2023–2024 | NCI SBIR

INVESTOR INITIATIVES

SHOWCASE COMPANIES

NATIONAL CANCER INSTITUTE | SBIR DEVELOPMENT CENTER

INVESTOR | INITIATIVES

SHAPING THE FUTURE OF HEALTH CARE

MEETING THE MODERN WORLD'S DEMAND FOR FAST, ACCESSIBLE, AND ACCURATE CANCER SOLUTIONS

- Quicker drug development
- Digital health care solutions for personalized, remote monitoring
- Earlier, faster, more accurate disease detection
- Earlier investment in biotech startups

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BIOPHARMACEUTICALS

Company	Technology Type	Indication
Accuronix Therapeutics	Small molecule targeting sigma-2 receptor	Pancreatic adenocarcinoma, synovial sarcoma, other rare tumors
Allterum Therapeutics (Fannin Partners)	Anti-CD127 antibody	Acute lymphoblastic leukemia
AVM Biotechnology	Novel non-toxic preconditioning regimen for cancer cell therapy	Relapsed/refractory non-Hodgkin's lymphoma/leukemia
BioMimetix	Novel therapeutic class of redox active metalloporphyrin compounds	Glioblastoma, head and neck cancer, anal/rectal cancer, ovarian cancer
Curadel Surgical Innovations	Theranostic drugs for optical surgical navigation	Solid tumors (colorectal carcinoma, head and neck cancer, pancreatic cancer)
Enzyme by Design	Novel glutaminase-free mammalian asparaginase with minimized immunogenicity	Acute lymphoblastic leukemia
Immunophotonics	Pioneering Interventional Immuno-Oncology™	Solid tumor ablation and radiation market (melanoma, soft tissue sarcoma, non-small cell lung cancer, colorectal cancer with liver metastasis, hepatocellular carcinoma)
Indee Labs	Instruments for more effective engineered cell therapies	Cell-based immunotherapies
Kuda Therapeutics	Novel dual HIF-α inhibitor and inducer of ferroptosis	Kidney cancer
Luminary Therapeutics	Novel gamma delta allogenic manufacturing platform	CAR-T therapy
Microvascular Therapeutics	CD90-targeted phase shift microbubbles for HIFU-mediated non-thermal ablation of tumors	Brain tumors
Modulation Therapeutics	First-in-class targeted radiotherapies	Metastatic melanoma

Privo Technologies	Nanoparticle-based drug delivery platform	Oral carcinoma in situ, solid tumors
Reveal Pharma	Gadolinium-free MRI contrast agent	Liver, kidney MRI
RNA Nanotherapeutics	Multifunctional RNA nanoparticles	Breast cancer
StemSynergy Therapeutics	Small molecule modulators of key signaling pathways (WNT, Notch, MYC, Hippo)	Familial adenomatous polyposis, colorectal cancer
Stingray Therapeutics	Potent and selective oral ENPP1 inhibitor	Triple negative breast cancer, microsatellite stable colorectal cancer, locally advanced pancreatic cancer, renal cell carcinoma
Talus Bioscience	Transcription factor inhibitors for targeted cancer therapeutics	Chordoma
Ternalys Therapeutics	Engineered, non-coding microRNA-based therapy	Glioblastoma
Tezcat Biosciences	Metabolically selective RAS cancer therapeutics	Mutant RAS relapsed/refractory multiple myeloma
Trace Biosciences	Nerve-specific imaging agents for surgery	Prostatectomy
TransCode Therapeutics	Targeted therapy for metastatic cancer	Metastatic cancer
Vivreon Biosciences	Oral, gut-restricted therapeutic	Enterocolitis caused by immune checkpoint inhibitor immunotherapy

DIAGNOSTICS/TOOLS

Company	Technology Type	Indication
EarlyDx	Blood-based cfDNA multi-cancer test	Early cancer diagnosis (liver cancer, lung cancer)
Lifegene-Biomarks	Precision DNA methylation PCR tests in biofluids	Cervical cancer prevention
MicrOmics	Tool developer for ultra-sensitive proteomics analysis	Single-cell proteomics

DEVICES

Company	Technology Type	Indication
Alpenglow Biosciences	AI-enabled 3D spatial biology platform	Prostate cancer, breast cancer, immuno-oncology
Ananya Health	Self-contained, portable cryoablation device	Cervical cancer prevention
Arsenal Medical	Solvent-free, shear-responsive, silicone-based biomaterial	Hypervascular extra-axial brain tumors (meningiomas)
Clarix Imaging	Bringing true 3D clarity to specimen imaging	Breast-conserving surgery (lumpectomy)
Euclid Beamlabs	Electronic brachytherapy device	Cancer radiotherapy
Leuko Labs	Non-invasive white blood cell monitoring	Chemotherapy-induced febrile neutropenia
Navigation Sciences	Real-time margin measurement for precision cancer surgery	Lung cancer and other soft tissue tumors
NE Scientific	Intraoperative guidance platform	Percutaneous ablation

Savage Medical	Novel device alternative to temporary diverting ostomies	Low rectal cancer resections
TheraBionic	Novel, portable, radiowave-delivering therapeutic device	Hepatocellular carcinoma

DIGITAL HEALTH

Company	Technology Type	Indication
Envisagenics	Using AI to develop therapies	RNA splicing diseases (acute myeloid leukemia, non-small cell lung cancer, melanoma, breast cancer)
Vizlitics (d/b/a Cancer Insights)	AI platform for clinical decision support	Cancer patient care
Xanthos Health	Social care referral platform	Cancer patient care

SHORT COMPANY SUMMARIES

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

ACCURONIX THERAPEUTICS

SMALL MOLECULE TARGETING SIGMA-2 RECEPTOR

LOCATION
ST. LOUIS, MO

STAGE
PRE-CLINICAL

Accuronix Therapeutics is a leader in discovering and developing a new class of drugs that work by selectively targeting the σ-2 (sigma-2) receptor on cancer cells to deliver cytotoxic payloads. The Accuronix team has established an innovative platform and a lead drug candidate based on advances in characterizing the molecular-targeted drug conjugate approach to cancer therapy. The σ-2 receptors are highly expressed on the surface of rapidly proliferating cancer cells. They internalize upon ligand binding, allowing the delivery of therapeutic agents to intracellular targets. The result is a chemotherapeutic with increased effectiveness and reduction in toxicity risk.

ALLTERUM THERAPEUTICS (FANNIN PARTNERS)

ANTI-CD127 ANTIBODY

LOCATION
HOUSTON, TX

STAGE
PRE-CLINICAL DEVELOPMENT

Fannin/Allterum is developing 4A10, a chimeric monoclonal antibody targeting the IL-7 receptor subunit alpha (CD127). The 4A10 antibody is being developed for relapsed and refractory acute lymphoblastic leukemia and potentially other CD127-expressing hematological cancers. 4A10's anti-cancer activity has been demonstrated using multiple cell lines and PDX models.

AVM BIOTECHNOLOGY

NOVEL NON-TOXIC PRECONDITIONING REGIMEN FOR CANCER CELL THERAPY

LOCATION
SEATTLE, WA

STAGE
IN CLINICAL TRIALS: PHASE II

AVM Biotechnology has launched Phase II of an adaptive design expansion cohort trial of AVM0703 administered as a single intravenous infusion to patients with non-Hodgkin's lymphoma/leukemia at specialty cancer centers across the United States. AVM0703, administered in a one-hour infusion, rapidly induces and mobilizes novel bispecific gamma delta TCR+ invariant TCR+ Natural Killer T-like (AVM-NKT) cells that are cancer-type agnostic. It is a reformulation of dexamethasone sodium phosphate but has been manufactured without the toxic preservatives, permitting it to be given at the suprapharmacologic dose necessary to induce the novel immune cells.

BIOMIMETIX

NOVEL THERAPEUTIC CLASS OF REDOX ACTIVE METALLOPORPHYRIN COMPOUNDS

LOCATION
GREENWOOD VILLAGE, CO

STAGE
IN CLINICAL TRIALS: PHASE II

BioMimetix is developing a novel therapeutic with a unique dual action that (1) enhances tumor killing while (2) protecting healthy tissue. Animal models, as well as early clinical studies, demonstrate efficacy in many types of cancer treated with radiotherapy and chemotherapy. BioMimetix has five open INDs and two lead compounds in clinical trials spanning oncology and dermatology. Efficacy and safety have been demonstrated in several clinical trials, including high-grade glioma, head and neck cancer, and anal cancer.

CURADEL SURGICAL INNOVATIONS

THERANOSTIC DRUGS FOR OPTICAL SURGICAL NAVIGATION

LOCATION
NATICK, MA

STAGE
IN CLINICAL TRIALS: PHASE I, PHASE II, PHASE III, PIVOTAL

Curadel Surgical Innovations, Inc., is a clinical-stage pharmaceutical company developing theranostic drugs for optical surgical navigation, also known as image-guided surgery. FLARE® drugs are small molecule near-infrared (NIR) fluorophores that convert one wavelength of light into a different wavelength. By using them with FDA- and EMA-approved NIR cameras, FLARE® drugs visually highlight any desired target or targets for the surgeon in real time and with high resolution.

ENZYME BY DESIGN

NOVEL GLUTAMINASE-FREE MAMMALIAN ASPARAGINASE WITH MINIMIZED IMMUNOGENICITY

LOCATION
CHICAGO, IL

STAGE
PRE-CLINICAL DEVELOPMENT

Asparaginase is an enzyme drug that starves specific tumor cells with a biomarker-identifiable metabolic weakness. It is a well-validated target with current versions suffering from very high toxicity that limits their use. Enzyme by Design's innovative asparaginase enzyme has been engineered to maximize tolerability by reducing immunogenicity and eliminating off-target effects by being the first highly selective asparaginase, while fully maintaining its anticancer asparaginase activity.

IMMUNOPHOTONICS

PIONEERING INTERVENTIONAL IMMUNO-ONCOLOGY™

LOCATION
ST. LOUIS, MO

STAGE
IN CLINICAL TRIALS: PHASE II

Immunophotonics is developing IP-001, a synthetic biopolymer that potentiates a systemic immune response when injected after a routine tumor ablation. It is designed to (1) harness tumor debris post-ablation, prolonging its availability and increasing uptake by antigen presenting cells (APCs); and (2) activate APCs through a multimodal approach that includes stimulation of interferon genes, which in turn drives a systemic adaptive immunity. IP-001 is also applicable for other areas like infectious disease prevention.

INDEE LABS

INSTRUMENTS FOR MORE EFFECTIVE ENGINEERED CELL THERAPIES

LOCATION
BERKELEY, CA

STAGE
NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE; PRE-CLINICAL DEVELOPMENT; COMMERCIALLY AVAILABLE

Indee Labs develops, markets, and sells Hydropore Research Use Only instruments and consumables. Hydropore is a simple, scalable, compact, and gentle platform that has been shown to (1) reduce perturbation and (2) improve the function of genome-edited chimeric antigen receptor T cells and regulatory T cells in vitro all while being able to (3) process millions to tens of millions of cells in seconds. Hydropore also (4) uses commercial or off-the-shelf GMP-grade buffers.

KUDA THERAPEUTICS

NOVEL DUAL HIF-α INHIBITOR AND INDUCER OF FERROPTOSIS

LOCATION
SALT LAKE CITY, UT

STAGE
PRE-CLINICAL DEVELOPMENT

Kuda has developed an orally available small molecule with a dual mechanism of action—KD061 inhibits the tumor drivers hypoxia inducible factors HIF-1α and HIF-2α, and triggers cell death via ferroptosis. Ferroptosis is a novel mechanism of iron- and lipid-dependent cell death to which kidney cancer cells are uniquely sensitive, providing a therapeutic window for the induction of cell death with minimal toxicity to normal tissue. KD061 is a first-in-class treatment approach for kidney cancer.

LUMINARY THERAPEUTICS

NOVEL GAMMA DELTA ALLOGENIC MANUFACTURING PLATFORM

LOCATION
MINNEAPOLIS, MN

STAGE
PRE-CLINICAL DEVELOPMENT; IN CLINICAL TRIALS: PHASE I

Luminary is a clinical stage CAR-T therapy company using a unique allogeneic manufacturing platform that achieves approximately 150 doses per manufacturing run. This significantly reduces the cost of the therapies and improves patient access.

MICROVASCULAR THERAPEUTICS

CD90-TARGETED PHASE SHIFT MICROBUBBLES FOR HIFU-MEDIATED NON-THERMAL ABLATION OF TUMORS

LOCATION
TUCSON, AZ

STAGE
PRE-CLINICAL DEVELOPMENT

Microvascular Therapeutics (MVT) is a biotechnology company specializing in the development of microbubble and nanotechnology products for the diagnosis and treatment of diseases. MVT has invented a first-in-class ultrasound contrast agent, MVT-100, which strives to be the best combination of image quality, storage/handling, and side-effect profile of any ultrasound contrast agent on the market.

MODULATION THERAPEUTICS

FIRST-IN-CLASS TARGETED RADIOTHERAPIES

LOCATION
MORGANTOWN, WV

STAGE
IN CLINICAL TRIALS: PHASE I

MTI-201 is an intravenously administered precision targeted alpha radiotherapy for treating metastatic melanoma cancers, which otherwise will not respond to current standard of care therapies. This novel compound selectively targets the highly expressed MC1R receptor found on metastatic melanoma cancers and carries a payload of the Actinium 225 alpha particle to the target, effectively killing advanced-stage treatment-resistant melanoma cancers.

PRIVO TECHNOLOGIES

NANOPARTICLE-BASED DRUG DELIVERY PLATFORM

LOCATION
PEABODY, MA

STAGE
PRE-CLINICAL DEVELOPMENT; IN CLINICAL TRIALS: PHASE II, PHASE III, PIVOTAL

PRV111 is a nano-engineered, drug delivery device formulated from bio-compatible materials that is capable of loco-regional delivery of drug products that are traditionally hindered by dose-limiting toxicities. PRV211 is a similar technology that is capable of intraoperative use, particularly following tumor resectioning in solid tumors.

REVEAL PHARMA

GADOLINIUM-FREE MRI CONTRAST AGENT

LOCATION
CAMBRIDGE, MA

STAGE
IN CLINICAL TRIALS: PHASE I, PHASE II

Reveal is developing a clinical stage gadolinium-free MRI contrast agent designed to replace GBCAs. Reveal's RVP technology uses biocompatible manganese and has an innovative "cage" design enabling high MR signal and high stability. Reveal's first product is a general-purpose MRI contrast agent RVP-001, which may also enable liver-specific imaging. RVP-001 has completed a first-in-human study and they expect to begin a clinical imaging study in patients soon.

RNA NANOTHERAPEUTICS

MULTIFUNCTIONAL RNA NANOPARTICLES

LOCATION
MASON, OH

STAGE
PRE-CLINICAL DEVELOPMENT

RNA Nanotherapeutics is developing an innovative RNA-nanotechnology-based approach to specifically target a novel key therapy resistance gene in breast cancer to overcome treatment resistance. The success of the product will provide not only novel therapies to overcome a major obstacle in current breast cancer treatment but also a platform approach that can be readily expanded and adapted to target other pathways and treat other cancers and diseases.

STEMSYNERGY THERAPEUTICS

SMALL MOLECULE MODULATORS OF KEY SIGNALING PATHWAYS (WNT, NOTCH, MYC, HIPPO)

LOCATION
MIAMI, FL

STAGE
PRE-CLINICAL DEVELOPMENT

StemSynergy has identified small molecule MYC degraders to treat c-myc-dependent cancers. StemSynergy's MYC degraders harbor excellent drug-like properties and are effective in inhibiting the growth of c-myc-dependent lung and colon cancers without apparent toxicity in pre-clinical models. The company's MYC degraders have potential to impact the lives of millions of cancer patients in the United States and represent a significant market opportunity.

STINGRAY THERAPEUTICS

POTENT AND SELECTIVE ORAL ENPP1 INHIBITOR

LOCATION
HOUSTON, TX

STAGE
PRE-CLINICAL DEVELOPMENT

Stingray is developing SR-8541A, a selective, potent small molecule inhibitor of ectonucleotide pyrophosphatase/phosphodiesterase family member 1 (ENPP1). ENPP1 is the critical molecule cancers use to suppress innate immunity and interferon production, rechanneling the pathway to produce adenosine, a very important broadly acting immunosuppressive and pro-metastatic molecule. Stingray believes adding an ENPP1 inhibitor to checkpoint inhibitors (ICIs) will be successful in many cancers where ICIs do not work today.

TALUS BIOSCIENCE

TRANSCRIPTION FACTOR INHIBITORS FOR TARGETED CANCER THERAPEUTICS

LOCATION
SEATTLE, WA

STAGE
PRE-CLINICAL DEVELOPMENT

Talus Bio discovers and develops therapeutics for previously undruggable transcription factors. To accomplish this, Talus Bio has invented and commercialized the first global regulome sequencing technology, measuring the activity of all proteins that regulate DNA in live, unmodified human cells.

TERNALYS THERAPEUTICS

ENGINEERED, NON-CODING MICRO-RNA-BASED THERAPY

LOCATION
CHAPEL HILL, NC

STAGE
PRE-CLINICAL DEVELOPMENT

Ternalys Therapeutics is focused on overcoming cancer resistance through "epigenetic reprogramming." The company has developed engineered, non-coding microRNAs clusters that are delivered on a novel scaffold, the SAGUARO platform, for precision multitargeting of intractable cancers. While microRNA-based therapy is not new, the concepts of (1) a clustered microRNAs strategy, (2) the targeting of an otherwise undruggable epigenetic complex, and (3) the genetic engineering methods for its implementation, are.

TEZCAT BIOSCIENCES

METABOLICALLY SELECTIVE RAS CANCER THERAPEUTICS

LOCATION
AVON, CT

STAGE
PRE-CLINICAL DEVELOPMENT

The Tezcat core technology is a protein-based therapeutic delivery platform that penetrates, accumulates in, and is internalized specifically by RAS tumors using a novel escape-resistant targeting mechanism.

TRACE BIOSCIENCES

NERVE-SPECIFIC IMAGING AGENTS FOR SURGERY

LOCATION
PORTLAND, OR

STAGE
PRE-CLINICAL DEVELOPMENT

Trace Biosciences is creating imaging agents to make surgery safer and more effective. Using fluorescence, Trace's targeted imaging agents specifically highlight nerves and enable real-time, direct visualization of these delicate and important structures for sparing or repair. The technology has been validated in small and large animal models as well as human specimens and is currently under clinical translation toward first-in-human clinical trials.

TRANSCODE THERAPEUTICS

TARGETED THERAPY FOR METASTATIC CANCER

LOCATION
BOSTON, MA

STAGE
IN CLINICAL TRIALS: PHASE 0

TransCode Therapeutics is a clinical-stage RNA oncology company advancing focused solutions to intractable problems in the diagnosis and treatment of metastatic disease. As an asset-focused platform company, TransCode deploys delivery of nucleic acid payloads to primary and metastatic cancers. The company's programs focus on previously undruggable genetic targets to overcome the challenges of cancer progression and relapse.

VIVREON BIOSCIENCES

ORAL, GUT-RESTRICTED THERAPEUTIC

LOCATION
SAN DIEGO, CA

STAGE
PRE-CLINICAL DEVELOPMENT

Vivreon Biosciences is commercializing an oral, gut-selective therapeutic for the treatment of enterocolitis caused by immune checkpoint inhibitor (ICPI) immunotherapy. Vivreon's program is designed to be a colon restrictive, safe and effective therapy that works directly at the site of ICPI-induced intestinal inflammation without systemic absorption, and can be co-administered with immunotherapies to treat colitis side effects without interfering with the primary cancer killing activity.

EARLYDX

BLOOD-BASED CF-DNA MULTI-CANCER TEST

LOCATION
LOS ANGELES, CA

STAGE
PRE-CLINICAL DEVELOPMENT; IN CLINICAL TRIALS: EARLY FEASIBILITY

EarlyDx's MethylScan test is a blood-based early cancer detection product incorporating both a proprietary assay technology and a machine learning algorithm. The company's MethylScan assay selectively builds a sequencing library from methylation-informative cfDNA fragments. An ensemble machine learning classifier combines multiple epigenomic and genomic features to not only detect cancer at its early stages but also locate its tissue of origin.

LIFEGENE-BIOMARKS

PRECISION DNA METHYLATION PCR TESTS IN BIOFLUIDS

LOCATION
SAN JUAN, PUERTO RICO

STAGE
PHASE IV BIOMARKER DEVELOPMENT TRIAL

DNA methylation has been shown to detect HPV-associated, premalignant cervical lesions with advanced clinical disease. The CervicalMethDx test is a quantitative Methylation Specific PCR (qMSP) that can stratify patients at high risk of CIN2+ lesions before they are referred to colposcopy-driven biopsies in resource-rich countries or excision therapy in resource-poor countries.

MICROMICS

TOOL
DEVELOPER FOR
ULTRA-SENSITIVE
PROTEOMICS
ANALYSIS

LOCATION
SPANISH FORK, UT

STAGE
NON-CLINICAL
TECHNOLOGY
IN PROTOTYPE
DEVELOPMENT

MicrOmics provides specialized/validated reagent, substrates, columns, and other consumables for single-cell proteomics (SCP). By using the company's patented storage loop mediated multiplexed LC technology, they have developed a platform that achieves a highly sensitive, robust, and high-throughput workflow for SCP and other low-input biochemical analyses.

ALPENGLOW BIOSCIENCES

AI-ENABLED 3D SPATIAL BIOLOGY PLATFORM

LOCATION
SEATTLE, WA

STAGE
COMMERCIALLY AVAILABLE; PLATFORM DEPLOYED IN RESEARCH, PRECLINICAL, AND CLINICAL SETTINGS FOR A RANGE OF APPLICATIONS AND DISEASE AREAS

Alpenglow's patented hybrid open-top light sheet system, called the 3Di, is capable of imaging hundreds of organoids or dozens of biopsies in resolution that approaches confocal microscopy, but on the speed and scale of MRI. Combining high resolution with scale produces enormous data sets that are mined using AI to identify novel insights only found by looking in 3D. These insights are used to identify 3D biomarkers for patient selection in clinical trials and accelerate preclinical drug development.

ANANYA HEALTH

SELF-CONTAINED, PORTABLE CRYOABLATION DEVICE

LOCATION
SAN FRANCISCO, CA

STAGE
NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE

Ananya Health is building a self-contained cryoablation device to freeze abnormal cells in the cervix and prevent them from becoming cervical cancer, without any consumable cryogen. The company's proprietary platform enables standard of care outcomes ten times cheaper than traditional cryo, and accessible at the primary care level even without a supply of CO2 or nitrous oxide.

ARSENAL MEDICAL

SOLVENT-FREE, SHEAR-RESPONSIVE, SILICONE-BASED BIOMATERIAL

LOCATION
WALTHAM, MA

STAGE
IN CLINICAL TRIALS: EARLY FEASIBILITY

Arsenal Medical, Inc., is a platform company that develops purpose-built biomaterials to meet underserved clinical needs. Arsenal has developed the Flow Responsive Embolic, a solvent-free, shear-responsive, silicone-based biomaterial, intended for use in the pre-operative embolization of hypervascular extra-axial brain tumors (e.g., meningiomas). It is purpose-built to be an easy-to-use embolic agent that is compatible with diagnostic imaging modalities and provides safe and extensive devascularization of brain tumors to facilitate their resection.

CLARIX IMAGING

BRINGING TRUE 3D CLARITY TO SPECIMEN IMAGING

LOCATION
CHICAGO, IL

STAGE
COMMERCIALLY AVAILABLE

Clarix Imaging brings clarity to lumpectomy margin visualization with the volumetric specimen imager (VSI), an FDA-cleared point-of-care intraoperative X-ray imaging system. VSI offers breast cancer surgeons unique, high-resolution 3D computed tomography specimen images in minutes to allow surgeons to precisely locate positive margins and address the current 25% average reoperation rate in breast-conserving surgery.

EUCLID BEAMLABS

ELECTRONIC BRACHYTHERAPY DEVICE

LOCATION
BELTSVILLE, MD

STAGE
NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

Euclid has developed an electronic brachytherapy (EB) device that replaces the typical LDR design with an ultra-lightweight design capable of HDR EB. This development has been called a new treatment paradigm by clinicians, as it provides a wide range of cancer-treating radiation to customize clinical HDR brachytherapy treatment plans. Euclid's technology can immediately retrofit LDR EB equipment (accelerator upgrade) or be developed to a full EB system for healthcare professionals.

