2022–2023 | 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 and diagnosis
- And much more

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DEAR READER,

The past few years have certainly taught me a lot and have undoubtedly shown the world the importance of ensuring that the proper technologies are in place to take care of patients right when they need them. Our jobs as funders of early stage technologies are of the utmost importance, and it is up to us to identify and champion the technologies that will be essential down the road. Because of COVID-19, we have seen an increased need for quicker drug development, digital health solutions that allow for more personalized remote patient monitoring, and diagnostics that can detect disease earlier, faster, and more accurately. Investing earlier in biotech startups has become critical given the market downturn and has allowed investors to use their dollars more effectively to help build, develop, and shape the future of healthcare.

We have a highly diverse early stage portfolio here at the National Cancer Institute SBIR Development Center (NCI SBIR), with more than 400 active oncology focused projects at any given time that span the technology areas of therapeutics, devices, diagnostics, research tools, and digital health. Oftentimes, the grants and contracts awarded through our program are the first money into a company. Some companies, however, come into the program venture- or partner-backed but need seed funding to develop new aspects of their platform. Either way, the funding is a necessary step down the path of commercialization. However, we all know that government funding alone cannot take a company all that way.

THIS IS WHERE YOU COME IN.

I am honored to present you the top 35 companies selected for the 2022-2023 NCI SBIR Investor Initiatives Showcase program. These companies have not only been vetted by the NIH peer review process and NCI SBIR board review – they have also been vetted by some of the country's top VC investors and strategic partners through our annual Investor Initiatives program. Through this additional rigorous review process, companies are scored on 10 criteria, including commercial potential, patient impact, management team, and business strategy, and reviewers determine if the companies have a compelling value proposition and are ready to pitch to investors. This year, 97 companies applied; the 35 you will see in this book were determined to be ready for investment and/or partnership, and each will be attending and pitching at industry events across the country over the next year.

A variety of oncology indications and technology areas are represented, including therapeutics for drug-resistant cancers, interventional immuno-oncology, antibody platforms, novel drug delivery (and drug filtration) platforms, early detection diagnostics, a CAR-T cell manufacturing platform, devices for precise margin measurement during surgery, home blood cell monitoring, digital clinical care platforms, and precision medicine platforms for radiopharmaceutical therapy.

These companies are changing the way cancer care is developed, delivered, and managed. Now is the time to join them. I encourage you to take a look at the companies highlighted in this book.

Sincerely,

MICHAEL WEINGARTEN
DIRECTOR, NCI SBIR DEVELOPMENT CENTER

If you see any companies that fit your interests and would like to learn more, please email Brittany Connors at brittany.connors@nih.gov. She can gather a non-confidential slide deck or make direct introductions.

BIOPHARMACEUTICALS

Company	Technology Type	Initial Organ(s)/Indication(s)
EtiraRx	Cytotoxic drugs for previously untreatable cancers	Therapy-resistant breast cancer
Grannus Therapeutics	Small molecule inhibitors of HSP90	Advanced triple negative breast cancer (TNBC), bladder cancer
Immunophotonics	Pioneering Interventional Immuno-Oncology	Melanoma, Soft tissue sarcoma, Hepatocellular carcinoma, other solid tumors
Luminary Therapeutics	Novel Gamma Delta Cellular Therapy	Mantle cell cancer, myeloma
OncoTAb	Patented monoclonal antibody platform	Various
Reveal Pharmaceuticals	First-in-class gadolinium-free MRI contrast agent	CNS imaging
Sanarentero	Bioengineered drug detoxifying bacteria	Chemotherapy induced diarrhea
SIRPant Immunotherapeutics	Novel autologous macrophage cell therapy for solid tumors	Relapsed/Refractory Non-Hodgkin Lymphoma, Cutaneous T-cell Lymphoma, Head & Neck cancer
Synthis Therapeutics	Novel checkpoint inhibitor-TGF beta combination therapy	Colorectal cancer
Tradewind BioScience	Multifaceted Attack Antibodies for cancer	Drug resistant ovarian cancer
Trevarx Biomedical	Radioligand platforms that identify and treat cancer	Breast cancer, Ovarian cancer, prostate cancer
Wildflower Biopharma	Novel small molecule splicing modulator	Chronic lymphocytic leukemia
XPose Therapeutics	Small molecules targeting various points in DDR pathways	Various

DRUG DELIVERY PLATFORMS

Company	Technology Type	Initial Organ(s)/Indication(s)
Advanced Chemotherapy Technologies	Surgically implanted iontophoresis delivery system	Pancreatic Cancer
Ernest Pharmaceuticals	Engineering bacteria to treat solid tumors	Liver Cancer
Filtro Medical	Intra-vascular catheter filtration device to reduce Dox Tox	Liver Cancer
Privo Technologies	Nano-engineered topical mucoadhesive patch technology	Oral cancer, solid tumors
Rise Therapeutics	Oral biologics delivery platform and drug candidates	Various

DIAGNOSTICS/TOOLS

Company	Technology Type	Initial Organ(s)/Indication(s)
EarlyDiagnostics	Liquid biopsy tests for early cancer detection	Hepatocellular carcinoma, lung cancer
Lodestone Biomedical	In vivo biomarker monitoring	Glioblastoma
OpenCell Technologies	Intracellular delivery platform suitable for difficult-transfect-cells	Transfection market
PreCyte	Indicator cell assay platform for blood-based diagnosis	Lung cancer
Proteios Technology	Manufacturing platform for CAR-T Cells	Multiple

DEVICES

Company	Technology Type	Initial Organ(s)/Indication(s)
Clarix Imaging	FDA approved Intraoperative volumetric specimen imaging system	Breast cancer surgery
Cooler Heads	FDA approved portable scalp cooling device	Chemotherapy induced alopecia
Leuko Labs	Non-invasive, at-home white blood cell monitoring device	Chemotherapy induced febrile neutropenia
Madorra	Home-use, non-hormonal ultrasound device	Breast cancer survivors/vaginal atrophy
MALCOVA	3D, dual breast X-ray imaging platform	Breast cancer
Navigation Sciences	Real-time margin measurement for precision cancer surgery	Lung cancer
Savage Medical	Novel device for fecal diversion	Rectal cancer

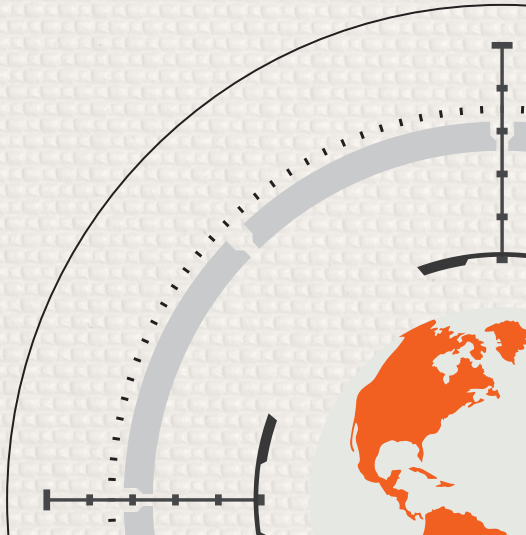
DIGITAL HEALTH

Company	Technology Type	Initial Organ(s)/Indication(s)
Carevive Systems	End-to-end digital oncology clinical care platform	Multiple
Elimu Informatics	Clinical decision support tool for cancer symptom management	Multiple
Melax Tech	Clinical and Biomedical Sciences Natural Language Processing	Multiple
Rapid	Precision Medicine for Radiopharmaceutical Therapy	Multiple
Voximetry	Personalized, dosimetry-guided Radiopharmaceutical Therapy	Prostate RPT

SHORT COMPANY SUMMARIES

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

For more information or an introduction, please contact Brittany Connors at brittany.connors@nih.gov.



ETIRARX

CYTOTOXIC DRUGS FOR PREVIOUSLY UNTREATABLE CANCERS

LOCATION
DALLAS, TX

STAGE
PRE-CLINICAL DEVELOPMENT

EtiraRx is developing novel small molecules for multiple cancer indications, including therapy-resistant breast cancers. Current development is focused on compounds that induce programmed cell death by enhancing endoplasmic reticulum (ER) stress, a novel and emerging target for cancer treatment. EtiraRx's extensive preclinical work has shown significant and consistent activity of the lead compound, ERX-315, against therapy-resistant breast cancers in vitro and in vivo and patient derived tumor models ex vivo. Phase 1a human trials are planned to commence May 2023 in a 'basket' study design. Simultaneous formulation studies are ongoing to optimize oral formulation which is likely for the next stage clinical trials. A Phase 1b/2 clinical trial will then be performed with the oral formulated drug. EtiraRx is raising a $12 million Series A for Phase 1a/Phase 1b clinical trials and the development work for Phase 2 trial approval.

GRANNUS THERAPEUTICS

FIRST-IN-CLASS HSP90β-SELECTIVE INHIBITOR

LOCATION
INDIANAPOLIS, IN

STAGE
PRE-CLINICAL DEVELOPMENT

Grannus Therapeutics is a platform company focused on developing and commercializing small molecule inhibitors that selectively target individual isoforms of the Hsp90 family of chaperone proteins. By selectively targeting individual isoforms, Grannus has overcome the safety limitations of previous non-isoform selective (pan) inhibitors while still delivering strong efficacy results that meet current unmet medical need. Grannus's lead program is a first-in-class Hsp90β-selective inhibitor for the treatment of advanced triple negative breast (TNBC) and bladder cancer. Grannus will explore the potential for regulatory designations such as orphan and breakthrough status as well as potential accelerated approval pathways. Grannus is seeking $2.5M to support IND-enabling and regulatory activities. After a pre-IND, Grannus will initiate a ~$20M Series A.

IMMUNOPHOTONICS

PIONEERING INTERVENTIONAL IMMUNO-ONCOLOGY

LOCATION
ST. LOUIS, MO

STAGE
IN CLINICAL TRIALS (SWITZERLAND); PRE-CLINICAL DEVELOPMENT (US)

Immunophotonics is developing 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. Early clinical data has shown shrinkage of both treated tumors and distant metastases. Immunophotonics has completed confirmatory Phase 1 clinical trials and commenced Phase 2 trials assessing efficacy in Switzerland. The company expects IND filing in the US in 2023. The company is currently pursuing a two-tranche, $55 million raise.

LUMINARY THERAPEUTICS

NOVEL GAMMA DELTA CELLULAR THERAPY

LOCATION
MINNEAPOLIS, MN

STAGE
PRE-CLINICAL DEVELOPMENT

Luminary is a clinical cell therapy company focused on combining advanced receptor design with superior cell engineering to overcome antigen escape and T cell dysfunction. The company's novel ligand-based BAFF CAR designed to bind three targets is set to enter the clinic in Q3 2022. Luminary is looking to raise $18M to $25M to fund approved Phase I trial for Mantle Cell Cancer and to scale up of Gamma Delta manufacturing process supporting any CAR or TCR for an allogeneic finished product, and to bring solid tumor proof of concept to IND submission.

ONCOTAB

PATENTED MONOCLONAL ANTIBODY PLATFORM

LOCATION
CHARLOTTE, NC

STAGE
PRE-CLINICAL DEVELOPMENT (ONE PRODUCT, A BLOOD TEST TO SCREEN FOR EPITHELIAL CANCERS IS COMMERCIALLY AVAILABLE)

OncoTAb is developing multiple agents to target the tumor form of MUC1 (or tMUC1). Since tMUC1 is shed from tumor cells into circulation, it can be used as a biomarker to detect cancer and a target on tumors for the delivery of a cytotoxic agent or immunotherapies. To date, the company has developed a fully humanized monoclonal antibody (hTAB004) and is in the early stages of developing a tMUC1-targeting nanobody and a peptide that will offer a range of pharmacokinetic properties. OncoTAb is seeking $7 million to take hTAB004 and the bi-specific T-cell engager antibody (MUCD3) through FIH trials.

REVEAL PHARMACEUTICALS

GADOLINIUM-FREE MRI CONTRAST AGENT

LOCATION
CAMBRIDGE, MA

STAGE
IN CLINICAL TRIALS: PHASE I

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 first-in-class gadolinium-free MRI contrast agent, solves a critical safety issue that impacts 40 million scans per year. NCI is funding first in human clinical trials of Reveal's RVP-001; investor capital will enable Phase 2, accelerate RVP-001 toward NDA, and support development of a molecular imaging agent for fibrotic diseases.

SANARENTERO

DRUG DETOXIFYING BACTERIA FOR CHEMOTHERAPY INDUCED GUT INJURY SMALL

LOCATION
PEARLAND, TX

STAGE
PRE-CLINICAL DEVELOPMENT

Sanarentero is a women-owned, early-stage biopharmaceutical startup developing the licensed and patent-pending technology of bioengineered drug detoxifying bacteria (DDB) for protection against intestinal damage induced by therapeutic drugs and toxic molecules. Currently, there is no mechanism-based effective solution in the market for preventing drug-induced gut damage and associated symptoms such as diarrhea. Sanarentero is raising $2 Million for the next 2 years for technology development, hiring key resources for product and business development, regulatory and clinical consulting, patent portfolio management, GMP manufacturing and packaging, clinical studies of DDB, and marketing of DDB as a probiotic supplement.

SIRPANT IMMUNOTHERAPEUTICS

EMPOWERING CANCER-SPECIFIC IMMUNOTHERAPY FOR SOLID TUMORS

LOCATION
HUMMELSTOWN, PA

STAGE
PRE-CLINICAL DEVELOPMENT

SIRPant Immunotherapeutics is focused on the development of novel autologous macrophage cell therapy for solid tumors. SIRPant technology comprises an innovative approach to engineer SIRPα^{low} macrophages for robust phagocytosis and initiation of tumor-specific immune responses. SIRPant's proprietary macrophage modification overcomes resistance to the effects of immunosuppressive cytokines and reprograms the tumor microenvironment toward a pro-inflammatory state, resulting in destruction of the tumor and initiation of tumor specific adaptive immune responses. SIRPant anticipates IND filing by end of 2022 and FIH studies initiating H1 2023. SIRPant is raising a Series B of $50 - $100M to fund Phase 1-2 trials in R/R NHL, Cutaneous T-cell Lymphoma and Head & Neck cancer.

SYNTHIS THERAPEUTICS

NOVEL CHECKPOINT INHIBITOR-TGF BETA COMBINATION THERAPY

LOCATION
NEW YORK, NY

STAGE
PRE-CLINICAL DEVELOPMENT

Synthis is developing a novel therapeutic platform that evolved from an idea to develop safer and more efficacious therapies that eliminate one of the most immunosuppressive pathways in virtually all cancers, known as TGF-β. The company's first-in-class, therapeutic platform selectively and safely blocks the TGF-β pathway in immune cells to drive tumor clearance and long-term cancer remission. Synthis has designed and tested multiple drug candidates and demonstrated efficacy with their lead, SYN101, which reverses TGF-β mediated immune suppression and drives tumor clearance in vivo. The company is currently raising a $3M seed extension round to 1) expand in vivo studies, 2) demonstrate safety and 3) deliver an IND ready development candidate by Q2 2023.

