance and the poor sensitivity of ultrasound. Our solution uses a small amount of blood (1-2mL) that can be collected during a patient's normal bloodwork, or at most any doctor's office or diagnostic lab, getting around the inconvenience of navigating complicated healthcare systems, scheduling, and attending additional appointments associated with ultrasound screening. Furthermore, with our Phase 2 case-controlled biomarker study between UCLA and Cedars-Sinai showing a sensitivity of 91% with a specificity of ~86%, this test is likely to detect many early HCC cases that would otherwise be missed by ultrasound. Two additional points worth noting are that: (1) our PCR test has low enough costs to easily be priced at or below ultrasound vs. next gen sequencing-based ctDNA tests, which often cost ~$1K per test, and (2) this test would function as an alternative to ultrasound screening, so positive results would still be sent for MRI/CT disease confirmation and staging, which greatly reduces the regulatory risk of the test. Further, our EV capture platform has demonstrated uses in other diseases with other types of readouts, including measuring EV protease activity and digital PCR readouts of EV contents. These have publications showing utility in a number of other diseases, including for early AD detection, assessing osteosarcoma disease status, early detection of PDAC, companion diagnosis potential in prostate cancer, and more.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Eximius has exclusively licensed multiple patents from UCLA. The patents covering our liver cancer test are entitled "Covalent chemistry enables extracellular vesicle purification on nanosubstrates toward early detection of hepatocellular carcinoma" (2021, WO2021195549A1) and "Extracellular vesicle protein assay for noninvasive diagnostics" (2023, WO2023196867). In parallel, Eximius has been working closely with Wilson Sonsini to develop additional non-infringe block positions including but not limited to assay chemistry, instrumentation, and expanded clinical and research utilities. Eximius was granted the Breakthrough Device designation by the FDA in December 2022. This designation represents a significant milestone for the company, as it expedites the De Novo approval pathway for Eximius HCC EV SP test. We are currently in the process of preparing this test for LDT use, and we consider it our flagship product. We will use data generated at the CLIA stage to help us work toward establishing necessary reimbursement codes. At the same time, we submit our Q-sub to the FDA to lock down an appropriate trial design for our anticipated De Novo pathway.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Dec. 2022	Breakthrough Device designation
Sept. 2023	Direct to Phase 2 SBIR and First full-time hire
June 2026	Design Lockdown 10/26-Complete CDMO transfer and validate CDMO manufactured kits
Dec. 2026	Launch test as an LDT
April 2027	Finish FDA Q-Sub on clinical trial design
Sept. 2027	Complete Series A raise of $10M

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2022	Seed funding	Individual Investors	$350K
2023-2027	Direct to Phase II SBIR from NCI		$2M

USE OF PROCEEDS

We are raising $10M to enable us to set up outside GMP manufacturing for our test and build production equivalent kits for clinical and analytical validation; transition our test to LDT use with a local CLIA lab partner; collect health economic data necessary to establish a reimbursement code specific for out test; make key hires (in commercialization, operations, product development); market our test to local hospital systems; and enhance our IP portfolio. These funds should allow us to launch our test as a CLIA Lab LDT, expand its use in the Los Angeles, CA, region beyond our existing clinical partners, and sustain the company at least through initiation of a clinical trial for FDA submission.

KEY TEAM MEMBERS

Hsian-Rong Tseng, PhD: Hsian-Rong is a professor at UCLA focused on the development of liquid biopsies for cancer diagnosis, and is the co-founder/acting CEO of Eximius Diagnostics. He has 33 years of experience in organic chemistry, as well as 23 years of experience in micro- and nanofabrication for applications. He has founded three companies to commercialize these technologies and established an extensive collaboration network with liver cancer programs at UCLA and Cedars-Sinai Medical Center.

Han-Yu Chuang, Ph.D: Han-Yu is Eximius' CTO. She has over 14 years of industrial experience with global clients in the biotechnology and pharmaceutical industries in developing IVD and LDT molecular diagnostics and clinical testing services. Formerly, she was VP of technology in Guardant Health's oncology division. Before that, she also worked for Illumina and Roche and established the informatics team at Cradle Genomics, a non-invasive prenatal testing start-up.

Matthew Smalley, MBA: Matthew is the operations Manager at Eximius Diagnostics. He has a B.S. in Biology from Caltech and an MBA from CSUN. Prior to Eximius, Mr. Smalley worked as a project manager for CytoLumina, another cancer liquid biopsy start-up. In 2020, he founded Delphire Technologies and led the company through its initial fundraising efforts. He previously worked for SoCalBio, where he oversaw the trade association's Innovation Catalyst program, which screens emerging biotech companies for its investor conference and pairs them with industry mentors.

IMCARE BIOTECH, INC.

Blood-Based Liver Cancer Diagnostic

Aaron Yefel Lu | yl@imcarebiotech.com | 215-489-4906 | imcarebiotech.com

COMPANY OVERVIEW

ImCare Biotech is a biotechnology company dedicated to transforming the detection and treatment of liver cancer, where current surveillance methods often miss early-stage disease. Our non-invasive, multi-analyte assay combines a proprietary algorithm with our novel LC-SPIK biomarker to accurately identify cancer in its earliest, most treatable stages. We are launching this high-precision screening commercially by 2027 as a laboratory-developed test (LDT) while concurrently pursuing full FDA approval to drastically improve patient survival rates.

MARKET & COMMERCIALIZATION STRATEGY

The U.S. liver cancer diagnostics market is projected to grow at a compound annual growth rate (CAGR) of ~6.5%, driven by the urgent need to monitor high-risk populations. In the United States, approximately 8M individuals with cirrhosis or chronic hepatitis B require regular surveillance, creating a total addressable market (TAM) of $2.5B annually. Globally, the high-risk population exceeds 160M, representing a $6B annual opportunity. There are significant limitations with HCC surveillance in the current standard of care, which uses ultrasound plus alpha-fetoprotein (AFP). Ultrasound is operator-dependent, inconvenient for patients, and insensitive to small tumors, while AFP alone misses more than half of early-stage cases. ImCare Seravue Liver test addresses this gap with a high-sensitivity, blood-based assay that fits existing AASLD guidelines as a cost-effective alternative to ultrasound plus AFP. By shifting detection to curative early stages, our test aims to greatly improve survival outcomes. Current and Future Commercial Applications: ImCare's primary commercial application is a surveillance tool for early HCC detection in high-risk patients, utilizing our proprietary multi-analyte AI panel (LC-SPIK, AFP, and DCP). Leveraging this core technology, we plan to expand into companion diagnostics, which are designed to quantify treatment efficacy and guide therapeutic selection. Concurrently, we are advancing a multi-cancer assay that pairs LC-SPIK with novel biomarkers to detect cholangiocarcinoma and other malignancies.