LEUKO LABS

NON-INVASIVE WHITE BLOOD CELL MONITORING

LOCATION
BOSTON, MA

STAGE
IN CLINICAL TRIALS: PHASE II, FEASIBILITY/PILOT

Leuko has developed PointCheck™, the first noninvasive white blood cell test that enables frequent at-home monitoring to improve clinical outcomes and quality of life for cancer chemotherapy patients. The technology combines microscopy and AI to collect and analyze videos of blood flowing through superficial capillaries.

NAVIGATION SCIENCES

REAL-TIME MARGIN MEASUREMENT FOR PRECISION CANCER SURGERY

LOCATION
BROOKLINE, MA

STAGE
IN CLINICAL TRIALS: FEASIBILITY/PILOT

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

NE SCIENTIFIC

INTRAOPERATIVE GUIDANCE PLATFORM

LOCATION
BOSTON, MA

STAGE
PRE-CLINICAL DEVELOPMENT; IN CLINICAL TRIALS

NE Scientific develops software for simulating ablations and other procedures. The simulation is used to better plan the procedure or to guide the physician during the procedure, adjusting the plan as the procedure takes place.

SAVAGE MEDICAL

NOVEL DEVICE ALTERNATIVE TO TEMPORARY DIVERTING OSTOMIES

LOCATION
FREMONT, CA

STAGE
PRE-CLINICAL DEVELOPMENT; IN CLINICAL TRIALS: EARLY FEASIBILITY

Savage Medical is developing a simple device that temporarily protects the colon from fecal contamination and eliminates need for vast majority of diverting surgical ostomies. Proprietary negative pressure anchoring system that provides rock-solid anchoring and air/fluid-tight bypass that is safe and atraumatic to the bowel wall.

THERABIONIC

NOVEL, PORTABLE, RADIOWAVE-DELIVERING THERAPEUTIC DEVICE

LOCATION
WINSTON-SALEM, NC

STAGE
IN CLINICAL TRIALS: PHASE III; HUMANITARIAN USE DESIGNATION (2022)

TheraBionic is a cancer treatment company that has developed a novel, portable, battery-operated medical device for the systemic, targeted treatment of cancer. Treatment is administered by means of a spoon-shaped antenna held on the anterior part of the tongue for three one-hour treatments daily. The device emits low and safe levels of radiofrequency electromagnetic fields, which are modulated at tumor-specific frequencies delivered to the entire body.

ENVISAGENICS

USING AI TO DEVELOP THERAPIES

LOCATION
NEW YORK, NY

STAGE
COMMERCIALLY AVAILABLE

SpliceCore is Envisagenics' software platform for the discovery of disease-specific alternative splicing events for therapeutic development by integrating proprietary machine learning algorithms, high-performance computing, and RNA-splicing analytics. SpliceIO, the latest extension of the platform, enables the discovery of splicing-derived antigenic peptides addressable with immunotherapeutic approaches.

VIZLITICS (D/B/A CANCER INSIGHTS)

AI PLATFORM FOR CLINICAL DECISION SUPPORT

LOCATION
BEDFORD HILLS, NY

STAGE
PRE-CLINICAL DEVELOPMENT; FDA APPROVAL NOT APPLICABLE

Vizlitics is a healthcare technology company delivering AI-based oncology decision support software. Vizlitics' mission is to deliver clinical excellence and outstanding patient care through AI and clinical workflow innovation. In 2020, the company launched its first product, called Cancer Insights. Cancer Insights is an EMR-integrated cloud-based decision support tool that delivers oncology innovation to providers, payers, and pharma. Cancer Insights currently delivers three commercial products: New Consult Workflow, Tumor Board Management, and Oncology Data Insights.

XANTHOS HEALTH

SOCIAL CARE REFERRAL PLATFORM

LOCATION
ST. PAUL, MN

STAGE
PROTOTYPE FULLY DEVELOPED; IN BETA TESTING

XanthosHealth's ConnectedNest is a social care referral platform for cancer patients. The platform is a multifaceted, electronic health record-enabled health information technology built to screen and assess patients' social needs and connect individuals to the most appropriate community based organizations that can address patients' needs with the overall goal of improving the health and psycho-social outcomes of these individuals.

COMPANY OVERVIEWS

For an introduction to any of these companies, please contact Brittany Connors at brittany.connors@nih.gov.

ACCURONIX THERAPEUTICS, INC.

Small Molecule Targeting Sigma-2 Receptor

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COMPANY OVERVIEW

Accuronix is a small biopharma company developing drugs for cancer treatment. The company's lead molecule, ACXT-3102, is in preclinical development through an exclusive license of the technology from Washington University in St. Louis (WUSTL). ACXT-3102 is a drug conjugate with two functional domains: (1) sigma-2 ligand-based delivery domain facilitating fast and efficient internalization and (2) dm-Erastin effector domain that inhibits the cystine-glutamate antiporter (xCT; SLC7A11), thereby preventing uptake of vital precursors necessary to defend the cells from oxidative stress and death. ACXT-3102 selectively targets cancer cells that overexpress the sigma-2 receptor; cellular uptake is required for biological activity. A salt form was selected that is highly water soluble, facilitating oral delivery for preclinical IND-enabling studies. The primary clinical focus is pancreatic adenocarcinoma, but experimental evidence supports that ACXT-3102 is effective in other types of cancer (alone or in combination with other drugs). The company has made 1 kilogram of compound to support preclinical development, with GLP toxicology studies planned to start in Q3 2023. Accuronix is targeting an IND submission in late 2024.

MARKET & COMMERCIALIZATION STRATEGY

As Accuronix is in preclinical development, they have not yet thoroughly formulated their marketing and commercialization strategy. The company's current philosophy is to partner with a larger pharma company after receiving IND approval to initiate clinical testing.

TECHNICAL & COMPETITIVE ADVANTAGE

ACXT-3102 selectively targets cancer cells that express the sigma-2 receptor. Erastin was previously shown to be ineffective because it requires cellular uptake to inhibit the xCT transporter from the internal side of the membrane and induce metabolic stress, leading to cell death by accumulation of reactive oxygen species. By conjugating erastin to a sigma-2 receptor ligand, cellular uptake of erastin is quick and effective to kill the cancer cells. Accuronix has demonstrated efficient scale-up to the 1 kg level to obtain material for IND-enabling studies and has efficacy data in multiple mouse tumor models, including both syngeneic and xenograft models.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Accuronix plans to file an IND for ACXT-3102 for treatment of pancreatic adenocarcinoma. Discussions have considered the possibility of a Phase I trial for different types of cancers, then expanding the arms for cancers that show acceptable efficacy. This will be decided after further discussion with clinicians prior to IND. Accuronix has a very mature multinational patent estate through an exclusive license agreement with WUSTL Office of Technology Management. They have granted patents in the United States, European Union, and 12 individual countries.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
June 2019	Mesylate salt identified as highly soluble, orally available, and efficacious in mouse tumor models
May 2020	Pilot toxicology studies in Sprague Dawley rats showed no dose-limiting tox up to 45 mg/kg once daily gavage
August 2023	Initiate IND-enabling mouse GLP toxicology studies at CRO
January 2024	Initiate IND-enabling nonrodent species (TBD) GLP toxicology studies at CRO
December 2024	Target date to file IND for ACXT-3102 in pancreatic adenocarcinoma

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
December 2015	Seed Round #1	Initial investment into Accuronix	$662K
2016-2018	Seed funding	Subsequent seed funding rounds	$1.50M
September 2019	Seed funding	Subsequent seed funding round	$112.5K
September 2019	Grant	Phase I STTR award for one year	$220K
June 2021	Grant	Phase II STTR award for two years	$2.034M

USE OF PROCEEDS

Accuronix looks to raise $10M (two tranches of $5M). The first tranche (by Q1 2024) will support remaining IND-enabling studies, preparation and filing of IND to FDA and designing and the Phase I clinical trials for ACXT-3102. The second tranche (by Q1 2025) will support initiating and conducting the Phase I clinical trial.

KEY TEAM MEMBERS

Bradley T. Keller PhD (President and CEO): More than 35 years in pharmaceutical drug discovery and development in both larger pharma companies as well as small, start-up companies.

William G. Hawkins MD, FACS (Founder): Chief, Section of Hepatobiliary, Pancreatic, and Gastrointestinal Surgery; Director, WUSTL SPORE in Pancreatic Cancer; Director, HPB Fellowship program; head of research laboratory as subawardee for Accuronix STTR grant.

Dirk Spitzer PhD (Head of Pharmacology): R01-funded chemist and inventor at WUSTL (large and small molecules).

ALLTERUM THERAPEUTICS, INC.

Anti-CD127 antibody to treat leukemia

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COMPANY OVERVIEW

Allterum Therapeutics, Inc., a Fannin-established company, is developing 4A10, a monoclonal antibody directed against CD127 (IL-7 receptor subunit alpha, or IL7R). 4A10 was in-licensed from NCI to treat patients with acute lymphoblastic leukemia (ALL), the most frequently diagnosed childhood cancer. Label expansion opportunities include other CD127-expressing cancers. The program: (1) addresses a clear unmet medical need with a promising new agent; (2) targets CD127, which is validated and supported by robust preclinical evidence of efficacy; (3) addresses an ultra-orphan patient population with a well-defined path to regulatory approval; (4) has mitigated key early development risks (CMC, safety, regulatory); (5) is commercially attractive with label expansion opportunities and pharma interest; and (6) is led by a senior management team and advisors with a track record of success.

MARKET & COMMERCIALIZATION STRATEGY

Allterum's initial focus is on patients with ALL, starting with those with relapsed disease who have a 30% five-year survival, then moving upstream as part of combination therapy. The company estimates peak U.S. sales of approximately $300M per year for ALL, with similar ex-U.S. revenue. Label expansion opportunities include other CD127-expressing hematological cancers including lymphocytic leukemias, T- and B-cell lymphomas, and subsets of Acute Myeloid Leukemia (AML). Allterum also has rare-disease designation, which makes it eligible for a priority voucher on initial approval; vouchers have been sold recently for more than $100M. The company is prepared to take the drug through marketing approval but is open to partnering with a pharma company if it would accelerate the program and the terms are attractive.

TECHNICAL & COMPETITIVE ADVANTAGE

4A10 has high affinity (Kd = 3.7 nM) and has shown robust preclinical activity in multiple in vitro and in vivo models. 4A10 has a dual mechanism of action: it inhibits IL-7 signaling and induces antibody-dependent cellular cytotoxicity (ADCC). 4A10's primary differentiator is as an efficacious drug sitting at the top of the IL-7/TSLP pathway. Since 4A10 is expected to be well-tolerated without additive toxicities, it could be used alone or in combination with other drugs including small-molecule inhibitors along the pathway.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Allterum has received pre-IND guidance from FDA as well as Orphan Drug and Pediatric Rare Disease designations. The company will conduct a Phase I dose-escalation study with about 30 patients, followed by Phase IIA expansion in r/r ALL subpopulations. Based on regulatory precedence in acute leukemias, the company expects that a single Phase II pivotal trial will support marketing approval. 4A10 is protected by broad issued and pending patents covering composition of matter and method of use (U.S. Pats. 10,392,441 and 11,111,306). The patents, which expire in October 2036 absent any extension, are licensed exclusively to Allterum.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Completed milestones	Manufacturing: Robust MCB; DS scaled up to 200L with good yield/purity (Fujifilm Diosynth); 50 mg/mL stable clinical formulation Safety: Pilot nonhuman primate (NHP) study; well-tolerated with NOAEL at the highest administered dose Clinical/Regulatory: pre-IND guidance, finalized protocol reflecting guidance; partnership with TACL, other major sites
H2 2023	Complete pivotal GLP toxicology study in NHP; initiate GMP manufacturing batch
H1 2024	Submit IND package to FDA; enroll first Phase I patient
H1 2025	Complete Phase I, determine RP2D; initiate Phase IIA trial(s)
2026	Complete Phase IIA trial(s); initiate pivotal trial(s)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2019	Grant	CPRIT Seed Product Development Grant (Award No. DP190025)	$2.9M
2020	Seed raise	Fannin Allterum Holdings I, LLC (SPV managed by Fannin)	$1.8M
2022	Grant	NCI SBIR Direct Phase II Grant (Award No. 1R44CA268530-01A1)	$1.9M
2023	Grant (in-kind support)	NCI Experimental Therapeutics (NExT) Program	~$5M
2023	Grant	CPRIT Product Development Grant (Award No. DP230071)	$11.7M

USE OF PROCEEDS

$28M in financing will take Allterum through its Phase I/IIA trials, which will provide clinical proof of concept. The company has $18M in grant funding from CPRIT and NCI to support this work and seeks an additional $10M in supplemental Series A funding.

KEY TEAM MEMBERS

Atul Varadhachary MD, PhD (CEO): 30 years of development experience, including leading a therapy into global Phase III trials.

Phil Breitfeld, MD (CMO): More than 30 years of experience in pediatric hematology/oncology in both industry and academia.

John Schaumberg, PhD (Head of Clinical Operations): More than 30 years of drug development expertise in pharma and biotech companies and CROs.

AVM BIOTECHNOLOGY, INC.

Unleashing immune potential

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COMPANY OVERVIEW

AVM Biotechnology is developing and advancing AVM0703, a proprietary formulation of concentrated dexamethasone. This formulation permits the very high dosing necessary to activate the release and trigger the production of the body's supercharged gamma delta+ Natural Killer T-like (AVM-NKT) immune cells. These AVM-NKT cells have unique immune response properties in comparison to ordinary T-cells and rapidly appear following a single AVM0703 dose. Pre-clinical and early clinical data indicate that these cells could play a significant role in several diseases and conditions.

MARKET & COMMERCIALIZATION STRATEGY

AVM Biotechnology is in discussions with a global pharma company regarding partnering and licensing AVM0703 to replace chemotherapy that is currently required before cell therapy. There is also an opportunity to open solid tumors to cell therapy, as AVM0703 has been demonstrated to penetrate even very desmoplastic or collagen-encased solid tumors. AVM Biotechnology plans to enroll in the Phase II trial in R/R NHL to leverage data to apply for accelerated FDA approval to market to one R/R NHL subtype (20,000 U.S. patients annually). The company also plans to partner with a global pharma company prior to launching trials in additional indications or combination therapies.

TECHNICAL & COMPETITIVE ADVANTAGE

AVM0703 mobilizes a naturally occurring γδTCR+ iTCR+ NKT-like cell and does not require cell manufacturing facilities nor cold chain storage. The drug can be manufactured in as little as seven hours, is stable for at least 18 months at room temperature, and CoGs is less than 10% of a biologic, yet the drug has premium pricing potential based on survival. AVM0703 is administered on an outpatient basis in a one-hour intravenous infusion. Side effects have been largely Grade 1, and patient response is rapid. Patients with very poor prognosis tolerate and respond to the drug very well in contrast to CarT, bispecific T cell engagers (BITES), and other approved therapies. AVM0703 is additive/synergistic when given before immuno-chemotherapy and CarT cells.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The AVM0703 dose-escalation trial was designed as a first-in-human 3+3 since doses this high have never been administered; however, since its API is dexamethasone phosphate, the 505(b)(2) pathway is applicable to refer to for toxicology data. AVM0703 is protected by eight worldwide granted or pending composition of matter, methods of use, and formulation patents.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
March 2023	Phase I dose-escalation in R/R NHL complete with 100% 9-month survival for n=6 dosed at RP2D
March-May 2023	Enrolled an additional six patients in Phase II in R/R NHL, including two patients into repeat dosing in 21-day cycles
March 2023	Received approval for Year 2 Phase II SBIR grant from NIDDK for preclinical studies to reverse type 1 diabetes
May 2023	Received approval for Year 2 Phase II SBIR grant from NCI to support ongoing clinical trial in R/R NHL

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020-2021	Funding round	Friends and family round	$6.8M
2022	Grant	Two-year Phase II SBIR from NIDDK	$1.632M
2022	Grant	Two-year Phase II SBIR from NCI	$2.0M
2022	Funding round	Convertible notes (5) from same investors who previously invested in 2020 round	$1.6M

USE OF PROCEEDS

AVM Biotechnology is currently raising $25M to further enroll in the Phase II trial in R/R NHL for accelerated approval; launch a Phase IB trial in metastatic pancreatic cancer pretreating before standard of care, including checkpoint inhibitors; and continue to build out the business and licensing team, intellectual property strategy, and infrastructure.

KEY TEAM MEMBERS

Theresa A. Deisher, PhD (Founder, CSO & Acting CEO): Dr. Deisher holds a doctoral degree in molecular and cellular physiology from Stanford University School of Medicine. She is the inventor on more than 47 issued US/EU/JP patents and several discoveries outlicensed to global pharma companies. She has more than 30 years of pharmaceutical leadership experience including Genentech, Repligen, ZymoGenetics, Immunex, and Amgen. She has led multidisciplinary development projects whose team members included scientists and directors from research, computational bioinformatics, statistics, regulatory affairs, and clinical development, marketing, and commercialization departments. Dr. Deisher oversees the AVM drug development program.

Todd Bertsch (Chief Business Officer): Mr. Bertsch is a seasoned strategy and business development executive with more than two decades of experience in finance. He was previously a venture partner at VU Venture Fund, and managing director at Weild & Co., Inc., where he streamlined operations by providing client-focused corporate finance and capital-raising services, including M&A, strategic advisory, private placements, and public securities. He leads AVM's business, technical, and operational functions to ensure business growth.

Daniel G Spina (Director): Mr. Spina was a managing director at Bear Stearns (JPMorgan) for 23 years.

BIOMIMETIX

Transforming the efficacy and safety of chemoradiation

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COMPANY OVERVIEW

BioMimetix is developing a new drug class—redox-active metalloporphyrins—that has been shown to greatly enhance the efficacy and safety of chemoradiation. BioMimetix is a late-stage company with five open INDs, mostly in Phase 2 clinical trials. BioMimetix has been granted FDA Breakthrough Therapy designation, and its clinical trials are demonstrating both increased survival and the ability to mitigate harmful side effects of radiation and chemotherapy.

MARKET & COMMERCIALIZATION STRATEGY

BioMimetix plans to realize the platform potential of its drug by securing multiple approvals in cancers treated by chemoradiation. The company's preclinical and emerging clinical data demonstrate that its metalloporphyrins extend survival and quality of life in many cancers. BioMimetix continues to target and develop positive clinical data in one of the most difficult-to-treat cancers, glioblastoma, and is also focusing on other areas of high unmet need, including head and neck, anal/rectal, and ovarian cancers.

TECHNICAL & COMPETITIVE ADVANTAGE

BioMimetix is developing a new drug class with applicability to many oncology indications. The drug is well-tolerated and has an impressive safety record, having been administered to more than 160 patients across several clinical trials. The company's CEO, Dr. James Crapo, is a leading expert in the formulation and development of metalloporphyrins, having spent more than 40 years researching these compounds.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The company plans to leverage its FDA Breakthrough Therapy designation to expedite approval in their first oncology indication. Once approved for glioblastoma, the company will work to secure approvals in additional cancer indications. BioMimetix continues to work on its intellectual property, having secured or laid the groundwork for several additional methods of use and formulation/synthesis patents.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Completed	Launch of Phase 2 trial in anal cancer & completion of Phase I trial in head & neck cancer
July 2023	Begin analysis of final endpoint (overall survival) in randomized, Phase 2 high-grade glioma trial

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2010-present	Seed round	Ongoing capital raised through seed investment group	$22M
May 2020	NCI grant	Grant for Phase 2 high-grade glioma trial	$2M
August 2021	NCI bridge grant	Bridge grant for Phase 2 high-grade glioma trial	$4M

USE OF PROCEEDS

BioMimetix is targeting a $50M-$75M Series A raise. Proceeds will be used to expand the executive team, fund CMC work to finalize manufacturing of the drug for commercialization, expand the Phase 2 clinical trial program, and launch the registration Phase 3 trial for glioblastoma.

KEY TEAM MEMBERS

Dr. James D. Crapo (CEO): 40 years of experience in discovery and development of metalloporphyrin compounds. Prior roles and experience include: chief, Pulmonary and Critical Care Medicine, Duke University; chair, Department of Medicine, National Jewish Health; principal investigator, COPDGene; president, American Thoracic Society; and author of more than 300 peer-reviewed publications and author of 30 patents.

Rob Hellewell (President & CBO): Leads the company's business development, partnering, and fundraising efforts, leveraging 20 years of experience in developing business and strategic partnerships. Former practicing attorney at Skadden, Arps, Slate, Meagher & Flom.

David Silberstein (COO): Leads the company's operations. Prior experience includes leading NIH-funded research on biochemistry of inflammation at Harvard Medical School; leading pharmacology and chemistry initiatives and serving as the supporting science lead for products with aggregate sales of more than $30B at AstraZenica; author of 50 peer-reviewed publications; and author of more than 20 patents.

CURADEL SURGICAL INNOVATIONS, INC.

NIR fluorescent drugs for optical surgical navigation

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COMPANY OVERVIEW

Curadel Surgical Innovations, Inc. (CSI) is a clinical-stage pharma company developing theranostic drugs for optical surgical navigation (OSN), also known as image-guided surgery. CSI's FLARE® brand of near-infrared (NIR) theranostic drugs solve the fundamental problem of human surgery by providing visual contrast where none would otherwise exist. FLARE drugs enable a surgeon to quickly and visually find, resect, or repair normal tissues such as blood vessels, ureters, nerves, and lymph nodes, as well as benign and malignant tumors, all in real time and with high sensitivity and specificity. CSI's theranostic drugs form the foundation in the new and expanding field of OSN, which currently has a market size of $5B and an annual CAGR of 14%. CSI's flagship product is nizaracianine triflutate (aka ZW800-1), which is about to enter its pivotal trial and already has a contracted a leading global distribution partner. A planned Series B financing will focus on the development and marketing approval of cRGD-ZW800-1, a drug that "lights up" all solid tumors, as shown in Phase II studies of colorectal carcinoma, head and neck cancer, and pancreatic cancer, to name a few.

MARKET & COMMERCIALIZATION STRATEGY

CSI's goal is to revolutionize highly important aspects of a broad range of human surgeries. CSI has a large portfolio of FLARE drugs that target various high-volume surgical procedures, such as cancer resection, ureter identification and repair, sentinel lymph node identification and resection, endometriosis, and vascular angiography, to name a few. CSI has also become highly familiar with both EMA and FDA regulatory processes in the theranostic drug space, permitting dual launch of new FLARE drugs in the United States and the European Union. Based on independent market research, cRGD-ZW800-1 has a SAM of more than $1B annually in the Unites States and the European Union.

TECHNICAL & COMPETITIVE ADVANTAGE

CSI has developed a cost- and time-efficient "templated" approach to FLARE drug development, which encompasses nonclinical, clinical, quality, and regulatory tasks for a fraction of the cost and time of conventional drugs. Zwitterionic chemical structures result in ultralow nonspecific binding and uptake and extremely sensitive tumor detection.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

More than two dozen patents have been issued worldwide on FLARE technology. The technology has already been audited to 21 CFR 210/100 and 21 CFR 11.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2017-2019	Phase I and initial Phase III (colorectal carcinoma) trials of cRGD-ZW800-1 (published)
December 2022	Approval for Centralised Review of ZW800-1 by the EMA
April 2023	Completion of Phase II dose-ranging trial of cRGD-ZW800-1 in head and neck cancer. Start of pancreatic cancer trial.
May 2022	D120 Paediatric Investigational Plan (PIP) of ZW800-1 approved by the EMA
June 2022	Completion of multidose Phase I trial of ZW800-1 that enables long surgeries
September 2021-June 2022	Phase II/III pivotal trial in the Unites States and the European Union for ZW800-1

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
1999-2020	NIH grants	Nondilutive funding of R&D underlying FLARE technology	$31M
2020	Series A	Series A preferred financing	$1.6M
2023	Series A1	Series A1 preferred financing	$2.0M

USE OF PROCEEDS

A $30M+ Series B financing planned for early 2024 will complete the commercial launch of ZW800-1 and lead to filings of an NDA and a MAA for cRGD-ZW800-1.

KEY TEAM MEMBERS

John V. Frangioni, MD, PhD (CEO): Founder and CEO responsible for vision and vision execution, financings, and strategic alliances.

J. Kris Piper (Chief of Regulatory and Quality): Administers regulatory and quality activities of the company. Supervises directors and managers in each division.

Kathleen M. O'Riordan, PhD (Director of Regulatory): Regulatory strategy and filings, interaction with regulatory agencies, and supervision of clinical trials team.

Mark W. Bordo (Director of Chemistry): CMC and specifications of all FLARE drugs. Analytical methods development and validation.