TRADEWIND BIOSCIENCE

MULTIFACETED ATTACK ANTIBODIES FOR CANCER

LOCATION
SAN CARLOS, CA

STAGE
PRE-CLINICAL DEVELOPMENT

Tradewind is dedicated to developing therapeutics for the most aggressive and difficult to treat cancers. The company's STTR-funded therapeutic is a multifaceted attack antibody. The antibody robs cancer cells of the autocrine/paracrine signaling they have come to depend on which causes a direct effect on primary and disseminated cancer cells. A second mechanism of action, that has also been validated in vivo, is that it inhibits myeloid-derived suppressor cells (MDSCs), which are potently stimulated by Tradewind's secreted ligand target. These immune cells are notorious for their ability to suppress anti-tumor T cell immunity. Potent cooperativity with checkpoint inhibitors has been demonstrated in immune-competent models. Tradewind's initial focus is on advanced ovarian cancer patients since the biology is a good fit as ascites growth and recurrence go hand-in-hand. The company is seeking funds to complete pre-IND inflection points and to get the company to IND filing in early 2025.

TREVARX BIOMEDICAL

NOVEL RADIOPHARMACEUTICAL PLATFORMS THAT TURN DEADLY DISEASES INTO MANAGEABLE CONDITIONS

LOCATION
PHILADELPHIA, PA

STAGE
PRE-CLINICAL DEVELOPMENT/IN CLINICAL TRIALS: PHASE II

Trevarx Biomedical develops paradigm-changing small molecule radiopharmaceutical platforms that identify and kill tumors at the sub-cellular level. The company's first two products are built on a PARP inhibitor platform: first, a PET companion diagnostic Fluorine-18 Fluorthanatrace ("FTT"), is currently in fully funded Phase 2 multi-center trial in breast cancer and second, an alpha radiotherapy Astatine-211 Parthanatine ("PTT") which has published in vivo data demonstrating tumor cell death through delivery of cytotoxic 211At to subcellular cancer DNA and is currently in pre-clinical development for ovarian cancer. Trevarx is raising $10 million to fund infrastructure for FTT Ph 3 NDA and PTT Ph 1 POC trials, complete Phase 2 Joint Pharma/FTT efficacy trials, build FTT commercial network for NDA and commercial rollout, complete PTT pre-clinical POC and Phase 1 OVCA trial, and to expand IP portfolio.

WILDFLOWER BIOPHARMA

NOVEL SMALL MOLECULE SPLICING MODULATOR IN CLL

LOCATION
ENCINITAS, CA

STAGE
PRE-CLINICAL DEVELOPMENT

Wildflower Biopharma, Inc. (WBI) has a patented series of small molecules, including sudemycin D6 (SD6), which target the SF3B1 spliceosome protein. SD6 has been selected for clinical development and has progressed through the initial phases of IND-enabling studies. Recurrent mutations in SF3B1 and other splicing proteins in tumors leads to an oncogenic pre-mRNA splicing program that exposes a unique vulnerability to agents such as SD6, in these cancers. Wildflower is seeking $10-12 million for the completion of IND enabling studies and a Phase I clinical trial in CLL.

XPOSE THERAPEUTICS

TARGETING THE DNA REPAIR ENZYME APE1 TO TREAT CANCER

LOCATION
SAN CARLOS, CA

STAGE
NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE

XPose has developed APE1 inhibitors of superior potency and specificity using a novel high-throughput protein X-ray crystallography-based fragment screening approach. Beyond APE1, which is in lead optimization, the company's pipeline includes several targets in different stages of hit generation, hit-to-lead development, and lead optimization, important for the development of novel cancer therapeutics (small molecule inhibitors, targeted protein degradation) using the platform. XPose is raising $20M to deploy the platform on various targets and advance to preclinical studies on the lead programs.

ADVANCED CHEMOTHERAPY TECHNOLOGIES

SURGICALLY IMPLANTED IONTOPHORESIS DELIVERY SYSTEM

LOCATION
RALEIGH, NC

STAGE
PRE-CLINICAL DEVELOPMENT

Advanced Chemotherapy Technologies (ACT) has developed a novel drug delivery system for local delivery to internal tissues/organs with pancreatic cancer as the first indication. The company's iontophoresis delivery system creates both electroosmotic and electroconductive flow of drug deep into the tumor that overcomes the traditional tumor defense mechanisms, leading to tumor cell death. ACT has shown that delivery of chemotherapy with the iontophoretic delivery system shrinks tumors in PDX models better than any other treatment ever tested. ACT held a Pre-Sub meeting with the FDA and agreed on the 505(b)2 regulatory path for its pancreatic cancer indication and on a modest clinical program with less than 300 total patients required. The Phase 1b study is scheduled to begin in 2023. ACT is seeking $20M to complete the Phase 1b dose escalation trial and to fund development in three new indications.

ERNEST PHARMACEUTICALS

BACTERIAL DRUG DELIVERY SYSTEM THAT RELEASES BIOLOGICS DIRECTLY INTO CANCER CELL CYTOPLASM

LOCATION
HADLEY, MA

STAGE
PRE-CLINICAL DEVELOPMENT

Ernest Pharmaceutical's bacterial delivery platform is based on an attenuated Salmonella strain that produces biological therapeutics *in situ*, invades cancer cells in solid tumors and delivers the protein directly into the cancer cell cytoplasm. Salmonella have the inherent capacity to home to tumors specifically, thus sparing normal tissues. Ernest is currently in the preclinical phase of drug development and preparing for an FDA INTERACT meeting. A drug candidate has been determined for liver cancer and the start of IND-enabling studies is set for 2023. Ernest is raising a Series A round of $17M to execute IND-enabling studies and complete GMP manufacturing of EBT-302.

FILTRO MEDICAL

INTRA-VASCULAR CATHETER FILTRATION DEVICE TO REDUCE DOX TOX

LOCATION
SAN JOSE, CA

STAGE
PRE-CLINICAL DEVELOPMENT

IAC with Doxorubicin (Dox) has proven to be a successful method demonstrating mortality benefit in randomized controlled trials for treating non-operative primary liver cancer, the third leading cause of cancer deaths worldwide, due to its ability to maximize drug dosage to tumor while limiting systemic dose and toxicity. Still, up to 50% of the chemo in IAC escapes the tumor and causes toxicity. Filtro is developing the ChemoFilter™ (CF), an intra-vascular catheter filtration device that would be percutaneously placed within the vein draining the organ undergoing intra-arterial chemotherapy (IAC) in order to capture this escaping chemotherapy from the bloodstream. The company intends to apply for a De Novo 510(k) and Breakthrough Device Designation and is raising up to $750k in supplemental financing using a SAFE instrument for discretionary spending.

PRIVO TECHNOLOGIES

NANO-ENGINEERED TOPICAL MUCOADHESIVE PATCH TECHNOLOGY

LOCATION
PEABODY, MA

STAGE
IN CLINICAL TRIALS: PHASE III/PIVOTAL

Privo has developed a nanoengineered platform, PRVTM, to redesign the mechanism of action of potent but toxic drugs in unconventional ways where the unique formulation causes new, safe, and more effective mechanism of action. Privo's initial product based on this platform is a topical transmucosal patch (PRV111) for the treatment of oral cancer. When placed on the tumor, PRV111 releases and retains high concentration of cisplatin-loaded nanoparticles (NPs) into the tumor. The efficacy and safety of PRV111 was evaluated in a Phase I/II trial treating subjects with oral cavity cancer. There was an overall response rate of 87% and over 70% reduction in tumor volume among the responding subjects. PRV211 is a similar product to the PRV111, however it is intended for intraoperative use on solid tumors. Privo is seeking $5M to support PRV 211's Phase 1/2 Clinical Trial. Privo is also seeking to raise $22M to support PRV 111's (lead asset) Phase 3 pivotal registration clinical trial and NDA submission.

RISE THERAPEUTICS

LEVERAGING THE MICROBIOME TO DEVELOP NOVEL IMMUNE MEDICINES

LOCATION
ROCKVILLE, MD

STAGE
PRE-CLINICAL DEVELOPMENT

Rise Therapeutics is focused on developing targeted immunological-based biological therapies using a unique and proprietary oral biologics delivery platform. Rise utilizes new microbiome discoveries to develop innovative, first-in-class immune modulatory drugs for the treatment of inflammation, autoimmunity, cancer, and infection. Rise is raising a $3 million Seed Round to support clinical enrollment for Phase 1 clinical proof-of-concept study of the lead therapy.

EARLYDIAGNOSTICS

DETECTING AND LOCATING CANCER EARLY

LOCATION
LOS ANGELES, CA

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

EarlyDx is devoted to providing accurate, affordable, and non-invasive liquid biopsy products for early cancer detection. The company's assay technology can enrich methylation-informative cell-free DNA fragments from a tube of blood and simultaneously provide multiple epigenomic and genomic features. The company's ensemble machine learning algorithm integrates all features for cancer classification. EarlyDx's MethylScan test, at the specificity of 97.9%, achieves a sensitivity of 85.9% in detecting all-stage cancers (colon, lung, liver, stomach) and a sensitivity of 81.4% in detecting early-stage (I and II) cancers. The company will first seek 510(k) regulatory approval of MethylScan test for two intended uses (HCC and lung cancer surveillance in at-risk patients). After initial market penetration and clinical adoption, the company will seek De Novo pathway for the test's use for multi-cancer detection and tissue of origin localization. EarlyDx plans to raise $10M to support a clinical trial with the nation's largest healthcare provider, build its own CLIA facilities, and establish partnerships to launch LDT and IVD applications.

LODESTONE BIOMEDICAL

IMMEDIATE DETECTION OF TREATMENT RESPONSE

LOCATION
LEBANON, NH

STAGE
PRE-CLINICAL DEVELOPMENT

Lodestone is developing an "Immunotherapy Response Indication System" (IRIS) as a platform technology for precisely profiling biomarker expression patterns in the tumor immune microenvironment (TIME). The company's goal is to track real-time responses within the TIME to immune checkpoint blockade in solid tumors, thus enabling the design of patient-specific treatment regimens that could improve patient outcomes.

OPENCELL TECHNOLOGIES

INTRACELLULAR DELIVERY PLATFORM SUITABLE FOR DIFFICULT-TRANSFECT-CELLS

LOCATION
ST. LOUIS, MO

STAGE
NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

OpenCell Technologies develops efficient, high-throughput, and scalable transfection devices for applications in cell and gene therapy. By combining acoustic shear poration to mechanically disrupt the cell membrane, with electrophoretic action to drive payload delivery, OpenCell's proprietary POROS platform provides a gentler alternative to traditional macromolecular delivery methods. POROS features precise control of biophysical actions on a single-cell basis and has enabled the delivery of a range of payloads into hard-to-transfect cells. OpenCell is raising $5 million to complete the next-generation POROS platform capable of continuous flow operation at clinical volumes, hire additional full-time employees, and expand relationships with active strategic partners.

PRECYTE

ELEVATING BLOOD-BASED DIAGNOSTICS USING CELLS AS BIOSENSORS

LOCATION
CHICAGO, IL

STAGE
PRE-CLINICAL DEVELOPMENT

PreCyte has developed a broadly applicable and inexpensive assay for use in blood-based diagnostics (the Indicator Cell Assay Platform, or iCAP), with lead application in lung cancer (LC). LC-iCAP has greater specificity than CT in assessing patients with indeterminate post-CT cancer risk which enables many patients with benign nodules to avoid invasive biopsy. By using cells as biosensors, the iCAP overcomes such barriers to developing blood-based diagnostics as broad dynamic range of blood components, low abundance of specific markers, and high levels of noise. PreCyte is seeking ~$1 million to support a one-year external validation study, initiation of an observational clinical validation study, and building the team (hiring of a part-time CEO).

PROTEIOS TECHNOLOGY

ENABLING THE DISCOVERY AND MANUFACTURING OF ADVANCED THERAPEUTICS

LOCATION
ISSAQUAH, WA

STAGE
NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

Proteios has incorporated their patented affinity tag into a proprietary, tag-free platform for the multivariate (parallel) purification of any biological, including cell subpopulations, antibodies, and viruses. The Proteios Chimera Platform is a high-performance, cost-effective alternative to antibody-based and flow-based methods and is scalable from Research to Manufacturing and Diagnostics. Proteios will be seeking 510(k) clearance from the FDA. The company is seeking $7.5M Series A funding to develop and launch research-scale cell isolation kits, develop and launch research-scale antibody purification kits, gain regulatory approval and launch biopharmaceutical purification for manufacturing, and to develop an at-scale cell therapy manufacturing device.

CLARIX IMAGING

BRINGING TRUE 3D CLARITY TO SPECIMEN IMAGING

LOCATION
CHICAGO, IL

STAGE
COMMERCIALLY AVAILABLE/FDA 510(K) CLEARED

Clarix Imaging, a revenue-generating medical technology company, is developing the Volumetric Specimen Imaging (VSI) platform, which generates true 3D images of surgical specimens with unprecedented clarity in real-time using unique image reconstruction algorithms. The company is initially targeting breast cancer surgery with the FDA-cleared VSI-360™ for use intraoperatively during lumpectomy, a surgery to remove tumor from the breast, currently associated with high reoperation rates of 25%. VSI-360™ is portable and estimated to lower reoperation rates to less than 5%. Clarix is raising a $30M Series A round to fund manufacturing, working capital, marketing/sales, and R&D for pipeline applications.

COOLER HEADS

PIONEERING CANCER SIDE EFFECT MANAGEMENT

LOCATION
SAN DIEGO, CA

STAGE
COMMERCIALLY AVAILABLE/FDA 510(K) CLEARED

Cooler Heads Care has engineered an improved method of using scalp cooling to prevent chemotherapy induced hair loss for cancer patients. Scalp cooling is proven to be an effective therapy to reduce chemotherapy induced hair loss, but it is not widely adopted because the legacy systems require the patient to be in an infusion chair for twice the amount of time needed for their actual chemotherapy. The company's FDA approved, patient-centered device is designed to be portable, low-cost, and effective at reducing or preventing hair loss. Cooler Heads is raising a $10M Series A for 12% COGS, 39% engineering, 24% sales and marketing and 26% G&A.

LEUKO LABS

NONINVASIVE WHITE BLOOD CELL MONITORING TO IMPROVE CANCER CHEMOTHERAPY OUTCOMES

LOCATION
BOSTON, MA

STAGE
IN CLINICAL TRIALS: PHASE III/PIVOTAL

Leuko, an MIT spinout, has developed PointCheckTM, the first medical device that enables non-invasive, at-home and frequent white blood cell monitoring, triggering timely interventions by the care team that can reduce febrile neutropenia hospital readmissions by 50%. 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. Leuko is looking to raise a $5M Series A to complete pivotal trial and FDA clearance, US commercial launch and label expansion to follow-on indications.

MADORRA

RESTORING POSTMENOPAUSAL QUALITY OF LIFE

LOCATION
PORTLAND, OR

STAGE
IN CLINICAL TRIALS: PHASE II/ FEASIBILITY/PILOT

Madorra is developing devices to replace pharmaceuticals with better, safer solutions for unmet needs in women's health. Madorra's first product is a revolutionary treatment for vaginal atrophy with FDA Breakthrough Designation. Breast cancer survivors (BCS) have the largest unmet need and therefore represent Madorra's first target customer. The only effective treatment options for vaginal atrophy available today are hormone-based; yet hormone use is contraindicated for BCS because of the risk of cancer recurrence. The Madorra therapy is patented ultrasound technology with strong clinical data, and the company is working towards FDA clearance—three things that no other home-use device offers. The company is raising a $26M Series B to fund the pivotal trial and the company for 2.5 years.