TECHNICAL & COMPETITIVE ADVANTAGE

The test targets a newly discovered biomarker, LC-SPIK, and combines that with existing biomarkers and a machine learning model. The resulting specificity and sensitivity for detecting early-stage HCC is superior to what currently exists.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Our regulatory strategy is helped by the FDA Breakthrough Device designation (BDD) granted to our technology, which expedites the review process. We are currently in the process of launching a pivotal, multi-site prospective clinical trial (clinicaltrials.gov NCT06994130) involving 1000+ subjects to support a De Novo classification submission for FDA market clearance. Following FDA De Novo clearance, we will leverage the FDA BDD to expedite transitional Medicare coverage. We are pursuing a proprietary laboratory analyses (PLA) code through AMA, with pricing established by CMS to enable test-specific billing and long-term reimbursement. We anticipate reimbursement rates in the range of $250-$350 for Seravue Liver, which is aligned with current CMS coverage for diagnostic multi-analyte algorithmic assays for other conditions and diseases. Intellectual Property: ImCare Biotech is the only company holding intellectual property for the detection of the LC-SPIK protein. The company's IP portfolio includes three patents (granted in key jurisdictions with additional global applications pending) that broadly cover method claims, composition of matter for the monoclonal antibodies, and detection methods. ImCare has also invested more than a decade in R&D to develop the specific know-how regarding the screening and scalable production of these functional antibodies, which are protected as trade secrets.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	FDA Breakthrough Device designation
2021	NIH grant funding to develop Seravue
2026	First patient enrolled in FDA pivotal clinical study for LC-SPIK
2026	Finalized/submitted AI algorithm for Seravue Liver test to NYSDOH LDT
2027	Commercial LDT launch for Seravue Liver test
2028	Complete 2-year FDA pivotal study with follow-up

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020		Seed round	$680K
2021		Venture round of family offices	$3.3M
2021		NIH grant funding	$3.9M
2025		NIH grant funding for AI development	$364K

USE OF PROCEEDS

We are raising a $15M Series A. These funds are designated to achieve three critical milestones: (1) Clinical Validation: completing a multi-site, 2,000-patient pivotal study to support our FDA 510(k) submission; (2) Commercial Launch: scaling our sales and marketing operations for the initial LDT launch and securing CPT reimbursement codes; and (3) Operational Expansion: finalizing the transfer of our assay to automated high-throughput platforms and expanding our ISO-13485 manufacturing capabilities.

KEY TEAM MEMBERS

Xuanyong Lu, Founder

Aaron Lu, CEO

Matthew Lee, COO

Karteek Kadimisetty, CSO

Bobby Biswal, VP of Engineering

ORBIT GENOMICS, INC.

Genomic Cancer Diagnostics Platform

Dede Willis | dwillis@orbitgenomics.com | 303-589-9845 | orbitgenomics.com

COMPANY OVERVIEW

Orbit Genomics is advancing a scalable precision healthcare platform designed to support multiple high-value products across the continuum of care. While commercializing its first product for early-stage lung cancer diagnosis, the company is leveraging the same platform to build a pipeline spanning disease diagnosis, treatment selection, disease prevention, and healthy aging. This platform-based strategy enables multiple commercial opportunities from a common technology foundation, supporting capital-efficient pipeline expansion, diversified revenue streams, and long-term value creation while addressing significant unmet needs across multiple disease areas.

MARKET & COMMERCIALIZATION STRATEGY

Orbit Genomics is initially focused on the approximately 2M Americans each year diagnosed with indeterminate pulmonary nodules (IPNs), representing an estimated $7B U.S. market opportunity. The company is commercializing its laboratory-developed test (LDT) through its CLIA laboratory, enabling commercialization without FDA review while pursuing reimbursement and adoption through clinical utility studies. Commercialization will focus on physicians managing patients with IPNs, supported by existing partnerships with leading key opinion leaders (KOLs) and strategic commercial collaborations to accelerate adoption. While conducting clinical studies to commercialize OrbiSeq-L, the company will continue leveraging the OrbiSeq™ platform to expand its product pipeline.

TECHNICAL & COMPETITIVE ADVANTAGE

Short tandem repeats (STRs) are highly informative regions of the genome that influence gene regulation, genome stability, DNA repair, and disease biology. Conventional genomic technologies cannot accurately analyze these regions, leaving an important source of biological information largely inaccessible. Orbit Genomics' proprietary OrbiSeq™ platform overcomes this longstanding limitation using proprietary algorithms to reconstruct STRs from standard sequencing data and AI-enabled analysis to develop clinically actionable products. Orbit Genomics is the only company capable of genome-wide STR analysis at scale, creating a differentiated biological signal that enables a new generation of products for diagnosis, treatment, disease prevention, and healthy aging.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Orbit Genomics is commercializing OrbiSeq-L as an LDT through its CLIA laboratory, enabling commercialization without FDA review. The company's intellectual property portfolio includes issued and pending patents protecting its platform and product applications, all of which are fully owned by the company. Proprietary algorithms, curated genomic databases, AI-enabled product development, and trade secrets provide additional layers of protection and create durable barriers to entry. In the United States, Orbit will commercialize directly through its CLIA laboratory while partnering with established diagnostic companies internationally to obtain country-specific regulatory approvals and commercialize future products.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Jan. 2022	Completed initial seed financing and launched company operations
Q4 2022	CLIA laboratory fully operational and commercial OrbiSeq platform completed
2023-2024	Key collaborations established with the Icahn School of Medicine at Mt. Sinai, Advocate/Atrium Health, Moffitt Cancer Center, Kaiser Permanente, and Houston Methodist
Sept. 2024	Awarded Direct to Phase II SBIR Grant from NIH/NCI to develop a subtyping lung cancer diagnostic test.
H2 2026	OrbiSeq-L CLIA validation completed and clinical utility studies initiated
H2 2027	First commercial sales of OrbiSeq-L
2028	Full commercial launch of OrbiSeq-L throughout the United States