Tammy A. Gauthier (Manager of Quality): Authoring and management of CSI's QMS. Qualification of vendors. Compliance of all GxP activities of the company.

ENZYME BY DESIGN INC.

Designing Disruptive Cancer Therapeutics

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COMPANY OVERVIEW

Enzyme by Design Inc. (EbD) is a University of Illinois at Chicago spin-off from the laboratory of Professor Arnon Lavie. EbD's preclinical stage pipeline consists of three innovative cancer therapeutic assets that use a novel enzyme asparaginase, EBD-300, and are engineered for pan-cancer applicability in both blood and solid cancers with biomarker selection for patient sensitivity. The company's "secret sauce" is its team members' expertise in structural biology and protein engineering and their ability to design biologics that are highly effective at killing cancer cells while also being well-tolerated by patients. The company has been highly successful in attracting nondilutive NCI SBIR/STTR grants (more than $3.5M in aggregate) and was recently accepted to the NCI NExT program, which will take EBD-300 through IND enabling and allowance. This high level of NCI support is an indication of the strength of the science and the clinical need the EbD addresses. An outstanding board of directors has been guiding the growth of EbD, and a scientific advisory board with world-renowned key opinion leaders has also been critical to EbD's success. EbD is currently seeking investors to help accelerate the path to the clinic.

MARKET & COMMERCIALIZATION STRATEGY

While asparaginases are an established cornerstone for treating pediatric acute lymphoblastic leukemia (ALL), adults are rarely given this effective drug due to toxicity, which is more pronounced in adults. Despite representing approximately 40% of ALL patients, adults account for more than 80% of ALL deaths, clearly demonstrating a high unmet need for a safer asparaginase for these patients. EbD's most advanced asset ("Asset 1") is EBD-300, for use not only in the entire ALL patient population but also other indications, primarily for adults, that contain the asparaginase-sensitivity signature. The current first-line asparaginase is Oncaspar (worldwide revenue $280M, 2021). Hypersensitive patients are switched to the alternative bacterial asparaginase Rylaze (approved in the United States only, revenue $282M, 2022). EbD's go-to-market strategy is to become the preferred second-line asparaginase by demonstrating its superior safety, efficacy, and convenience. EbD's Asset #3 is an EBD-300 variant targeted to have greatly reduced dosing frequency. This is slated to become the preferred first-line asparaginase in ALL with potential for expansion into acute myeloid leukemia (AML) and liver, colorectal, and breast cancers.

TECHNICAL & COMPETITIVE ADVANTAGE

To reduce treatment disruption or termination and improve ALL patient outcomes, EbD is developing EBD-300, the first mammalian asparaginase engineered for maximum safety due to extensive humanization. It is the only known asparaginase to combine the sought-after properties of tumor-killing power with high selectivity for starving tumor cells without causing damage to healthy cells through a secondary enzymatic activity present in all current FDA-approved bacterial asparaginases. Numerous in vivo studies demonstrate EBD-300's strong anticancer power paired with its unique low-toxicity profile. Unlike Rylaze, which is given i.m. 3x/week at a high dose, EBD-300 is designed for once weekly i.v. injection. Thus, the four significant advantages of EBD-300 over Rylaze are: (1) lower immunogenicity, (2) lower required dosing, (3) i.v. versus i.m. administration, and (4) zero off-target activity. ALL KOLs

stated that these advantages would make EBD-300 clearly preferable in the clinic compared to Rylaze. The company's Asset #2 is a TRAIL-asparaginase fusion. Through its unique engineering and dual tumor cell-killing mechanism of action, it overcomes prior TRAIL hurdles and demonstrates higher efficacy compared to Abbvie's ABBV-621 currently in clinical trials.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The clinical trial strategy for EBD-300 is to conduct a rapid Phase I trial in healthy volunteers (there is precedent with Rylaze) to obtain first human PK data and tolerability, followed by a Phase I trial in patients who are hypersensitive to Oncaspar. Due to the vast clinical experience with asparaginase, efficacy is accepted as demonstrating sufficient asparaginase activity to deplete blood asparagine (i.e., no OS or PFS endpoints are needed). Successful Phase 1 trials showing improved tolerability and adequate dosing would be the company's first potential exit point. If required, EbD proceeds to an open-label Phase II trial comparing EBD-300 and Rylaze. There is precedent for accelerated approval after a successful Phase II trial; this would be the second potential exit point. Moreover, the improved tolerability of EBD-300 opens up new indications not actionable by the current asparaginases and will be addressed in future clinical trials. U.S. composition of matter patents protect the EbD-engineered asparaginase and TRAIL-asparaginase fusion. The IP belongs to the University of Illinois, and EbD has an exclusive option and is currently in negotiations for the license terms.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	Preclinical in vivo efficacy and toxicity studies in ALL for novel asparaginase – Asset #1
2020	Discovery POC in vivo efficacy in AML and pancreatic for Gen 1 of novel TRAIL receptor agonist – Asset #2
2021	Discovery POC in vivo efficacy in ALL for half-life extended novel asparaginase – Asset #3
2022	Engineered maximized safety and stability profile resulting in Lead Development Candidate finalization – Asset #1
H2 2023	CMC – Upstream and Downstream Process Development – Asset #1
H2 2024	Preclinical POC in vivo PK, efficacy, and tox for Gen 2 Asset #2 and Asset #3
H2 2025	IND allowance of Asset #1

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018-2020	Two Phase I STTR grants	Two Phase I STTRs, two Phase I SBIRs, Phase II SBIR, NIH I-Corps	>$3.5M
2023	NCI NExT program	Conduct IND-enabling IND allowance of novel asparaginase Asset #1 (EBD-300)	In-kind support

USE OF PROCEEDS

EbD seeks $7M plus NExT support to obtain IND-allowance for EBD-300; $4M to finalize the development of the TRAIL-receptor agonist (selection of DC) and begin IND-enabling work; and $2M to finalize the development of EBD-300 with half-life extension technology (selection of DC) and begin IND-enabling work.

KEY TEAM MEMBERS

Arnon Lavie, PhD, (CEO/CSO): Expert in biochemistry, enzymology, and rational structure-based drug design. Highly published professor at University of Illinois at Chicago for more than 20 years. Responsible for high-level company strategy and vision.

Amanda M. Schalk, PhD, (COO, Principal Scientist, and PI on NIH grants): Expert in protein engineering and experienced in project management, bookkeeping. Responsible for operational administrative duties.

Jon Weston, MBA, (Interim CFO and Head of Business Development): Former 2x CEO, expert in market analysis

IMMUNOPHOTONICS, INC.

Pioneering Interventional Immuno-Oncology™

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COMPANY OVERVIEW

Immunophotonics, Inc., is a privately owned clinical-stage biotech company that provides an innovative solution to combat solid metastatic cancers. The company is in Phase 2 clinical development of IP-001, an immune-stimulating drug designed to induce tumor- specific, potent antitumor immune activation when administered after standard-of-care interventional oncology procedures that use energy to destroy tumors, such as tumor ablation or radiation. A single intratumoral injection of IP-001 can ignite a systemically active cancer immunotherapy able to reach distant untreated metastases. Early clinical data has shown shrinkage of both treated tumors and distant metastases.

MARKET & COMMERCIALIZATION STRATEGY

The total market potential of IP-001 is closely related to the global solid tumor ablation and radiation market, which comprises over one million ablations and nine million radiation treatments each year. The total accessible market is derived from the indications the company is currently pursuing, namely melanoma, soft tissue sarcoma, lung (NSCLC), colorectal cancer with liver metastases, and hepatocellular carcinoma (HCC), which together represent over 60% of all ablations. Moreover, IP-001 is the first immuno-oncology drug intended for use by interventional radiologists as part of their preexisting workflow. Taken together, adding IP-001 to existing ablation procedures represents a multi-billion dollar de novo market opportunity. Immunophotonics has a clear vision to outlicense its intellectual property by indication or partner with big pharma for combinational treatment with other immuno-oncology therapeutics. The company has begun discussions with several potential partners and welcomes contact with companies having the capability to bring IP-001 to market for the benefit of patients around the world.

TECHNICAL & COMPETITIVE ADVANTAGE

IP-001 is a first-in-class drug in the emerging field of Interventional Immuno-Oncology™ (IIO), which Immunophotonics is pioneering. An intratumoral injection of IP-001 in the context of a routine tumor ablation can induce both an innate and adaptive immune response against whole-cell-derived tumor antigens. This unique approach delivers a repertoire of tumor antigens to generate a robust immune response, in contrast to other approaches that select single tumor-associated antigens. The mechanism of action of IP-001 is multimodal, interfering in the cancer-immunity cycle at several steps. IP-001 is designed to enhance interactions of tumor antigens with dendritic cells, improve the motility of tumor-infiltrating T cells, promote surveillance of tumor tissue, and generate long-term protective immunity. IP-001 turns an interventional procedure intended to treat single lesions into a systemic treatment, enabling identification, attack, and elimination of both the treated tumor and the remaining tumors located throughout the body.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Immunophotonics completed a phase 1 clinical trial and commenced phase 2 cohorts assessing preliminary efficacy and exploratory immunology in four solid tumor indications. The company's phase 2 cohorts are open in Switzerland, the United Kingdom, Germany, France, and, most recently, the United States (first U.S. patient expected in Q3 2023). IP-001 is part of a robust intellectual property platform with patents secured in over 50 countries. Additional patent applications have been filed to cover further methods of use and related compositions of matter. Because the technology underlying IP-001 works by inducing an immune response, there are numerous other potential applications outside of oncology (e.g, prevention and treatment of infectious diseases). The company is working with its key opinion leaders in medical oncology and interventional radiology toward the development of a pivotal clinical trial, which may be initiated by the end of 2024.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2021	Phase 1 clinical development completed with excellent safety and tolerability proven
Q2 2022	Advancement into phase 2a clinical development in Switzerland in several solid tumor indications
Q2 2023	U.S. Investigational New Drug Application authorized to proceed by FDA
Q3 2023	First patients treated in France, Germany, United Kingdom, and United States

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
Pre-2014	Early Funding	Seed financing and early nondilutive financing	$2.8M
2014-2018	Funding round	Series A preferred stock sold in multiple tranches	$6.6M
2019-2023	Funding round	Series B preferred stock sold in multiple tranches	$27.3M
2021	Grant	Phase I / Phase II fast-track SBIR grant	$2.4M

USE OF PROCEEDS

The company is currently pursuing a $50M Series C raise, the proceeds from which will be used to enhance the company's product pipeline, fuel clinical phase 2 expansion proof-of-concept studies, and support a phase 2/3 clinical trial.

KEY TEAM MEMBERS

Lu Alleruzzo, CEO & co-founder: Bioengineer with an MBA and 10+ years in the life sciences industry.

Dr. David Anderson, CSO. Ph.D.: Veteran of the biotech industry with deep expertise in target-based drug development.

Dr. Tomas Hode, CIO & co-founder. Ph.D.: More than 30 years' experience in life sciences, both in industry and academia.

Dr. Siu Kit Lam, Sr. VP of R&D. Ph.D. in immunology: Oversees all facets of non-clinical research at Immunophotonics.

INDEE LABS

Instruments for More Effective Engineered Cell Therapies

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COMPANY OVERVIEW

Indee Labs is a biotechnology start-up developing Hydropore™, which enables modified immune cell R&D with improved yield and function using a simple workflow, commercial GMP-grade buffers, and a small footprint. The team at Indee Labs works with three of the top 10 pharmaceutical companies, various life science and biotechnology companies, and academic institutions including University of California San Francisco, Medical University of South Carolina, and Stanford. Indee Labs is backed by IndieBio/SOSV, Y Combinator, Social Capital, Founders Fund, and the National Institutes of Health, among others.

MARKET & COMMERCIALIZATION STRATEGY

Hydropore is currently sold for Research Use Only and actively being used for cell biology and engineered cell therapy research. This allows Indee Labs to access the $1B transfection reagents market and follow up with a picks-and-shovels play into the engineered immune cell therapy such as T cell immunotherapy ($20B, over 20% CAGR) for therapeutic markets like cancer ($153B, over 4% CAGR), autoimmune disorders ($190B, over 7% CAGR), heart disease, and aging.

TECHNICAL & COMPETITIVE ADVANTAGE

Hydropore is simple, efficient, gentle, and effective. A single chip can process between one and 100 million cells, and typically improves the yield of gene-edited cells by 1.5- to 2-fold when compared to electroporation. It also improves the function of modified immune cells like CAR-T and CAR-Treg cells. Hydropore is also the most compact platform and reduces reagents consumption by 10- to 50-fold when compared to other nascent delivery technologies.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Hydropore cell therapy will not be regulated as a registered medical device; however, it will require Type II FDA Device Master File. Indee Labs maintains two patent families (WO20161098641 and WO2019084624A1) with patents or patents pending in the United States, Australia, Canada, China, Europe, and Japan.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	Publication on mRNA delivery to human primary T cells with minimal perturbation
2021	Publication on genome-editing T cells with Cas9 RNPs with minimal perturbation
2022	$2M contract award from NCI to scale up and out Hydropore for cell therapy
2023	Independent publication on high-throughput screening of cell models using Hydropore

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016-23	Nondilutive	Various nondilutive funding from the United States and Australia	$4.9M
2017	Pre-seed	Led by SOSV/IndieBio and Y Combinator	$1.3M
2018	Seed	Led by Founders Fund and Main Sequences Ventures	$2.6M
2023	Venture round	Led by BroadOak Capital and DeciBio's BioTools Fund	$2.2M

USE OF PROCEEDS

Indee Labs is seeking $10M in Series A financing in H1 2023 to: (1) grow its Research Use Only chip and instrument sales while (2) accelerating partnering for a cell therapy manufacturing instrument and chip developed during the company's $2M milestone-based contract with NCI (75N91022C00053).

KEY TEAM MEMBERS

Ryan Pawell (Founder and CEO): Y Combinator alumnus, published author, angel investor, and subject matter expert in biomicrofluidics. He leads Indee Labs and is responsible for day-to-day operations, fundraising, business development, and developing Hydropore.

Rich Stoner, PhD (Independent Director): Launching a new startup in cell therapy after serving as the CSO of National Resilience and Synthego. He guides Indee Labs' strategy, fundraising, and lab automation efforts.

Bryan Poltilove (Investor Director): Managing director of BroadOak Capital's BioTools Fund and previously a vice president at Thermofisher where he launched the Rotea cell separation instrument and led the BrammerBio acquisition. He guides Indee Labs' strategy, fundraising, and business development efforts.

KUDA THERAPEUTICS

Developing Novel Therapeutics for Kidney Cancer

Mei Koh, Ph.D. | mei.koh@kudatherapeutics.com | 520-780-8476 | kudatherapeutics.com

COMPANY OVERVIEW

Founded in 2016, Kuda Therapeutics, Inc., is an oncology company based in Salt Lake City focused on the development of first-in-class therapeutics for kidney cancer. To date, Kuda is funded entirely by nondilutive government grants (approximately $3M) and retains full ownership of intellectual property rights to its lead product.

MARKET & COMMERCIALIZATION STRATEGY

Clear cell renal cell carcinoma (ccRCC), a common and aggressive form of kidney cancer, is resistant to conventional chemotherapy and radiation, and a field of functionally similar immune checkpoint inhibitors (ICIs) and tyrosine kinase inhibitors (TKIs) comprise the standard of care for patients with advanced ccRCC. The effectiveness of these agents is restricted by inherent and acquired resistance, and most patients do not show durable responses to these treatments. There are few treatment options for patients who develop resistance, which constitutes a significant unmet medical need. Thus, only 14% of patients with advanced ccRCC survive for more than five years. The global kidney cancer drug market is estimated at approximately $7B annually, with an annual growth rate of 6%. Kuda was recently awarded a $2M SBIR Phase II grant from NCI that will be used to conduct IND-enabling nonclinical studies for its lead molecule, KD061.

TECHNICAL & COMPETITIVE ADVANTAGE

Kuda has developed the first orally available small molecule dual inhibitor of hypoxia inducible factor (HIF)-1α and HIF-2α and inducer of ferroptosis with significant antitumor activity (> 60%) in animal cancer models, and no detectable toxicities at the therapeutic dose. HIF-2α is a validated therapeutic target, demonstrated by the recent FDA approval of belzutifan (Merck), a selective inhibitor of HIF-2α, for cancers associated with VHL disease including ccRCC. Ferroptosis is a novel mechanism of iron- and lipid-dependent cell death to which cancer cells are uniquely sensitive, due to their elevated levels of iron and lipids compared to normal tissue. Ferroptosis induction thus provides a therapeutic window for the induction of tumor cell death with minimal toxicity to normal tissue. Significantly, cancer cells that are resistant to standard therapies maintain sensitivity to ferroptosis, making ferroptosis induction a potentially transformational treatment strategy for cancer, yet orally available ferroptosis inducers with efficacy in mouse models of cancer have not yet been identified (apart from KD061). By combining HIF inhibition with ferroptosis induction, KD061 has the potential to dramatically improve outcomes for ccRCC patients, and potentially those with other tumor types.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Kuda's focus is to complete the nonclinical and toxicological studies needed to support an IND filing on its lead product, KD061. The intellectual property to KD061 and related compounds are fully owned by Kuda. U.S. patent US 11,447 B1 covering composition of matter and methods of use for the first-generation Kuda compounds (KD01-42) was granted by the USPTO and published on September 20, 2022. The Patent Cooperation Treaty PCT/US2022/072679 for the second-generation compounds that includes KD061 was filed June 1, 2022 and is pending.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2014	Completions of high throughput screen for inhibitors of HIF-2α – hit identification and validation
Q2 2021	Completion of SAR resulting in lead identification (KD061) and efficacy validation in mouse models of kidney cancer
Q3 2023	KD061 drug substance identification, manufacturing, and characterization
Q4 2024	Completion of IND-enabling studies, pre-IND meeting
Q2 2025	IND filing

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2012-2014	NIH/NIDA R03 grant	High-throughput screen for selective inhibitors of HIF-2α	$100K
2018-2020	NIH/NCI SBIR Phase 1 grant	Lead identification	$355K
2020-2023	DoD KCRP Idea Award	Lead optimization/efficacy validation	$560K
2023-2025	NIH/NCI SBIR Phase 2 grant	KD061 manufacturing, IND-enabling studies	$2M

USE OF PROCEEDS

The company is seeking $2.5M from private investors to fund the remaining costs associated with the IND filing activity.

KEY TEAM MEMBERS

Mei Koh, PhD (Co-Founder, CEO, Director): With over 20 years' experience in cancer therapeutics with focus on HIF signaling in kidney cancer, Dr. Koh leads the scientific efforts at Kuda including preclinical, manufacturing, and IND-enabling studies.

Travis Ehlinger, MBA (Co-Founder, CFO, Director): Mr. Ehlinger has 20 years' experience in project and financial risk management. He manages Kuda's financial and legal obligations.

Robert Lippert, MBA (Director): Mr. Lippert has over 35 years of biopharma/drug development experience and oversees the development of the business plan, investor slide deck, and fundraising efforts while providing guidance on company operational activities.

LUMINARY THERAPEUTICS

Gamma Delta Allogeneic / Solid Tumor CAR-T

Jeff Liter | j.liter@luminarytx.com | 612-309-7653 | luminarytx.com

COMPANY OVERVIEW

Luminary is a clinical stage CAR-T therapy company using a unique allogeneic manufacturing platform based on preserving both Vδ1 and Vδ2 gamma delta cells. This approach has the distinct advantages of using both the innate and adaptive properties of these cells to improve cancer clearing powers. Luminary's products use a proprietary method to cloak the cells from the recipient's immune system, and the company is actively developing multiple targets for its solid tumor program. This program employs proprietary co-stimulatory signaling methods to ensure T-cell persistence, enhancing the effectiveness of Luminary's therapies. Furthermore, Luminary's ligand-based BAFF CAR for hematologic cancers boasts three antigen receptors specifically designed to overcome antigen escape.

MARKET & COMMERCIALIZATION STRATEGY

Luminary's market and commercialization strategy leverages its expertise to take therapeutics from the bench to a de-risked proven clinical stage. The company approaches target development with a high level of selectivity, striking a balance between addressing unmet clinical needs and exploring a wide range of oncology indications. Central to Luminary's strategy is the pursuit of partnerships and/or outlicensing opportunities with organizations that possess the ideal capabilities to effectively commercialize proven therapeutic assets. By collaborating with industry leaders, the company will maximize the potential impact of its therapies to ensure they reach the market successfully. By executing this market and commercialization strategy, Luminary will bring innovative therapeutics to patients while simultaneously delivering attractive returns to valued investors.

TECHNICAL & COMPETITIVE ADVANTAGE

Luminary's allogeneic manufacturing platform achieves approximately 150 doses per manufacturing run. This significantly reduces the cost of the therapies and improves patient access. Achieving its expansion rates of engineered gamma delta cells, Luminary is at the forefront of cost leadership. Luminary's solid tumor program includes a dual targeting CAR design with optimal co-stimulation and metabolic fitness to enhance antitumor activity in solid tumors. The benefit of this approach has been published in *Nature Cancer*.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Luminary has a long-standing contractor relationship with a former CBER reviewer who guides the company's IND submissions. Luminary's last IND was approved in 27 days from first submission. Wilson Sonsini, the company's IP counsel, files all internally developed IP and oversees the IP prosecution strategy for the company's in-licensed technology with academic institutions.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
March 2022	Two Phase I INDs cleared: Luminary is conducting two Phase I trials utilizing its three antigen BAFF CAR: NHL trial (auto) and relapsed MM trial (auto).
October 2023	File SLE and SLC IND for Phase I trial: Luminary will file an autoimmune Phase I trial for lupus and systemic scleroderma (auto) October 23
November 2023	Pre-IND filing solid tumor: Luminary will file a pre-IND briefing package with the FDA in Q4 2023 for an allogeneic basket study of head and neck, recurrent ovarian, and recurrent colorectal cancers.
April 2024	File solid tumor IND: Luminary expects to file for an allogeneic Phase I solid tumor study in Q2 2024.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	SBIR Phase I	Fusion of MyD88 protein to T cells	$400K
2021	SBIR Phase I	Dual CAR targeting the stroma with a FAP CAR	$400K
2023	SBIR Fast Track	Scale-up of BAFF CAR on gamma delta manufacturing platform with both V1 & V2	$2.4M
2023	SBIR Phase 1	BAFF CAR for SLE (lupus) – Allogeneic	$300K

USE OF PROCEEDS

Luminary is raising $30M to be used to expand the team and conduct two Phase I trials: an allogeneic solid tumor trial for recurrent ovarian and colorectal cancers and an allogeneic lupus and systemic scleroderma trial.

KEY TEAM MEMBERS

Jeff Liter (CEO): Sets company strategy, leads organization, fundraises, manages investor relations, sets manufacturing strategy, leads clinical development.

Beau Webber (CSO): Sets development strategy with CEO and CTO, leads technical research, ensures experimental design integrity, troubleshoots with staff.

Branden Moriarity (CTO): Sets development strategy with CEO and CSO, searches for new technical advantages to incorporate into company.

MICROVASCULAR THERAPEUTICS, INC.

Pioneering In Ultrasound And Theranostics Agents

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COMPANY OVERVIEW

Microvascular Therapeutics, Inc., is a clinical stage biopharma company pioneering in ultrasound contrast and theranostic products for the treatment of various therapeutic indications, including oncology, vascular thrombosis, and inflammation.

MARKET & COMMERCIALIZATION STRATEGY

Brain and other central nervous system (CNS) cancers are the 10th leading cause of death for men and women. It is estimated that 18,990 deaths (11,020 men and 7,970 women) from primary cancerous brain and CNS tumors will occur in the United States in 2023. In 2020, an estimated 251,329 people worldwide died from primary cancerous brain and CNS tumors. As per DelveInsight analysis, the brain cancer market size in the 7MM (the United States, the EU-4 [Italy, Spain, France, and Germany], the United Kingdom, and Japan) was approximately $2.7B in 2021. The estimated total primary brain tumor incident cases in the 7MM were approximately $60K in 2021. Microvascular Therapeutics intends to codevelop its product and commercialize it in 2028-2029 in partnership with an interested industrial partner with an ultrasound delivery device.