MALCOVA

PATIENT-SPECIFIC
3D BREAST IMAGING

LOCATION
BALTIMORE, MD

STAGE
PRE-CLINICAL
DEVELOPMENT

MALCOVA Inc. develops technologies for enhanced breast cancer detection to overcome the largest challenge in the field – reliable cancer detection and diagnostics in women with dense breast tissue (nearly half of the female population in the US). MALCOVA's technology is poised to solve this problem as the first safe and comfortable 3-D X-ray-based high quality imaging platform available to the breast cancer radiology market. MALCOVA aims to secure $7M by Q2 2023 and an additional $3-4M by Q1 2024 to support expansion of the team, development of the scanner beta prototype, production of design files under design control, contract manufacturing costs, regulatory pathway costs, pilot and clinical trial expenses.

NAVIGATION SCIENCES

REAL-TIME MARGIN
MEASUREMENT
FOR PRECISION
CANCER SURGERY

LOCATION
BROOKLINE, MA

STAGE
IN CLINICAL TRIALS:
EARLY FEASIBILITY

Navigation Sciences is a clinical-stage company developing the NaviSci™ System for the tissue conserving removal of lung cancer and other soft tissue tumors. The system integrates Augmented Reality (AR) with surgical hardware to guide precise surgical resection by enabling for the first time, real-time in-vivo margin measurement. The system is undergoing a 25-patient prospective clinical trial, initiated in Fall 2021, for treating early-stage lung cancer. The study is designed to support a Class II 510(k) submission to the FDA for US market clearance. Navigation Sciences is seeking $5 million to complete the clinical feasibility trial, implement workflow product enhancements, user interface, software development, quality system, 510k application, and fund a post-market clinical study.

SAVAGE MEDICAL

NOVEL DEVICE ALTERNATIVE TO TEMPORARY DIVERTING OSTOMIES

LOCATION
BELMONT, CA

STAGE
PRE-CLINICAL DEVELOPMENT

Savage Medical's ColoSeal™ ICD System eliminates the need for most protective ostomy surgeries by providing a simple, safe, and easily reversible device solution for fecal diversion. The initial indication for this device is rectal cancer, the most common form of colon cancer. Savage is in discussion with FDA on the De Novo vs PMA pathway as they prepare the IDE submission. The company is raising $8M to fund acceleration of US clinical trial timelines, OUS clinical trials, and Regulatory Approvals and to set up Pivotal RCT Trial.

CAREVIVE SYSTEMS

END-TO-END DIGITAL ONCOLOGY CLINICAL CARE PLATFORM IMPROVING THE TREATMENT EXPERIENCE

LOCATION
BOSTON, MA

STAGE
COMMERCIALLY AVAILABLE

Carevive Systems, Inc. is an oncology-focused health technology company centered on understanding and improving the experience of patients with cancer. The platform enables clinicians to monitor and manage their patients remotely, which improves clinical outcomes and patient quality of life. Carevive is currently raising a Series D to continue to build their provider network, collect patient data at scale, create an economic engine with life sciences, and enter the payer market.

ELIMU INFORMATICS

ADVANCED CANCER SYMPTOM MANAGEMENT

LOCATION
EL CERRITO, CA

STAGE
NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE

Elimu Informatics is focused on developing clinical decision support solutions, enabling electronic health records (EHR) integration using Fast Healthcare Interoperability Resource (FHIR®) standards, and facilitating semantic normalization of data. Products include EHR-integrated applications for managing cancer-related symptoms, depression, hypertension, post-operative opioid use, hypertensive disorders of pregnancy postpartum, and SARS-CoV-2 infected patients monitoring at home. CDS-Sx is designed to collect symptom severity directly from patients that will be combined with the patients' EHR information for processing through symptom management algorithms prepared from evidence-based guidelines to generate explicit, actionable guidance recommendations.

MELAX TECH

CLINICAL AND BIOMEDICAL SCIENCES NATURAL LANGUAGE PROCESSING

LOCATION
HOUSTON, TX

STAGE
COMMERCIALLY AVAILABLE

Melax Tech empowers healthcare and life sciences organizations to use natural language processing (NLP) coupled with AI methods to solve real-world problems. Melax has had success selling into the areas of hospitals/academic medicine, biopharma, and health IT companies and has several $1B+ companies among as clients. Melax is looking to raise $5M million dollars to evolve one of their applications from a stand-alone application into an integrated platform-based architecture. This will allow them to expand our base by allowing us to rapidly incorporate new AI and NLP methods, as well as build targeted applications for the Pharmaceutical and healthcare domains.

RAPID

PRECISION MEDICINE FOR RADIOPHARMACEUTICAL THERAPY

LOCATION
BALTIMORE, MD

STAGE
NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

Rapid develops evidence-based precision dosimetry software to optimize dosing of radiopharmaceutical therapies. The company is developing a comprehensive, cloud-based software for RPT dosimetry that enables remote, multi-disciplinary collaboration. Rapid also provides comprehensive expert services related to quantitative imaging, and dosimetry, in support of pre-clinical and clinical studies needed for regulatory approval and the effective and safe clinical implementation of radiopharmaceuticals. Raised funds will enable Rapid to complete at least near-release versions of a suite of dosimetry and quantitative imaging tools.

VOXIMETRY

FIGHTING CANCER. MAKING IT PERSONAL.

LOCATION
MADISON, WI

STAGE
NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

Voximetry's Torch™ software application makes Radiopharmaceutical Therapy (RPT) safer and more effective. Torch analyzes pre-treatment Nuclear Medicine (NM) scans to model each patient's unique drug interaction and estimate the optimal number of therapy cycles and dose to administer per cycle. As the only GPU-accelerated solution on the market, Torch increases compute power by 5 orders of magnitude to reduce calc times (literally from hours to seconds), facilitating extreme accuracy in the clinic for the first time. Torch has been submitted for 510(k) clearance. Voximetry is raising a $1.5M seed round to cover the costs of operations for approximately one year.

ONE-PAGE COMPANY OVERVIEWS

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

ETIRARX, INC

Developing drugs for therapy-resistant breast cancers

Russell Hayward | russell@etirarx.com | 214-213-0688 | etirarx.com

COMPANY OVERVIEW

EtiraRx is developing novel small molecules for multiple cancer indications, including therapy-resistant breast cancers. The company's pipeline of compounds target novel and established molecular targets essential for tumorigenesis and are based on an oligobenzamide platform licensed from the University of Texas. Current development is focused on compounds that induce programmed cell death by enhancing endoplasmic reticulum (ER) stress, a novel and emerging target for cancer treatment. EtiraRx's extensive preclinical work has shown significant and consistent activity of the lead compound, ERX-315, against therapy-resistant breast cancers in vitro and in vivo and patient derived tumor models ex vivo. The unique mechanism of action of ERX-315 has the potential to revolutionize the management of patients with therapy-resistant breast cancers with a durable, effective, non-toxic therapy. EtiraRx is exploring additional indications including therapy-resistant ovarian, pancreatic and brain cancers.

MARKET & COMMERCIALIZATION STRATEGY

More than $17 billion a year is spent treating therapy-resistant breast cancers, yet durable responses are uncommon. There are more than 130,000 patients with breast tumors who have failed at least one line of treatment in the United States each year. The potential annual revenue opportunity is well over $5 billion in the US alone. EtiraRx has raised $2M of a $3M seed round and expects to complete the round September 2022. A Series A round of $12M with a closing date of EOY2022 has opened and EtiraRx has participation commitments from several equity firms. Prior to commencing Phase 2 clinical trials, the company will complete a $30M Series B round. EtiraRx expects FDA Accelerated Approval following successful Phase 2 clinical trials given the drug is treating an unmet need across multiple tumor types.

TECHNICAL & COMPETITIVE ADVANTAGE

There are no effective drugs against therapy-resistant breast cancer. The genetic heterogeneity of therapy-resistant cancers limits the utility of most targeted therapeutic strategies. ERX-315 works by targeting a common fundamental molecular vulnerability in therapy-resistant cancers - their high basal level of ER stress. ERX-315 shuts down de novo protein synthesis, further enhancing ER stress in these cancer cells and resulting in cancer cell death. ERX-315 does not affect normal cells. ERX-315 is designed to be orally administered, associated with a favorable therapeutic window and is potent against multiple types of therapy-resistant breast cancer. ERX-315 is likely to have first mover advantage as a first-in-class therapeutic agent.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The lead asset is completing formulation studies prior to commencing pharmacokinetic studies followed by 28-day toxicology studies. Phase 1a human trials are planned to commence May 2023 in a 'basket' study design. Simultaneous formulation studies are ongoing to optimize oral formulation which is likely for the next stage clinical trials. A Phase 1b/2 clinical trial will then be performed with the oral formulated drug. The company has licensed the technology from the University of Texas System which include 8 patents, US provisional patent applications, and PCT applications in multiple jurisdictions. The ERX-315 structural patent expires 12/2039 while its molecular target and its MoA patent expires 2/2043. An FTO analysis identified no competing patents.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2/2023	Completion of pre-clinical GLP tox studies & Ethics filing for Australian Phase 1 trials
4/2023	FIH Phase 1 trials

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
Pre-2021	Grants	Non-dilutive grants funded the developed of our technology	$18.5M
2021	NIH Grant	SBIR Grant to accelerate IND enabling studies	$2.0M
2022	Seed Round	SAFE equity round	$2.0M

USE OF PROCEEDS

EtiraRx is raising a $12 million Series A for Phase 1a/Phase 1b clinical trials and the development work for Phase 2 trial approval.

KEY TEAM MEMBERS

Russell Hayward: Chief Executive Officer, Entrepreneur in multiple fields for the past 40 years

Ganesh Raj, M.D., PhD: Founder and Chief Scientific Officer, American Society of Clinical Investigation; Paul Peters Chair of Urology, co-leader of Experimental Therapeutics program at UTSW

Sharron Gargosky, PhD: Head of Clinical Development and Operations, 20+ years experience in the biotechnology and biopharma industry directing Regulatory, Chemistry Manufacturing and Controls, Quality Assurance, Non-clinical and Clinical programs; Has overseen programs in more than 15 countries

GRANNUS THERAPEUTICS, INC.

Overcoming the toxicity and dosing challenges of pan inhibitors

John Foglesong | jfoglesong@grannustherapeutics.com | 317-414-6205

COMPANY OVERVIEW

Grannus Therapeutics is a pre-clinical platform company focused on developing and commercializing small molecule inhibitors that selectively target individual isoforms of the Hsp90 family of chaperone proteins. By selectively targeting individual isoforms, Grannus has overcome the safety limitations of previous non-isoform selective (pan) inhibitors while still delivering strong efficacy results that meet current unmet medical need. Grannus's lead program is a first-in-class Hsp90β-selective inhibitor for the treatment of advanced triple negative breast (TNBC) and bladder cancer. The Grannus team has decades of experience developing and commercializing therapeutics in academia and at leading pharmaceutical and biotechnology companies of various sizes. The company has received ~$700k in Federal and State grants and recently closed a $1M seed round with private investors.

MARKET & COMMERCIALIZATION STRATEGY

Bladder and TNBC are both large and growing markets with significant unmet medical need, especially in late line therapy. Although new product launches are anticipated in both indications, forecasts indicate that chemotherapy will maintain a significant market share in late line therapy over the next ten years (~65% TNBC and ~40% BC). This creates an opportunity to position Hsp90β-selective inhibitors as an attractive option vs chemotherapy alone. There is also potential to expand via other indications, earlier lines of therapy, and/or combination with immunotherapies. Grannus plans to progress the program through Phase 1 clinical trials, and then enter a co-development deal, license the program, or be acquired by a large pharma/biotech to support approval and commercialization.

TECHNICAL & COMPETITIVE ADVANTAGE

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

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

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

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2022	In-Vivo Efficacy and H2H Toxicology Studies (vs pan inhibitors)
Q3 2023	Completion of ADME/DMPK and Exploratory In-Vivo Toxicology Studies
Q4 2023	Pre-IND Meeting

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	NCI Grant	Ph 1 STTR Grant	$233K
2021	Grant	Elevate Ventures / IEDC STTR matching grants	$100K
2021	NEI Grant	Ph 1 STTR Grant for development of Grp94-selective inhibitor in glaucoma	$346K
2022	Seed Round	Outside capital from Pit Road Fund and Angel Investors	$1M

USE OF PROCEEDS

Grannus is seeking additional funds to support IND-enabling and regulatory activities via a SBIR Ph II grant of ~$2M, and a ~$2.5M seed-1 round. After a pre-IND meeting, Grannus will initiate a ~$20M Series A round to support growth and Phase 1 clinical trials.

KEY TEAM MEMBERS

John Foglesong, MBA: Co-Founder, President & CEO, 20-year industry veteran with deep oncology expertise from his time at Genentech and Atara, where he focused on late-stage development and commercialization of multiple oncology and other biotechnology products

Dr. Sanket Mishra MS, PhD.: Co-Founder, Expert in Hsp90 isoform-selective inhibitors and a co-inventor of the Grannus technologies. RADYUS Research, Grannus's R&D operating partner supplementing the team and supporting R&D operations. RADYUS's team of 4 expert consultants brings 75+ years of combined work experience providing scientific expertise, strategic guidance, and operational implantation through their network of CROs

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 with 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 pre-existing 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 out-license its intellectual property by indication or partner with big pharma for combinational treatment with other immune-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.

TECHNICAL & COMPETITIVE ADVANTAGE

IP-001 is a first-in-class drug in the emerging field of Interventional Immuno-OncologyTM (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. IP-001 interferes 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 to treat single lesions into a systemic treatment enabling identification, attack, and elimination of both the treated tumor and distant metastases.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Immunophotonics has completed confirmatory Phase 1 clinical trials and commenced Phase 2 trials assessing efficacy in Switzerland. The company will be expanding its Phase 2 trial into additional European countries in 2022, followed by submission of a U.S. IND, anticipated in 2023. IP-001 is part of an intellectual property platform with patents secured in nearly 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).

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 a number of solid tumor indications
Q2 2023	Interim Phase 2a Clinical Data Analysis

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
Pre-2014	Early Funding	Seed financing and early non-dilutive financing	$2.8M
2014–2018	Funding Round	Series A preferred stock sold in multiple tranches on a rolling-closing basis	$6.6M
2019–2022	Funding Round	Series B preferred stock sold in multiple tranches on a rolling-closing basis	$21.4M
2021	Grant	Phase 1 / Phase 2 Fast-Track SBIR Grant	$2.4M

USE OF PROCEEDS

The company is currently pursuing a two-tranche, $55 million raise, the proceeds from which will be used to enhance the company's product pipeline and fuel clinical proof-of-concept and efficacy studies.

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., 30+ years' experience in life sciences, both in industry and academia

LUMINARY THERAPEUTICS

Novel Gamma Delta Cellular Therapy Company

Jeff Liter, President & CEO | j.liter@luminarytx.com | 612-309-763 | luminarytx.com

COMPANY OVERVIEW

Luminary is a clinical cell therapy company focused on combining advanced receptor design with superior cell engineering to overcome antigen escape and T cell dysfunction. The company's novel ligand-based BAFF CAR designed to bind three targets is set to enter the clinic in Q3 2022. The CAR received an FDA approved IND for a Phase I clinical trial for the treatment of Mantle Cell Lymphoma and Multiple Myeloma. The company was founded by the team from B-MoGen that achieved a successful 5X exit in only three years. Luminary is seeking Series A financing with venture firms or strategic partners to support the first clinical trial and to develop the disruptive Universal Receptor IP that can modulate antigen specificity.