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2022	Non-Dilutive Funding	Colorado Office of Economic Development and International Trade (OEDIT) Advanced Industries Early-Stage Capital & Retention Grant	$250K
2022	Dilutive Seed Funding		$3.3M
2024	Non-Dilutive Funding	Direct to Phase II NIH/NCI SBIR Grant	$2M
2026	Pre-A Convertible Note		$1M

USE OF PROCEEDS

Orbit Genomics is currently raising a $1M Pre-A convertible note to achieve key commercialization milestones, including completion of validation, initiation of clinical utility studies, and first commercial sales of OrbiSeq-L. A subsequent $15M Series A financing will fund full U.S. commercialization of OrbiSeq-L, expansion of commercial operations, and continued development of additional products leveraging the OrbiSeq™ platform.

KEY TEAM MEMBERS

Dede Willis, President & CEO Dede Willis is president, CEO, and cofounder of Orbit Genomics. She is a life science executive with more than 25 years of experience building and commercializing diagnostics, medical devices, therapeutics, and research products. Her expertise spans corporate strategy, fundraising, product development, clinical operations, regulatory strategy, manufacturing, and global commercialization, including leadership roles in multiple venture-backed companies and successful acquisitions.

Harold "Skip" Garner, PhD, Chief Scientific Officer Harold "Skip" Garner, PhD, is CSO, cofounder, and inventor of the OrbiSeq™ platform. An internationally recognized genomics and bioinformatics pioneer, he has founded multiple life science companies, secured more than $15M in NIH funding, published over 220 scientific papers, and pioneered technologies successfully commercialized through acquisitions by Roche and LGC.

SUS CLINICALS, INC.

Large-Animal Preclinical Cancer Model

Kyle Schachtschneider | kyle@susclinicals.com | 201-334-6968 | Susclinicals.com

COMPANY OVERVIEW

Researchers today rely on inexpensive but minimally predictive mouse testing combined with safety-only testing (usually in nonhuman primates/canines, which have significant societal concerns) to move to expensive, time-consuming human clinical trials, with <5% of drugs progressing to patients. Further, device-based approaches (e.g. catheter-based drug delivery, ablation) are impossible to test in tumor-bearing rodents due to their size. Our genetically modified Oncopig® leverages the many similarities between the pig (*Sus scrofa*) and human. For decades, pigs have been used for "replacement parts" (e.g. heart valves). More recently, advances in xenotransplantation indicate that pig organs can be used in humans. However, it was the mapping of the pig genome that demonstrated that pigs and humans have a 98% overlap genetically (along with similar metabolic and immune systems). This inspired the development of the Oncopig, the only large animal research platform that reliably replicates human cancers on demand. By activating two embedded genetic mutations, we generate human-like tumors in as little as two weeks, with a >95% success rate. Once tumors have formed, therapeutics can be tested in vivo, generating predictive data that help clients define next steps, including regulatory filings, human trials, and readiness for market.

MARKET & COMMERCIALIZATION STRATEGY

The global large animal preclinical research market (animals and services) is over $20B (+4-6% CAGR). Within this, the specific market for oncology work alone is nearly $5B, affording significant revenue potential. Target clients span the full range of cancer therapeutics, including medical devices (our early adopters), diagnostics, and pharmaceuticals. The Oncopig has been commercially availalle since it was FDA-cleared in 2022. We work in partnership with top-tier clinical research organizations (CROs) to deliver services to our clients.

TECHNICAL & COMPETITIVE ADVANTAGE

Sus Clinicals is the only company currently offering an inducible porcine cancer model, capable of generating relevant tumors in as little as one week. Competitive advantage comes from exclusive global rights to the transgenic porcine model, plus other worldwide, exclusive licenses that, combined with internal R&D, support new product and service offerings. Our skilled team has extensive scientific expertise, know-how, and a record of securing non-dilutive grant funding, all of which fuels a robust innovation program.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The Oncopig received FDA clearance in 2022. Additional offerings currently in development will likely need to go through a similar clearance process. We benefit from global exclusive licenses to our core technologies, and we anticipate pursuing additional internal IP generated by our scientific team.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
April 2020	Company formation and initial global exclusive license to Oncopig from Univ. of Illinois
Feb. 2022	FDA clearance
May 2022	First revenue; Scientific Advisory Council formed
June 2023	Global exclusive license to novel immune-evasion IP from Univ. of Wisconsin
Nov. 2023	Global exclusive license to mini-Oncopig from Univ. of Wisconsin
Jan. 2024	$2M SBIR grant
Sept. 2024	First international expansion via sublicense with Versa Biomedical (Spain)
Sept. 2025	Closed $4.7M Series Seed round
June 2026	Surpassed $5M in cumulative Oncopig studies conducted to date

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2023	Convertible note		$2.7M
2025	Series Seed	Non-dilutive SBIR funding across oncology, optic neuritis, ADEM, lupus, Crohn's, and lung cancer	$2M
2026	Growth capital bridge round via SAFE	($500K raised to date)	$2M

USE OF PROCEEDS

Raising $2M. Use of funds:

- Business Development: Staffing and targeted marketing ($750K)
- R&D Pipeline: Mini-Oncopig — Build up breeding herd and generate data for FDA clearance of new, smaller version specifically tailored to expand penetration in pharma sector ($250K)
- Immune Evasion Technology/PDX Pig Platform — Complete validation work and conduct initial pilots to support FDA clearance and marketing of breakthrough new offering ($500K)
- Operational Improvements: Establish new Oncopig breeding site at third-party non-academic contractor to replace or augment current University of Illinois location ($500K)

KEY TEAM MEMBERS

Steve Baggott (CEO) Steve Baggott brings 18 years of global business development leadership at Procter & Gamble, where he helped shape its Connect+Develop innovation strategy and led or oversaw hundreds of strategic partnerships, licensing agreements, acquisitions, and joint ventures. He is an investor and board director at QCA Ventures and was previously COO of Sus Clinicals.