TECHNICAL & COMPETITIVE ADVANTAGE

MVT-101 is a phase shift microbubble that is formulated with a patented blend of phospholipids entrapping the active pharmaceutical ingredient, oftafluoropropane gas. The product is a first-in-class product and competes with therapeutics (with toxicities-related side effects and limited BBB penetration). In combination with devices opening the BBB, MVT-101 delivered i.v. with high-intensity focused ultrasound (HIFU) can nonthermally ablate the brain tumor.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

MVT-101 is likely to be regulated as a device for this therapeutic indication (as it has already done for its use for disrupting blood clots in vascular thrombosis) and in combination with the MRgFUS instrumentation (ExAblate™ developed by Insightec). The formulation is patented by the company (US62/011,469; US62/324,599 and US13/186,373), and the condensing process to manufacture MVT-101 is exclusively licensed from Triangle Biotechnology (US61/505,915 and US61/864,277).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2009	Founding of Microvascular Therapeutics
2018	Exclusive licensing agreement with TBI for condensing microbubbles into phase shift microbubbles
2019	Licensing agreement with UNC and Columbia University for brain application of PSMB
2022	NCI Phase I award for the POC studies of MVT-101 for nonthermal ablation with HIFU of brain tumor
2023	Guidance from FDA to regulate MVT-101 as a device for sonothrombolysis

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2009	Seed	The company's founder, Dr. Unger, provided the initial capital for the company	$2.1M
2010-2023	Grants (NCI, DoD)	The company received several grants for several products and indications	$11.7M
2020	In kind	Founder built the GMP manufacturing suite (ISO5/7 certified) and worked for free	$5M
2023	Convertible note	Open Round	$350K

USE OF PROCEEDS

The company is fundraising a $5M convertible note for IND-enabling studies of MVT-101 for nonthermal ablation combined with HIFU of brain tumors (primary and metastases). Microvascular Therapeutics would also initiate a pilot clinical study ex-U.S. (Australia) to obtain supporting data for the IDE package.

KEY TEAM MEMBERS

Emmanuelle J. Meuillet, PhD (COO/CSO): Dr. Meuillet directs all operations and scientific activities at the company. She has a strong background in oncology.

Evan C. Unger, MD (Chair of BOD): Dr. Unger has more than 40 years of expertise in the field of ultrasound and microbubble technology. He advises the team.

Graeme Woodworth, MD: Dr. Woodworth is an expert clinician in brain and tumor neurosurgery. He will co-lead the clinical trial.

Randy Lynn Jensen, MD, PhD: Dr. Jensen is also an expert clinician with a particular emphasis on treating meningiomas, metastatic brain tumors, and malignant gliomas. He will co-lead the clinical trial.

AZ Technica (Consulting Group): AZ Technica provides regulatory expertise for the pre-IDE and IDE documentation submission.

MODULATION
Therapeutics

MODULATION THERAPEUTICS, INC.

Targeted Radiotherapy for Metastatic Melanoma Treatment

Lori Hazlehurst | hazlehurst@modulationtherapeutics.com | 304-282-4036 | modulationtherapeutics.com

COMPANY OVERVIEW

Modulation Therapeutics, Inc. (MTI), founded in 2011, has developed three independent first-in-class drug candidates in clinical and late preclinical stages of development. The clinical-stage asset is MTI-201, an 225Actinium-labeled peptide radiotherapeutic that targets melanocortin 1 receptor (MC1R) and shows no observed toxicity. It also shows significant survival advantage in preclinical animal models for cutaneous and uveal melanoma. The Phase 1 clinical trial of 225Ac-MTI-201 in metastatic uveal melanoma patients has no reported drug-related adverse events. The PET imaging analog, 64Cu-MTI-201, has been prepared as a companion diagnostic. Clinical class MTI-201 has the potential to effectively treat 8,000 melanoma patients per year in the United States alone. Patients with metastatic disease have an average six-month life expectancy. MTI's late preclinical drug candidates have the combined potential to treat more than 100,000 patients per year.

MARKET & COMMERCIALIZATION STRATEGY

Independent market assessment indicates the addressable market for melanoma is $5.6B. MTI estimates a market share opportunity of more than $1B for MTI-201. MTI was granted Orphan Drug designation by the FDA for the use of MTI-201 to treat primary or metastatic uveal melanoma. MTI-201 has also been granted a fast-track designation by the FDA due to lack of highly effective treatment available for most metastatic melanoma patients. Early marketing approval following a successful Phase 2 trial is strategically feasible via FDA Breakthrough Therapy designation. Expansion to other melanoma treatment indications, such as refractory metastatic cutaneous melanoma (MCM) and other rarer forms of melanoma, can further expand market share.

TECHNICAL & COMPETITIVE ADVANTAGE

Immunohistochemistry analysis of human melanoma samples shows high expression of MC1R. MTI-201 has the highest reported MC1R isoform specificity compared to competitor MC1R-targeted ligands. Several 225Ac-MTI-201 analogs were prepared, and analogs with lower LogDs favored liver over kidney clearance, and because the liver is more radioresistant relative to the kidneys, MTI's lead compound with a somewhat hydrophobic linker has favorable efficacy with tolerable toxicity. The Ac-225 payload produces 4-alpha particles with very higher energy deposition that travels less than 100 microns from the radionuclide source, versus potential competitors' beta-emitting radiolabeled MC1R targeting ligands that demonstrate lower energy transfer. The Ac-225 long 10-day half-life uniquely supports a centralized manufacturing and distribution, substantially lowering therapy production cost and providing patients with convenience and choice of local treatment clinic.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

FDA Breakthrough Therapy designation is a focus of the regulatory strategy for achieving early market access for the dire unmet need in metastatic melanoma. An IND amendment is currently pending adding refractory metastatic cutaneous patients to the current Phase I clinical trial. A new IND for a PET imaging analog, 64Cu-MTI-201, will be submitted to support the Phase I imaging trial followed by an IND to support the multidose MTI-201 Phase II trial. A new patent application for Cu64-MTI-201 PET imaging agent has been filed this year.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
November 2021	FDA IND approval to start Phase I clinical trial MTI-201
Q1 2024	Initiate Phase I human trial for Cu64-MTI-201 companion imaging agent
Q2 2025	Initiate Phase II human trial – multidose
Q1 2026	Outlicense / partner

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2011-2017	Grants and investments	NCI SBIR and state grants	$3.07M
2018-2020	Grants and investments	NCI and institutional investments	$6.93M
2020-2023	Grants	NCI	$2.4M

USE OF PROCEEDS

The company is seeking $8.5M to complete the milestones above, leading to marketing approval and exit in 2026.

KEY TEAM MEMBERS

Lori Hazlehurst (CEO): More than 30 years of drug development experience and an expert in cancer pharmacology.

Mark McLaughlin (VP): More than 30 years of drug development experience and an expert in peptide synthesis.

Tim Hazlehurst (COO): More than 30 years of business development experience, including seven years in biotech.

Privo technologies.
Tough On Cancer, Easy On Patients

PRIVO TECHNOLOGIES, INC.

Nano-Engineered Topical Mucoadhesive Patch Platform

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

COMPANY OVERVIEW

Privo is a Phase III clinical stage company that has developed an innovative, nanoengineered drug delivery technology that can be administered in multiple dosage forms, such as a topical patch, intraoperative patch/hydrogel, and intratumor injectable. Privo's novel platform allows its scientists to reformulate existing chemotherapy drugs to have the ability to deliver and retain high concentrations localized in the tumor. This can significantly improve the efficacy of current therapies and decrease their systemic toxicities. Privo's initial product is a topical transmucosal patch (PRV111) for the treatment of oral cancer. PRV111 is a mucoadhesive polymeric patch with embedded cisplatin-loaded nanoparticles and a nonpermeable backing that facilitates unidirectional drug release, prevents drug loss, and masks taste. When placed on the tumor, PRV111 releases and retains a high concentration of cisplatin-loaded nanoparticles into the tumor. The cisplatin-loaded nanoparticles in the patch have optimized size, charge, and permeation parameters to ensure that cisplatin is locally retained within the tumor tissue and not exposed to systemic bodily circulation. PRV211 is an intraoperative patch intended for surgery (solid tumors) and is applied directly to the resected tumor bed to eliminate remaining tumor cells left behind, preventing micrometastases. PRV131, a potent, controlled-release intratumor injectable, has been developed in collaboration with Johns Hopkins Neurosurgery and has shown promising results in treating aggressive glioma tumors.

MARKET & COMMERCIALIZATION STRATEGY

Oral cancer is the sixth most common cancer globally and commonly presents with locally advanced disease, which has a recurrence rate of about 50%. Both conventional treatments and newer immunotherapies have severe side effects, limiting their efficacy. In head and neck cancer alone, the addressable patient population in the United States for PRV111 and PRV211 is approximately 80,000 patients annually, with a market potential of $900M-$1B within five years of launch. PRV111 and PRV211 are effective against all solid tumor types present in mucosal tissue. Following approval, the revenue from PRV111/211 will be used to fund additional clinical trials for label expansion. Results from preliminary market research showed more than 80% physician adoption rate and a 95% positive perception of therapies. Privo is interested in outlicensing PRV111 and PRV211 to regional partners.

TECHNICAL & COMPETITIVE ADVANTAGE

In a Phase I/II trial treating subjects with oral cavity cancer, among the responding subjects, there was an overall response rate of 87% and over 70% reduction in tumor volume. The pharmacokinetic profile showed the drug concentration remained local to the tumor (265 times higher than systemic therapy) and locoregional lymph nodes (162 times higher than systemic therapy) and did not enter systemic circulation (700 times lower than systemic therapy). This technology can be combined with other therapies in several types of cancer. Furthermore, PRV111 demonstrates the ability to make the tumor

"hot," suggesting synergy with cancer immunotherapies. Oral tumors are commonly found in areas such as the tongue and buccal tissue, where nanoparticles must penetrate deeply to destroy all cancer cells. Privo's permeation enhancer is composed of a proprietary bile salt mixture that is applied to the tumor surface prior to patch application. This permeation enhancer primes the tumor area for deeper permeation of cisplatin nanoparticles.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Privo plans to file an NDA for PRV111 via the 505(b)(2) pathway. PRV111 will be approved, marketed, and reimbursed as a new drug. Privo has strong intellectual property protection, with a patent life expiring in 2037. Privo has four issued patents (owned solely by Privo) that are sufficiently broad in scope to allow for various APIs and indications.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
November 2017	IND Approval
July 2020	Completion of Phase I/II Clinical Study
February 2022	CIS protocol submitted to FDA-no comments or concerns received from the Agency since submission
2022	IRB approval documentation submitted to FDA & CIS protocol receives IRB approval & Large Pharma partnership

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018 and 2022	Grant	NCI SBIR NOSI & Phase II	$5.5M
2021	PE Investment	AIM-HI Accelerator Fund's Women's Venture Competition	$0.9M
2021	Grant	NIH NIDCR SBIR Commercialization Readiness Pilot	$3.0M
2019	Grant	FDA Orphan Drug Development Award	$2.0M

USE OF PROCEEDS

Privo is seeking $5M for PRV 211's Phase I/II trial and $22M for PRV 111's Phase III pivotal registration trial and NDA submission.

KEY TEAM MEMBERS

Manijeh Goldberg, PhD, MBA, MS (CEO): With more than 25 years' industry experience, Dr. Goldberg has taken several healthcare products from concept to commercialization.

Nishant Agrawal, MD (CMO): Dr. Agrawal is the director of head and neck surgical oncology at the University of Chicago Medicine.

Charlie Morris, MD (Interim CMO): Dr. Morris is an oncologist with more than 30 years in drug development and has contributed to several blockbuster drugs from AstraZeneca.

REVEAL PHARMACEUTICALS

The Future of Medical Insight

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COMPANY OVERVIEW

Reveal Pharmaceuticals is revolutionizing MRI contrast agents to improve patient safety and to grant new insight into complex diseases. Reveal's clinical stage RVP-001, a gadolinium-free MRI contrast agent, solves a critical safety issue that impacts 40 million scans per year. Additionally, the Company is building on the RVP platform with a fibrogenesis molecular imaging agent in preclinical development, promising unprecedented insight to detect, stage, and monitor treatment response in many cancers and fibrotic diseases (e.g., NASH, heart failure, kidney fibrosis).

MARKET & COMMERCIALIZATION STRATEGY

MRI gadolinium-based contrast agents (GBCAs) provide essential insight to detect and stage cancer and other diseases, guide treatment, and monitor response to therapy. Forty million contrast-enhanced (CE) MRI scans are performed each year, a growing $2B addressable market. However, all GBCAs contain gadolinium and bear a Food and Drug Administration boxed warning as well as warnings and suspensions from regulators worldwide. All GBCAs cause accumulation of toxic gadolinium in the brain and body of all patients. GBCAs can also trigger devastating fibrosis. Those at greatest risk include people who need repeated CE-MRI scans, people with kidney disease, and children. The dilemma: Expose patients to a toxic heavy metal or deny them vital insight from CE-MRI. Reveal's lead product, RVP-001, is in National Cancer Institute (NCI)-funded clinical trials to confirm that it is a safe, gadolinium-free alternative to GBCAs and will provide equivalent diagnostic information. Market dynamics demonstrate that this is a highly safety sensitive winner-take-most market. Physicians will use RVP-001 for their most vulnerable patients; workflow and safety considerations will drive broad adoption of RVP-001 for all.

TECHNICAL & COMPETITIVE ADVANTAGE

First-in-class RVP-001 is the first general purpose gadolinium-free MRI contrast agent to enter clinical trials. Based on biocompatible manganese and designed to be a direct replacement for current MRI contrast agents, RVP-001 seamlessly fits existing radiology workflows and the established reimbursement model. Nonclinical data show RVP-001 to be safer than GBCAs, with equivalent imaging efficacy to GBCAs across multiple disease and animal models. First-in-class RVP-001 is in NCI-funded Phase 1 clinical trials. Reveal's team are world experts in MRI and molecular imaging, with unmatched ability to develop the pipeline and drive success.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Reveal is following the established regulatory path used by all approved general purpose MRI contrast agents. RVP-001 has been substantially de-risked; general purpose MRI agents have an exceptional track record of 100% success from Phase 1 through NDA. RVP-001's first indication is central nervous system imaging (50% of total market), followed by additional indications (e.g., breast, pediatric). Invented at Harvard/Massachusetts General Hospital, RVP-001 is patented in major global markets; a second patent covers a broad related class, supporting the pipeline.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2022	Phase 1 clinical trials (ongoing)
2023	First imaging trial in patients/dose range study
2024	Identification of lead candidate for IND-enabling work in fibrogenesis/Expanded Phase 2 imaging study

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017-2018	Grant, accelerator	NIDDK Fast Track SBIR; MassChallenge winner; NHLBI SMARTT; MLSC MassNext Gen	$1.4M
2019	Grant	MLSC Milestone Achievement Program; NCI Fast-Track SBIR; continuing NIDDK grant	$1.2M
2020	Grant	NIDDK Commercialization Readiness Program SBIR; NHLBI SBIR; continuing NCI + NIDDK SBIRs	$2.3M
2021	Grant	NCI Fast-Track SBIR; NCI Direct to Phase II SBIR; MassVentures SMART Phase 1	$2.3M
2022	Grant	NIDDK Fast-Track SBIR; MassVentures SMART Phase 2; continuing SBIRs	$1.4M
2016-2022	Founders, investors	INFCapped notes (clean cap table; minority of equity)	

USE OF PROCEEDS

NCI is funding first-in-human clinical trials of Reveal's first-in-class gadolinium-free MRI contrast agent RVP-001. Reveal is anticipating raising up to $45M to support Phase 2 trials, accelerate RVP-001 toward NDA, and support development of a molecular imaging agent for fibrotic diseases.

KEY TEAM MEMBERS

Vera Hoffman, MBA (CEO and Founder): Expert in business innovation; developed the initial business plan for Acquia ($1B exit, 2019).

Peter Caravan, PhD (Co-Founder): World leader in MRI contrast; professor, Harvard Medical School.

Srinivasan Mukundan, MD, PhD (Medical Director): Distinguished neuroradiologist; former chief of MRI, Brigham Health.

RNA Nano THERAPEUTICS™

RNA NANOTHERAPEUTICS LLC

Reshape the Cancer Therapy Landscape

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COMPANY OVERVIEW

RNA Nanotherapeutics' goal is to develop multifunctional RNA nanoparticles as next-generation new therapies with better efficacy and minimal side effects. The company is currently focusing on developing RNA nanotherapeutics to overcome breast cancer treatment resistance, which can also be expanded as a platform technology to treat other cancer and diseases.

MARKET & COMMERCIALIZATION STRATEGY

Breast cancer remains one of the most frequent cancers in the United States, with 297,790 new diagnoses of invasive breast cancer and 43,700 deaths estimated in 2023. Recurrence and therapy resistance are very common for ER+ breast cancer, and the current treatments are highly toxic with limited effectiveness despite new advancements. RNA Nanotherapeutics' product targets metastatic ER+ breast cancer patients who have relapsed from at least one line of endocrine therapy; the current market size is about $16B. The company's RNA nanotherapeutics can be readily manufactured by its partner, Avecia/Nitto, delivered through existing pharmaceutical channels and medical practices, and used in combination with current breast cancer regimens to augment treatment efficacy and reduce toxicity.

TECHNICAL & COMPETITIVE ADVANTAGE

RNA Nanotherapeutics has developed innovative multifunctional RNA nanoparticles to specifically target a novel key therapy-resistant gene, MED1, in breast cancer to overcome resistance. MED1 is a key downstream effector of the two most well-known breast cancer drivers, estrogen receptor and HER2, and functions at the last step of transcription initiation. MED1 is likely to be less prone to developing resistance. Compared to other small molecule and biologics approaches, RNA nanotechnology has distinct advantages of simultaneous targeting and therapy, controlled synthesis and self-assembly, high stability, low toxicity, and immunogenicity.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The patent on this technology (US11,110,182) was granted in September 2021. RNA Nanotherapeutics is currently engaging with leading consultants at PPD and Parexel to develop regulatory and clinical strategies. With increased FDA approvals and broad use of RNA vaccines and medicines, the company fully anticipates that its RNA nanotherapeutics represent a highly promising next-generation therapy to benefit patient care through better efficacy, fewer side effects, and improved patient quality of life.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
September 2021	Lead optimization, in vitro and in vivo efficacy and toxicity studies, patent awarded
December 2022	Scale up nanoparticle manufacturing
December 2024	cGMP nanoparticle manufacturing/CMC (Q2 2024) and GLP pharmacology and toxicology studies (Q4 2024)
June 2025	Regulatory affairs, clinical protocols and IND filing

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
September 2021	Grant	Ohio Third Frontier TVSF/ESP Fund	$270K
September 2022	Grant	NCI STTR Phase I grant and I-Corps Supplement	$461.5K

USE OF PROCEEDS

RNA Nanotherapeutics is seeking about $7.5M to support the required IND studies for filing of our product and others including cGMP grade manufacturing/CMC and GLP pharmacology and toxicology studies, regulatory and clinical consulting and filing for FDA approval of clinical trials, research and development of product pipelines and associated overhead costs.

KEY TEAM MEMBERS

Xiaoting Zhang, PhD (President and Founder): Dr. Zhang is a leading expert at the forefront of both breast cancer and RNA nanotechnology research fields. His more than 20 years of research led to the discovery of MED1 as a novel key breast cancer therapeutic-resistant gene, and the invention of the company's patented RNA nanotherapeutics.

Gregory Bick, PhD (CSO): Dr. Bick has worked in Dr. Zhang's lab investigating the role of MED1 and the development of RNA nanotherapeutics. He has also received post-graduate certificates in clinical and translational research and innovation management and is responsible for therapeutics development and moving innovative products into the market.

Elyse Lower, MD (CMO): Dr. Lower is a leading breast cancer oncologist and emeritus professor and director of the Breast Cancer Center of Excellence at the University of Cincinnati Cancer Center. She is a long-time collaborator with Dr. Zhang and is guiding the usage, patient selections, and clinical trial designs for the company's RNA nanotherapeutics.

Marc Lemaitre, PhD: Dr. Lemaitre has extensive experience in production, QA, and development with oligonucleotide therapeutics. He was CEO of Girindus America, supervised many GMP oligonucleotide manufacturing, and authored CMCs for IND applications. He brings expertise on the product development, manufacture, and testing of the company's RNA nanotherapeutics.

Joe Buse: Mr. Buse is a seasoned business executive in healthcare innovation and commercialization. He worked in many different pharmaceutical companies including Johnson & Johnson, Purdue Pharma, and Wyeth (Pfizer), and served as VP and SVP of innovation and business development for Catalina Health, PDR/LDM Group (ConnectiveRx), Inmar, TrialScope, and MNG Health.

SSTI

StemSynergy Therapeutics, Inc.

STEMSYNERGY THERAPEUTICS

Innovative, Targeted Cancer Therapeutics

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COMPANY OVERVIEW

StemSynergy Therapeutics (SSTI) specializes in the discovery and development of novel therapeutics that target mechanisms and signaling pathways that are fundamental to cancers. SSTI's approach is to identify the drug-targetable biology within these pathways to provide greater efficacy with minimal toxicity over current therapies. The company has a robust preclinical pipeline with seven innovative therapeutics, including the MYC degraders, under development.

MARKET & COMMERCIALIZATION STRATEGY

Nearly two million Americans will be diagnosed with cancer, and over half a million will die of their diseases, in 2023. These dismal numbers illustrate the largely unmet need for better cancer treatments that safely and efficaciously target tumors and prevent recurrence and metastasis. MYC proteins are the "holy grail" cancer targets; more than 70% of all cancers depend on MYC proteins. SSTI's commercial strategy is to partner with clinical stage pharmaceutical companies to take its lead MYC degraders into the clinic. The company also plans to capitalize and develop its MYC degraders for an IPO with subsequent commercialization.

TECHNICAL & COMPETITIVE ADVANTAGE

SSTI therapeutics target biology central to tumor growth and recurrence at innovative nodes within important signaling pathways. Its MYC degraders were based on breakthrough science regarding MYC protein stability. The company's compounds are first-in-class to directly target the MYC:Aurora A binding interface and are potent inhibitors of endogenous c-myc in cancer cells. SSTI's compounds are orally available and efficacious in treating c-myc-dependent tumors in rodents without displaying toxicity.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The IP of SSTI's assets is protected by patents. SSTI is the sole owner of its MYC degraders and has filed a patent (Application No. PCT/US2021/017456) to cover its novel scaffolds. The company has also received Orphan Drug designation and exclusivity for the development of a clinical therapeutic for the treatment of familial adenomatous polyposis (FAP). SSTI's goal is to partner or license these assets with pharma companies for clinical development.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2008	Discovery of the first Casein Kinase 1 alpha (CK1alpha) activator, a potent inhibitor of the WNT pathway
2015	Pyrvinium – Orphan Drug designation awarded
2016	Discovery of the first specific Notch Pathway inhibitor
2017	Partnership/licensing agreement with Exelixis, Inc.
2018	Expansion of Exelixis partnership agreement for development of next-generation CK1alpha activators
2021	Discovery of first-in-class MYC degraders

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2008	Angel	Initial angel investment	$200K
2010, 2012	NCI SBIRs	Phase I and II grants – WNT inhibitors for the treatment of colorectal cancer	$2.1M
2012, 2014	NCI SBIRs	Phase I and II grants – WNT inhibitors for the treatment of advanced lung cancer	$1.76M
2015	NCI STTR	Phase I – Repurposing pyrvinium as an orphan drug for FAP	$225K
2016	NCI SBIR	Phase I grant – Development of a LRP6 mAb for triple negative breast cancer	$225K
2016	NIGMS SBIR	Phase I grant – Development of WNT inhibitors for regenerative burn healing	$225K
2017	NCI SBIR, Exelixis Inc.	Phase IIb grant – Development of WNT inhibitors for treatment of colorectal cancer. Funding match from Exelixis, Inc.	$6M ($3M + $3M)
2018	Exelixis, Inc.	Expansion of the partnership for WNT therapeutic program	Undisclosed
2018	NCI SBIR	Phase I/II fast track – Repurposing pyrvinium for FAP	$2.3M
2018, 2021	NCI SBIR	Phase I and II grants – Notch signaling inhibitors as targeted therapeutics for cancer	$2.3M
2020	NCI SBIR	Phase I grant – Development of a NACK inhibitor	$300K
2021	Exelixis, Inc.	Partnership for NOTCH therapeutic program	Undisclosed
2022	NCI SBIR	Phase I grant – Development of MYC degraders	$300K

USE OF PROCEEDS

SSTI currently has no revenue. All additional funding is reinvested into developing its pipeline.

KEY TEAM MEMBERS

Anthony J. Capobianco, PhD (President): University of Miami, Miller School of Medicine NOTCH expert, Instrumental in partnering with Exelixis for StemSynergy's WNT and NOTCH programs.