MARKET & COMMERCIALIZATION STRATEGY

Luminary's commercialization strategy is two pronged. They will out-license their IP to other biotech companies furthering development efforts and will also establish commercial partnerships with large pharma/biotech companies to bring their assets to market. Luminary's asset development is focused on breakthrough CAR and TCR therapies that are more efficacious and cost-effective than existing commercial therapies. This goal is accomplished by coupling novel CARs and TCRs with Luminary's unique manufacturing platform comprised of allogeneic gamma delta expansion and their non-viral gene modification process. Luminary de-risks these therapies by conducting Phase I and Phase II trials, if necessary, in preparation for partnering opportunities.

TECHNICAL & COMPETITIVE ADVANTAGE

Luminary advantages include:

1. Gamma Delta allogeneic manufacturing platform preserving both Vδ1 and Vδ2 in the final CAR/TCR product
2. Safer and more cost effective non-viral gene engineering process
3. Ability to get clinical grade reagents for any CAR or TCR in 4 months

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

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

KEY MILESTONES

DATE/YEAR	DESCRIPTION
3/2022	FDA clearance for two Phase I clinical trials (Mantle Cell & Myeloma) approved in 19 months from in-license
9/2022	Complete scale up to patient doses of BAFF CAR in gamma delta cells
6/2023	Complete IND enabling studies for gamma delta therapies
6/2024	Submit IND for solid tumors

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2019	Funding (Seed)	Initial Seed Raise	$1.5M
2020	Grant	NIH Grant #1R43CA254794-01 (Fusion Protein MyD88)	$400K
2021	2nd Seed Fund	2nd Seed Fund	$1.2M
2021	Grant	NIH Grant 1 R43 CA254820-01A1 (Dual CAR)	$400K
2022	3rd Seed Fund	3rd Seed Fund	$1.7M

USE OF PROCEEDS

Luminary is looking to raise $18M to $25M for the following: (1) Fund approved Phase I trial for Mantle Cell Cancer to prove safety and level of efficacy (early indication on reduced relapse rates due to antigen escape) (2) Scale up of Gamma Delta manufacturing process supporting any CAR or TCR for an allogeneic finished product (3) Bring solid tumor proof of concept to IND submission.

KEY TEAM MEMBERS

Jeff Liter, President & CEO, 12 years of Cell & Gene therapy covering cell manufacturing (COO of CDMO) CEO Tools company, CEO of 2 therapeutic companies

Beau Webber, Chief Scientific Officer, Expert in synergizing genome engineering, stem cell biology, and adoptive cellular therapy to develop novel treatments for genetic disease and cancer

Branden Moriarity, Chief Innovation Officer, Brings translational expertise to Luminary in the areas of cutting-edge genome engineering technologies including CRISPR/Cas9, base editor technology, transposons, and rAAV. These tools allow for high frequency gene knockout, gene knock-in, induction of targeted sequence changes, and activation and/or repression of endogenous gene expression

ONCOTAB, INC.

Addressing unmet needs in cancer diagnosis and treatment

Rahul Puril | rahul@oncotab.com | 1-855-ONCOTAB | oncotab.com

COMPANY OVERVIEW

OncoTAb, Inc.'s mission to develop and commercialize a continuum of products to address unmet needs in cancer diagnosis and treatment. To achieve this mission, OncoTAb is developing multiple agents to target the tumor form of MUC1 (or tMUC1). Since tMUC1 is shed from tumor cells into circulation, it can be used as a biomarker to detect cancer and a target on tumors for the delivery of a cytotoxic agent or immunotherapies. To date, the company has developed a fully humanized monoclonal antibody (hTAB004) and is in the early stages of developing a tMUC1-targeting nanobody and a peptide that will offer a range of pharmacokinetic properties. OncoTAb has demonstrated the feasibility of targeting tMUC1 to image and treat epithelial tumors and the ability to monitor circulating tMUC1 levels to detect the growth of epithelial cancers.

MARKET & COMMERCIALIZATION STRATEGY

OncoTAb's commercial stage product is a blood test (Agkura® Personal Score or APS) that can accurately measure circulating tMUC1 to detect the growth of epithelial cancers. APS has demonstrated detection of aggressive interval breast cancers up to two years before detection by mammography and identified pancreatic cancer patients not responding to treatment. The TAM for the APS test in the US is $22 billion. OncoTAb's imaging and targeted therapy products are in pre-clinical stages and the global TAM for these products to address unmet needs related to Triple Negative Breast Cancer, Metastatic Breast Cancer and Pancreatic Cancer is $50 Billion. OncoTAb's business model is to develop novel products and partner with global companies for commercialization.

TECHNICAL & COMPETITIVE ADVANTAGE

OncoTAb's scientific founder is a world-renowned expert on tMUC1. Her expertise led to the development of hTAB004 with attributes that overcome those of previous antibodies that have failed in the clinic. For example, hTAB004 does not form complexes in circulation with shed tMUC1 like huC242 and BrevaRex mAb-AR20.5. hTAB004 has excellent internalization characteristics that are necessary for targeted radiotherapy and internalizes twice as much and hence will have a much higher therapeutic window compared to PAM4 which reached Phase III clinical trial. Finally, hTAB004 targets 95% of breast cancers across all subtypes (on >90% cells) as well as over 80% of PDA tissue. In comparison, huDS67 targeted ~30% cells on <35% of breast cancer tissue samples.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

hTAB004 and its fragments are protected by 11 issued and several pending patents. The APS test has been offered on a small scale under CLIA regulations in the US and India. OncoTAb plans to conduct prospective clinical studies to screen for breast and pancreatic cancer, following which they will pursue FDA clearance of the APS test and a large-scale commercial launch. For the imaging and targeted therapy products, the strategy is to lead the development through first-in-human clinical studies and then license the technologies to global companies for further validation, regulatory approvals, and commercialization.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	Published exceptional pre-clinical results demonstrating imaging and 100% survival with targeted radiotherapy
2020	Launched APS test in India with DDRC-SRL Diagnostic Laboratories
2023	Secure additional capital to take hTAB004 and MUCD3 through FIH clinical trials

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2012-2014	2 Angel Rounds	IMAF Charlotte and 2 groups of physicians	$1.75M
2014	Research Loan	NC Biotechnology Center funded development of imaging using the antibody	$0.18M
2015-2018	Grants, contracts, debt/loans	NCI-funded Phase 1 grants & contract; Founder: convertible debt/re-payable loans	$1.09M
2021-2022	2 Grants	NCI funded Phase 1 awards: PC Screening & bi-specific T cell engager	$0.66M

USE OF PROCEEDS

OncoTAb is seeking $ 7 million to take hTAB004 and the bi-specific T-cell engager antibody through FIH trials. Given the revenue potential of the continuum of products developed with TAB004, the company expects to be acquired when milestones are achieved.

KEY TEAM MEMBERS

Rahul Puri, Ph.D., CEO, 30+ years' experience across multiple commercial sectors; 18 issued and 1 pending patent

Pinku Mukherjee, Ph.D., CSO, Irwin Belk Endowed Professor for Cancer Research and Associate Dean of Research/Graduate Studies, UNC Charlotte; 2015 Oliver Max Gardner Award; Participated in several FDA clinical trials at Mayo Clinic; 100+ peer-reviewed journal publications/proceedings

Taffy Williams, Ph.D., Chairman, Extensive pharmaceutical experience; Former President and CEO of Photogen Technologies; Former President and Founder of InKine Pharmaceutical Company; and CEO, Chairman and President of Panax

REVEAL PHARMACEUTICALS

The Future of Medical Insight

Vera Hoffman | ir@revealpharma.com | revealpharma.com

COMPANY OVERVIEW

Reveal Pharmaceuticals is revolutionizing MRI contrast agents to improve patient safety and 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. The company is also building on the RVP platform with a fibrogenesis molecular imaging agent in pre-clinical 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 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 an FDA 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 NCI-funded clinical trials to confirm that it is a safe gadolinium-free alternative to GBCAs and will provide equivalent diagnostic information.

TECHNICAL & COMPETITIVE ADVANTAGE

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. 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 CNS imaging (50% of total market), followed by additional indications (e.g., breast, pediatric). Invented at Harvard/MGH, 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)
2022-2023	Clinical proof of concept: imaging study
2023	Phase 2 clinical trials

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	Capped notes (clean cap table; minority of equity)	

USE OF PROCEEDS

NCI is funding first-in-human clinical trials of Reveal's gadolinium-free MRI contrast agent RVP-001. Investor capital will enable Phase 2, 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

SANARENTERO LLC

Developing Innovative Technologies for Improved Gut Resilience

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COMPANY OVERVIEW

Sanarentero is a women-owned, early-stage Biopharmaceutical startup developing the licensed and patent-pending technology of bioengineered drug detoxifying bacteria (DDB) for protection against intestinal damage induced by therapeutic drugs and toxic molecules. Rashim Singh and Professor Ming Hu co-founded Sanarentero in October 2019 and registered in the state of Texas. Sanarentero has a strong technical core team with expertise in early-stage drug discovery and development, in addition to engagement with business, clinical, and technical advisors/consultants to successfully achieve early-stage development milestones.

MARKET & COMMERCIALIZATION STRATEGY

Sanarentero recently conducted customer discovery (100+ interviews) as part of the NIH I-Corps Program and developed their market and commercialization strategy. The company will first launch DDB as a probiotic supplement for detoxifying harmful toxins and drugs exposed to the gut environment. There are several disease symptoms associated with the accumulation of toxins in the gut and no probiotic currently on the market is capable of gut detoxification. This unique value proposition will allow DDB to easily capture a 1% market share of the total global probiotics supplement market ($6.5 billion) in the first 3 years of the launch. This will generate revenue and provide much-needed capital to perform clinical studies in disease populations (e.g., cancer, organ transplant) to further develop DDB as a live therapeutic product for the indication of drug-induced diarrhea.

TECHNICAL & COMPETITIVE ADVANTAGE

Sanarentero is the recipient of an STTR Phase 1 award from NCI for its innovative platform technology of bioengineered microbes overexpressing a detoxifying enzyme for reducing gut exposure to toxic drugs and molecules. Currently, there is no mechanism-based effective solution in the market for preventing drug-induced gut damage and associated symptoms such as diarrhea. Sanarentero has the competitive advantage of using a single probiotic strain capable of the specific metabolic function allowing better quality control and efficacy readout. In addition, DDB will act only in the gut environment with no significant interference with systemic exposure and efficacy of drugs, and without significantly impacting gut physiology and its microbiota structure and function.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The company will get an exclusive license for the background IP from the academic institute and file a worldwide composition patent of DDB as a detoxifying agent for several drugs and endogenous substrates. Sanarentero will then register DDB as New Dietary Ingredients (NDI), followed by a small clinical study in the healthy population. This will allow them to collect real-world evidence of tolerability and benefits to support the market launch of DDB as a dietary supplement. They will file a new indication patent extension for DDB for irinotecan-induced diarrhea using preclinical efficacy data and plan to strategically collect patient experience and symptom data post-launch and use it to file IND for carrying out safety and tolerability studies in cancer patients. Sanarentero will file secondary patents for new indications and drugs during the IP life cycle and will also seek Orphan Drug indication status for faster regulatory approval.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Current-12/31/2022	Evidence of detoxification of drugs and endogenous substrates in the animal model
10/01/2023-3/31/2023	Composition Patent Filing and Notification of New Dietary Ingredients (NDI) to FDA
4/1/2023-7/31/2023	GMP Manufacturing and Packaging of DDB/Placebo for Clinical Studies
8/01/2023-07/31/2024	Randomized Placebo-controlled Clinical Trial in the healthy subjects

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020-2021	Grant	NIH SBIR Phase 1 Funding	$377K
2021-2022	Grant	NIH STTR Phase 1 Funding	$452K

USE OF PROCEEDS

Sanarentero is raising $2 Million for the next 2 years for technology development ($400K), hiring key resources for product and business development ($400K), regulatory and clinical consulting ($100K), patent portfolio management ($200K), GMP manufacturing and packaging ($300K); clinical studies of DDB ($200K), marketing of DDB as a probiotic supplement ($400K).

KEY TEAM MEMBERS

Rashim Singh, PhD: Co-founder/President/CFO/Principal Investigator, Expert in formulation/drug delivery technology, IRB approval of clinical trial protocols, ADME-PK

Ming Hu, PhD: Co-founder/CSO/Interim-CEO, Expert in drug-induced toxicity, ADME-PK, IND submission, preclinical efficacy studies

Srinivas Rao Chadaram, PhD, MBA: Business Consultant, Expert in customer discovery, early-stage investments for biotech startups, strategic relationships with KOL/Clinicians/Big Pharma, and product launch

SIRPANT IMMUNOTHERAPEUTICS

Empowering Cancer-Specific Immunotherapy for Solid Tumors

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COMPANY OVERVIEW

SIRPant Immunotherapeutics is focused on the development of novel autologous macrophage cell therapy for solid tumors. The company believes its proprietary technologies for empowering patient innate and adaptive immune responses against cancer will play a leading role in the successful treatment of solid tumors. SIRPant technology comprises an innovative approach to engineer SIRPα low macrophages for robust phagocytosis and initiation of tumor-specific immune responses. Cells from a standard Leukapheresis are manipulated in vitro and delivered to the tumor via direct injection or IV infusion. SIRPant's proprietary macrophage modification overcomes resistance to the effects of immunosuppressive cytokines and reprograms the tumor microenvironment toward a pro-inflammatory state, resulting in destruction of the tumor and initiation of tumor specific adaptive immune responses. SIRPant anticipates IND filing by end of 2022 and FIH studies initiating H1 2023.

MARKET & COMMERCIALIZATION STRATEGY

The company intends to pursue clinical development in several indications with unmet needs. FIH studies will be in Relapsed/Refractory Non-Hodgkin Lymphoma patients with a palpable accessible, subcutaneous, or superficial lesion. A second IND for solid tumor cancers is anticipated for H1 2023 and initial studies will focus on Head & Neck Cancer as a neo-adjuvant to surgical excision. The company will pursue a development strategy that allows for commercialization while maintaining an openness for partnering and/or acquisition. SIRPant will assure product approval and market penetration while maximizing investor returns.

TECHNICAL & COMPETITIVE ADVANTAGE

SIRPant technology comprises an innovative approach to engineer SIRPαlow macrophages without genetic modification or manipulation for robust phagocytosis of tumors and initiation of tumor-specific immune responses. Cells from a simple blood draw, are cultured in vitro with the company's proprietary PhagoAct™, and are delivered to the tumor via direct injection or IV infusion. SIRPant's proprietary macrophage modification overcomes resistance to the effects of immunosuppressive cytokines and reprograms the tumor microenvironment toward a pro-inflammatory state. This results in digestion of the tumor and initiation of tumor specific adaptive immune responses. This cellular therapy approach was chosen based on studies that demonstrated that this response cannot be recapitulated or even approximated using anti-SIRPα or CD-47 antibodies.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

SIRPant submitted a pre-IND meeting package for R/R NHL and received written response from the FDA. SIRPant expects to file an IND for liquid tumors Q4 2022. A pre-IND meeting package for Head & Neck Cancer will be submitted Q3 2022 and SIRPant expects to file a solid tumor IND in H1 2023. The company has exclusive license for two patent families licensed from Georgia State University and has filed a third family covering internally derived inventions enabling the SIRPant-M™ technology platform.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4, 2022	File Liquid Cancer IND
Q2, 2023	File Solid Tumor IND

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	Series A	Bios Partners, BioAdvance, Georgia Research Alliance Venture Fund, Radical Radish, Seed Folio	$27M
2021	Grant	NCI SBIR (NIH): SIRPant Technology for anti-Cancer Immunity	$400K

USE OF PROCEEDS

SIRPant is raising a Series B of $50 - $100M to fund Phase 1-2 trials in R/R NHL, Cutaneous T-cell Lymphoma and Head & Neck cancer while advancing R&D efforts focused on utilization of macrophages to influence immune mediated disease.