Lawrence B. Schook, PhD (CSO and Co-Founder) Dr. Schook is a pioneer in the use of pigs in biomedical research, leading the global effort to sequence the pig genome in 2012, and the Illinois team that developed the transgenic Oncopig.

Kyle M. Schachtschneider, PhD (VP of R&D & Services) Dr. Schachtschneider is a co-inventor of the Oncopig and has over a decade of experience with transgenic animals.

Gradient Health

GRADIENT HEALTH, INC.

Real-World Data (RWD) Research Platform

Joshua Miller | josh@gradienthealth.io | 954-729-3963 | gradienthealth.io

COMPANY OVERVIEW

Gradient Health is a real-world data (RWD) research platform providing access to over 20 million de-identified medical imaging studies representing approximately 1% of the U.S. adult population. The platform enables AI researchers and developers to access diverse, multi-modal medical imaging data—including radiology (CT, MR, X-ray, mammography, ultrasound) and digitized pathology slides spanning major cancer indications—linked to longitudinal electronic health records via privacy-preserving record linkage.

Gradient Health's data licensing model has demonstrated rapid commercial traction, growing from $1M in 2023 to $3M in 2024 to $7.2M in 2025, serving leading AI research labs including OpenAI, Anthropic, and Meta, as well as medical device and pharmaceutical companies.

With NCI SBIR support, Gradient Health is extending its platform into a federated cloud infrastructure—a secure network of Trusted Domain compute nodes—that enables hospitals to make their imaging and pathology data available for AI research without requiring data to leave institutional control. This directly addresses the NCI-funded mandate to create large, representative datasets for cancer AI development, dramatically expanding the supply and demographic diversity of available training data.

The federated architecture transforms healthcare data from a cost center into a revenue driver for participating health systems, addressing critical gaps in cancer AI: insufficient training data diversity, lack of representative datasets across demographics and cancer types, and the prohibitive cost of secure compute infrastructure. Gradient Health leads the productization and commercialization of this platform, leveraging its existing commercial data licensing engine and relationships with over 1,000 hospital sites.

MARKET & COMMERCIALIZATION STRATEGY

AI in medical imaging is projected to reach $14.2B by 2032, and digital pathology is expected to grow to $1.74B by 2028. Deploying regulated AI in healthcare requires significant investment in training data access, secure compute, and compliance infrastructure. We estimate average per-organization R&D spend of $400K–$1.5M on these needs, implying a core U.S. Serviceable Addressable Market (SAM) of ~$0.7B–$1.4B for data and compute infrastructure.

Gradient Health addresses a critical unmet need: AI developers spend an estimated 80% of their time on data preparation rather than model innovation, and most available training datasets lack the demographic representativeness required for equitable cancer AI. The platform eliminates data preparation friction while ensuring representative coverage across patient populations.

Current products: (1) RWD data licensing platform for medical imaging and linked clinical data; (2) Federated search and cohort discovery engine; (3) Cloud-optimized medical imaging data storage and access.

Pipeline products: (1) Federated Trusted Domain compute nodes for secure AI development on institutional data; (2) App marketplace for AI tools, annotation services, and FDA Regulatory Science Toolkits (RSTKs); (3) Federated learning infrastructure for cross-institutional model training; (4) Consumption-based compute services with Trusted Domain security premium. The cancer AI segment is particularly high-growth, driven by FDA emphasis on diverse training data for algorithm validation and increasing demand for real-world evidence in oncology.

TECHNICAL & COMPETITIVE ADVANTAGE

Gradient's network of hospital systems serves as a moat, as does its proprietary deidentification technology.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The platform is data infrastructure and does not require FDA clearance. The platform integrates FDA RSTKs as service offerings, enabling AI developers to validate models within the platform. The FDA is a direct collaborator on the NCI-supported program. Reimbursement is not applicable to the platform; revenue is generated through data licensing and compute consumption fees. Provisional patent filed in 2022 to cover System and Method for Reversibly Deidentifying Medical Imagery.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2024	$3.2M in Revenue
2025	$5.2M in Revenue
2026	$22M YTD

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2022	Seed Round	Venture South	$2M
2023	SEED+	Remy	$2.75M
2025	SAFE	Remy + Venture South	$3.7M

USE OF PROCEEDS

The company is currently seeking $10M–$40M in venture funding within the next 12 months to accelerate sales and go-to-market expansion, engineering team growth, hospital enrollment subsidies to scale data coverage and representativeness, and sovereign cloud infrastructure deployment. Targeting close by mid-2026, with funds deployed over 18–24 months.

KEY TEAM MEMBERS

Joshua Miller, CEO
Sai Cheemalapati, CTO
Pia Spratley, CPO
Daniel Klass, CFO
Benji Meltzer, COO
Rod Greco, CRO
Katelin Kennedy, CCO

IMVARIA

Clinical AI Platform

Joshua Reicher | jreicher@imvaria.com | 858-922-8960 | imvaria.com

COMPANY OVERVIEW

IMVARIA is an applied clinical AI company and Medicare-registered IDTF commercializing FDA-authorized AI technology in high-impact disease states. Its cleared products, Fibresolve (IPF/ILD diagnosis) and ScreenDx (lung nodule/ILD detection), plus pre-market Bronchosolve (nodule malignancy risk), use multimodal AI to improve patient outcomes.

MARKET & COMMERCIALIZATION STRATEGY

IMVARIA generates revenue across three active commercial channels. First, direct payer-reimbursed clinical services: Fibresolve is billed under CPT 0877T/0880T through Medicare and commercial payers. Second, health system partnerships: IMVARIA is building physician- and practice-level adoption through EHR-integrated ordering workflows, clinical liaison outreach, and pulmonology-focused sales channels. Third, pharma and clinical trial relationships: IMVARIA has established an IP framework for custom-tuned applications, enabling parallel pharma partnerships while preserving freedom to operate across multiple industry collaborators simultaneously.