Ethan Lee, MD, PhD: Vanderbilt University, School of Medicine WNT expert, Instrumental in partnering with Exelixis for StemSynergy's WNT and NOTCH programs.

David J. Robbins, PhD: Georgetown University WNT and HEDGEHOG expert, Instrumental in partnering with Exelixis for StemSynergy's WNT and NOTCH programs.

William A. Weiss, MD, PhD: University of California San Francisco, Helen Diller Family Comprehensive Cancer Center MYC expert, inventor of a prototypical MYC degrader compound that StemSynergy's technology is based on.

STINGRAY
THERAPEUTICS

STINGRAY THERAPEUTICS, INC.

Bringing Forward the Next Revolution in Immune Oncology

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COMPANY OVERVIEW

In 2016, Stingray was the first company to begin developing an ENPP1 (ectonucleotide pyrophosphatase/phosphodiesterase 1) inhibitor for immune oncology. Cancers upregulate ENPP1, blocking innate immunity and its production of interferon, instead rechanneling the pathway to produce adenosine, a potent immunosuppressive and prometastatic molecule. When interferon cannot flow locally, cancer is able to grow unseen by our immune system, which normally stops it before it gains momentum. Other immune oncology therapies, all working in the other main arm of the immune system called adaptive immunity, do not work well when ENPP1 is badly overexpressed. By inhibiting ENPP1, we restore the therapeutic utility of other agents and allow a broad set of cancers that do not respond to adaptive checkpoint inhibitors to be well-treated when our agent, SR-8541A, is added to the regimen. Our first combination study will be in triple negative breast cancer (TNBC) with PD-1 and CTLA-4 checkpoint inhibitor, the breast cancer with the highest mortality rate and thus a high medical need.

MARKET & COMMERCIALIZATION STRATEGY

Pharmaceuticals typically start in a smaller market for their initial indication and then expand through additional clinical trials and marketing authorizations. In this case, TNBC would be the initial indication, in hopes that the eventual indication would include all high-expressing ENPP1 tumors. For TNBC, Stingray estimates its therapy could be used in about 10% of breast cancer cases—28,155 new U.S. cases per year and 367,000 total U.S. cases per year. If the therapy is successful in displacing the standard of care for TNBC, and if Stingray's therapy is used in just 15% of all new cases (4,223 patients) and 5% of all patients (18,350) who are facing recurring disease, at a price point of $150,000 per case, an eventual sales level of $3.4B is attainable (22,573 U.S. patients per year) just in TNBC.

TECHNICAL & COMPETITIVE ADVANTAGE

Stingray's compound, SR-8541A, is ahead of its competition, with the single exception of one competing compound that Stingray believes to be inferior because of its poor absorption into the body and high patient-to-patient variability in blood levels. This competitor has had difficulty recruiting patients into their first-in-man study and unable to announce any solid findings thus far. Stingray's team comprises renowned and seasoned professionals including oncologists, cancer molecular biologists, immune oncology clinical development professionals, and experienced pharmaceutical and biotech business professionals. The company does not have many programs following them as late starters, but it is very hard to make these programs successful.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The company has seven composition of matter and method of use patents with four approved in the United States and three in process. Stingray has also filed internationally to gain protection in a broad set of countries. SR-8541A has an accepted IND in the United States, and Stingray is starting its first study in Australia in the summer of 2023. After single and combination dose escalation has been shown safe, the company plans a broad set of clinical studies in many cancers where it has seen good synergy with existing agents and where the standard of care has poor response. These include TNBC, microsatellite stable colorectal cancer, locally advanced pancreatic cancer, and renal cell carcinoma.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
April 2023	IND acceptance by FDA
September 2023	First patient dosed in Phase 1A
March 2024	Start of SR-8541A + Balstilimab (novel IgG4 anti-PD1) + Botensilimab (Fc enhanced anti-CTLA-4) Phase 1-2 in microsatellite stable colorectal cancer
May 2024	Start of SR-8541A + Tecentriq (atezolizumab) + Avastin (bevacizumab) in first line plus hepatocellular carcinoma

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Seed Series 1 (complete)	Angels, high net worth individuals, regional VCs	$2M
2020	Seed Series 2 (complete)	Angels, high net worth individuals, regional VCs	$2.5M
2022	Seed Series 3 (ongoing)	Angels, high net worth individuals, regional VCs	$2.5M
2022	Direct to Phase 2 SBIR	Ahead of schedule, started September 15, 2022	$2M

USE OF PROCEEDS

Stingray is raising $2.5M Seed Series 3 at a $17.5M pre-money valuation, with $750K remaining in the raise. This completes the Phase 1A clinical study. The company is looking for a lead investor for its Series A to fund two Phase 1-2 combination studies.

KEY TEAM MEMBERS

Jonathan Northrup, MBA, (CEO & Co-Founder): Worked 28 years at Eli Lilly; left as SVP of corporate business development. Fifteen years in biotech; CEO of four biotechs.

Sunil Sharma, MD, FACP, MBA (Chief Medical and Research Officer): Phase 1-2 medical oncologist with a deep interest in drug discovery.

Monil Shah, PharmD, MBA (VP of Development): Deeply experienced in clinical development of immune oncology.

Uma Bhatt, CPA (CFO): Has several roles in biotech leading financial and operational duties.

TALUS BIO

Transcription Factor Inhibitors for Targeted Cancer Therapeutics

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COMPANY OVERVIEW

Talus Bio discovers and develops small molecule therapeutics for previously undruggable transcription factors (TF). The company has built a discovery platform called MARMOT employing next-generation proteomics, automated biology, and AI to test a candidate molecule against all TFs simultaneously in live, unmodified cells.

MARKET & COMMERCIALIZATION STRATEGY

Talus Bio's lead program is focused on a direct inhibitor of Brachyury, a transcription factor driver of chordoma. These tumors are generally rare, but they consistently overexpress the developmental transcription factor brachyury (TBXT), a transcription factor normally inactivated in adult tissue. Further work has shown that these tumors are dependent on TBXT for their growth and survival. Currently, there are no standard therapeutic options available. Talus Bio has discovered a series of molecules that directly bind to the TBXT protein, inhibit its ability to actively engage with DNA, and eventually lead to the destabilization and degradation of the TBXT protein. The company is currently working to optimize these molecules in hit-to-lead medicinal chemistry, focusing on improving potency in its live-cell assay as well as improving selectivity over all other transcription factors and kinases. Talus Bio has begun in vivo validation for a lead series of TBXT inhibitors and plans to nominate a development candidate by the end of 2023. In addition to the chordoma program, four other hits against clinically validated targets were identified during screening in 2022. Series A funds will be used to initiate hit-to-lead development for two of these hits in 2024.

TECHNICAL & COMPETITIVE ADVANTAGE

The Talus Bio MARMOT platform is the only technology that currently can provide potency and selectivity assessment of small molecule transcription factor modulators. In short, the cell-based assay simultaneously measures a compound's ability to disrupt any of the 1,000+ genome-bound proteins in live cells. The technology is analogous to KinomeScan profiling, but for the TF family and other genome regulators. Innovations in three domains were required to develop this technology. Talus Bio couples innovations in cell biology and protein biochemistry with new mass spectrometry proteomics methods and downstream data analytics with machine learning to provide a platform for efficient and robust isolation, measurement, and quantification of the regulome. This technology, coupled with the proprietary chemical libraries that Talus Bio has built and the proprietary compound:regulome database being generated comprise the MARMOT platform, an efficient platform for the discovery and development of small molecule transcription factor modulators.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The proteomics technology enabling MARMOT has been patented by the Altius Institute for Biomedical Sciences. Talus has secured an exclusive commercial license for the patented technology (patent application 16/417,658). A series of three patents were filed by Talus Bio in 2022 to protect key innovations in the automation and scaling of TF-Scan profiling. The proprietary mass spectrometry methods, computational pipeline, data analytics workflow, and results database will be protected as trade secrets. In addition to its technology patents, Talus Bio is preparing patent applications for the chemical series of its lead Brachyury inhibitor program, to be submitted in H2 2023.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2021	Lab set up and team built; early technology validation and partial automation; built scalable, ML-enabled data processing pipeline
2022	Full end-to-end platform automation; completed first 1M compound: regulome screening effort; began hit validation for top six hits arising from screen
2023	Initiated chordoma program hit to lead; began first in vivo studies with lead molecule

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	NSF SBIR grant	Technology commercialization and validation	$250K
2020	Pre-seed round	Led by Fifty Years VC for technology commercialization and validation	$1.5M
2021	Seed round	Led by NFX Bio for technology automation, initial regulome screening, hit validation and hit-to-lead	$7.5M
2022	NIH grants	Technology extensions and hit discovery	$2.8M
2023	WA State CARE grants	Funding for screening and hit validation for two additional disease indications	$2.4M

USE OF PROCEEDS

Talus Bio is raising a $25M Series A round to accomplish the following milestones: (1) complete IND-enabling data package for lead chordoma program; (2) nominate development candidates for two additional oncology targets; (3) discover and validate a tractable hit series for six additional clinically valuable targets; (4) initiate one strategic pharma collaborative platform partnership; and (5) build database to 100M data points to enable first AI models of the regulome.

KEY TEAM MEMBERS

Alex Federation, PhD (CEO and Co-Founder): Dr. Federation invented the technology that underlies the MARMOT platform during his postdoctoral fellowship in computational epigenomics and cancer biology at the Altius Institute for Biomedical Research. He received his PhD in chemical biology from Harvard, focusing on drug development for genome regulators.

Lindsay Pino, PhD (CTO and Co-Founder): Dr. Pino has more than 10 years of experience in developing proteomics methods for studying human diseases. During her training, Dr. Pino developed techniques for scalable proteomics, addressing in particular the challenges associated with building and analyzing large-scale datasets.

Michelle Briscoe (COO): Ms. Briscoe previously held a leadership role at Brooks Applied Labs, where she served as president and CEO since 2013 and orchestrated an acquisition in 2020. At Brooks, Ms. Briscoe was responsible for all aspects of company management and operations.

TERNALYS THERAPEUTICS, INC.

Overcoming Cancer Resistance Through Epigenetic Reprogramming

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COMPANY OVERVIEW

Ternalys Therapeutics is focused on overcoming cancer resistance through "epigenetic reprogramming." The company has developed engineered, noncoding microRNAs clusters that are delivered on a novel scaffold, the SAGUARO platform, for precision multitargeting of intractable cancers. While microRNA-based therapy is not new, the concepts of (1) a clustered microRNAs strategy, (2) the targeting of an otherwise undruggable epigenetic complex, and (3) the genetic engineering methods for its implementation, are. Ternalys' scientific team has demonstrated that microRNAs administered in such artificial clusters (effectively "microRNA replacement therapy"), rather than singularly as in the past, produce significantly more potent therapeutic responses and block the expression of multiple targeted messenger RNAs. The SAGUARO platform is applicable to broad range of intractable cancers and non-oncologic targets, is synergistic with and enabling of other existing and experimental therapies, and can be designed with different RNA pieces to retain additional desired functions after cleavage.

MARKET & COMMERCIALIZATION STRATEGY

The SAGUARO platform has the potential to address a range of intractable cancers, and the expansion of this understanding will be a prime focus of the company's near-term efforts. In glioblastoma, the company's initial focus, despite significant efforts across a broad range of molecules and therapeutic approaches, little progress has been made toward extending the quality or quantity of life, with the average lifespan post-diagnosis remaining in the one- to two-year range. GBM market research projections vary widely, but the predominant projections are that the current market size is in the $2B range in the United States, growing to an expected $8B-$10B by the end of the decade.

TECHNICAL & COMPETITIVE ADVANTAGE

Synchronizing the expression of multiple microRNAs in a single carrier scaffold has displayed significant anticancer synergism; abrogated the epigenetic-mediated, multiprotein tumor survival mechanism; and resulted in a five-fold increase in survival when combined with chemotherapy in murine glioblastoma models. These transgenic microRNA clusters display intercellular propagation in vivo, via extracellular vesicles, extending their biological effect throughout the whole tumor. By preventing the loss of microRNAs and the cascade of tumor responses, SAGUARO-delivered microRNAs should work interactively and synergistically with any therapeutic approach that elicits an epigenetic response.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Ternalys anticipates that, as already evidenced in early in vivo work, using the SAGUARO scaffold to deliver multiple microRNAs will be synergistic with other therapeutic approaches. This creates a clear clinical development pathway and regulatory strategy of proving superiority to the current standards of care, initially in the high unmet need area of glioblastoma. The IP underpinning Ternalys was developed at Mass General Brigham by Ternalys' founding scientists. Patent applications protecting this IP, including broad composition of matter claims, are actively being prosecuted in the United States and internationally.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
January 2019	Key Publication: The functional synergism of microRNA clustering provides therapeutically relevant epigenetic interference in glioblastoma. Bhaskaran V, et al. Nat Commun. 2019 Jan 25;10(1):442
April 2019	Key Patent: Compositions and Therapeutic Methods Of MicroRNA Gene Delivery. PCT/US2019/029988
Recent	Proof of Principle: Demonstrated highly significant increase in survival of mice with orthotopic human glioblastoma xenografts treated with the technology alone as well as combined with standard of care chemotherapy
In Process	IND filing for first-in-human clinical trial in subjects with glioblastoma
In Process	Expansion of SAGUARO platform to other intractable cancers (current focus: head and neck, ovarian, bladder cancers)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017+	NCI grants to Dr. Peruzzi	Grants to Dr. Peruzzi at MGB leading to the development of the SAGUARO technology	~$3.5mm
2022	NCI STTR grant to Ternalys	Optimizing Composition and Delivery of a Novel RNA Therapy for Glioblastoma	$276K

USE OF PROCEEDS

Ternalys seeks a maximum target of $10M-$15M for two prime objectives: (1) further develop SAGUARO platform technology to incorporate different and/or more miRNAs with additional potential indications; and (2) advance TT-003 GBM indication to IND readiness as demonstration of SAGUARO platform potential.

KEY TEAM MEMBERS

Kenneth I. Moch (Chairman and CEO): Serial biotech entrepreneur focused on developing novel first-in-class medicines that address unmet needs in chronic and acute life-threatening diseases.

E. Antonio Chiocca, MD, PhD (SAB Chair and Board Member): Neurosurgeon-in-chief and chair, Department of Neurosurgery, Brigham and Women's Hospital; surgical director, Center for Neuro-oncology, Dana-Farber Cancer Institute.

Pierpaolo Peruzzi, MD, PhD (Founding Scientist and Board Member): Director, Laboratory of Epigenetic Neurosurgery and RNA Therapeutics, Brigham and Women's Hospital; assistant professor of neurosurgery, Harvard Medical School.

Michelle Higgin, PhD (Development, Regulatory and Project Management): Managing principal, PharmaDirections; versatile development and regulatory strategist in all phases of drug development, with primary competencies in aggressive program management of discovery, DMPK, CMC, preclinical pharmacology, nonclinical, regulatory, and early phase clinical trials.

TEZCAT BIOSCIENCES

Metabolically Selective RAS Cancer Therapeutics

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COMPANY OVERVIEW

Tezcat Biosciences is developing a portfolio of metabolically selective protein-drug conjugates to target and eliminate RAS cancers.

MARKET & COMMERCIALIZATION STRATEGY

Tezcat's initial indication for its lead asset, TZT-102, is for patients with mutant RAS relapsed/refractory multiple myeloma (MM) who have received at least three lines of therapy, representing a market opportunity of approximately $1.86B in the United States. Follow-on indications include solid tumors (e.g., NSCLC, colorectal, pancreatic) that harbor mutant RAS and are currently un-addressable by available treatment options. Tezcat anticipates IND submission and beginning of first-in-human trials with its lead asset by the beginning of 2025.

TECHNICAL & COMPETITIVE ADVANTAGE

With the high rate of heterogeneity within MM and obstacles in current treatment guidelines based on a patient's complex treatment history, the ability to use a precision medicine approach in MM is highly desirable. Tezcat's approach with TZT-102 relies on the presence of mutant RAS to be highly effective in an anti-MM response. Therefore, TZT-102 can potentially address the 70% of relapsed/refractory MM patients who harbor a RAS mutation. TZT-102 would be the first MM approach that is specifically tailored for the pan-RAS patient population that represents the majority of relapse/refractory.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Tezcat's TZT-102 will be regulated in the United States by the FDA through the Center for Drug Evaluation and Research; the company is required to submit an IND application for conducting clinical studies and a biologics license application for market approval. Tezcat intends to pursue any FDA programs designed to assist sponsors in accelerating drug development of therapeutic drugs and biologics. Tezcat has not yet engaged with any regulatory authorities regarding TZT-102; however, Tezcat intends to request a pre-IND meeting with the FDA to gain concurrence on the TZT-102 manufacturing, toxicology, and clinical development plans, including Fast Track designation, prior to submitting an IND. This meeting should take place by the end of 2024.

Tezcat has exclusive, worldwide rights to the core technology underlying the approach (PCT application entered into national phase in 2023 – license from NYU). Tezcat has since submitted an additional PCT application broadening protection unique to its mechanism of action. An FTO analysis by a third-party has been performed for the lead asset, TZT-102.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q2 2024	Completion of pre-IND meeting with the FDA for TZT-102
Q2 2025	Completion of pre-IND meeting with the FDA for TZT-107 (follow-on asset)
Q4 2025	IND submission for TZT-102
Q2 2026	Completion of Phase 1a for TZT-102

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	NIH/NCI 1R41CA250616-01A1	A novel monobody-drug conjugate to treat mutant RAS multiple myeloma	$400K
2020	J&J QuickFire Challenge Award	Exploratory experiments using TZT-102 in mouse models of PDAC	$75K
2021	NIH/NCI 1R41CA265512-01	A novel monobody-drug conjugate to treat mutant KRas pancreatic cancer	$609K
2023	NIH/NCI 2R44CA250616-02	A novel monobody-drug conjugate to treat mutant RAS multiple myeloma	$1.9M

USE OF PROCEEDS

Tezcat is seeking a $19M round to expand its team, file new patent applications, fund cGMP manufacturing & GLP studies, fund preclinical development of follow-on assets, and cover IND submission of the lead asset (TZT-102).

KEY TEAM MEMBERS

Craig Ramirez, PhD, (Co-Founder and CEO): Dr. Ramirez made the key discoveries underlying Tezcat's approach in Dr. Bar-Sagi's lab at NYU. In addition to research, Dr. Ramirez has been engaged in various entrepreneurship and executive programs, including Entrepreneurship Lab (Bio and Health Tech NYC), the Texas Medical Center Accelerator for Cancer Therapeutics, and Johnson & Johnson's CEO Development Program, to further develop the core skill sets and relationships for successful biotech ventures.

Andrew Hauser, PhD (Co-Founder and COO): Dr. Hauser is a scientific founder of Tezcat Bio. In addition to his scientific expertise, he obtained broad experience in project and team management and served as the senior specialist in research integrity and compliance at NYU Langone Health, where he ensured that biomedical research was conducted in accordance with applicable legal, regulatory, and contractual obligations.

TRACE BIOSCIENCES

Nerve-Specific Imaging Agents for Surgery

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COMPANY OVERVIEW

Trace Biosciences is creating imaging agents for surgery that specifically highlight nerves with the goal of eliminating surgical nerve damage. Nerve injury is a major complication of surgery affecting 25 million patients annually worldwide and incurring undue pain, loss of function, and high cost for follow-on treatment and pain management. Trace Biosciences' technology, Nerve Trace, enables real-time nerve visualization using fluorescence via existing clinical imaging systems. Nerve Trace can highlight nerves that were previously invisible and allow surgeons to "cut by color." Through nondilutive funding and pre-seed investments, the company has raised more than $4.5M to date to complete the proof-of-concept, lead optimization, and clinical translation of the technology. Trace Biosciences seeks further funding to support early phase clinical trials of this promising technology that has the potential to revolutionize surgery.

MARKET & COMMERCIALIZATION STRATEGY

Nerve Trace presents a $10B total addressable market opportunity as it becomes standard of care for surgery. The company's first target is prostatectomy, where nerve damage is the #1 complication and 60%-80% of patients suffer lasting incontinence and impotence due to nerve damage. With 525,000 patients undergoing prostatectomy annually, this represents a $1.05B total market with high need and streamlined integration into imaging systems of the surgical robots used. Nerve Trace presents an opportunity to expand into several other high volume high risk indications, such as hysterectomy, thyroidectomy, or hernia repair.

TECHNICAL & COMPETITIVE ADVANTAGE

Nerve Trace has a strong advantage over other nerve targeting fluorescence contrast agents as well as the clinical gold standard. Alume Biosciences and Illuminare Biotechnologies are developing nerve-specific imaging agents that fluoresce in the visible wavelength range. Using near-infrared fluorescence, Nerve Trace enables surgeons to light up the nerves with high contrast and resolution, enabling identification of even small-caliber nerves and buried nerves, a significant advantage over competing techniques. Additionally, near-infrared fluorescence enables integration into the surgical workflow using the existing clinical imaging system infrastructure, a much lower barrier to adoption and market penetration.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Following IND approval, Phase 1 clinical trials for early efficacy and safety in patients are planned to begin in 2024. Subsequent Phase 2 and 3 trials will provide efficacy data for nerve visualization efficacy in prostatectomy patients prior to NDA approval. Our IP is well protected with one issued patent and four PCT applications covering composition of matter and methods of use.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
March 2023	Library screening and lead optimization (>300 novel fluorophores synthesized and tested)
December 2023	GMP manufacturing, establishment of codevelopment partnerships with industry
June 2024	GLP pharmacology and toxicology testing and IND approval
August 2024	Phase 1 clinical trial initiated
August 2025	Phase 2 clinical trial initiated

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018-2020	Pilot grants	OHSU, MJ Murdock Charitable Trust pilot commercialization grants	$250K
2021-2023	SBIR/STTR grants	NIH NCI Fast-track and Phase I SBIR, NIH NIBIB Phase I SBIR, NSF Phase I STTR	$3.6M
2021	Pre-seed	SciFounders SAFE Investment	$400K
2023	Pre-seed	Elevate Capital and ONAMI SAFE Investment	$275K

USE OF PROCEEDS

Trace Biosciences plans to raise $4M by Q3 2024, which will enable completion of Phase 1 clinical trials. These funds will enable the company to build a strong team with expertise in successful imaging agent clinical development and market launch, including a key executive hire with investor fundraising and prior FDA approval experience to bolster its efforts for rapid and efficient clinical translation. Additionally, these funds will enable engagement of clinical CRO and regulatory consultants for the execution of the Phase 1 study and plan future trials.

KEY TEAM MEMBERS

Connor Barth, PhD – Cofounder & CEO: Inventor of Nerve Trace technology, more than 10 years of experience in fluorescence guided surgery, proven leader of Trace Biosciences

Summer Gibbs, PhD – Cofounder & CSO: Inventor of Nerve Trace technology, more than 20 years of experience in the surgical technologies, leader in field of nerve imaging agents

Lei Wang, PhD – Cofounder & CTO: Inventor of Nerve Trace technology, expert chemist with a catalog of more than 400 novel small molecule fluorophores

TRANSCODE THERAPEUTICS, INC.

A Clinical-Stage RNA Oncology Company Focused on Treating Metastatic Cancer

Zdravka Medarova | zdravka.medarova@transcode.therapeutics.com | 978-397-0985 | transcodetherapeutics.com

COMPANY OVERVIEW

TransCode Therapeutics is a clinical-stage RNA oncology company advancing focused solutions to intractable problems in the diagnosis and treatment of metastatic disease. As an asset-focused platform company, TransCode deploys delivery of nucleic acid payloads to primary and metastatic cancers. The company's programs focus on previously undruggable genetic targets to overcome the challenges of cancer progression and relapse. Its lead therapeutic candidate, TTX-MC138, targets microRNA-10b, or miRNA-10b, a master regulator of metastatic cell viability in a range of cancers. TransCode has an approved eIND application to conduct a Phase 0 clinical trial intended to demonstrate quantitative delivery of TTX-MC138 to metastatic lesions in subjects with advanced solid tumors. With multiple near-term inflection points, TransCode is poised to leverage future growth in gene therapy.

MARKET & COMMERCIALIZATION STRATEGY

Globally, more than nine million deaths occur annually due to metastatic disease. TransCode's metastatic market opportunity and commercial challenge mirrors the early days of chemotherapy and immunotherapy. Three internal programs targeting RNA de-risk the success of TransCode's platform by approaching the dynamic nature of cancer with an inhibitor of metastatic progression, an adaptive immune modulator, and an innate immune activator—all tumor type-agnostic programs. The programs offer multiple value inflection points reflective of a typical R&D timeline that also provide commercialization strategy-enabling data.