KEY TEAM MEMBERS

Robert J. Towarnicki: Founder, President, & CEO, 40+ years' experience in pharma and biotech; served as President of six biotech companies and raised $300M+; Has served on Board of multiple public and private companies and at BIO/Pennsylvania BIO

Nathanel McCurley, PhD: VP, Research & Development, 20+ years in academic science and industrial research; formerly Becton Dickinson's Molecular Diagnostics R&D division

Rita N. Bárcia, PhD: VP, Process Development & Operations, 20 years in life science research and biotechnology; Former VP, R&D at Sentien Biotech; Former leadership positions in several European Biotech startup companies

SYNTHIS THERAPEUTICS

Novel checkpoint inhibitor-TGFβ combination therapy

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COMPANY OVERVIEW

Synthis Therapeutics is an NYC-based seed stage biotech company dedicated to the innovation of targeted therapies that harnesses the power of patients' own immune system to eliminate metastatic cancer. Their novel therapeutic platform evolved from an idea to develop safer and more efficacious therapies that eliminate one of the most immunosuppressive pathways in virtually all cancers, known as TGF-β. The company's first in class, therapeutic platform selectively and safely blocks the TGF-β pathway in immune cells to drive tumor clearance and long-term cancer remission.

MARKET & COMMERCIALIZATION STRATEGY

Nearly 150,000 new cases of advanced colorectal cancer (CRC) are diagnosed each year in the US. Metastatic CRC patients have the 2nd highest cancer associated deaths (50,000 deaths annually) and a 5-year survival rate of 15%. However, first line immune checkpoint inhibitors benefit <20% of CRC patients. Elevated TGF-β serum levels define a more aggressive CRC patient population and drives immune checkpoint resistance. More importantly, because 37% of all CRC patients have a TGF-β activated molecular signature, CRC represents a potential $2B market for the platform. Because Synthis can define a unique TGF-β specific patient population, the company can segregate patients into those most likely to targeted TGF-β therapies.

TECHNICAL & COMPETITIVE ADVANTAGE

TGF–β is a validated cancer pathway and key immunosuppressive pathway in many solid tumors. Early development of TGF–β therapies has been hampered by systemic toxicity. To bypass host toxicity and drive immune-mediated tumor clearance, Synthis has developed a first in class immune cell targeted, TGF–β antagonist, SYN-101. By employing next generation, innovative antibody drug conjugate (ADC) technology, SYN101 reverses TGF–β signaling only in immune cells and bypasses systemic toxicity. SYN101 is superior to current anti-TGF–β approaches because it: a) is safer, b) reverses TGF–β mediated immune suppression, and c) increases the therapeutic window. Combination of SYN-101 with checkpoint therapies will increase CRC patient survival rates. There are multiple pharma companies with both small (MedPacto) and large molecule (EMD Serono, Sanofi, Scholar Rock) TGF–β pathway inhibitors in Phase I/II oncology clinical trials. However, because these inhibitors block TGF-β systemically, the current competition is predicted to have similar toxicity issues and limited efficacy that crippled the development of previous TGF-β antagonists. Synthis is the only company developing a platform of cell targeted therapies to selectively block TGF-β mediated immune suppression and drive tumor clearance.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Synthis has designed and tested multiple drug candidates and demonstrated efficacy with their lead, SYN101, which reverses TGF-β mediated immune suppression and drives tumor clearance in vivo. Synthis has an extensive US patent and PCT portfolio. IP & technology are fully owned by Synthis. No academic licenses are required.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2022	De-risked platform with SYN101 mediated in vivo tumor clearance & PD markers
Q2 2023	Deliver an IND ready development candidate

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018-2020	Grants	NCI SBIR (NIH) g	$820K
2021	Seed investment	Viva BioInnovator Venture Fund	$2M

USE OF PROCEEDS

Synthis is currently raising a $3M seed extension round to 1) expand in vivo studies, 2) demonstrate safety and 3) deliver an IND ready development candidate by Q2 2023.

KEY TEAM MEMBERS

Dori Thomas-Karyat, PhD: Founder & CEO, Immuno-oncology & TGF-β expert with 20+ years of experience in academia and pharmaceutical industry

Robert Lutz, PhD: Chief Development Officer, 30+ years of biotech experience; Former ImmunoGen VP; ADC Pioneer

William Tanner, PhD, MBA: Chief Financial Officer, 20+ years financial analyst for biotech/pharma; Spent 20 years as biotech and biopharma research analyst for leading healthcare investment banks (SG Cowen, Leerink Swann, etc.); Co-founder and CFO of ImmunoGenesis

TRADEWIND BIOSCIENCE, INC.

Multifaceted Attack Antibodies For Cancer

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COMPANY OVERVIEW

Tradewind is dedicated to developing therapeutics for the most aggressive and difficult to treat cancers. The company's STTR-funded therapeutic is a multifaceted attack antibody. The antibody robs cancer cells of the autocrine/paracrine signaling they have come to depend on which causes a direct effect on primary and disseminated cancer cells. A second mechanism of the antibody, that has also been validated in vivo, is that it inhibits myeloid-derived suppressor cells (MDSCs), which are potently stimulated by Tradewind's secreted ligand target. These immune cells are notorious for their ability to suppress anti-tumor T cell immunity. Potent cooperativity with checkpoint inhibitors has been demonstrated in immune-competent models. Tradewind's initial focus is on advanced ovarian cancer patients since the biology is a good fit as ascites growth and recurrence go hand-in-hand. Eventually the antibody can find a home in other indications where the target protein is expressed.

MARKET & COMMERCIALIZATION STRATEGY

Ideally, Tradewind will license their first asset to bring it to costly Phase III trials. The company's research focus is to develop a strong licensing package around the first asset that demonstrates its utility and potential to move from late stage to first line treatment in ovarian cancer. In vivo validation studies aim to clearly demonstrate utility in a combination approach with checkpoint inhibitors, PARP inhibitors and DNA-damaging chemotherapies. Tradewind has had meetings with several pharma companies that informed the company's development path. Tradewind is open to partnering with companies with an interest in the pre-clinical asset.

TECHNICAL & COMPETITIVE ADVANTAGE

The rationale for Tradewind's therapeutic approach is based on proprietary knowledge around how the secreted target protein functions. For example, the immune-mediated mechanism of action, based on MDSC function, is novel and unpublished. Importantly, this function lends the approach a distinct advantage over therapeutics that aim solely to mobilize T cell immunity by suppressing MDSC function. It will mediate a multi-pronged attack on human cancer. Tradewind has developed therapeutic antibodies that have picomolar KD, can attack primary and metastatic cancer, suppress MDSCs to enable T cell immunity and, in PK experiments can persist for weeks at levels where activity will be maintained in vivo. The therapeutic candidate is ready to enter process development given funding and can be a first- and best-in-class therapeutic.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Tradewind's lead program is on track for IND filing in early 2025, so that the company can commence a clinical trial in late-stage, drug resistant ovarian cancer patients. Esophageal cancer is currently the backup indication. To ensure ovarian cancer is an appropriate indication for the target, Tradewind will consider utilizing the services of the CRO, TRACER. The advantage of this early human study is that it will demonstrate that a therapeutic antibody localizes to the tumor of interest, information that may not be available until a Phase II clinical trial. Tradewind has an exclusive agreement with the University of Michigan. In 2022, Tradewind plans a composition of matter filing covering lead therapeutic antibody sequences. This will restart the patent clock around the affinity matured antibody sequences. Additionally, the company will pursue biomarker patent filing. Tradewind has two potential biomarkers that can work together to predict patients that will respond to the therapeutic as a stand-alone therapy.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	Humanization and affinity maturation of antibodies for the lead program
2020	Validation of direct anti-cancer activity in immunocompromised mouse ovarian PDX models
2021	Validation of anti-MDSC and checkpoint inhibitor synergy in immunocompetent syngeneic model
2022	PK assessment and other assays of developability

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Funding – SAFE	Y Combinator investment	$120K
2018	Funding – Multiple SAFEs	6 individual Angel investors	$120K
2021	Grant	NCI STTR – Partnered with Ron Buckanovich, University of Pittsburgh	$405K

USE OF PROCEEDS

Tradewind will need $13M to get to IND in 3.5 years and an additional $2M for their bispecific antibody development program.

KEY TEAM MEMBERS

Thaddeus Allen, PhD: CEO, Trained with J. Michael Bishop, UCSF; >30 publications; Y Combinator graduate; Former VP Translational Biology - Anticancer Bioscience, Ltd.; Seed to Series A with the One Health Company
Melanie Finlayson, MBA: CBO, Expertise in capital raising, M&A (public and private life science co.'s); Funded 30+ small/medium-sized enterprises with risk capital
Ron Buckanovich, MD PhD: Academic Founder and SAB, Trained at Cornell Medical College and Rockefeller Inst.; Professor of Medicine, U of Pittsburgh; Director of the Ovarian Cancer Center of Excellence and Co-Director of Women's Cancer Research Center (Pitt.); Elected, American Society of Clinical Investigators

TREVARX BIOMEDICAL, INC.

Developing radioligand platforms that identify and cure cancer

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COMPANY OVERVIEW

Trevarx Biomedical develops paradigm-changing small molecule radiopharmaceutical platforms that identify and kill tumors at the sub-cellular level. The company's first two products are built on a PARP inhibitor platform: first, a PET companion diagnostic Fluorine-18 Fluorthanatrace ("FTT"), is currently in fully funded Phase 2 multi-center trial in breast cancer and second, an alpha radiotherapy Astatine-211 Parthanatine ("PTT") which has published in vivo data demonstrating tumor cell death through delivery of cytotoxic 211At to subcellular cancer DNA and is currently in pre-clinical development for ovarian cancer. Trevarx's PET companion diagnostic FTT identifies PARP-1 tumors, predicts patient response and guides effective treatment, sparing patients unnecessary toxicity. With a three-year research lead over its competition, FTT is a companion diagnostic to current PARPi therapies and a predictive biomarker for PTT. PTT is the only alpha radiotherapeutic deployed as a small molecule targeting sub-cellular cancer DNA with a lethal radioactive charge to the cell nucleus, preventing repair and reproduction.

MARKET & COMMERCIALIZATION STRATEGY

FTT has a $1.8 billion addressable market (US, EU) for breast and ovarian cancers. PTT has a greater than $26 billion addressable market (US, EU) for ovarian and breast cancers. To date, over 150 patients have been imaged with FTT in Phase 2 trials in all four indications approved for PARPi treatment. Trevarx provides critical support in the form of GMP manufacturing supply, regulatory, multi-center trial development, and funding essential for rapid commercialization. Trevarx intends to license or sell to pharma/PET companies close to commercialization stage for PET biomarkers or Phase 2 α-RPT clinical trials.

TECHNICAL & COMPETITIVE ADVANTAGE

Trevarx's platform is a PARPi analogue that shares a common binding site with all approved PARPi's. FTT will be first to market due to its lead over other PARPi companion diagnostics that published only preclinical or Phase 1 data for non-FDA approved indication. FTT Phase 2 results demonstrate in vivo drug blocking for PARPi's and early indications of PARPi response efficacy in breast and ovarian cancers as well PARP-1 expression associated with Gleason Grade/Decipher for prostate cancer. PTT's small molecule profile enables it to reach the PARP-1 tumor quickly to release powerful targeted alpha radiation at the sub-cellular nucleus and clears the body quickly due to its 7.2-hour half-life. Actinium-225 efforts require cage linker technology, creating larger molecules unable to get to the cancer cell nucleus with off radiation concerns of its 10-day half-life as well as significant higher production complexity and cost.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Trevarx's IND for FTT Phase 2 multi-center breast cancer trial cleared February 2022. Prior to FTT Phase 3 Trial, a Pre-IND/Pre-NDA meeting will be requested. Trevarx and Penn will jointly request a pre-IND meeting to determine supporting research for the Phase 1 IND for PTT. Trevarx will seek orphan drug designation for pediatric neuroblastoma. Trevarx plans to reach the clinical market with composition-of-matter patent coverage for each product in a large majority of the worldwide pharmaceutical market. FTT is covered by issued patents owned by WUSTL and licensed exclusively in all fields of use by Trevarx. These patents have a term to Jan 2035 and are issued in the US, Europe, China, Japan, and Canada. PTT is covered by issued patents and pending applications owned by Penn and licensed exclusively in the field of therapeutic use-methods of treatment using these compositions may be forthcoming, depending on early clinical findings. The US patent has a term to May 2039 and is pending in Europe, China, Japan and Canada.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Jan 2023	First patient dosed for Phase 2B FTT efficacy joint Pharma/Trevarx trial
Feb 2024	Last patient dosed for Phase 2 Breast Cancer Multicenter trial
Mar 2024 & Jan 2025	Phase 1 PTT Trial Launch & Phase 3 FTT Trial Launch

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016-2021	Founders' capital	Jean Cho/David Mankoff/Robert & Benita Mach equity investment	$352K
July 2019	Pre-seed financing	Convertible Promissory Notes (Convert at discount to Series A)	$650K
Mar 2021	RO1 NCI Grant	5 Year AIP-RO1CA25717-01 (Penn with Trevarx, MCACC, WUSTL as subs)	$4M
Apr 2021	STTR Grant	Phase 1 STTR 1R41CA2621269-01 (Trevarx with Penn as sub)	$400K

USE OF PROCEEDS

Trevarx is raising $10 million for FTT Ph 3 NDA and PTT Ph 1 POC trials, complete Phase 2 Joint Pharma/FTT efficacy trials, build FTT commercial network for NDA and commercial rollout, complete PTT pre-clinical POC and Phase 1 OVCA trial, and to expand IP.

KEY TEAM MEMBERS

Jean Cho, MBA: CEO, Former Group Manager for Desktop Apps and Product/Strategic Planning and marketing manager for Office and Consumer Products at Microsoft, VP Corporate Finance at Drexel Burham Lambert
David Mankoff, MD/PhD: Co-Founder/Scientific Advisory Board, Expert in molecular imaging and radiotherapy; Experience as leader in translating novel methods from pre-clinical studies to multi-center cancer imaging trials; Currently vice-chair for Research in Radiology at Penn
Robert Mach, PhD: Co-Founder/Scientific Advisory Board, Internationally recognized developer of small molecule radiopharmaceuticals; Currently Director of Radiochemistry at Penn

WILDFLOWER BIOPHARMA, INC.