TECHNICAL & COMPETITIVE ADVANTAGE

IMVARIA's competitive advantage rests on a strong technical team building a fully regulatory-enabled AI stack, from data pipeline through FDA clearance to reimbursement. The company holds FDA De Novo and 510(k) clearances for Fibresolve and ScreenDx, plus CMS Medicare IDTF registration and active CPT billing codes (0877T/0880T) — a rare combination that most AI diagnostics competitors lack. This end-to-end regulatory and reimbursement infrastructure, paired with proprietary clinical datasets and multimodal vision transformer architectures, creates a durable moat: Competitors face years of regulatory and coding work that IMVARIA has already completed and is actively defending against misuse by less-differentiated entrants.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

IMVARIA has developed a streamlined, repeatable regulatory process spanning documentation generation, FDA interaction, and clinical study execution — enabling efficient De Novo and 510(k) submissions for Fibresolve and ScreenDx, with next-gen tech currently in review. This infrastructure supports rapid iteration as new tech develops. IMVARIA's IP portfolio includes two issued U.S. patents (US12315152B2, US12354749B2) covering core diagnostic methods, with a pending continuation application broadening claims to a more general ML model and system-level architecture. Combined with active CMS coding strategy, this creates strong barriers to competitive replication.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2023	ScreenDx launched into pharma (DI-ILD fine-tuning) and health system partnerships
2026	Fibresolve clinical utility study published, demonstrating payer-relevant real-world outcomes
2026	Fibresolve v3 launched, adding multiclass ILD pattern classification across five CT morphologies
2026-2027	Bronchosolve FDA 510(k) clearance for pulmonary nodule malignancy risk stratification
Ongoing	Multiple peer-reviewed publications and conference presentations

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020		Seed round led by Creative Ventures	$3M
2026		Amount undisclosed from LabCorp and other investors	
To date		Amount undisclosed Total raised to date	~$7M

USE OF PROCEEDS

IMVARIA is raising $15M to fund commercialization — sales and marketing to clinicians — to scale toward $10M in revenue, expand its product pipeline (10 new offerings), and grow pharma business development partnerships.

KEY TEAM MEMBERS

Dr. Joshua Reicher, CEO, Founder, Board Member: Stanford radiology/CS faculty; prior Google AI, Palo Alto Investors (healthcare hedge fund), ML-in-medicine publications, extensive coding background.

Dr. Michael Muelly, CTO, Founder, Board Member: Stanford radiology/CS faculty; prior Google Cloud Healthcare PM, co-founded imaging and network security start-ups. ML-in-medical-imaging publications.

MPATH HEALTH
(DIGITAL HEALTH NAVIGATION SOLUTIONS, INC.)

Digital Oncology Navigation Platform for Cancer Screening Enablement

Dave Miller | dave@mpathhealth.com | 336-830-2551 | mpathhealth.com

COMPANY OVERVIEW

Digital Health Navigation Solutions, Inc. (d/b/a mPATH Health) is a Winston-Salem, NC, vertical SaaS company that closes cancer screening gaps for health systems and payers. Over half of Americans miss guideline-recommended cancer screening, producing late-stage diagnoses for patients and, for provider and payer organizations, resulting in financial losses from missed quality-bonus payments. EHR reminders identify and notify patients but stop there; human navigators close gaps effectively but cost $450–$600 per patient and cannot scale. mPATH is an end-to-end, direct-to-patient digital navigation platform. It ingests a weekly nine-field CSV from any EHR; reaches patients by text, email, or portal; verifies true screening eligibility through interactive questions and algorithms; educates with behavioral science multimedia designed for low-literacy populations; and enables patients to self-order their screening test — over half of engaged eligible patients do so with no staff contact. AI agents manage escalation and follow-through to completion. Modules cover colorectal, lung, breast, and cervical cancer screening, with additional HEDIS-measure modules in development. Deployment takes 3–4 weeks with no EHR integration project. The platform was developed over 15+ years with more than $8M in NCI funding and is the only solution in its category validated in multiple randomized controlled trials. The company was founded in 2022 by two academic physician-informaticists and holds an exclusive worldwide license in perpetuity to the mPATH technology from Wake Forest University Health Sciences.

MARKET & COMMERCIALIZATION STRATEGY

Primary customers are U.S. health systems, accountable care organizations, payers, and federally qualified health centers — approximately 2,200 health systems and ACOs serving 115M adults in the target screening age range. Demand is driven by the shift to value-based reimbursement: CMS Stars and HEDIS performance directly determine plan revenue, and Medicare quality bonus payments exceed $10B annually. The value-based care payment market is growing roughly 10% per year. Serviceable market is approximately $413M for a single screening module, scaling to $1.2B at three modules and $5B+ across 12 modules as the platform extends to additional preventive care measures. mPATH sells direct to population-health, quality, and cancer-center leadership, landing with a single module and panel, then expanding modules and covered lives. Current customers include Atrium Health, Kintegra Health, and UNC School of Medicine. Contracted ARR is approximately $130K, with $62K live as customers ramp to full deployment. The active pipeline is $3.1M across 26 opportunities, with $1.1M+ in late stage, spanning multi-state health systems, two statewide health plans, FQHC networks, NCI-designated cancer centers, state health departments, the U.S. Department of Veterans Affairs, and MedTech/pharma research partnerships. Commercial gross margin was 82% in 2025. Pricing is an annual per-patient SaaS subscription with volume discounts, priced at a fraction of the value created.