TECHNICAL & COMPETITIVE ADVANTAGE

In terms of know-how, patents, and trade secrets, the company's competitive advantage stems from 18 years of working to deliver oligonucleotides to cancer cells, a decades-long challenge. The nanocarrier-based RNA delivery platform, TTX, is tunable to predesigned specifications to deliver therapeutic oligonucleotides to an RNA target in tumors and metastases without compromising its integrity. TransCode has translated this fundamental work into clinical application generating knowledge, relationships, and data.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

TransCode is developing RNA therapeutics for the treatment of several tumor indications. TransCode received written authorization from the FDA to proceed with its first-in-human Phase 0 clinical trial (eIND 163800, NCT05908773). TransCode also plans to submit an IND application to the FDA in H2 2023 requesting approval to initiate and conduct a Phase 1/2 clinical trial. TransCode's patent strategy seeks to obtain exclusivity around the nanoparticles themselves, in combination with various types of cargos, and methods of use thereof. Overall, the company's IP estate enables a corporate strategy of a primary focus on the clinical development of the non-coding RNA antagomir TTX-MC138, while prosecuting a secondary strategy of partnering other applications of the TTX delivery platform including RNAi applied to a checkpoint inhibitor, template directed innate immune activation, mRNA-based cancer vaccine, CRISPR-like gene-targeting/editing, and focused radiotherapy combinations of the same.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q2 2023	Topline readout FIH trial
Q3 2023	Complete IND enabling studies for Phase I/II
Q3 2023	Finalize DP manufacturing TTX-MC138 for Phase I/II clinical trial
Q4 2023	File IND for Ph I/II for TTX-MC138

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
December 2016- July 2018	Seed capital	Angel investors	$2.24M
April 2021	SBIR	NCI	$2.3M
July 2021	IPO	Think Equity	$25.4M
February 2023	Follow-on offering	HC Wainwright	$1.5M
June 2023	Follow-on offering	HC Wainwright	$7M

USE OF PROCEEDS

TransCode is currently seeking $20M-$40M of funding to support Phase I/II clinical trials with TTX-MC138 and to advance therapeutic candidates in TransCode's pipeline, including TTX-siPDL1 (checkpoint inhibitor), TTX-RIGA (PRR agonist), TTX-mRNA (cancer vaccine), and TTX-CRISPR (a CRISPR-like gene editing tool) through development to enable clinical trials.

KEY TEAM MEMBERS

Michael Dudley (Co-Founder and CEO): More than 40 years of executive leadership experience in the fields of medical device, diagnostics, and therapeutics.

Dr. Zdravka Medarova (Co-Founder and CTO): Internationally recognized leader in the field of noncoding RNAs for cancer therapy and one of the inventors of TransCode's technology.

Tom Fitzgerald (CFO): More than 30 years of accomplishments as a CFO and an investment banker for companies from emerging growth to turnarounds to Fortune 500 companies in the life sciences, technology, financial, and industrial sectors.

Vivreon Gastrosciences
Oral Immune Therapeutics

VIVREON GASTROSCIENCES, INC.

An Inflammatory Bowel Diseases Therapeutics Company

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COMPANY OVERVIEW

Vivreon Gastrosciences is commercializing an oral, gut-restricted therapeutic for the treatment of enterocolitis caused by immune checkpoint inhibitor (ICI) immunotherapy. Vivreon's program is designed to be a gut-restricted, safe, and effective therapy that works directly at the site of ICI-induced intestinal inflammation without systemic absorption and can be co-administered with ICIs to treat colitis side effects—gastrointestinal immune-related adverse events (GI irAEs)—without interfering with the primary cancer-killing activity. Vivreon's candidate therapeutic is safe in animals and demonstrates immunosuppression in animal models of colitis and ex vivo colon biopsies from ICI patients currently experiencing GI irAEs. Combined, these data predict clinical efficacy. We are currently conducting process and analytical research and development prior to GLP toxicology studies. Vivreon intends to conduct a Phase I study in patients experiencing ICI GI irAEs, allowing for early in-human proof of concept (POC).

MARKET & COMMERCIALIZATION STRATEGY

Every year, nearly 100,000 new ICI patients develop GI irAEs and have to discontinue their primary anticancer therapy, resulting in billions of dollars in lost ICI sales. Vivreon is confident that positive Phase I clinical trial results with in-human POC will promote interest in licensing deals from pharmaceutical partners. Should Vivreon's candidate therapeutic prove to be effective at treating ICI-induced colitis, it will allow for more patients to be treated with ICI therapies and for longer treatment durations, increasing the revenue potential for current and future ICIs. As such, ideal partners are organizations that currently have marketed ICI therapies, such as Merck and BMS. The path for getting Vivreon into the hands of doctors and patients for treating ICI GI irAEs will be similar to how Zofran was prescribed to treat chemotherapy nausea and vomiting side effects. Both are pharmacy benefit products used to treat side effects of primary cancer therapies, covered by major commercial, Medicare, and Medicaid formularies.

TECHNICAL & COMPETITIVE ADVANTAGE

Vivreon's candidate therapeutic represents the first combination potential with ICIs to treat GI irAEs and allow cancer patients to complete their full ICI therapy regimen. Vivreon's gut-restricted CRAC channel therapeutic program provides an entirely novel mechanism of action for enterocolitis management. Vivreon offers the advantage of acting directly at the source of pathogenic leukocyte activation within the gut, calcium influx, a process that is upstream of numerous enterocolitis disease-causing processes including leukocyte proliferation and inflammatory cytokine secretion. Vivreon is developing the first gut-restricted CRAC channel inhibitor, allowing for localized delivery following oral administration, suppressing colitis, avoiding systemic immunosuppression side effects, and preserving the anticancer activity of the primary ICI.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Vivreon is pursuing a commercial IND for its candidate small molecule therapeutic. The company has already received initial FDA feedback through the NCI CARE Regulatory Program. In addition, Vivreon requests Fast Track designation for ICI-induced colitis. Vivreon's patent was issued in 2019, and all composition of matter and therapeutic use claims have passed prosecution in major market countries.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2024	IND studies
Q2 2025	IND submission
Q3 2025	Phase 1 clinical trials

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	Equity financing	Seed investment from S&B Pharma	$2M

USE OF PROCEEDS

Vivreon intends to raise $25M to establish in-human POC for its ICI-induced colitis program, of which $5M is required to complete IND studies and submission; $20M is slated for completing clinical POC, which requires Phase 1a SAD/MAD in healthy volunteers and Phase 1b MRD/MRD expansion in patients experiencing ICI GI irAEs, allowing for early in-human POC. After establishing in-human POC in Phase I clinical trials, Vivreon expects to have de-risked the program enough to attract a pharmaceutical partner who will finance remaining commercialization efforts along with upfront and milestone-driven payments.

KEY TEAM MEMBERS

Milton Greenberg, PhD (CEO): A CRAC channel expert, Dr. Greenberg leads the Vivreon team, including obtaining grant funding and seed investment, while delivering on programmatic milestones and abstract publication.

John Ransom, PhD (CSO): Dr. Ransom is a biotech industry veteran and CRAC channel drug discovery expert. He guides Vivreon R&D.

Andrew Newman, PhD (COO): Dr. Newman manages development activities, including overseeing consultants and contract labs.

Omed Muzaffery, MS, MBA (CFO):
Mr. Muzaffery has global business experience and manages company finances, reporting, and audits.

EARLYDIAGNOSTICS INC.

Detecting and Locating Cancer Early

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COMPANY OVERVIEW

EarlyDiagnostics Inc. ("EarlyDx") is a seed-stage company that was co-founded in 2017 by professors from UCLA and Stanford University. The company provides liquid biopsy products for early cancer diagnosis and offers a knowledge-based diagnostics platform for precision medicine. EarlyDx's MethylScan test, a blood-based cfDNA multicancer test that combines an advanced assay technique with machine learning algorithms, achieves an 80.7% sensitivity in detecting cancers across all stages and a 74.5% sensitivity in detecting early-stage cancer while maintaining a specificity of 97.9%. The test demonstrates 85% accuracy for predicting tissue-of-origin of early-stage cancer. Complementing its diagnostic capabilities, EarlyDx has developed an AI-powered computing platform known as EarlyDx-Cloud. This platform leverages the power of genome-wide methylation profiles obtained from cfDNA, alongside analysis of imaging data, to facilitate informed decision-making in precision medicine and support the development of new transformative products for health monitoring.

MARKET & COMMERCIALIZATION STRATEGY

The MethylScan test targets the early cancer diagnosis market, a segment of the global cancer diagnostics market projected to reach $249B by 2026 with a 7% CAGR. Genomics-based multicancer early detection has the potential to reshape cancer diagnosis and therapeutics. Early detection of cancer at a resectable stage eliminates the need for therapeutic treatment. The cfDNA test's simplicity, noninvasiveness, and cost-effectiveness surpasses imaging-based modalities. EarlyDx plans to penetrate the cancer diagnosis market through a decentralized sample-to-result testing model, using its own CLIA lab (under construction) and partnerships with major diagnostic networks to ensure broad access to the MethylScan test for a wide patient population.

TECHNICAL & COMPETITIVE ADVANTAGE

EarlyDx differentiates itself from its competitors through four key advantages: (1) Enhanced power: EarlyDx's methylome test offers five times greater CpG coverage than major competitors, using proprietary CancerLocator/CancerDetector algorithms to maximize information extraction from methylation patterns, resulting in a more accurate test. (2) Lower cost: EarlyDx's methylome test is priced at less than 8% of conventional methylome sequencing. (3) Easy-to-use and robust: supported by EarlyDx-Cloud, the assay can be easily distributed to molecular diagnostic labs, expanding customer accessibility. (4) Potential for broader disease detection: methylation plays an essential role in the development and progression of numerous common diseases. Analysis of genome-wide methylation data accumulated from the MethylScan test enables the development of new tests for monitoring various diseases and overall health.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

EarlyDx has designated hepatocellular surveillance and lung cancer surveillance in at-risk populations as the initial indications for the intended use of MethylScan test. These indications have well-defined regulatory pathways. Through the support of an NCI Phase II SBIR award, EarlyDx and its collaborators are conducting a double-blind clinical validation to gather pilot clinical study data necessary for larger clinical trials. Additionally, EarlyDx is actively seeking participation in the Vanguard trial for multicancer testing. EarlyDx currently holds one granted patent and has four additional patents in the PCT stage.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2023	CEO recruitment
Q1 2024	Completion of company space expansion and CLIA lab construction
Q2 2024	Release of preliminary results from the double-blind clinical study
Q3 2024	Initiation of a clinical trial for early detection of lung cancer in at-risk patients

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Pre-seed round	Angel investor / Venture capital	$2M
2020	Seed-1 round	Venture capitals	$5M
2022	SBIR Grant	NCI	$1.9M
2023	Seed-2 round	Venture capitals	$2M

USE OF PROCEEDS

EarlyDx aims to secure $10M in funding to facilitate pivotal clinical trials.

KEY TEAM MEMBERS

Jasmine Zhou, PhD (Co-Founder and Co-CEO), is responsible for overseeing R&D, business development, and fundraising.

Guanghui Hu, PhD (Co-CEO), focuses on business development and marketing. Both Co-CEOs will be replaced by a full-time CEO.

Xiaohui Ni, PhD (CTO), leads assay development and serves as the principal investigator for the SBIR Phase II grant.

Jim Liu, PhD (CCO), is responsible for cloud computing and serves as the principal investigator of the SBIR Phase II contract.

Mary Stackpole, PhD (VP, Bioinformatics), Expert in NGS data analysis and liquid biopsy technologies

LIFEGENE-BIOMARKS, INC.

Precision DNA Methylation PCR Tests in Biofluids

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COMPANY OVERVIEW

LifeGene BioMarks, Inc. (LifeGene) is a Puerto Rican company with access to unique economic and tax incentives and advantages by operating within an autonomous tax jurisdiction of the United States. The performance of the company's precision DNA methylation PCR tests and the team's collective experience provides a competitive advantage entering the post-pandemic market. LifeGene has secured close to $8M in undiluted funds from Fast-Track NIH SBIR and Puerto Rico Science, Technology and Research Trust SBIR Cash Match awards, which, together with Act 60 tax decree incentives, will finance the development of the IP protected CervicalMethDx and OralMethDx In-Vitro Diagnostic Devices (IVD) in U.S. and other markets.

MARKET & COMMERCIALIZATION STRATEGY

LifeGene is implementing a hub-and-spoke model for the distribution of PCR tests, beginning with the cervical cancer prevention space, which is poised to reach $11B by 2026 at an estimated CAGR of 6.2%. The post-pandemic excess in installed PCR capacity in the centralized laboratory and direct-to-consumer diagnostic market represents a unique strategic inflection point on which LifeGene can capitalize. The CervicalMethDx and OralMethDx PCR tests will capture underutilized post-pandemic PCR capacity in worldwide markets in the next five years. LifeGene will use the Act 60 tax decree provisions to access nondilutive capital in the form of government grants and monetized Puerto Rican R&D tax credits, in addition to nonsecurities financing supported through private or government-backed loan programs.

TECHNICAL & COMPETITIVE ADVANTAGE

The CervicalMethDx test has two main competitors. The QIAsure Methylation Test for Cervical Cancer Risk (QIAGEN) and the GynTect Test (Oncgnostics) are both PCR assays. GynTect uses six DNA methylation markers to detect CIN2+ lesions with 64% sensitivity, 97% specificity, and 93% NPV in 221 samples. QIAsure uses two DNA methylation markers to detect CIN2+ lesions with 74% sensitivity, 70% specificity, and 82% NPV in 254 samples. The CervicalMethDx test uses two DNA methylation markers to detect CIN2+ lesions with 92% sensitivity, 100% specificity, and 99% NPV in 466 samples.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The company's consultant, QA Consulting, has developed a regulatory strategy for the CervicalMethDx to be available in the U.S. market either through a 510(k) submission or de novo route using the following Indications for Use statement: "The CervicalMethDx test is a methylation-specific PCR (MSP) test to be used as an adjunct to a physician's clinical decision-making in HPV positive women prior to colposcopy-driven biopsies." QA Consulting is preparing an application to the FDA presubmission program. We are also working with Akerman LLP law firm to negotiate with Johns Hopkins University for exclusive licenses to the CervicalMethDx, OralMethDx and GastricMethDx intellectual property.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
September 2019-September 2023	Awarded $7.7M in undiluted funding and granted 15-year-long tax decree with priority date of 2/2020
October 2023 - October 2025	Launch CervicalMethDx LDT test in U.S. and ex-U.S. markets; Continue R&D OralMethDx and GastricMethDx
October 2025 (expected)	Obtain 510(k) designation and reimbursement code for the CervicalMethDx

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2019-2022	SBIR-NIMHD + Cash Match	Precision methylation biomarkers linked to cancer disparities	$2.2M
2021-2024	SBIR-NIMHD + Cash Match	Precision methylation biomarkers for cervical cancer prevention in low resource settings	$2.7M
2023-2026	SBIR-NIMHD + Cash Match	Precision DNA methylation test to reduce oral cancer disparities low-resource settings	$2.7M

USE OF PROCEEDS

LifeGene is seeking $15M to launch the CervicalMethDx in selected US and other markets (1) launch the CervicalMethDx v1.0 as a Laboratory Develop Test (LDT) in five midsize (5-10 million residents) clinical laboratories in the United States; (2) launch the CervicalMethDx v1.0 in capitation-based healthcare systems with clinical laboratory capacity in US and ex-US; (3) outsource CervicalMethDx launch in selected US and other markets channels to commercialization organizations; (4) obtain 510(k) designation and reimbursement code for the CervicalMethDx v.2.0; 5) Launch the OralMethDx in US and other markets.

KEY TEAM MEMBERS

Rafael Guerrero Preston DrPH, MPH

Founder and CEO duties include overseeing the implementation of scientific, fundraising, and administrative goals; a successful innovator and disruptor in the discovery of molecular markers for cancer diagnosis, early detection, and clinical management.

David Sidransky, MD

Chairman of the Board duties at LifeGene include providing clinical, managerial, and entrepreneurial leadership. Dr. Sidransky is one of the world's most highly cited researchers in clinic and medical journals, with more than 700 peer-reviewed publications and dozens of biotechnology patents. He has served as founder and board member of more than 15 biotechnology companies and was, until the merger with Eli Lilly, a director of ImClone Systems Inc., a global biopharmaceutical company committed to advancing oncology care.

Luis Perez, JD

Member of the Board duties at LifeGene include advising on legal, tax, and corporate mattters. He is partner and Co-Chair of the Latin America & the Caribbean Practice at Akerman, LLP. Mr. Perez's primary practice area is complex commercial litigation and arbitration both at the national and international level.

MICROMICS TECHNOLOGIES

A Tool Developer for Ultrasensitive Proteomics Analysis

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COMPANY OVERVIEW

The mission of MicrOmics Technologies is to develop and deploy reagents, consumables, and instruments for ultrasensitive biochemical analyses, including in-depth single cell proteomics. The company's products will enable biomedical researchers to develop improved cancer therapies and diagnostics and address other health-related challenges.

MARKET & COMMERCIALIZATION STRATEGY

Commercial solutions now exist for cell isolation and reagent dispensing at the beginning of the single-cell proteomics (SCP) workflow, and highly sensitive mass spectrometry is available at the end of the workflow, but there is a large gap in the middle comprising sample introduction, separations, and ionization. The company's objective is to provide robust sample-to-answer workflows for nonspecialist end users for SCP and other trace bioanalyses. MicrOmics Technologies plans to conduct its marketing campaign mainly through conference exhibitions as well as emerging symposia focused specifically on SCP and spatial proteomics. Email marketing campaigns are also relatively cost-efficient approaches for customer outreach.

TECHNICAL & COMPETITIVE ADVANTAGE

SCP has become a reality only with groundbreaking advances in experimental design such as SCoPE-MS, improved sample preparation such as nanoPOTS from MicrOmics Technologies CEO Dr. Ryan Kelly, and increasingly sensitive mass spectrometers. As a leading group in this field, MicrOmics Technologies' proprietary technology is capable of not only operating in this ultrasensitive regime, but through the novel use of multiple columns and an online cleanup step, the company can achieve much higher throughput than competing platforms by continuously delivering peptides to the mass spectrometer with no interruption between samples. Currently, no competitor offers MicrOmics Technologies' combination of sensitivity, robustness, and throughput.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Research tools are subjected to fewer regulations; thus, MicrOmics Technologies plans to conduct CE certification for its final product. The company has exclusively licensed the core patent from Brigham Young University, while other intellectual property related to emitter fabrication and LC column-packing is currently held as a trade secret.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
August 2020	MicrOmics Technologies founded
December 2020	Began selling consumables for sensitive proteomics analysis
September 2021	SBIR projects
October 2023	Begin prototype development
March 2025	Production of final product

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	Start	MicrOmics Technologies founded; began offering other consumables	$50K
2021	SBIR Phase I	Phase I of SBIR single-cell project	$455K

USE OF PROCEEDS

The company plans to raise $500K to $1M in the next one to two years to accelerate its prototyping and production operation.

KEY TEAM MEMBERS

Ryan Kelly, PhD, CEO: Dr. Kelly is a pioneer in the new field of SCP. He will have primary responsibility for project deliverables and will be involved with platform development, processing of samples, analysis and interpretation of obtained data, and the assessment of progress and feasibility.

Xiaofeng Xie, PhD, CTO: As an expert in analytical hardware and software development, with specific expertise in ultrasensitive nanoflow liquid chromatography and single-cell proteomics, Dr. Xie will have primary responsibility for project deliverables and will be involved experimentally with platform development, processing of samples, analysis and interpretation of obtained data, and the assessment of progress and feasibility.

Kerry Nugent, MS, VP of Sales and Marketing: Mr. Nugent has more than 40 years of relevant industry experience, including 20 years as the founder and CEO of Michrom Bioresources, which he sold to Bruker Corp. Mr. Nugent will contribute to design and assembly of the integrated platform and will be primarily responsible for interfacing with users at the beta test sites, collecting feedback from users, and incorporating these insights into redesigns.

ALPENGLOW BIOSCIENCES

3D Spatial Biology

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COMPANY OVERVIEW

Alpenglow Biosciences is a venture-backed company focused on accelerating drug development and improving clinical diagnostics with AI-enabled 3D imaging technology. Their 3D spatial biology platform solution provides new spatial biology insights with greater accuracy by nondestructively digitizing entire tissues. Alpenglow partners with pharmaceutical companies to bring better therapeutics to market faster through greater understanding of mechanism of action, efficacy and toxicology, and patient trial enrollment using their patented platform. Five of the top 10 pharma companies already work with Alpenglow to accelerate development timelines, save costs, gain new insights, and improve therapeutic success.

MARKET & COMMERCIALIZATION STRATEGY

Alpenglow operates in the $15B spatial biology market, which is segmented into discovery, translational, and clinical submarkets, with clinical accounting for more than 50% of the total market. Alpenglow's platform is tailor-made for clinical applications with its patented open-top geometry that can rapidly digitize entire tissue samples in an automated fashion at a scale and throughput needed for discerning Alpenglow customers like the Mayo Clinic. Led by a physician founder, the technology integrates seamlessly into existing clinical workflows. Alpenglow has strong traction in the discovery and translational markets, collaborating with five of the top 10 pharma companies to accelerate their drug development pipelines through device sales and recurring software services, and is partnering with clinical labs and hospital systems to create laboratory developed tests (LDTs) for 3D spatial biology applications.

TECHNICAL & COMPETITIVE ADVANTAGE

The value proposition of Alpenglow is simple: all other spatial biology players look at the world in 2D; Alpenglow sees it in 3D. 3D captures the entire tissue specimen, rather than a fraction of it, eliminating selection bias due to sample heterogeneity. The extra data captured in 3D reduces mischaracterization of disease, which occurs as often as 25% of the time in a single 2D slice—this can mean the difference between a drug's success or failure. Furthermore, clinical trials can be powered significantly better by utilizing data from the entire tissue sample, reducing the number of patients needed, accelerating clinical phases, and leaving more time for commercialization. Additionally, other light sheet instruments that produce 3D images lack the open-top configuration, limiting use to discovery applications; Alpenglow's open-top geometry enables high-throughput screening of dozens or hundreds of samples at a time.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Alpenglow's intellectual property portfolio includes seven patent families with two issued and others in various stages of prosecution. The company has IP covering its key technology innovations including the open-top geometry of its microscope, sample holders that represent a consumables line of revenue, and the software for handling image data that enables the company's significant recurring revenue stream from data processing. Alpenglow's current products are Research Use Only, and the company intends to seek FDA Class I clearance for its microscope in early 2024 with additional AI-enabled software products planned for FDA Class II in late 2024.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
December 2022	Earned more than $1M in pharma revenue, deployed five instruments around the world, first clinical placement
March 2023	Launched clinical partnership with Mayo Clinic including investment and joint sales development
August 2023	Generate first clinical trials data and revenue for a pharma sponsor
March 2024	Launch FDA Cleared Class I 3Di instrument

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	Priced Round	Led by Dynamk Capital with participation from WRF, Alexandria RE, Hammamatsu	$4M
2022	Grant	Secured four NIH & SBIR Phase I grants (100% success rate)	$1M
2023	Convertible note	Secured investment from existing and new investors	$3.7M
2023	Grant	Secured WA Cares Andy Hill grant	$1.6M

USE OF PROCEEDS

Alpenglow's $20M funding round in early 2024 will be used for clinical trials expansion including establishing a regulatory framework for AI-enabled 3D spatial biology diagnostics, further product development for 3D spatial analysis software, and growth of the sales and marketing team to drive additional traction.

KEY TEAM MEMBERS

Nicholas Reder, MD, MPH, Co-Founder and CEO: Co-inventor of technology and board-certified pathologist; responsible for leading company through clinical success.

Michael Dutton, CFO: More than 40 years of finance experience and multiple-time startup executive.

Steve Pemberton, SVP Commercial Development: More than 20 years in diagnostics and life sciences tools commercialization; responsible for sales and marketing development.