Targeting oncogenic mutations in the cancer spliceosome

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COMPANY OVERVIEW

Wildflower Biopharma, Inc. (WBI) has a patented series of small molecules, including sudemycin D6 (SD6), which target the SF3B1 spliceosome protein. SD6 has been selected for clinical development and has progressed through the initial phases of IND-enabling studies. Recurrent mutations in SF3B1 and other splicing proteins in tumors leads to an oncogenic pre-mRNA splicing program that exposes a unique vulnerability to agents such as SD6, in these cancers. WBI is seeking qualified entrepreneurial investors or partners to complete the preclinical development and initiate clinical trials for chronic lymphocytic leukemia (CLL) and/or other attractive indications. Wildflower is a small startup that is committed to bringing new drugs to the clinic and are flexible in their business approach.

MARKET & COMMERCIALIZATION STRATEGY

WBI is seeking funding for the final steps in the non-clinical IND-enabling studies and the initial clinical development (Phase I). The company's vision is to find a partner for marketing and commercialization of the drug under mutually agreeable terms. WBI believes that though the market for CLL has been crowded, new opportunities have emerged as growing numbers of patients have developed resistance to existing standard of care therapeutics. WBI has evidence that SD6 works in synergy with some standard of care drugs such as Ibrutinib in the targeting of human CLL.

TECHNICAL & COMPETITIVE ADVANTAGE

WBI has acquired rights to two issued US patents developed in the laboratory of Thomas R. Webb, PhD while he was a research professor at St. Jude Children's Hospital. Dr. Webb (who is the scientific founder of WBI) is the lead inventor on these patents, was the first person to develop a chemically stable synthetic drug-like analog of FR-901,464 and has extensive knowledge in the field.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Numerous opportunities are available to expand and extend the IP position around WBI's flagship drug SD6, including as an orphan drug. A future development partner would most likely determine the regulatory strategy after Phase I.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
January, 2021	Completion of initial non-GLP rat and dog PK and toxicity study pre-IND report
Q4 2022	Start Phase I trials for CLL
2023	Complete IND filing for SD6

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020-2022	1R41CA254498-01A1	Efficacy of a novel small-molecule splicing modulator (SD6) in chronic lymphocytic leukemia (CLL) mouse model	$399K

USE OF PROCEEDS

Wildflower is seeking $10-12 million for the completion of IND enabling studies and a Phase I clinical trial in CLL.

KEY TEAM MEMBERS

Thomas R. Webb, PhD: CEO & CSO, Former executive leadership roles (VP of R&D for ChemBridge Corporation) where he co-chaired large collaborative drug discovery projects with major pharmaceutical companies (including Pfizer and GSK); Former Director, Medicinal Chemistry in the Center for Chemical Biology in SRI Biosciences and St. Jude Children's Research Hospital; 78+ publications, 33 issued US patents, with 4,400+ citations of his work

Steve Morris, MD: CMO, Board-certified internist (Univ. of Texas SW HSC) and medical oncologist (Yale University School of Medicine); Served on staff at St. Jude Children's Research Hospital for 25 years; Led a basic/translational research laboratory at St. Jude that discovered and characterized oncogenes that cause a variety of human cancers, most notably anaplastic lymphoma kinase (ALK); Co-founded Insight Genetics; Founded two additional diagnostics firms – HealthChart LLC and its Chinese sister company Jinlu Biotechnology

Mads Riegel: VP of Operations, Experience includes startup entities and an executive leadership in his family business in Norway; Former BD Director at Venomyx; Former Business Analyst at ViaeX Technologies

XPOSE THERAPEUTICS

Targeting the DNA repair enzyme APE1 to treat cancer

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COMPANY OVERVIEW

Cancer cells respond to increases in DNA damage from elevated metabolism or exposure to therapeutic genotoxins by upregulating their DNA damage response (DDR) pathways. The base excision repair (BER) pathway corrects damage to single DNA bases through the action of several enzymes, including the key participant apurinic/apyrimidinic endonuclease 1 (APE1). APE1 is implicated in over 20 human cancers and its increased expression is associated with enhanced growth, migration, and drug resistance in human tumor cells and decreased patient survival of cancer-affected individuals. APE1 potentiates effects of DNA-damaging agents and anticancer therapies and can induce synthetic lethality in cancer cell models, making it an attractive target in numerous cancer indications and therapeutic modalities. XPose has developed APE1 inhibitors of superior potency and specificity using a novel high-throughput protein X-ray crystallography-based fragment screening approach. Beyond APE1, which is in lead optimization, the company's pipeline includes several targets in different stages of hit generation, hit-to-lead development, and lead optimization, important for the development of novel cancer therapeutics (small molecule inhibitors, targeted protein degradation) using the platform.

MARKET & COMMERCIALIZATION STRATEGY

APE1 is implicated in over 20 cancers. Beyond APE1, XPose is bolstering their DDR pipeline. FEN1 recognizes and releases 5'-unannealed single-stranded flap regions. Targeting FEN1 has been demonstrated pre-clinically to (i) enhance the efficacy of temozolomide (TMZ) or cisplatin therapies (such as used to treat brain, bladder, head and neck, lung, ovarian, and testicular cancers); (ii) block proliferation of tamoxifen-resistant breast cancers; and (iii) promote SL of homologous recombination repair (HRR)-deficient cancers (such as BRCA-derived breast or ovarian cancer) or cancers exhibiting microsatellite instability (MSI), such as observed in colon, gastric and endometrial tumors. Despite the promise of targeting FEN1 in cancer, no FEN1 targeting agent has yet advanced to clinic. Additionally, PolH is a DNA polymerase that bypasses lesions due to UV damage and is deployed to replication foci for translesion synthesis (TLS) DDR. Specifically in cancer treatment with a standard-of-care treatment like cisplatin where DNA-cisplatin adducts form in cancer cells to kill them, PolH can bypass DNA-cisplatin adduct lesions, negating benefits of cisplatin treatment and the development of cisplatin resistance. PolH-deficient cells can be sensitized to platinum-based chemotherapies and PolH overexpression has also been linked to the development of chemoresistance also been seen in head and neck squamous cell carcinomas and non-small cell lung carcinomas. PolH inhibition is implicated in treating cisplatin-resistant ovarian cancers, and in cancers with synthetic lethality with ATR, another DDR target. The company's Commercialization Strategy focuses on strategic partnering and licensing opportunities. They are hoping to secure one or more of these over the next by the end of 2022.

TECHNICAL & COMPETITIVE ADVANTAGE

XPose has identified inhibitors distinct from others in APE1, FEN1 and POLH spaces and solely owns/controls all chemical matter IP

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

XPose is planning for patent filing on the APE1 and FEN1 inhibitors and targeted protein degraders after additional lead optimization.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Feb 2024	Targeted protein degradation/PROTAC development on FEN1 & APE1
Feb 2025	Lead optimization and preclinical studies on APE1

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
8/2019	Pre-Seed	Founders	$7.5K
8/2020	SBIR Phase I	NIH/NCI	$300K

USE OF PROCEEDS

XPose is raising $20M through a combination of strategic partnering/R&D collaborations, private investments, and non-dilutive grant funding. Funds will be used to deploy the platform on various targets and advance to preclinical studies on the lead programs.

KEY TEAM MEMBERS

Debanu Das, PhD: Co-Founder & CEO, 20 years in protein crystallography, structure-and fragment-based drug discovery, structural biology/biology (Lawrence Berkeley Nat'l Lab/UC Berkeley, SLAC Nat'l Accelerator Lab, Stanford, Accelero Biostructures); Authored/co-authored ~45 publications

Matthew Duncton, PhD: Co-Founder, VP Medicinal Chemistry, 20+ years in medicinal chemistry, drug discovery (Merck, Vernalis, OSI Pharmaceuticals, ImClone Systems, Renovis, Rigel Pharmaceuticals); Author/inventor on 90+ papers and patents

Ashley Deacon, PhD: Co-Founder, VP Structural Biology, 30 years in synchrotron-based protein crystallography research, structure-and fragment-based drug discovery and structural biology (Cornell, SLAC National Accelerator Lab/Stanford, Accelero Biostructures); Authored/co-authored ~150 publications

ADVANCED CHEMOTHERAPY TECHNOLOGIES

Giving patients more time

Tony Voiers, CEO | tvoiers@advancedchemotech.com | 919-368-0522 | advancedchemotech.com

COMPANY OVERVIEW

Advanced Chemotherapy Technologies (ACT), a Delaware C-corp. based in North Carolina's Research Triangle Park, has developed a novel drug delivery system for local delivery to internal tissues/organs with pancreatic cancer as the first indication. In many cancers, the tumor is encased in avascular fibrous tissue that limits the penetration of intravenously delivered chemotherapies. It is common to try to overcome the poor vascularity by delivering massive doses of systemic chemotherapies, which result in devastating side effects that force many patients to stop treatment. ACT has overcome these issues by developing a surgically implanted iontophoresis delivery system that delivers higher doses of chemotherapies directly into the tumor tissue while lowering systemic toxicity. This technology advancement enables ACT to develop new treatments for existing therapies, both within cancer and in other life-threatening conditions where local delivery could be advantageous over systemic.

MARKET & COMMERCIALIZATION STRATEGY

Each year, 58,000 people in the US are diagnosed with pancreatic cancer and their prognosis is extremely bleak, with a five-year survival rate of only 10%. Surgery provides the best chance for these patients, but curative surgery is not available to 85% of patients - those with Stage 3 (locally advanced non-resectable) and Stage 4 (metastatic) disease. ACT plans to initially focus on treating the 24,000 patients diagnosed with Stage 3 cancer each year. These patients are ineligible for surgery because the tumor has expanded into nearby major blood vessels or nerves, which are vital structures that cannot be removed. ACT's chemotherapy delivery approach has shown great promise in shrinking pancreatic tumors away from major blood vessels and nerves and making curative surgery possible for these patients. ACT is seeking to improve life expectancy for these patients by 3-6 months and is estimating the price per procedure to be at $50,000, yielding a total addressable market opportunity of $1.2B. Additional opportunities in solid tumor drug delivery, immunostimulation, and non-viral gene therapy vectors push the market opportunity over $5B.

TECHNICAL & COMPETITIVE ADVANTAGE

Pancreatic cancer has a 5-year survival rate of 10%, lower than any other major cancer. Survival rates go up dramatically if the tumor can be removed surgically, but unfortunately, only 15% of these patients are eligible for surgery. Another 40% of patients, those with locally advanced non-resectable tumors, could benefit from the higher survival rates if their tumors could be shrunk to the point where they would now qualify for this surgery. This is where ACT's drug delivery system comes in. The company's iontophoresis delivery system creates both electroosmotic and electroconductive flow of drug deep into the tumor that overcomes the tumors traditional defense mechanisms, leading to tumor cell death. ACT has shown that delivery of chemotherapy with the iontophoretic delivery system shrinks tumors in PDX models better than any other treatment ever tested. ACT expects that treatment with their drug delivery system will lead to more patients becoming eligible for surgery, increasing survival.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

ACT held a Pre-Sub meeting with the FDA and agreed on the 505(b)2 regulatory path for its pancreatic cancer indication and on a modest clinical program with less than 300 total patients required. The Phase 1b study, scheduled to begin in 2023, will evaluate safety in a traditional dose escalation format to confirm the therapeutic dose, followed by a randomized trial to show improved outcomes. ACT has an exclusive world-wide license for IP from the UNC for IP covering the use of an iontophoresis device for delivery of therapeutics inside the body (issued in 12 countries).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q2-2023	Completing of pre-clinical studies and submission of IND
Q4-2023	Initiation of Phase 1B clinical trial (first patient enrolled)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2014-17	Seed	Initial infusion of capital by early investors	$840K
2018, 2021	NIH Fasttrack, Phase IIB grants	Preclinical development in preparation for IND/Complete pre-clinical, start trial	$2.1M, $4M
2018	NC Biotech Center Loan	Economic development loan (unsecured)	$250K
2020	Series A	Investment by Khosla Ventures and Spectrum Financial	$8M
2022	Series A follow-on	Follow-on Series A investment by Khosla Ventures	$3.6M

USE OF PROCEEDS

ACT is seeking $20M to complete Phase 1b dose escalation trial and fund development in three new indications.

KEY TEAM MEMBERS

Tony Voiers: CEO, 30+ years' experience in medical device and pharmaceutical development
Bill Daunch, PhD: CTO, 25+ years' experience in medical device and material science development

ERNEST PHARMACEUTICALS

Engineering bacteria to treat solid tumors

Nele Van Dessel | vandessel@ernestpharma.com | 413-561-6043 | ernestpharma.com

COMPANY OVERVIEW

There is a critical unmet need for the treatment of most solid tumors, with a cost of $107B to the US healthcare system every year. Ernest Pharmaceuticals is developing a bacterial drug delivery system that can release biologics directly into the cancer cell cytoplasm of solid malignancies. Therapeutic bacteria have unique properties that enable them to treat metastatic disease and inoperable tumors. These organisms are motile and actively penetrate tumor tissue. In contrast, chemotherapeutic molecules poorly penetrate tissue, which leaves large regions untreated and is a primary cause of patient mortality. Active motility will overcome these intrinsic transport barriers.

MARKET & COMMERCIALIZATION STRATEGY

Ernest's commercialization strategy is two-fold: 1) Licensing/co-development of the delivery platform for partnered compounds and 2) In-house development of Ernest's own bacterial therapies. For its own pipeline, Ernest Pharmaceuticals is focusing on hard-to-treat tumors, such as liver and pancreatic cancer, which have a five-year overall survival of 11% and 3%, with a yearly cost of $1.03B and $3.71B to the US healthcare system, respectively.

TECHNICAL & COMPETITIVE ADVANTAGE

Ernest's bacterial delivery platform is based on an attenuated Salmonella strain that produces biological therapeutics in situ, invades cancer cells in solid tumors and delivers the protein directly into the cancer cell cytoplasm. Salmonella have the inherent capacity to home to tumors specifically, thus sparing normal tissues. Once in tumors, bacteria produce the therapeutic payload in situ, preventing off-target side effects and degradation of the payload in the blood. The bacteria are then triggered to invade, actively passing the cell membrane barrier, and to release the therapeutic cargo directly into the cytosol, bypassing endosomal uptake. This specific cytosolic release enables the targeting of several intracellular pathways that are currently undruggable. The bacterial vector can also colonize both primary tumors and metastasis and can treat the full tumor burden of a patient.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Ernest Pharmaceuticals is currently in the preclinical phase of drug development and preparing for an FDA INTERACT meeting. A drug candidate has been determined for liver cancer and the start of IND-enabling studies is set for 2023. An IND application for EBT-302, Ernest's pipeline candidate for liver cancer, will be filed in 2025. Ernest has exclusive license terms with UMass Amherst for the patent US20170333490A1 which contains the foundational bacterial delivery technology. The license also covers three PCT filing in prosecution, containing the vector improvements, and a provisional for a new immune strategy.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	Toxicology and biodistribution of the bacterial delivery platform
2021	Development third generation delivery vector – Strain selected for clinical development
2023-2024	IND-enabling studies
2024	Pre-IND meeting with FDA
2025	Filing IND

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Grant	NSF Phase I SBIR (1819794)	$225K
2018	Grant	NIH Phase I SBIR 1R43CA233136-01	$223K
2020	Grant	NIH Phase I SBIR 1R43CA250941-01A1	$284K
2020	Grant	NSF Phase II SBIR (2035560)	$1M

USE OF PROCEEDS

Ernest is raising a Series A round of $17M to execute IND-enabling studies and complete GMP manufacturing of EBT-302. This will result in an IND filing in 2025 and the start of a Phase I clinical trial.