TECHNICAL & COMPETITIVE ADVANTAGE

mPATH's advantage is peer-reviewed evidence no competitor possesses. In randomized controlled trials, mPATH increased lung cancer screening completion by 44% versus active control (*JAMA*, 2025) and doubled colorectal cancer screening completion, 30% versus 15% (*Annals of Internal Medicine*). A third study demonstrated that mPATH identifies approximately three times as many screening-eligible patients as EHR data alone (*American Journal of Preventive Medicine*). Published results also show equivalent effectiveness across race, ethnicity, and socioeconomic strata — evidence increasingly required as organizations stratify quality measures. To date: 26,000+ patients enrolled in clinical studies, 100,000+ patients served, and 15 peer-reviewed publications. Competing

approaches fall into three tiers. (1) EHR-native tools (Epic/MyChart reminders) identify and notify but do not verify eligibility, motivate, or convert. (2) Patient engagement platforms such as CipherHealth and CareMessage automate outreach but stop at messaging. (3) Human navigation covers the full journey but at $450–$600 per patient with no path to scale. mPATH is the only solution combining eligibility algorithms, behavioral science engagement, patient self-ordering, and randomized-trial proof of completion. Architecturally, mPATH runs external to the EHR, requiring only a scheduled CSV. This eliminates integration projects, enables 3- to 4-week deployment versus 9–12 months for integration-dependent vendors, and makes the platform EHR-agnostic across Epic, Cerner, Athena, and eClinicalWorks. The codebase supports white-labeling per customer, and the module architecture allows new screening types to be added on the same platform.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

mPATH's functionality was deliberately designed to remain below the FDA's threshold for Software as a Medical Device; the platform does not diagnose, treat, or provide device-level clinical decision support. The company therefore has no FDA regulatory requirements or pending submissions. The platform is SOC 2 Type 2 certified and HIPAA-compliant, operating on a HIPAA-compliant cloud infrastructure, and received the DiMe Seal from the Digital Medicine Society (2026) for digital health quality. Performance reporting is aligned to HEDIS measures. Patient outreach practices are structured for TCPA compliance. Intellectual property comprises three pending U.S. patents; an exclusive, perpetual, worldwide license from Wake Forest University Health Sciences to develop, market, and sell the mPATH platform; proprietary behavioral science content and educational media; and a peer-reviewed evidence base that functions as a practical barrier to entry, requiring years and substantial funding to replicate.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Pre-2022	$6M+ in competitive NCI funding awarded to develop, refine, and test mPATH at Wake Forest University School of Medicine
2018	Randomized trial published in *Annals of Internal Medicine* shows mPATH doubles colorectal cancer screening completion
June 2022	Company formed; acquired exclusive worldwide license in perpetuity to mPATH from Wake Forest University Health Sciences
July 2022	Convertible note financing launched, led by WSPR-DHN LLC
Oct. 2022	Technology stack transferred from Wake Forest University to company-owned HIPAA-compliant cloud infrastructure
April 2023	Awarded NIH Fast-Track STTR to support commercialization; first tranche received
June 2023	First commercial customer live in production
Sept. 2024	Closed $1M Series Seed Preferred round led by Oncology Ventures Fund I LP; all outstanding convertible notes converted to Series Seed-2 Preferred
2025	Breast cancer screening module released; selected for CancerX; won HLTH Techquity Award
Nov. 2025	Lung cancer screening randomized trial published in *JAMA* — 44% increase in screening completion 2
2026	Received DiMe Seal; launched cervical cancer screening module and AI navigation agents
June 2026	Initial close of $1.5M seed extension, led by VentureSouth with Oncology Ventures participating above pro-rata

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2022–2024	Pre-Seed/ Convertible Notes	(Note Purchase Agreement dated July 19, 2022) Seed convertible note financing led by WSPR-DHN LLC, with participation from FCP Ventures I, Atlanta Technology Angels, RTP Angel Fund, First Launch Capital Fund, VentureSouth Investments A, and individual angels; converted into Series Seed-2 Preferred Stock at the Series Seed closing	$706K
2023–2025	Non-Dilutive Grant Funding	NIH Fast-Track STTR Phase I/II supporting commercialization	$2.3M
2023	Non-Dilutive State Award	One NC Small Business Program matching award	$75K
Sept. 2024	Series Seed-1 Preferred	Priced equity round led by Oncology Ventures Fund I LP ($750K), with participation from FCP Ventures I, RTP Angel Fund, Atlanta Technology Angels, and individual investors; 1,508,000 shares issued at $0.6631 per share	$1M
2026	Seed Extension (Series Seed-3) Preferred	Priced round at $10M pre-money led by VentureSouth, with Oncology Ventures participating above its pro-rata share; initial close June 25, 2026; final close September 2026, $1.5M target; closed to date	$650K

USE OF PROCEEDS

mPATH Health is raising a $1.5M seed extension, a priced equity round at $10M pre-money led by VentureSouth and $650K closed at the initial closing on June 25, 2026. The company is raising a final $300K–$500K ahead of a September 2026 final close. Proceeds will be deployed approximately as follows: $650K to commercial growth and customer success — expanding sales capacity to convert the current $3.1M pipeline and supporting deployment of new customers; $500K to product and technology — completing new modules, extending AI navigation agents, and expanding from four toward nine screening modules; and $350K to operations and infrastructure. This capital provides 24+ months of runway and funds three milestones that de-risk a Series A: 14+ paying customers and $2M ARR, multi-module adoption in more than 25% of accounts, and a documented deployment playbook demonstrating operational scalability.

KEY TEAM MEMBERS

David P. Miller, MD, MS — Founder & Chief Executive Officer: Board-certified in internal medicine and clinical informatics with 20+ years experience in developing, testing, and implementing digital health interventions. Principal investigator on the NCI-funded research program that produced mPATH, with 15 peer-reviewed publications including randomized trials in *JAMA* and *Annals of Internal Medicine*.

Dan Fiza — Head of Technology: Leads all software engineering for the mPATH platform, including the cloud architecture that enables EHR-agnostic deployment in 3–4 weeks with no integration project. Spent 9 years at Visneta, where he built and led the software development team, and brings that team-building experience to scaling mPATH's SOC 2 Type 2-certified, HIPAA-compliant platform across new screening modules.

Peter Kramer — Head of Business Operations; Operations executive and repeat healthcare founder: Co-founded Abiquis and served as its COO through a successful acquisition by HealthStream (NASDAQ: HSTM); co-founder of three healthcare start-ups.