ANANYA HEALTH

Portable Cryoablation to Prevent Cervical Cancer in any Clinic, Anywhere

Anu Parvatiyar, Cofounder & CEO | anu@ananya.health | ananya.health

COMPANY OVERVIEW

Ananya Health is building a self-contained cryoablation device to freeze abnormal cells in the cervix and prevent them from becoming cervical cancer, without any consumable cryogen. The company's proprietary platform enables standard of care outcomes ten times less expensive than traditional cryo, and accessible at the primary care level even without a supply of CO2 or nitrous oxide. Every two minutes, a woman dies of cervical cancer. Even though the disease is 95% preventable, it is the fourth leading cancer cause of death for women globally. Routine screening and early intervention when abnormal cells are found is key to preventing cervical cancer. However, even though screening tools (HPV tests, Pap smears, colposcopy) are widely available, less than 30% of women have access to early treatment options when the test comes back positive, because current tools require hospital-level infrastructure or highly trained specialists. Ananya Health is building a self-contained cryoablation device that does not require consumable cryogen, making early treatment possible at the point of diagnosis by a nurse, physician assistant, or other health worker, in any care site.

MARKET & COMMERCIALIZATION STRATEGY

An estimated 50 million women per year worldwide have CIN lesions, and current technologies are treating less than 30% of them right now. The market for early treatment is massive—$1.8B of total market opportunity in cervical cryoablation alone. Ananya Health's commercialization plan begins with an initial launch in Kenya. Ananya Health is working with a distributor in the Kenyan market that is interested in building a cervical cancer screen and treat in the more than 1,000 clinics in their network. Launching in the Kenya market allows Ananya Health to pilot the roll-out, training, and device maintenance in a smaller setting, while still gaining traction and visibility with global health organizations that act as coordinated purchasers for cervical cancer elimination efforts. The target customer of the company's platform is clinic owners in urban areas; the anticipated margin for a launch in Kenya is approximately 50%. Using initial launch data in Kenya and leveraging an FDA $510,000 clearance, the company will launch a second-generation device with a disposable sheath, aimed at the U.S. and India markets.

TECHNICAL & COMPETITIVE ADVANTAGE

Ananya Health's CRCL platform provides effective cryotherapy without requiring consumable cryogen gas. Eliminating the gas supply chain enables adoption at the primary care levels where screening for cervical abnormalities is currently happening.

It also significantly reduces the cost of each procedure, resulting in a cost savings to the patient and higher margins for providers. The system is highly portable, and battery operated, allowing for use in a variety of clinical settings. Finally, the provider burden is low; cervical cryotherapy can be (and often is) performed by nurses, physicians' assistants, or other nonphysician providers.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

FDA 510(k) clearance in mid-2024. Two provisional patents filed. Initial FTO assessment done Q4 2022.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
August 2021	Second acute animal study showing 5mm freeze on a fully battery-powered system
December 2021	Hired a CTO
December 2022	Achieved -60C on a single-stage compressor system
Q3 2023	Design Freeze and FDA Pre-Sub meeting
Q2 2024	510K submission

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	Initial Seed round	Angel investors, Seed funds, Y Combinator	$1M
2022	Phase I SBIR grant	Phase I grant from the National Cancer Institute	$400K
2023	Seed round - 2nd Tranche		$1.2M

USE OF PROCEEDS

Currently raising $1M (Seed 2) to support V&V testing and FDA 510k submission.

KEY TEAM MEMBERS

Anu Parvatiyar – Co-Founder & CEO: six years of medical device R&D (C. R. Bard), two 510ks, three products launched. Four years working with WHO, Gates Foundation, Govt of Nigeria to design and deploy technology for global health.

Allen Chang – CTO: Cofounder of Vertera Spine; acquired by NuVasive in 2017. Forbes 30 Under 30 in Manufacturing. More than 10 products launched and nine 510Ks cleared.

Julie Yip – Co-Founder & Project Lead / Engineer: Four years of med device startup experience in R&D. Cofounder of a femtech startup prior to Ananya Health.

ARSENAL MEDICAL

Transforming Medical Devices with Materials

Upma Sharma, CEO | usharma@arsenalmedical.com | 781-755-8100 | arsenalmedical.com

COMPANY OVERVIEW

Arsenal Medical is a clinical-stage platform company that develops purpose-built biomaterials for underserved clinical needs. Arsenal was founded by academic luminaries Robert Langer and George Whitesides, and serial entrepreneur-investor Carmichael Roberts, who shared a vision for how materials can transform medical devices. Arsenal is utilizing its materials expertise to develop medical devices for neurovascular and trauma indications, with combined total addressable markets of more than $5B. The science behind Arsenal's products has been validated by significant nondilutive funding from a diverse group of partners, including the Defense Advanced Research Projects Agency (DARPA) and National Institutes of Health (NIH). Current investors are Polaris Partners, North Bridge Venture Partners, and Intersouth Partners.

MARKET & COMMERCIALIZATION STRATEGY

The neurovascular embolization market is estimated to be more than $1B. Engagement with key opinion leaders indicates a clear need for an embolic designed specifically for growing applications such as preoperative embolization (POE) of meningiomas and the treatment of chronic subdural hematomas (cSDH), both of which require distal occlusion for optimal efficacy. Based on the annual number of embolized meningiomas, units used per procedure, and current pricing for liquid-based embolics, Arsenal estimates the total U.S. market value for POE of meningiomas to be more than $55M. This provides an initial point of entry into the neurovascular market, where there are currently no approved products for this indication.

TECHNICAL & COMPETITIVE ADVANTAGE

Arsenal's lead product for neurovascular embolization, the Flow Responsive Embolic (FRE), is specifically designed for delivery through small-diameter microcatheters to provide controlled penetration and occlusion deep into the neurovascular bed, which addresses a need in clinical applications such as hypervascular brain tumors (e.g., meningiomas) and chronic subdural hematomas. FRE is designed to be easy-to-use, solvent-free (i.e., biocompatible), radiopaque, and able to consistently provide deep and durable occlusion independent of operator experience. Arsenal's strong animal data shows superior embolization performance compared to PVA particles and Onyx, the existing embolic products on the market that were developed decades ago.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Arsenal utilized the data gathered under a $1.9M Direct to Phase II SBIR award from the National Cancer Institute to successfully submit a regulatory package to initiate an Australian 10-patient first-in-human (FIH) study in patients with hypervascular extra-axial tumors. Arsenal's innovative approach positions the FRE product competitively in the large and rapidly growing neurovascular embolic market.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
August 2023	Complete FIH clinical trial
May 2024	Obtain pivotal investigational device exemption approval
August 2024	Begin manufacturing scale-up/transfer
October 2024	Begin enrollment for pivotal clinical study

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2013–2022	Grants	NIH and Department of Defense	$53.6M
December 2011	Series A	Venture capital	$18.9K
2015/2019/2022	Series B/Series B2/Series B3	Venture capital	$31M

USE OF PROCEEDS

Arsenal is currently seeking $40M to execute a global pivotal study for the FRE material and obtain regulatory market approval.

KEY TEAM MEMBERS

Upma Sharma, PhD: CEO

More than 15 years' experience providing strategic, technical, and commercial oversight for Arsenal's programs. Previously of Lyra Therapeutics, where she advanced the company's biodegradable scaffold technology from concept through a successful Phase I clinical study in chronic sinusitis, resulting in a $30M venture capital raise and setting the stage for an initial public offering.

Lee Core: COO

More than 20 years of combination medical device experience. Successfully led product development to commercialize a variety of Class III PMA/510(k) products.

Carol Pekar: Clinical & Regulatory

Twenty years of clinical and regulatory experience delivering successful clinical trials and regulatory strategy for combination products, Class II/III medical devices, and veterinarian drugs. Experience spans more than 50 drug and device trials, including obtaining multiple premarket approvals.

CLARIX IMAGING

Bringing True 3D clarity to Specimen Imaging

Xiao Han | xiao.han@clarixiimaging.com | 872-760-3788 | clarixiimaging.com

COMPANY OVERVIEW

Clarix Imaging, a commercial-stage medical technology company, developed a high-resolution, 3D point-of-care imaging device for operating room use during lumpectomies (partial excision of the breast) to assess surgical margins to ensure that all cancerous tissue is removed during the initial surgery. Lumpectomies have repeat surgery rates of 25%. The company's clinical data, published in Annals of Surgical Oncology, demonstrated superiority when compared to other intraoperative specimen imaging methods. The company has plans to expand into assessing margins of other cancer types (e.g., lung, prostate, pancreas) with future applications in pathology and AI-enabled, image-guided robotics surgery. On track to make $3M in revenue in 2023 from sales of the device, disposables, and service contracts, Clarix Imaging is currently raising $15M for its next funding round.

MARKET & COMMERCIALIZATION STRATEGY

The company's initial market is the application in breast-conserving surgery (lumpectomy), followed by pathology and AI. There are more than 330,000 lumpectomies performed in the United States each year. The company has exhibited at more than 15 conferences beginning in late 2022 and has generated strong customer interest. The company's goal in the upcoming months is to convert leads into purchases following the typical 6- to 12-month sales cycle for capital equipment. Breast surgeons are the primary users of the company's technology.

TECHNICAL & COMPETITIVE ADVANTAGE

Clarix Imaging's Volumetric Specimen Imaging (VSI) platform is uniquely enabled by the breakthrough Sparse-Data Imaging technology, invented by Co-Founder Xiaochuan Pan, a world-renowned professor and imaging scientist with decades of research in the field. Compared with conventional 3D imaging such as computed tomography (CT), VSI requires a fraction of data acquisition, thus accelerating the imaging process by up to 10-fold without degrading image clarity. Moreover, VSI's compact design, fully automated operation, and cloud-based software allow seamless integration to existing operating room workflow. Competing approaches have inferior image clarity and sensitivity (2D X-ray) or lack compatibility with existing practice (e.g., manually operated probes or injected contrast agent).

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

VSI has received 510(k) clearance from the FDA to image excised specimens in 2D and 3D. The company is currently pursuing CE marking. The core intellectual property was licensed from the University of Chicago, and the company has filed additional patents.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
November 2022	Made first commercial sale
December 2023	Generate $3M in annual revenue
September 2024	Complete randomized, prospective 600-patient study
December 2024	Generate $15M in annual revenue

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016-2023	NIH NCI grant	Multiple awards	$6.6M
2018	Seed round	Angel investors, high net-worth individuals	$2M
2022	Pre-A round	Angel investors, high net-worth individuals, foreign corporate VC arm	$7.8M

USE OF PROCEEDS

The company is raising a $15M round to fund manufacturing of devices, working capital, and marketing to accelerate sales.

KEY TEAM MEMBERS

Xiao Han, PhD, Co-Founder and CEO: Dr. Han is a former University of Chicago radiology faculty with 15 years R&D and organization-building experience. He developed the product, spearheaded FDA approval, and built the current team. Dr. Han oversees the company's day-to-day operations.

Jason Dyer, Vice President of Sales: Mr. Dyer is a sales leader with more than 15 years of experience and a proven track record of exceeding sales targets in the breast cancer healthcare space. Jason was part of the senior executive leadership team that helped with the acquisition of Faxitron (developer of 2D breast imaging) by Hologic. Mr. Dyer leads the company's five-person sales team.

Gopal Mohanty, PhD, Vice President of Regulatory and Quality: Dr. Mohanty has more than 25 years of experience in the field of regulatory, quality, and compliance for medical devices. Throughout his professional career, he has worked at Baxter Healthcare, Boston Scientific, Johnson & Johnson, Life Technologies (acquired by ThermoFisher Scientific), and Danaher.

EUCLID BEAMLABS, LLC

Big Power in Small Packages

Darrin Leonhardt | d.leonhardt@euclidtechlabs.com | 301-637-0684 | euclidtechlabs.com

COMPANY OVERVIEW

Euclid Beamlabs develops next-generation medical, electron microscopy, and high-energy (synchrotron, free-electron laser) devices for the highest performance in the smallest packages. Euclid's disruptive technologies, systems, and components have been built around proven, SBIR-funded breakthroughs that were developed for performance levels once considered unachievable.

MARKET & COMMERCIALIZATION STRATEGY

The 2032 global electronic brachytherapy (EB) market is expected to reach $600M with strong shifts toward miniaturization and noninvasive surgeries; an aging global population with high-dose rate (HDR) is the largest market segment (61%) with the highest anticipated growth (8.5% CAGR). Euclid's unique oncology product is a potential global solution and, with the right partnerships, can provide needed care into areas that may not otherwise have access. The company's anticipated first step for this new EB technology is the upgrade of existing low-dose rate (LDR) EB machines, providing HDR capability and an introduction into the medical device industry. The company's established business relationship with Varian could lead to a larger partnership through such an upgrade to further develop and test the HDR market. Once sufficient backing to support an all-in-one system is clear, the product development can advance, including the development of a lower-cost system with extended treatment capabilities, targeting the emerging developing nation market that has a much lower barrier to entry.

TECHNICAL & COMPETITIVE ADVANTAGE

Euclid Beamlabs developed a compact 1MeV linac to provide the cancer treatment X-ray dose. The company's approach has been validated through a portable, lightweight, and cost-effective operating prototype that can generate HDR (1Gy/min @ 1cm) X-ray radiation with a mean energy of 300-400 KeV. Two key Euclid technologies employed are the compact dielectric loaded accelerator and a "brazeless" design paradigm for low-cost manufacturing and rapid prototyping and customization. The result has been an ultracompact, lightweight 1MeV electron source that can retrofit into existing LDR EB applicators as well as be further developed as a standalone HDR EB or intraoperative radiation therapy (IORT) system. Simulations confirmed by the Northwestern Proton Center have allowed treatment plans for several cancer types. In practice, a wider choice of accelerator geometry and performance (dose) can be provided globally for lower cost.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

As a newcomer to the medical industry, Euclid envisions a partnership with an experienced group that has proficiency in bringing medical devices to market or raising sufficient funding to hire a third-party entity to navigate any potential regulatory issues. With three utility patents granted, Euclid's technology IP is strong, and the company expects to develop more targeted applications for its system and specific methods and use cases.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q2 2023	Completed NIH/NCI Phase I ("A Compact and Retrofittable Electronic Brachytherapy Source for Cancer Radiotherapy")
Q4 2023	Complete 1 MeV prototype of metallic-based medical accelerator with robotic arm (DOE/NNSA Phase III)
Q1 2024	Obtain funding/partnership to complete development of dielectric loaded accelerator (DLA)
Q4 2024	Full DLA minimum viable product (MVP) ready for field trials

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2003-2023	Grants	Grants from DOE – Euclid Techlabs	$40.5M
2015-2023	Grants	Grants from DOE, DHHS, DHS, NASA, DOD – Euclid Beamlabs (includes NCI Phase I)	$13.2M

USE OF PROCEEDS

Euclid Beamlabs seeks to raise $5M to accelerate the following product development and commercialization initiatives: (1) Develop a fully integrated MVP to demonstrate the product capabilities to potential customers and investors. (2) Conduct comprehensive testing with the company's medical partners to ensure accuracy and develop trust within the medical community. (3) Engage external consultants to meet FDA requirements. (4) Expand the business team to build relationships with new and existing industry partners to strengthen Euclid's market presence. (5) Manufacturing scale-up to serve the EB retrofit market, positioning Euclid as an OEM provider to one or more market leaders. These steps will set the stage for a subsequent funding round, necessary for supplying new standalone HDR EB systems and initiating the manufacturing of IORT systems.

KEY TEAM MEMBERS

Dr. Chunguang Jing, CTO: Technical guidance/oversight on the DLA R&D as well as engineering design ownership; 20 years in advanced accelerator physics.

Dr. Darrin Leonhardt, Chief Innovation Officer: Industrial manufacturing; strong background in global multidisciplinary positions; 30 years in research and industrial physics.

Dr. Wade Rush, Director of Operations: Project management and engineering; PhD in physics; background in operations and logistics in the U.S. Army.

LEUKO

LEUKO LABS INC.

Noninvasive White Blood Cell Monitoring To Improve Cancer Chemotherapy Outcomes

Carlos Castro-Gonzalez, Co-Founder & CEO | carlos@leuko.com | 617-952-1827 | leuko.com

COMPANY OVERVIEW

Every year in the United States, 850,000 patients begin chemotherapy and 140,000 need to be hospitalized because of febrile neutropenia (FN), an infection resulting from contracting an illness while having low white blood cell (WBC) levels as a consequence of chemotherapy. FN hospitalizations bring negative clinical outcomes (7% mortality) and a total cost of $6.4B ($46k/case) in the United States alone. To solve this unmet need, Leuko, an MIT spin-out, has developed PointCheckTM, the first medical device that enables non-invasive, at-home, and frequent WBC monitoring, triggering timely interventions by the care team (e.g. prophylactic antibiotics or growth colony-stimulating factors) that can reduce FN hospital readmissions by 50%. Beyond cancer chemotherapy, Leuko aspires to additionally serve the 10 million immunocompromised U.S. patients who could also benefit from increased monitoring of their weakened immune systems.

MARKET & COMMERCIALIZATION STRATEGY

By saving 50% of FN-related hospitalizations, the total addressable market (TAM) is $3.2B per year in the United States (140k hospitalizations x $46k/case x 50%). Leuko's commercialization strategy, informed by hundreds of customer reviews, focuses on developing partnerships with the 16 largest Integrated Delivery Networks (IDNs) and Accountable Care Organizations (ACOsin the United States that treat one-fourth of all addressable chemotherapy patients, representing a beachhead of $800M per year. These organizations are an ideal target because of their incentives to generate healthcare savings. The company project initial revenue to come from a value-based leasing model that will be implemented following FDA approval. Expansion to fee-for-service providers will follow through reimbursement as a Durable Medical Equipment (DME) supplemented by remote patient monitoring (RPM) CPT codes. Future commercial applications include geographic expansion to Europe and globally, and to other therapeutic markets beyond cancer chemotherapy.

TECHNICAL & COMPETITIVE ADVANTAGE

PointCheck is the first noninvasive, 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 8 patents (3 issued, 5 applications).

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Leuko has worked with regulatory consultants (Hogan Lovells) and submitted a 513g request for classification to the FDA, which confirmed a Class II De Novo regulatory pathway. After this, the company conducted an in-person, presubmission meeting with the FDA, during which Leuko agreed on the intent for use (IFU) and design of the pivotal trial required for clearance, including sample size and performance targets. The company is setting up a quality management system to comply with 21 CFR part 820. Leuko's IP portfolio includes eight patents: three issued and five applications, including U.S. and PCT filings. Leuko's first three patents were developed at MIT with whom the company has an exclusive licensing agreement.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	Phase I trial: Clinical proof of concept of prototype device (nurse-operated) in 42 cancer patients.
2020	FDA presubmission: Class II De Novo classification, finalized pivotal trial (Phase III) design and intended use.
2021	Premarketing and partnerships: Unmet need validation, more than 100 customer interviews, LOS from 10 hospitals, 1 insurer, 1 medical device distributor, and 3 pharma companies.
2022	Phase II trial: Guided modifications for final device design (self-operated). Usability, safety & efficacy in 154 cancer patients.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Grant	NIH SBIR Phase I	$225K
2018	Awards	MassChallenge HealthTech, MIT 100k, Rice Business Plan Competition, etc.	$200K
2019	Funding Round (Seed)	Seed round led by Good Growth Capital, Pegasus Tech Ventures and Nina Capital	$2M
2020	Grant	NIH SBIR Phase II	$2M
2022	Funding Round (Series A)	Series A led by HTH VC	$5M

USE OF PROCEEDS

Leuko looks to raise a $5M Series A to support the following value-inflection milestones: complete pivotal trial and FDA clearance, U.S. commercial launch, and label expansion to follow-on indications.

KEY TEAM MEMBERS

Carlos Castro-Gonzalez, PhD (Co-Founder & Chief Executive Officer): More than 15 years of experience in biomedical engineering. Innovation & entrepreneurship training at MIT. Prior medical device startup experience.

Ian Butterworth, MSc (Co-Founder & Chief Technology Officer): >10 years of experience in hardware prototyping, electronics, and coding. MIT research engineer. Prior medical device startup experience.

Aurelien Bourquard, PhD (Co-Founder & Chief Data Scientist): >10 years of experience developing AI and computer vision algorithms. EPFL- and MIT-trained scientist.

Alvaro Sanchez-Ferro, MD, PhD (Co-Founder & Chief Medical Officer): >15 years of experience in medical practice, clinical studies, and biostatistics. MIT training. Prior medical device startup experience.

Paul Hartung (Director): >30 years of commercialization experience at corporate (GE) and two medical device startups (Cognoptix, Sonivance).

NAVIGATION SCIENCES

Real-Time Margin Measurement for Precision Cancer Surgery

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

COMPANY OVERVIEW

Navigation Sciences™ is a clinical stage company developing the NaviSci™ Intelligent Surgical System for the tissue conserving removal of lung cancer and other soft tissue tumors. The system integrates Augmented Reality (AR) and advanced software with surgical hardware to guide precise surgical resection by enabling for the first time, real-time in-vivo margin measurement. The system is designed to improve surgical outcomes – reduce recurrence risk and conserve lung function – shorten hospital length of stay and enhance surgical workflow.

MARKET & COMMERCIALIZATION STRATEGY

The NaviSci System, in its first application, lung cancer, has the potential to transform surgical treatment the way early-stage breast cancer surgery has evolved from mastectomy to lumpectomy – to the benefit of patients, physicians, providers, and payors.

Detection of small, potentially curable, early-stage lung tumors is increasing due to the emergence of low-dose CT scanning in high-risk lung cancer populations as the standard of care. By 2028, an estimated 60 percent of diagnosed lung nodules will be Stage 1. Recent clinical data published in the New England Journal of Medicine (NEJM, Feb. 9, 2023) support the use of tissue sparing surgical approaches in many early-stage lung cancer patients. In Feb. 2022, CMS issued a national coverage determination, effectively expanding the population eligible for CT lung cancer screening to more than 14 million patients.

TECHNICAL & COMPETITIVE ADVANTAGE

The NaviSci system is designed to provide a “GPS” for the surgeon to enable the physician to know precisely where the tumor and surrounding tissue are in relation to the surgical instrumentation and recommend where to excise the tumor. The system is the first to measure surgical margin in real-time, enabling significantly enhanced precision in tissue resection.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The NaviSci System completed a 25-patient prospective clinical trial for treating early-stage lung cancer. The study is designed to support a submission to the FDA for U.S. market clearance. The company has also defined a U.S.reimbursement pathway for the system within existing CPT and DRG ICD-10 codes. Navigation Sciences has 3 US and foreign patents pending.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2023	Pre-sub meeting with the FDA, workflow enhancements, user interface optimization, software development
2024	FDA 510(k) regulatory application

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Pre-seed	Co-Founders	$75K
2019	Seed	Family Offices	$1.5M
2020	Series A	Family Offices	$887.5K
2022	Series B	Family Offices	$2M

USE OF PROCEEDS

Navigation Sciences is currently seeking $5 million to implement workflow product enhancements, user interface, software development, quality system, 510k application, and fund a post-market clinical study.

KEY TEAM MEMBERS

Alan Lucas: CEO, Co-Founder, Director: 25+ years' experience as a CEO, in business development and marketing positions and consulting for development stage and emerging medical technology companies; global senior management experience enhancing investor value, including execution of successful cross boarder M&A transactions, fundraising, IPOs and private placements.

Raphael Bueno, MD: Co-founder, Director, SAB Chair: Chief of Thoracic and Cardiac Surgery and Co-Director of Lung Center, Brigham and Women's Hospital; Clinical research is focused on developing new strategies to target small lung nodules and GGOS as well as engineer innovative clinical trials using biological and immune therapies for thoracic cancer.

Jayender Jagadeesan, PhD: Co-founder and SAB Member: Assistant Professor at Harvard Medical School, Research Associate at the Brigham and Women's Hospital and Associate Member of the Broad Institute; Research interests include image-guided therapy, surgical navigation and robotics.

NE SCIENTIFIC

Perfecting Surgery Through Computer Science and AI

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COMPANY OVERVIEW

NE Scientific (NES) is the developer of Accublate™, a novel software for guiding percutaneous ablation. By simulating in real time the physics taking place during the procedure, the NES product helps physicians to better target the tumor tissues, increasing the chances that the whole tumor volume is destroyed. In a clinical trial at the Dartmouth Hitchcock Medical Center in Lebanon, New Hampshire, of 68 liver tumors treated by radiofrequency ablation, the recurrence rate was estimated to be 3.7% under Accublate guidance, versus 12.7% when no guidance software was used—a more than three-fold reduction in recurrence. NES is broadening its product line supporting microwave and laser ablation. Additionally, the company has recently signed a deal in the neurosurgical space licensing technologies for the simulation, planning, and guidance of convection-enhanced drug delivery and of deep brain stimulation. The overarching goal of NES is to improve surgical outcomes by applying computer science and AI.