KEY TEAM MEMBERS

Nele Van Dessel, Ph.D.: Co-founder and CEO, Co-inventor of the foundational technology; Bio-engineer by training; Ph.D. in biomedical sciences at the KULeuven, Belgium; Part of MassConnect program in 2019 and of MassNextGen in 2020

Neil Forbes, Ph.D.: Co-founder and Scientific Advisor, Professor of Chemical Engineering at UMass Amherst since 2003. For more than 20 years, Dr. Forbes' primary research focus has been determining the mechanisms of bacterial tumor targeting, and he is one of the world leaders in this field

John Ketchum, MBA: Business Advisor, John has 30+ years' experience in the biomedical space, including 28 years working for large pharmaceutical companies (GSK and Novartis), mostly in oncology

FILTRO MEDICAL

Intra-vascular catheter filtration device to reduce Dox Tox

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COMPANY OVERVIEW

Intravenous dosing of drugs for cancer chemotherapy is limited by systemic toxicity. Currently, the only way to remove drugs from the blood are through natural metabolism or costly measures such as dialysis. Intra-arterial chemotherapy (IAC) is performed in interventional radiology (IR), enabling direct delivery of chemotherapy to tumors by guiding micro-catheters into the arteries feeding these tumors. IAC with Doxorubicin (Dox) has proven to be a successful method demonstrating mortality benefit in randomized controlled trials for treating non-operative primary liver cancer, the third leading cause of cancer deaths worldwide, due to its ability to maximize drug dosage to tumor while limiting systemic dose and toxicity. Nonetheless, up to 50% of the chemo in IAC escapes the tumor and causes toxicity, such as heart failure, thereby limiting high-dose Dox therapy. Filtro is developing the ChemoFilter™ (CF), an intra-vascular catheter filtration device that would be percutaneously placed within the vein draining the organ undergoing IAC in order to capture this escaping chemotherapy from the bloodstream.

MARKET & COMMERCIALIZATION STRATEGY

Primary liver cancer is an attractive initial market with low barriers to entry and clinical adoption since TACE is the standard of care for patients with unresectable liver cancer. The worldwide market is estimated to be $1.5 billion. The secondary liver cancer (metastasis) market is estimated to be an additional $1.7 billion. Reducing systemic toxicity has the potential of enabling relatively high dose (2-4x) drug delivery. This value proposition offers a clear advantage for patients, physicians, and payors compared to existing therapies in the IAC sphere. This would maximize tumor response since Dox is known to be linearly effective at higher doses and reduce the required number of procedures by nearly 50%. As a result of improved tumor response and decreases number of procedures the CF is expected to reduce cost burden to the healthcare system by nearly $1 billion.

TECHNICAL & COMPETITIVE ADVANTAGE

Filtro has successfully completed proof of concept demonstrating the capture of the chemotherapeutic agent Doxorubicin. In the bench model, results demonstrated the resin successfully cleared the Dox by 92%. Additionally, simulated hepatic intra-arterial chemotherapy infusions performed in six pigs along with the use for the DF device demonstrated a reduction in toxicity of up to 50% in major organs.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Filtro intends to apply for a De Novo 510(k) and Breakthrough Device Designation. Filtro has an exclusive license for the ChemoFilter technology from the University of California San Francisco. Patents have been issued in various countries, including the US, Japan, China, Germany, France, and Great Britain.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	Proof of concept, Ref. C Yee et al. Radiology: Imaging Center 2019.
Q4 2022	Preclinical animal study
Q1 2024	First-in-Human

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	NIH (NCI) STTR Fasttrack	Endovascular ChemoFilter to Reduce Doxorubicin Toxicity during Intra-Arterial Chemotherapy	$2.4M

USE OF PROCEEDS

Filtro is in a strong position to introduce a clinically and commercially impactful product. Filtro has been awarded $2.4 million from the NIH with the aim of completing a First-in-Human study. The company is raising up to $750k in supplemental financing using a SAFE instrument for discretionary spending.

KEY TEAM MEMBERS

Steve Hetts, MD: Co-Founder, Clinical Advisor, Principal Investigator, Professor and Chief Interventional Neuroradiology, UCSF; Co-inventor of the ChemoFilter device; Extensive experience in endovascular therapies for stroke, aneurysms, vascular malformations, and tumors of the brain, spine, head and neck

James Hong: Co-Founder, CEO & President, 20+ years' R&D and executive management experience; Former CEO of Solinas Medical, R&D consultant at Sadra Medical, and Director of R&D at Arbor Surgical Technologies

Al Chin, MD: Co-Founder, Engineering and Technical Advisor, Co-inventor of the ChemoFilter device; 40-year history in medical device development; Co-founder of Origin Medsystems and Pavilion Medical Innovations; Has developed products generating $3.2 billion+ in revenue

PRIVO TECHNOLOGIES, INC.

Nano-engineered topical mucoadhesive patch platform

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COMPANY OVERVIEW

Privo has developed a nanoengineered platform, PRVTM, to make the mechanism of action of potent but toxic drugs safe and more effective. Privo's initial product is a topical transmucosal patch (PRV111) for the treatment of oral cancer. When placed on the tumor, PRV111 releases and retains high concentration of cisplatin-loaded nanoparticles (NPs) into the tumor. PRV111 consists of a mucoadhesive polymeric patch with embedded cisplatin-loaded NPs and a non-permeable backing that facilitates unidirectional drug release, prevents drug loss, and masks taste. PRV211 is a similar product to the PRV111, however it is intended for surgery (solid tumors) and therefore is sterile. The intraoperative patches can be customized to the size of the tumor bed, and several can be tiled over the areas where margins might be positive (near organs, bones, and arteries). For oral cancer patients with late stage (3/4) tumors that require surgery, PRV211 patches can be applied directly to the resected tumor bed to eliminate remaining tumor cells left behind, preventing micrometastases.

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 around 50%. Both conventional treatments and newer immunotherapies suffer from severe side effects, limiting their efficacy. In head and neck cancer alone, the US addressable patient population for PRV111 and PRV211 is approximately 80,000 patients annually, with a market potential of $900M-$1,000M 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 >80% physician adoption and a 95% positive perception of therapies. Privo is interested in out-licensing PRV111 and PRV211 to regional partners. Parties have already expressed substantial interest in licensing PRV111 and PRV211 for different geographic regions and indications.

TECHNICAL & COMPETITIVE ADVANTAGE

In a Phase I/II trial treating subjects with oral cavity cancer, 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 (265x higher than systemic therapy) and locoregional lymph nodes (162x higher than systemic therapy) and did not enter systemic circulation (700x lower than systemic therapy). This technology is capable of combination 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 NPs must penetrate deeply to destroy all cancer cells. Privo's permeation enhancer (PE) is composed of a proprietary bile salt mixture that is applied to the tumor surface prior to patch application. The PE primes the tumor area for deeper permeation of cisplatin NPs.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The regulatory strategy for PRV111 is an NDA filed via the 505(b)(2) pathway. This 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 3 issued patents (owned solely by Privo), that are sufficiently broad in scope to allow for various APIs and indications.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Nov. 2017	IND Approval
July 2020	Completion of Phase I/II Clinical Study
Feb. 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 & 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 1/2 trial and $22M for PRV 111's Phase 3 pivotal registration trial and NDA submission.

KEY TEAM MEMBERS

Manijeh Goldberg, PhD, MBA, MS: CEO, 25+ years' industry experience; has taken several healthcare products from concept to commercialization

Nishant Agrawal, MD: CMO, Director of Head and Neck Surgical Oncology at the University of Chicago Medicine

Charlie Morris, MD: Interim CMO, Oncologist with 30+ years in drug development; has contributed to several blockbuster drugs from AstraZeneca

RISE THERAPEUTICS, LLC

Leveraging the microbiome to develop novel immune medicines

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COMPANY OVERVIEW

Rise Therapeutics, LLC is an emerging, privately held company located in Rockville, Maryland which leverages its expertise in microbiome and immunological drug development to create cutting edge prescription therapies. With operations starting in 2017 and internal clinical GMP manufacturing infrastructure coming online in 2021, Rise Therapeutics is focused on developing targeted immunological-based biological therapies using a unique and proprietary oral biologics delivery platform. Rise utilizes new microbiome discoveries to develop innovative, first-in-class immune modulatory drugs for the treatment of inflammation, autoimmunity, cancer, and infection. These disease areas represent an enormous unmet need. Unlike traditional biological therapies which require injection or infusion, our delivery platform allows simple, convenient, and cost-effective oral delivery.

MARKET & COMMERCIALIZATION STRATEGY

Rise Therapeutics' exit plan is based upon multiple platform technology licenses and asset-centric acquisitions by pharma companies eager to catch up or build on to their existing product portfolios. The company's oral biologics delivery platform can support multiple drug product opportunities focused on microbiome-based targets. Rise currently has 4 assets (drug candidates), R-3750, R-2487, R-5780 and R-4329, which are focused on treating IBD, autoimmunity, cancer, and C. difficile infection, respectively. Exits will be driven by each asset with the first possible exit targeted within three years (2025), following early clinical readouts of our first in human clinical trial with R-3750. Comparable deals include 1) Delinia acquisition by Celgene-$300M upfront/$475M in milestone payments and 2) Necktar partnership with Eli Lilly-$150M upfront/$250M in milestone payments, and Padion acquisition by Merck for an astounding $1.8B. All three of these programs were Phase 1 clinical stage highlighting the value of emerging technology and drug candidates.

TECHNICAL & COMPETITIVE ADVANTAGE

TriPartite X (TPX) is the cornerstone platform technology that enables Rise Therapeutics to package and deliver synthetic biology- based therapies orally to the intestinal tract. The TPX expression operon was developed as a molecular solution to deploying a tailored composite, semi-synthetic promoter for suitable protein expression and delivery by select probiotic strains. This platform enables oral delivery of immunological-based, biological therapies via a novel DNA assembly approach which creates recombinant probiotics to escort targeted protein therapies to the site of action, the intestinal space. TPX is a large step forward in the context of biologics drug development, allowing the medical community to move away from regular injections and infusion strategies for biological therapies to a more convenient 'capsule-based' oral delivery perspective. Based upon the proprietary TPX oral delivery platform, Rise Therapeutics is developing four cutting edge products in areas of unmet medical need.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Currently, no synthetic biology-based drugs have been approved by the FDA, but several have been approved for early-stage clinical trials. There is an established process to move novel therapies of this class forward into clinical proof-of-concept studies, making this an attractive strategy for drug development. Unlike natural commensal strain therapies and genes that are found in nature and are not patentable, Rise Therapeutics' approach to redirect probiotic functionality represents a fertile framework in which to develop novel intellectual property, including strong composition and methods of use patent claims. This framework has enabled issuance of composition of matter and methods of use claims on all drug candidates. Moreover, Rise Therapeutics has issued claims on our TPX oral biologics delivery platform. Issued patents include Patent #9,452,205, #9,931,390, and #10,562,943.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q1 2023	Clinical trial initiation
Q3 2024	Completion of clinical trial

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017	Convertible note	Start-up Seed Funding	$200K
2021	NIH Grant	Phase I SBIR	$300K
2022	NIH Grant	Phase II SBIR	$2M

USE OF PROCEEDS

Rise is raising a $3 million Seed Round to support clinical enrollment for Phase 1 clinical proof-of-concept study of the lead therapy.

KEY TEAM MEMBERS

Gary Fanger, PhD: Founder, President & CEO, 20+ years in biotech industry developing novel therapeutics, establishing drug development alliances, and leading M&A activities

Christian Furlan Freguia, PhD: VP of Research, 10+ years in biotech sector with successful track record in developing new drugs/translating programs to human clinical trials

Sathya Janardhanan, MS: VP of Product Development & Manufacturing, 10+ years in setting up drug development programs and progressing those programs into Phase I and Phase II clinical trials

EARLYDIAGNOSTICS INC.

Detecting and Locating Cancer Early

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COMPANY OVERVIEW

EarlyDx is a seed-stage company co-founded in 2017 by professors and big data experts from UCLA and Stanford University. The company is devoted to providing accurate, affordable, and non-invasive liquid biopsy products for early cancer detection. EarlyDx owns IPs on both assay technology and computational algorithms. The company's assay technology can enrich methylation-informative cell-free DNA (cfDNA) fragments from a tube of blood and simultaneously provide multiple epigenomic and genomic features. The company's ensemble machine learning algorithm integrates all features for cancer classification. EarlyDx's MethylScan test, at the specificity of 97.9%, achieves a sensitivity of 85.9% in detecting all-stage cancers (colon, lung, liver, stomach) and a sensitivity of 81.4% in detecting early-stage (I and II) cancers.

MARKET & COMMERCIALIZATION STRATEGY

The company's lead product, MethylScan test, targets the early cancer diagnosis market. The global cancer diagnostics market is projected to grow at a compound annual growth rate (CAGR) of 7.0% and reach $249 billion by 2026. The early diagnosis market is experiencing the most rapid growth but largely remains unaddressed. The simple, non-invasive, and cost-effective nature of a cfDNA test is superior to imaging-based modalities, which require expensive instruments and have risks from radiation exposure. EarlyDx will adapt a decentralized testing and centralized data processing/reporting model for its business—the company will distribute its testing kit to customers through partners and provide a diagnostic cloud-computing platform for data processing and result reporting. The distributed MethylScan test is expected to bring in revenue soon. Over time, mining data in the centralized platform will create many transformative products and become the major driver of revenue.

TECHNICAL & COMPETITIVE ADVANTAGE

EarlyDx provides a sample-to-result test and differentiates itself from its direct competitors through three advantages: 1) EarlyDx provides a proprietary assay for enriching methylation-informative cfDNA fragments; 2) EarlyDx's proprietary CancerLocator/CancerDetector algorithms maximize the information obtained from methylation patterns and provide a more accurate test; 3) The genome-wide data collected by MethylScan test can be used for multi-purpose data mining. EarlyDx Cloud, the data processing hub, has been integrated with the largest cancer research data collection—NCI Cancer Research Data Commons.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The company will first seek 510(k) regulatory approval of MethylScan test for two intended uses (HCC and lung cancer surveillance in at-risk patients) with available predicates/gold standard. After initial market penetration and clinical adoption, the company will seek De Novo pathway for the test's use for multi-cancer detection and tissue of origin localization. Proprietary rights are critical for EarlyDx to operate in the early diagnosis space. EarlyDx's patent portfolio (WO2019/006269, PCT/US2020/030298, EP3464644A1/CN110168099A/JP2019521673A, PCT/US2018/051160), co-owned with or exclusively licensed from UCLA, protect both its assay technology and computational algorithms.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4/2022	Launch clinical trial of indeterminate pulmonary nodules diagnosis in partner with a nationwide healthcare provider
Q1/2024	Report results of double-blind clinical study on early detection of HCC
Q1/2024	Report results of double-blind clinical study on early detection of lung cancer
Q2/2024	Launch laboratory developed test

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Pre-seed round	Angel investor / Venture capital	$2M
2020	Grant	NCI SBIR Phase I	$352K
2020	Seed round	Venture capitals	$5M
2021	Contract	NCI SBIR Phase I	$396K

USE OF PROCEEDS

EarlyDx plans to raise $10M to support a clinical trial with the nation's largest healthcare provider, build its own CLIA facilities, and establish partnerships to launch LDT and IVD applications.