NEURALRAD LLC

AI-Powered Radiotherapy Software

Hao Jiang | hao.jiang@neuralrad.com | 734-358-8641 | neuralrad.com

COMPANY OVERVIEW

NeuralRad LLC is a medical technology company focused on developing AI solutions for radiation oncology. The company creates software designed to improve the efficiency, consistency, and accuracy of complex clinical workflows, particularly for patients receiving stereotactic radiosurgery and other precision radiation treatments. NeuralRad's technology supports automated tumor and organ segmentation, brain metastasis detection and labeling, treatment-session planning, longitudinal lesion tracking, and dose evaluation. By integrating advanced medical imaging, deep learning, and clinical workflow automation, NeuralRad aims to reduce repetitive manual work, support informed clinical decision-making, and help healthcare teams deliver more personalized and precise cancer care.

MARKET & COMMERCIALIZATION STRATEGY

NeuralRad serves the growing market for AI and workflow-automation solutions in radiation oncology. The company's primary customers include academic medical centers, community cancer centers, health systems, and radiation oncology practices that perform stereotactic radiosurgery and other image-guided radiation treatments. Initial commercialization efforts will focus on institutions treating patients with brain metastases, where clinical teams must manage time-intensive tasks such as tumor segmentation, lesion labeling, treatment-session planning, longitudinal follow-up, and dose evaluation. NeuralRad's commercialization strategy is based on a phased approach. The company will first expand research collaborations and clinical validation at leading medical centers to demonstrate workflow efficiency, clinical reliability, and compatibility with existing oncology systems. These partnerships will also support product refinement, regulatory documentation, and the development of clinical evidence required for broader adoption. Following regulatory clearance, NeuralRad plans to offer its software through annual institutional licenses, subscription-based pricing, and enterprise agreements. Pricing may be structured according to treatment volume, number of users, clinical sites, or selected software modules. The platform is designed to integrate with existing imaging, treatment planning, oncology information, and hospital systems, reducing implementation barriers and allowing institutions to adopt the technology without replacing their current infrastructure. The company will pursue commercialization through direct sales to hospitals, strategic partnerships with radiation therapy equipment manufacturers and oncology software companies, and collaborations with clinical research networks. Early customers and clinical partners will serve as reference sites, helping demonstrate the platform's value and supporting expansion into additional treatment areas. NeuralRad's long-term commercial opportunity extends beyond brain stereotactic radiosurgery. The company plans to apply its AI and agent-based workflow technologies to additional disease sites, treatment techniques, and clinical decision-support applications. By combining medical-image analysis, longitudinal patient data, and workflow automation, NeuralRad aims to become a scalable software platform for precision radiation oncology.

TECHNICAL & COMPETITIVE ADVANTAGE

NeuralRad technical advantage lies in its ability to combine advanced medical-image analysis with workflow automation designed specifically for radiation oncology. Rather than providing a single-purpose AI tool, NeuralRad is developing an integrated platform that supports multiple steps of the stereotactic radiosurgery workflow, including tumor segmentation, anatomical labeling, lesion grouping, treatment-session planning, longitudinal tracking, and dose evaluation. The platform is particularly suited for patients with multiple brain metastases, where clinicians may need to identify, review, label, and manage dozens of lesions across multiple imaging studies and treatment courses. NeuralRad's technology is designed to automate repetitive and time-consuming tasks while preserving clinician oversight. This approach can improve workflow consistency, reduce manual effort, and help clinical teams manage increasingly complex cases. A key competitive advantage is NeuralRad's lesion-level

intelligence. The platform can distinguish and label individual brain metastases, associate lesions across follow-up studies, and support evaluation of prior treatments and cumulative doses. This longitudinal capability goes beyond conventional segmentation software, which often focuses primarily on generating contours from a single imaging study. NeuralRad also incorporates treatment-specific workflow tools for Gamma Knife, CyberKnife, and linear accelerator-based stereotactic radiosurgery. Its algorithms can assist with lesion grouping, treatment-session splitting, and case organization based on clinical and technical constraints. This enables the platform to address practical treatment-planning challenges rather than functioning solely as an image-processing application. The system is designed for interoperability with existing clinical infrastructure, including medical imaging systems, treatment-planning systems, oncology information systems, and DICOM-based workflows. NeuralRad can be deployed through secure institutional or cloud-based environments, with privacy protections and deidentification capabilities designed to support clinical and research use. Additional competitive strengths include NeuralRad's access to clinical expertise, collaboration with academic medical centers, and focus on regulatory and clinical validation. The company's close interaction with radiation oncologists, medical physicists, and treatment-planning teams enables its products to be developed around real clinical needs and continuously refined using workflow feedback. By combining AI, longitudinal patient analysis, treatment-specific optimization, and clinical workflow integration, NeuralRad offers a differentiated platform that can support more efficient, consistent, and personalized radiation oncology care.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