MARKET & COMMERCIALIZATION STRATEGY

The global surgical simulation market is estimated to have a value of $1.9B today and is projected to reach a value of $4.2B by 2027 with a 16% CGAR. NES has a dual strategy: first, to make deals with medical device manufacturers like ClearPoint Neuro, where NES-developed software technology is incorporated or customized for a hardware product, and the partner oversees commercialization. In a second strategy, for certain products, NES will conduct an initial commercialization, ensuring that several KOL physicians worldwide are using its products. This will generate awareness for the products and put the company in a strong negotiating position when potential strategic partners demonstrate interest.

TECHNICAL & COMPETITIVE ADVANTAGE

NES has a strong technology background in two key areas: (1) modeling and simulation applied to biophysical systems, and (2) AI applied to radiology. In 2014, NES demonstrated, in a world first, the ability to simulate radiofrequency ablation in real time with the use of GPUs and advanced numerical techniques. Similarly, in 2020, NES achieved the capability to simulate microwave ablation in real time; these advancements are key to enabling the clinical use of the technology. To date, NES is the only entity to apply these technologies in a prospective clinical trial. NES has been recognized as one of “8 Startups Ahead of The Pulse in Healthcare” in a Forbes article promoted by NVIDIA, and the company has won the highly competitive Johnson & Johnson Lung Cancer Innovation QuickFire Challenge, resulting in a $250K prize and access to JLABS.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

NES has filed six patent applications, of which one has been issued and five are pending. With regard to the regulatory path, NES intends to apply for regulatory approvals in the Unites States, European Union, and China for three different products in the ablation space in 2024 and 2025, and the company plans to launch these products in those markets in 2024-2026.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2017	SBIR Phase II from the National Cancer Institute
2019	Won Johnson & Johnson QuickFire Lung Cancer Innovation Challenge
2019-2023	Clinical trial for liver cancer RF ablation
2022	Deal in neurosurgical space with ClearPoint Neuro
2025	Planning to conduct a clinical trial for microwave ablation under NCI sponsorship (submitted Phase II proposal)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2014	SBIR Phase I	NIH/NCI grant for initial development of RF ablation guidance	$220K
2017	SBIR Phase I	NIH/NCI grant for further development and clinical trial of RF ablation guidance	$1.65M
2019	Johnson & Johnson QuickFire Challenge award	Johnson & Johnson award supporting the development of microwave ablation guidance	$250K
2021/2022	Major Medical Devices Corp.	Nondilutive support for validation of microwave guidance technology	$210K
2022	ClearPoint Neuro	Licensing – $370K short time payment + royalties in the future	$370K

USE OF PROCEEDS

NES looks to raise $2.5M in a first dilutive round. The proceeds will support: (1) hiring three technical team members, one of whom is a key PhD who has collaborated with NES for seven years; (2) obtaining regulatory approvals for three products in the United States, European Union, and China; and (3) supporting initial pilot commercialization phases in the United States, European Union, and China.

KEY TEAM MEMBERS

Andrea Borsic, CEO: Background in biomedical engineering and computer science; former Dartmouth College research faculty.

Eric K. Hoffer, CMO: Director of Vascular and Interventional Radiology at Dartmouth; leads the clinical and animal studies.

Dave Dlesk, Company Advisor: Industry veteran, former Fortune 500 executive, and CEO of multiple companies in the healthcare space.

SAVAGE MEDICAL

Easing the Patient Journey for a Resilient Recovery

Dean Hu | dean.hu@savagemed.com | 510-206-0549 | savagemed.com

COMPANY OVERVIEW

Savage Medical is a clinical-stage medical device company targeting the $10B worldwide opportunity for the elimination of temporary ostomies. Temporary ostomies are the standard of care when colon protection is required; however, they drastically impact patient quality of life, are a huge source of complications, and have enormous healthcare costs. The company's proprietary technology provides the same protection as an ostomy while improving the patient experience, streamlining care pathways, and offering significant cost savings. The company has completed development of its first-generation device, ColoSeal, and has recently completed its first human clinical cases with great success.

MARKET & COMMERCIALIZATION STRATEGY

The first market the company is pursuing is low rectal cancer resections. The standard of care for these cases is nearly universally to perform a diverting ostomy to protect the anastomosis. The product offers cost savings of more than $70,000 per patient, even with high average sales price (ASP). Much of the U.S. market is concentrated in high-volume cancer centers, which often operate under a capitated payment model (up to 50% of the U.S. market) and would be able to directly take advantage of these cost savings. These cancer centers would be the initial target accounts and would be pursued with a direct sales force. There are also strong arguments for adoption in fee-for-service settings, including existing Diagnotic-Related Groups codes (DRGs) and Current Procedural Terminology codes (CPTs), which could be supplemented with new coding and coverage through NTAP or TCET. The company currently plans to use distributors.

TECHNICAL & COMPETITIVE ADVANTAGE

There are currently no technologies approved in the United States for this application. The two companies that are closest to market are SafeHeal and Colospan. Both have started U.S. pivotal studies, but due to technological limitations, both have had to stop their trials and redesign. These technological limitations are directly addressed by Savage Medical's proprietary technology, which has solved the challenging problem of how to anchor into the colon in a way that is safe, reliable, and easy-to-use. Competing approaches rely instead on constrictive external bands, rigid metal stents, and unsafe levels of negative pressure; these issues have led to competitors' clinical experiences being fraught with bowel trauma and unacceptable device migration rates.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Savage Medical anticipates the most likely regulatory path in the United States is a Premarket Approval (PMA) approval following a 200-patient randomized controlled trial, based on SafeHeal and ColoSpan. The company has 11 patents registered/granted in several U.S. and international territories and has other patents pending as well. The patents broadly cover the unique characteristic of the technology's ability to produce an immovable yet atraumatic anchor within a tissue cavity, as well as the delivery method and secondary retention mechanisms. The company has also had an independent IP counsel perform a freedom-to-operate search, which did not yield any concerns.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2022	Successful 12-subject porcine RCT demonstrating excellent protection from anastomotic leak
2023	First-in-human clinical study
2024	Pivotal RCT study
2026/2027	FDA approval

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015-2021	Seed funding	Founder, friends, and family funded (convertible notes); Synergy Ventures	$455K
2020-2021	Grants	NIH/NCI Phase I/II; NSF Phase I Award	$1.525M
2022	Bridge	Convertible notes, individuals, and Synergy Ventures	$735K

USE OF PROCEEDS

The company is currently targeting a $10M Series A placement. The primary use of funds will be to conduct clinical trials, predominantly the pivotal RCT trial that will likely be required for FDA approval. Funds will also support the surrounding regulatory and clinical framework as well as engineering and product supply continuity.

KEY TEAM MEMBERS

Kenton Fong, MD, Co-Founder and CEO: Dr. Kenton is an experienced medical device entrepreneur and surgeon who has founded two successful commercial-stage medical device companies, one of which was acquired by Acelity (3M). The technologies that he has helped invent and commercialize have been used to treat hundreds of thousands of patients.

Jeffrey Etter, Co-Founder and VP of Engineering: Mr. Etter has more than 25 years of experience in medical device R&D, product development, and commercialization. His key duties and responsibilities include product design, testing, vendor sourcing, and supply chain management. He has also held numerous senior positions including at Oculex Pharmaceuticals and Nellcor.

Dean Hu, COO: Mr. Hu brings years of medical device development and technology management experience to Savage Medical. His key duties include strategic alliances, business operations, and fundraising. He previously led Innovation and Business Development at Outset Inc. and was a co-founder at Spiracur Inc.

THERABIONIC INC.

Targeting Cancer's Achilles' Heel with Radiowaves

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COMPANY OVERVIEW

TheraBionic is a medical device company built on the discovery of tumor-specific frequencies for systemic targeted treatment of various forms of cancer. The TheraBionic device is a portable device for home use that delivers low levels of radiowaves to the entire body by means of a spoon-shaped antenna. Treatment is delivered three times a day for one hour. Clinical studies have shown 34% increased overall survival in patients with advanced hepatocellular carcinoma (the most common form of liver cancer). The TheraBionic device can be used safely in patients with severely impaired liver function and received FDA Breakthrough Therapy designation. In March 2023, the FDA approved TheraBionic's application for treating patients with advanced hepatocellular carcinoma who have failed first line and second line systemic therapies. FDA's inspection of TheraBionic was successfully conducted in July 2023, and FDA approval is expected in Q4 2023. This will be the first FDA-approved therapeutic option for patients who have failed first line and second line systemic therapies.

MARKET & COMMERCIALIZATION STRATEGY

Hepatocellular carcinoma is the third most common cause of cancer death worldwide. Approximately 41,210 new cases of hepatocellular carcinoma will be diagnosed in the United States in 2023. About half of them (more than 20,000 per year) will receive systemic therapy. The mainstay of systemic therapy consists of immunotherapy, tyrosine kinase inhibitors, and angiogenesis inhibitors. However, most FDA-approved agents can only be used in patients with well-preserved liver function. The TheraBionic device will therefore be the only therapeutic option for patients who have either failed, cannot tolerate or are ineligible for existing therapies. TheraBionic will market and commercialize its device similarly to Novocure, an FDA-approved medical device for the treatment of glioblastoma and mesothelioma. This will be a direct-to-patient distribution mode similar to but simpler and substantially less costly than Novocure, as training and technical support is done entirely remotely.

TECHNICAL & COMPETITIVE ADVANTAGE

TheraBionic is a revolutionary approach for the treatment of cancer. It is a novel systemic therapy capable of shrinking the primary tumor and its metastases without affecting nontumor cells. Treatment with the TheraBionic device is not associated with adverse events. It is therefore well-tolerated, even by patients with severely impaired liver function. This is a major competitive advantage in the treatment of hepatocellular carcinoma, as liver function declines with disease progression.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

TheraBionic is a few months away from FDA approval of its first indication, treatment of advanced hepatocellular carcinoma in patients with failed first line and second line systemic therapies. TheraBionic intellectual property is protected by international patents that expire in 2040. TheraBionic patents cover the use of tumor-specific frequencies.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
May 2019	FDA grants Breakthrough Therapy designation to the TheraBionic device for treatment of advanced hepatocellular carcinoma
July 2021	TheraBionic publishes the clinical outcome of 59 patients with advanced hepatocellular carcinoma treated with the TheraBionic device demonstrating a 34% increase in survival without significant adverse events
June 2022	FDA grants Humanitarian Use Designation to the TheraBionic device for treatment of persons ≥18 years of age with advanced hepatocellular carcinoma who fail first line and second line therapies
March-July 2023	FDA delivers a letter of approvability in March 2023, and FDA's inspection is completed in July 2023

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2000-2011	Founders' investment	Development and manufacturing of medical devices, feasibility study, phase I/II study, development of TheraBionic P1 device, CE and ISO 13485:2016 certifications	$6M
2018-2023	Angel Investors	FDA Breakthrough Designation, HUD approval, and HDE application	$4.3M

USE OF PROCEEDS

TheraBionic aims to secure $30M for marketing and distribution and completion of ongoing clinical studies.

KEY TEAM MEMBERS

Boris Pasche, MD, PhD, FACP: CEO, Co-Inventor and Developer of the TheraBionic device. Former Director of the Wake Forest Baptist Comprehensive Cancer Center.

Stefan Grant, MD, JD, MBA: General Counsel and business development.

Valerie K. Pasche, MD: COO and principal investigator of the NCI-funded randomized, multicenter study assessing the safety and effectiveness of TheraBionic in advanced hepatocellular carcinoma (clinicaltrials.gov ID NCT04526080).

ENVISAGENICS

Using AI to Develop Therapies for RNA-Splicing Diseases

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COMPANY OVERVIEW

Envisagenics is an AI-driven biotechnology company dedicated to transforming drug discovery and development by leveraging machine learning and deep RNA-splicing expertise. Envisagenics has developed SpliceCore®, a proprietary AI platform that enables the discovery of novel splicing-derived therapeutics, which is 400 times more likely to find novel drug targets than conventional genomic tools. The company uses machine learning to catalog and analyze a growing proprietary map of millions of RNA-splicing events to identify disease-specific drug targets and develop therapeutics that either target splicing-derived neoantigens with immunotherapies or correct splicing errors with RNA therapeutics. Envisagenics partners with biopharmaceutical companies and academic institutions to advance their drug discovery capabilities. To date, Envisagenics has commercial partnerships with BMS, Biogen, and the Lung Cancer Initiative at Johnson & Johnson.

MARKET & COMMERCIALIZATION STRATEGY

A growing number of biopharmaceutical companies are developing AI/machine learning technologies toward novel therapeutic discovery and development. Using AI for drug discovery represents 35% of the rapidly emerging application of AI in the healthcare market, which is projected to reach $22.2B globally by 2023 at a CAGR of 48.7%. The company intends to expand the application of SpliceCore to multiple indications through internal R&D programs and research collaborations with pharmaceutical partners.

TECHNICAL & COMPETITIVE ADVANTAGE

Envisagenics' SpliceCore software platform utilizes an exoncentric approach to analyzing RNA-splicing events. This approach results in a deeper search space for therapeutic targets compared to a traditional gene-centric approach. In addition, this method leverages distributed and scalable computing to accelerate target discovery. Envisagenics has developed a proprietary and stratified reference database, TXdb, with approximately 14 million unique splicing events, of which 85% are novel. Envisagenics has created a suite of proprietary algorithms to identify novel splicing-derived targets amenable for specific modalities, including RNA therapeutics and antibodies. The company's in-house lab experimentally qualifies the discoveries made by SpliceCore in cell lines and primary disease tissues and validates them using RNA therapeutics to confirm the modulation of any splicing event.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Envisagenics was spun out of Cold Spring Harbor Laboratory and was granted an exclusive, global, royalty-free license to the algorithms and databases that formed the basis of the SpliceCore platform. Envisagenics has filed three Patent Cooperation Treaty applications. These applications cover the software platform itself and cancer-related novel splicing variants as well as potential splicing-modulating therapeutics that are discovered by the platform.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2018	Winner of Johnson & Johnson AI for Drug Discovery QuickFire Challenge; became resident company at JLABS@NYC
2018	Winner of Innovate.AI challenge sponsored by M12 and Madrona Venture Group
2020	Research program agreement with the Lung Cancer Initiative at Johnson & Johnson
2021	Research collaboration agreement with Biogen
2022	Research collaboration agreement with BMS

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015	Pre-seed	Investment from Accelerate Long Island and the Long Island Emerging Technologies Fund	$100K
2015	Grant	Phase I SBIR grant from NIGMS for the development of SpliceCore	$225K
2017	Seed round	Investment from Third Kind Venture Capital, Cosine, Dynamk Capital, Dolby Family Ventures, NY Empire State Development, SV Angel	$2.35M
2018	Seed round	Investment from M12 (formerly Microsoft Ventures) and Madrona Venture Group	$1M
2018	Grant	Phase II SBIR from NIGMS for continued development of SpliceCore	$1.5M
2019	Grant	Phase I SBIR grant from NCI for expansion of SpliceCore for IO therapeutic development	$300K
2021	Series A	Investment from Red Cell Partners, M12, Madrona Venture Group, Third Kind Venture Capital, Dynamk Capital, and Empire State Development's venture capital arm, New York Ventures.	Not disclosed
2022	Grant	Direct to Phase II SBIR from NCI for development and validation of SpliceIO for neoantigen discovery	$2M

USE OF PROCEEDS

Envisagenics is raising a Series B round to scale application of its SpliceCore software platform for drug discovery and development. With this funding, Envisagenics will expand its breadth of programs with additional indications having strong evidence of splicing dysregulation. The company will accelerate its business development activities, including executing additional R&D research collaborations with pharmaceutical companies to discover and accelerate the development of novel therapeutics.

KEY TEAM MEMBERS

Maria Luisa Pineda, PhD (CEO): Experience in life science venture investing, business development, and operations; Under her leadership, Envisagenics has raised more than $7.5M from investors (not including undisclosed Series A raise) and she led the execution of three commercial deals with large cap biopharma companies, most recently with BMS.

Martin Akerman, PhD (CTO): Experienced quantitative biologist focused on RNA with several publications in high-impact journals and an extensive record or academic and industrial collaborations; Developed the proprietary algorithms that constitute the intelligence behind the SpliceCore platform.

Scientific Advisors: Omar Abdel-Wahab, MD; Sudhir Agrawal, D. Phil, FRSC; Adrian Krainer, PhD; Kalpana Merchant, PhD; Michael Zhang, PhD.

Business Development Advisor: Michael Grissinger, MBA.

VIZLITICS (D/B/A CANCER INSIGHTS)

An Oncology AI Platform for Clinical Decision Support

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COMPANY OVERVIEW

Vizlitics Inc. (DBA Cancer Insights) is an oncology AI company delivering innovative, data-enabled, and insights-driven clinical workflows. Current clients include AccessHope (collaboration of City of Hope, Dana Farber, and Emory University); OSF HealthCare; UCSF; and Northwestern Medicine.

MARKET & COMMERCIALIZATION STRATEGY

Cancer Insights focuses on health system and biopharma markets with a TAM of $16B in oncology. Cancer Insights enables large health systems with dedicated cancer centers to increase top line revenue growth by 10% and clinical efficiency by 40% through AI-enabled products like new consult workflow, tumor board management, clinical trial matching, and clinical pathway analytics.

TECHNICAL & COMPETITIVE ADVANTAGE

Cancer Insights has successfully deployed three technical innovations that are the foundation of all its products: (1) aggregation of patient records from 95% of U.S. health systems; (2) use of AI and oncology data model to extract insights; and (3) preintegration with electronic medical records for streamlined clinical insights. These innovations have also helped Cancer Insights win two NCI SBIR Phase I grants.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Cancer Insights products do not need regulatory approval. Cancer Insights IP includes proprietary methods and analytical processes that are incorporated into its core technology. The team is in the process of filing disclosures related to innovative methods and processes.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2018	Vizlitics Inc. founded as C-Corp
2019	Cancer Insights platform launched – HIPAA, SOC2, HITRUST certification with Epic EMR integration
2020	Cancer Insights connected into 95% of U.S. health systems for pulling medical records
2021	First product launched: New Consult Workflow. First NCI SBIR Phase I grant won. First customer signed. Second commercial product launched: Multidisciplinary Tumor Board Management.
2022	Second customer signed. Achieved $1M in 2022 revenue ($655K ARR).
2023	Third customer signed. Second NCI SBIR Phase I won. Fourth customer in contract. Upcoming product: Clinical Trial Matching.
2024	Win two to three additional commercial customers toward the goal of $2.5M-$3.5M in revenue
2025	Deliver $10M in commercial revenue

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018-2022	Founder Funding	Initial market study and prototype development; Cancer Insights platform development; two product launches	$1.1M
2022	NCI SBIR Phase I Grant	OncoPath co-development with Henry Ford Health System	$380K
2021	Founder Funding	EMR integration, tumor board software launched	$150K
2023	NCI SBIR Phase I Grant	VIPCare co-development with Dana Farber	$389K

USE OF PROCEEDS

Vizlitics aims to raise $5M to build out the sales team, launch new products, and build out a dedicated customer support team.

KEY TEAM MEMBERS

Tarun Kumar, CEO: Tarun is responsible for product vision, market intelligence, and sales. He spun a company out of IBM Research in 2017 as a co-founder and CTO. The company, Utopus Insights, developed industry-leading wind turbine energy forecasting and failure prediction models; it was bought by Vestas for $100M in 2018. Tarun holds 40 patents and has 24 publications.

Sharon Hensley Alford, PhD (CIO): Sharon holds a PhD in cancer epidemiology and has extensive hands-on experience with healthcare data, leading research grants and working collaboratively with providers, payers, and biopharma companies. She was the first oncology expert hired by IBM Watson Health to lead their oncology data analytics product line. Sharon has more than 50 publications in various healthcare-related topics.

Shilpa Mahatma (CTO): Shilpa is an award-winning product architectect who has developed and delivered innovative products from concept to production in multiple industry domains. She worked in the IBM T.J. Watson Research Center (New York) in the healthcare domain and was among the first employees at IBM tasked with forming the IBM Watson Health business unit. Shilpa holds 20 patents and has 15 publications in data analytics and healthcare.

XanthosHealth

XANTHOSHEALTH

A Community Approach to Facing Cancer Through Social Care

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COMPANY OVERVIEW

XanthosHealth improves the health of cancer patients, especially minorities and those in underserved communities, by connecting them—along with their caregivers, social workers, and oncologists—to relevant social services and community-based organizations (CBOs). The company's novel social care referral platform, ConnectedNest, has three core components:

- EmpowerNest: A mobile app that allows patients to self-screen and manage their own needs through community referrals.
- CommunityNest: A web portal that acts as a "community dashboard" where CBOs can create and maintain their offerings. XanthosHealth's algorithm curates these services in real time based on patient needs, eligibility, and CBO capacity.
- EngageNest: A HIPAA-secure, electronic health record-enabled interface for clinical teams to engage in the referral process. Clinicians can view services from the patient's perspective and make recommendations, chat with the patient and/or the CBO, and track the progress of each patient as well as view population-level data.

MARKET & COMMERCIALIZATION STRATEGY

XanthosHealth's go-to-market strategy is focused on the oncology market in Minnesota, where the company has partnerships through funded pilot studies. Minnesota has about 131,000 insured individuals whose cancer care costs total $1.45B annually. Many of these individuals face nonmedical challenges that may impact their health outcomes, and they would greatly benefit from accessing specialized social services and CBO offerings. XanthosHealth's primary target customers are providers (health systems, specialty oncology clinics) and payers (employers, commercial/public organizations), particularly those who are part of value-based contract arrangements. XanthosHealth is exploring potential licensing models to license components of the platform versus selling the unified system on a per-patient fee basis.

TECHNICAL & COMPETITIVE ADVANTAGE

XanthosHealth provides a streamlined, easy-to-use patient needs assessment that includes an update process to reflect any changes in patients' needs over time. The company provides the only real-time listing of community services. Unlike its competitors, XanthosHealth is able to effectively close the loop and track patient progress and use of services in real time. Competitors use software that integrates with the clinical care environment where the patient and the CBOs assume passive roles. Because these competing solutions are provider-centric, they require the patient to have a clinical encounter before they can receive a referral. Screening by clinic staff may also lead to social desirability biases; that is, a patient may deny having needs if those needs are perceived as socially undesirable. None of XanthosHealth's competitors use a patient-centered approach designed specifically to reflect how

patients prefer to access services. Current offerings also lack real-time listings of available services (such as pop-up clinics or traveling kitchens); thus, patients often access outdated databases with hundreds of organizations and need to manually check each organization's eligibility, taking away valuable time from treatment and normal life activities. With XanthosHealth, patients have access to a carefully curated list of organizations and services for which they are eligible.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

XanthosHealth does not require FDA clearance, as it does not replace a clinician's decision-making. The company is in the process of filing for provisional patents for the IP.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
September 2021-June 2022	Successful completion of the SBIR Phase I contract by NCI (Contract: 75N91021C00044)
September 2022	Participated, by invitation, as the only Minnesota company and the only start-up in the Sync for Social Needs Initiative announced by the White House, uniting leading health technology companies and health systems
March-June 2023	Selected and completed Beta MN accelerator cohort (by Minnesota Department of Employment and Economic Development and Optum)
May 2023	Silver Stevie Award for the Startup of the Year in Consumer Services Industries by the American Business Awards
June-October 2023	Semifinalist for Minnesota Cup in June (largest state entrepreneurship competition); finals are in August-September 2023
July-December 2023	Real-world pilot study in partnership with the Minnesota Cancer Alliance network of CBOs in the Twin Cities
September 2023	SBIR/STTR/ Phase II submission to NCI

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	University of Minnesota fund	R&D: Smart Community Health V2 – Background Technology for ConnectedNest	$133K
2022	NIH/NCI SBIR Phase I	R&D: Software to Address Social Determinants of Health in Oncology Clinics	$399K
2022	Launch Minnesota Grant	SBIR/STTR matching grant by Minnesota Department of Employment and Economic Development	$27.9K
2023	University of Minnesota fund	Pilot study: ConnectedNest – Demonstration in an Oncology Patient Population	$400K

USE OF PROCEEDS

XanthosHealth is seeking $1M for pilots, capital expenses, and working capital to build the full commercialization team and secure commercial contracts with its first five customers with a five-year net present value of approximately $4M. An additional $1M is sought for technical enhancements and white-label licensable products.

KEY TEAM MEMBERS

Pinar Karaca-Mandic, PhD, CEO: Dr. Karaca-Mandic is a world-leading health economist and founder of multiple national and international award-winning health IT and data platforms.

David Haynes, PhD, CTO: Dr. Haynes is a health geographer, IT and cancer disparities expert, and founder of award-winning social determinants of health visualization platforms.

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