NeuralRad LLC has made substantial progress toward regulatory clearance of its clinical software. The company has completed two FDA Pre-Submission, or Q-Sub, interactions and is currently in the final stage of the FDA 510(k) clearance process. Feedback received through these FDA engagements has helped guide the product's intended use, clinical claims, validation strategy, software documentation, risk management, and human-factors requirements. NeuralRad's regulatory program includes design controls, software requirements, risk-management documentation, cybersecurity planning, verification and validation testing, usability engineering, clinical-performance evaluation, and requirements traceability. The company is also developing and maintaining quality-system procedures for software configuration management, document control, complaint handling, corrective and preventive actions, and post-market monitoring. Clinical validation focuses on demonstrating the accuracy, reliability, safety, and workflow performance of NeuralRad's AI technologies. Evaluation measures include tumor-detection sensitivity, segmentation accuracy, false-positive rates, lesion-labeling accuracy, longitudinal lesion-tracking performance, processing time, and agreement with expert clinicians. Multi-institutional collaborations help evaluate performance across different imaging systems, clinical protocols, patient populations, and treatment environments. NeuralRad's intellectual-property strategy combines patent protection, software copyright, trade secrets, trademarks, contractual safeguards, and proprietary clinical expertise. Key innovations include methods for brain metastasis detection and segmentation, anatomical lesion labeling, false-positive reduction, treatment-session grouping, longitudinal lesion matching, dose accumulation, and agent-based radiation oncology workflow automation. The company further protects its competitive position through proprietary algorithms, curated clinical datasets, model-training methods, software architecture, workflow designs, and integration capabilities. Confidentiality agreements, invention-assignment provisions, data-use agreements, licensing terms, and controlled access to source code, models, and training data are used to safeguard these assets. NeuralRad works with intellectual-property and regulatory counsel to evaluate patentability, freedom to operate, product ownership, licensing considerations, and regulatory compliance. The company's intellectual-property strategy is closely aligned with its FDA 510(k) clearance activities, commercialization milestones, strategic partnerships, and planned expansion into domestic and international markets.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2018	Founded NeuralRad to develop AI and workflow-automation technologies for radiation oncology.
2021	Received an NIH/NCI SBIR Phase I award to support the initial development and evaluation of NeuralRad's AI-based radiation oncology software.
2023	Selected to present NeuralRad's AI technology at an International Atomic Energy Agency workshop on AI applications in radiation oncology.
2023	Received an NCI SBIR Phase II contract to advance the AimBMs platform for automated brain metastasis analysis and stereotactic radiosurgery workflow support.
2024	Expanded the platform to support automated brain metastasis segmentation, anatomical labeling, false-positive reduction, lesion grouping, and treatment-session planning.
2024	Began research deployment and clinical evaluation of NeuralRad technology at multiple academic medical centers and healthcare institutions.
2025	Completed the first FDA Q-Submission interaction to obtain regulatory feedback on intended use, validation requirements, clinical claims, and the planned 510(k) pathway.
2025–2026	Completed a second FDA Q-Submission interaction and incorporated FDA feedback into software validation, risk management, usability, cybersecurity, and regulatory documentation.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	NIH/NCI SBIR Phase I	Supported the initial feasibility study, technical development, and early validation of NeuralRad's AI-powered radiation oncology platform.	$40K
2023–2026	NIH/NCI SBIR Phase II	Supports advanced product development, clinical validation, regulatory preparation, and commercialization of the NeuralRad Brain platform for brain metastasis stereotactic radiosurgery.	$2M+

USE OF PROCEEDS

NeuralRad is currently raising $3M in venture and strategic investment capital to support FDA clearance, commercial launch, clinical deployment, and expansion of its AI platform for radiation oncology. The financing will provide the resources needed to transition NeuralRad from advanced product development and regulatory validation into a scalable commercial-stage medical software company. NeuralRad also plans to apply for the NCI SBIR Phase IIB Bridge Award, a commercialization-focused program designed to leverage private-sector investment through a one-to-one non-federal funding match. Subject to eligibility, application review, and award approval, the proposed $3M private financing could support an application for up to approximately $3M in matching federal funding, potentially providing NeuralRad with approximately $6M in combined private and non-dilutive capital. The Phase IIB award is competitive and is not guaranteed. NCI has described the program as requiring matching funds from outside the federal government and has historically offered awards of up to $4M. The anticipated use of the $3M investment is as follows: $600K – FDA Regulatory and Quality Activities: Complete the final stages of the FDA 510(k) clearance process, respond to FDA requests, complete software verification and validation, strengthen cybersecurity documentation, maintain design controls, and establish post-market quality and regulatory processes. $750K – Clinical Validation and Hospital Deployment: Conduct multi-institutional clinical validation, support pilot and commercial installations, evaluate performance across different imaging and treatment environments, and generate evidence demonstrating accuracy, safety, reliability, and workflow efficiency. $700K – Product Development and Technical Infrastructure: Expand the engineering team, enhance the clinical software platform, strengthen DICOM and hospital-system integrations, improve cybersecurity and deployment infrastructure, and develop additional AI and agent-based workflow capabilities. $600K – Commercialization and Market Expansion: Build sales, marketing, implementation, and customer-support capabilities; establish clinical reference sites; attend industry conferences; and develop partnerships with hospitals, radiation therapy manufacturers, and oncology software companies. $200K – Intellectual Property and Legal Activities: Support patent preparation and prosecution, freedom-to-operate analysis, licensing agreements, contracting, regulatory counsel, and protection of NeuralRad's proprietary algorithms, software, datasets, and workflow technologies. $150K – Working Capital and Corporate Operations: Fund insurance, accounting, administrative expenses, recruiting, business operations, and other costs required to support commercial growth. The financing, together with potential NCI SBIR Phase IIB matching funds, is expected to support key value-creating milestones, including FDA 510(k) clearance, completion of multi-institutional validation, initial commercial installations, strategic industry partnerships, recurring software revenue, and expansion of the NeuralRad platform into additional radiation oncology applications.

KEY TEAM MEMBERS

Hao Jiang, PhD — Co-Founder and CEO of NeuralRad and Assistant Professor at UT Southwestern Medical Center. Dr. Jiang has expertise in medical physics, AI, radiation oncology, medical imaging, and clinical software development. He leads the company's technology strategy, product development, clinical collaborations, fundraising, and commercialization activities.

Weiguo Lu, PhD — Co-Founder and Clinical Technology Advisor of NeuralRad and a medical physics expert at UT Southwestern Medical Center. Dr. Lu contributes expertise in radiation therapy, stereotactic radiosurgery, treatment planning, clinical workflow design, and the evaluation and validation of AI technologies for radiation oncology.

Xuejun Gu, PhD — Co-Founder and Scientific Advisor of NeuralRad and a medical physics and AI expert at Stanford University. Dr. Gu supports the company's scientific strategy, algorithm development, medical-image analysis, clinical research, and validation of AI-powered radiation oncology technologies.

Derick Zhou — Cybersecurity Expert. Mr. Zhou is a cybersecurity specialist responsible for guiding NeuralRad's security architecture, risk assessment, data protection, and secure software development practices. He supports the company's efforts to meet healthcare cybersecurity, patient-privacy, hospital IT, and FDA medical-device software requirements.

Yinghua Tao — FDA Regulatory Expert. Ms. Tao is a regulatory specialist with expertise in FDA requirements for medical devices and Software as a Medical Device. She advises NeuralRad on its FDA 510(k) strategy, Q-Sub interactions, regulatory documentation, design controls, risk management, software verification and validation, and quality-system compliance.