KEY TEAM MEMBERS

Guanghui Hu: Co-CEO, EY Entrepreneur of the Year; 20+ years' experience in entrepreneurship, venture investment, and business management

Xianghong Jasmine Zhou: Co-founder & Co-CEO, Professor of Pathology and Lab Medicine at UCLA; big data expert

Xiaohui Ni: CTO, Extensive experience in assay development and cancer genomics, and was the main contributor of LungLB Test (LungLife AI)

LODESTONE BIOMEDICAL

Immediate detection of treatment response

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COMPANY OVERVIEW

Lodestone is developing an "Immunotherapy Response Indication System" (IRIS) as a platform technology for precisely profiling biomarker expression patterns in the tumor immune microenvironment (TIME). The company's goal is to track real-time responses within the TIME to immune checkpoint blockade in solid tumors, thus enabling the design of patient-specific treatment regimens. Lodestone's IRIS platform offers a path to identify and measure "response biomarkers" to a specific treatment, instead of detecting a "predictive biomarker". Predictive biomarkers are an essential cornerstone in Checkpoint inhibitor (CPI) immunotherapy; however, up to 50% of patients have CPI-resistant tumors and are unresponsive. Response biomarkers measured in the TIME inform the clinician within weeks about the success and failure of the CPI to activate the immune system.

MARKET & COMMERCIALIZATION STRATEGY

Lodestone's pre-clinical system already has the potential to generate first revenue. The data that the pre-clinical system provides is crucial for drug development and testing. Most importantly, existing methods of obtaining this type of data in mice are very labor intensive and costly. Lodestone's goal is to assist drug developers from early stages of development, through all stages of clinical testing, and finally to the individual patient. This early interaction with drug developers enables Lodestone to develop the right assays that customers need, in quality and functionality that is needed to make meaningful treatment decisions. Winning the beachhead market of drug developers as early adopters is a crucial steppingstone that will enable Lodestone to generate a constant source of revenue, get early customer feedback and become part of customers' preclinical and clinical testing strategy.

TECHNICAL & COMPETITIVE ADVANTAGE

Lodestone has developed a novel system of implantable biosensor probes containing antibody-functionalized magnetic nanoparticles (fMNP), and a reader that uses human-safe AC magnetic fields, to achieve real-time monitoring of extracellular signaling proteins within the TIME. The IRIS platform combines two innovative components: a fully encapsulated, wireless, unpowered, biosensor containing fMNP; and a spectroscopic AC susceptibility reader device to non-invasively assay the expression levels of targets. Lodestone technology can support more frequent readouts, both systemic and local tissue level monitoring with multiple biosensors, and in vivo real time readouts. It is also noninvasive compared to the invasive technologies that currently exist (repeated blood draws, biopsies). Most importantly, Lodestone's IRIS platform can be used in a pre-clinical and clinical setting.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

IRIS is likely to be viewed by FDA as a combination (device/drug) product, with the device component as the Primary Mode of Action. The core element of the clinical product development strategy is the repurposing of an FDA-approved class 2 microdialysis catheter and implementing Lodestone's IRIS technology into the catheter tip. Lodestone has a proprietary nanoparticle system for in vivo molecular assays that overcomes several previously unsolved technical barriers, and two issued patents for cost-effective reader (licensed from Dartmouth College) that overcome the economic barrier.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020 & 2021	In Vitro capabilities & In Vivo capabilities/nanogram detection
In process 2022	Second generation Scanner
Planned for 2023	Signal Amplification Method/picogram detection & First sale

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017-2022	Seed Funding	Sum of all seed funding rounds	$1.525M
2021-2022	SBIR Ph 1 & Ph II	"In Vivo Pharmacotyping of Combination Therapy in Primary Brain Tumors" – NIH (NCI)	$2.4M
2022	Technology Impact Award	Yale-Lodestone collaboration/Cancer Research Institute	$200K

USE OF PROCEEDS

Lodestone is seeking $5M to convert office space into lab space ($1-$2M), $1M for equipment, and $2M for four years of salaries.

KEY TEAM MEMBERS

Solomon Diamond, PhD: CEO, 20 years' experience in medical imaging R&D; Associate Professor of Engineering at Dartmouth and Member of the Translational Engineering in Cancer Research Program at the Dartmouth-Hitchcock Medical Center; 50+ publications, 3600 citations, 8 US patents

Christian Knopke, PhD: COO, PhD at Physikalisch-Technische Bundesanstalt focusing on quantitative detection of magnetic nanoparticles in biological samples

Lisa Nguyen, BS: Biomedical Engineer, Expertise in patent examination (previously at USPTO); Worked extensively with bioassays in the life sciences/academic research

OPENCELL TECHNOLOGIES

Transfection and biomedical device manufacturer

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COMPANY OVERVIEW

OpenCell Technologies develops efficient, high-throughput, and scalable transfection devices for applications in cell and gene therapy. By combining acoustic shear poration to mechanically disrupt the cell membrane, with electrophoretic action to drive payload delivery, OpenCell's proprietary POROS platform provides a gentler alternative to traditional macromolecular delivery methods. POROS features precise control of biophysical actions on a single-cell basis and has enabled the delivery of a range of payloads into hard-to-transfect cells. OpenCell is developing a high-throughput, continuous flow system to address these limitations in the production of chimeric antigen receptor (CAR) T-cells for cancer therapy. POROS has also demonstrated unique advantages for simultaneous delivery of multiple payloads (protein/gene, gene/gene).

MARKET & COMMERCIALIZATION STRATEGY

OpenCell has identified the transfection market ($7.86B) as the primary commercial opportunity for the POROS platform. While biochemical transfection methods comprise the majority of the market, viral and physical transfection methods have shown higher growth rates recently (9% and 8% CAGR, respectively). Development of GMP-grade viral vector manufacturing capacity continues to hinder marketplace adoption of viral transfection (>18 months for development). OpenCell's technology uniquely addresses market need with the combined approach of physical membrane disruption and enhanced electrophoretic molecular delivery. OpenCell has worked with multiple strategic partners to incorporate the POROS platform into cell and gene editing workflows. POROS has inherent scalability, requires no specialized buffers, and enables complex molecule delivery. OpenCell is developing a continuous flow POROS device for clinical volumes (>100 mL, 1x108 cells/mL) to demonstrate superior CAR-T production.

TECHNICAL & COMPETITIVE ADVANTAGE

Standard methods for uniform delivery of DNA and RNA into difficult-to-transfect cells are neither robust nor scalable. POROS performance is competitive with current biochemical (Lipofectamine) and electroporation (MaxCyte's Flow Electroporation, Lonza's Nucleofector) systems but offers greater reagent/payload flexibility and greater cell viability. Electroporation requires high-amplitude electric fields to temporarily porate the cells resulting in low cell viability (<30% in some cases). Chemical methods are gentler by comparison but have shown poor performance. The POROS platform uses focused ultrasound waves (0.5-3.0 MHz) to create 100-150 nm sized membrane pores through acoustic shear poration (ASP). ASP has been shown to enable genetic modification of primary T cells and maintain high cell viability (>70%). POROS is the only patented micro-electromechanical systems technology that uses coordinated mechanical and electrical forces for enhanced biomolecule delivery.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Development of the next-generation POROS device will be in conjunction with Veranex. Final production devices upon delivery will have undergone GMP-compliant manufacturing. Specific regulatory strategy and device application will be finalized after securing a strategic partner(s). OpenCell has 11 issued patents covering acoustic shear poration, transfection using acoustic shear poration, combined operation with electrophoretic drive, and acoustically driven micromachined atomizers.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2022	Close Series B financing
2023	Partner with large-scale biotechnology company(s) & Complete high-throughput, next-gen POROS device
Q1 2024	Demonstrate clinical volume production of CAR-T cells

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2010	Grant	STTR, NSF	$225K
2019	Strategic Partnership	Strategic Partner (Large biopharma)	$75K
2015 & 2020	Venture	Common Place Holdings & Synchrony Bio; BioGenerator	$250K/125K
2009-2022	Grants	SBIR Phase I and II – NIH (NCI)	$3.4M

USE OF PROCEEDS

OpenCell is raising $5 million to complete the next-generation POROS platform capable of continuous flow operation at clinical volumes, hire additional full-time employees, and expand relationships with active strategic partners.

KEY TEAM MEMBERS

J. Mark Meacham, PhD: Founder, Technical Advisor, Assoc. Prof. in Mechanical Engineering/Materials Science, Washington U St. Louis
Michael M. Binkley, PhD: Director of Engineering, Mechanical Engineering Doctorate, Washington U St. Louis
Paul Olivo, MD, PhD: Scientific Advisor, Medical Product Development Expert

PRECYTE, INC.

Elevating Blood-based Diagnostics Using Cells as Biosensors

Jennifer Smith | jennifer@precyte.net | 206-920-4347 | precyte.net

COMPANY OVERVIEW

PreCyte has developed a broadly applicable and inexpensive assay for use in blood-based diagnostics (the Indicator Cell Assay Platform, or iCAP), with lead application in lung cancer (LC), the leading cause of US cancer death. CT screening improves survival but has a 94% false positive rate. PreCyte is developing a test (LC-iCAP) with greater specificity than CT to assess patients with indeterminate post-CT cancer risk, enabling patients with benign nodules to avoid invasive biopsy. The company is also developing a test to improve Alzheimer's drugs and has plans to develop tests for early detection of lung and other cancers and for detecting tumor hypoxia. Unlike traditional assays that rely on direct detection of molecules in blood, the iCAP uses cultured cells as biosensors, capitalizing on the natural ability of cells to detect and respond differently to signals present in serum. To develop the iCAP, Precyte exposes standardized cultured cells to serum from normal or diseased subjects, measures differential gene expression of the cells, and develops a model to distinguish disease from normal.

MARKET & COMMERCIALIZATION STRATEGY

The 1.3 million US patients with intermediate-risk nodules identified by CT scan per year would benefit from LC-iCAP. With full uptake of USPSTF CT screening recommendations, that number would be >4 million. With an LC-iCAP priced at ~$1.5K (below competitive tests), the potential US market alone is almost $2B. The assay will be commercialized as a laboratory developed test (LDT) under the Clinical Laboratory Improvement Act (CLIA) through a direct sales force or a distributor or by licensing the assay to an existing reference or specialty lab provider.

TECHNICAL & COMPETITIVE ADVANTAGE

By using cells as biosensors, the iCAP overcomes such barriers to developing blood-based diagnostics as broad dynamic range of blood components, low abundance of specific markers, and high levels of noise. LC-iCAP has better performance than currently marketed blood tests and would rescue 16-27% more patients (vs. competitors) with benign nodules from invasive follow-up testing, with no increase in false negatives. Additionally, unlike competitive blood tests, LC-iCAP has significant diagnostic performance independent of CT data, which suggests utility of the assay as a screening tool before CT scan, reducing radiation exposure and improving patient compliance with recommended LC screening. General advantages of iCAP include: 1) knowledge of the disease pathway is not required, 2) cells detect multiple types of molecules or combinations thereof, 3) iCAP is extendable to other hard-to-diagnose diseases, and 4) iCAP avoids existing biomarker IP because the readout is from biosensors and not from patient samples.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

PreCyte plans to launch the LC-iCAP as an LDT in a CLIA-certified lab. LDTs do not require FDA clearance, but the company has IRB oversight and will publish rigorous clinical validation studies to drive reimbursement, educate KOLs and generate demand. For Medicare reimbursement they will use a custom Category I code number with comparison code 0080U (Biodesix Nodify XL2), or 0092U (Magarray Reveal). iCAP's cell-based readout avoids existing patient biomarker IP and provides freedom to operate. PreCyte has filed a PCT international application with broad claims and a June 2020 priority date (based on US provisional). PreCyte plans to apply for continuations in US/Europe in Dec 2022.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2022	Complete analytical validation of LC-iCAP/ Raise $1MM seed funding
Q1 & Q3 2023	Publish analytical validation of LC-iCAP / Publish external validation of LC-iCAP/Raise $2MM Series A
Q2 2024	Commercial launch of LC-iCAP based on external validation
Q3 2025	Clinical validation of LC-iCAP (prospective observational)/ Raise $10MM Series B

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015/18	NIA SBIR Ph II/IIB	Optimization and validation of an indicator cell assay for early detection of Alzheimer's	$2MM/$3MM
2017	NIA SBIR Phase I	Rational drug selection for Alzheimer's disease using Indicator Cell Assay Platform	$300K
2016/18	NCI SBIR Phase I/II	Optimization and validation of an indicator cell assay for lung cancer	$300K/$2M

USE OF PROCEEDS

PreCyte is seeking ~$1 million to support a one-year external validation study, initiate an observational clinical validation study, and build the team.

KEY TEAM MEMBERS

Jennifer Smith, PhD: President, CSO, and Co-founder, 25+ years' experience in cell and systems biology

Robert Lunbeck, MBA: CBO, 25+ years' experience in business development and finance in life sciences and health care

Rob Lipshutz, PhD: Co-founder, Chairman of Board, Consultant, 25+ years' experience in molecular diagnostics/business development; led commercialization of first FDA-approved microarrays

PROTEIOS TECHNOLOGY, INC.

Enabling the discovery and manufacturing of advanced therapeutics

Bob Snyder | bob@proteios.com | 206-530-7577 | proteios.com

COMPANY OVERVIEW

Proteios is a spin-out from the University of Washington based on a superior patented affinity tag used for the purification of recombinant proteins. Proteios has incorporated the affinity tag into a proprietary, tag-free platform for the multivariate (parallel) purification of any biological, including cell subpopulations, antibodies, and viruses. The Proteios Chimera Platform is scalable from research to industrial for manufacturing and provides a common platform for the discovery and efficient manufacturing of advanced therapeutics.

MARKET & COMMERCIALIZATION STRATEGY

The global CAR-T market has grown exponentially since the first CAR-T approval reached the market in 2017. Autologous CAR-T cells are expensive to produce because they are manufactured on a patient-by-patient basis; the high cost of CAR-T cell therapies is primarily due to lower yield and high cost of cell isolation. The global market size for cell therapies is expected to reach $21 billion by 2028 with a CAGR of 20.4%. Proteios' commercialization strategy is to serve the cell therapy research market with novel cell isolation kits, and leverage R&D validations by introducing automated solutions for cell therapy manufacturing.

TECHNICAL & COMPETITIVE ADVANTAGE

Proteios has developed the Chimera Platform for the parallel isolation of any biological. It is a high-performance, cost-effective alternative to antibody-based and flow-based methods and is scalable from Research to Manufacturing and Diagnostics.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Proteios will be seeking 510(k) clearance from the FDA to demonstrate their cell therapy manufacturing device and consumables are safe and effective and substantially equivalent to the Miltenyi Biotec Prodigy. Proteios has an exclusive license from the University of Washington for recombinant protein/biopharmaceutical purification, and is currently developing IP to isolate other biologicals (e.g., T cells (i.e., CD4+, CD8+, CD19+, CD34+, etc.), NK cells (i.e., CD3+, CD56+, etc.), stem cells, antibodies, and viruses).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2022	Fully-automated, closed bench-scale prototype completed for the end-to-end manufacturing of autologous cell therapies
2022	Commercial launch of research-scale recombinant protein purification kits
2023	Commercial licensing of affinity tag for industrial-scale recombinant biopharmaceutical purification
2024	Commercial launch of research-scale cell isolation kits for T cell and NK cell subpopulations to enable cell therapy discovery
2024	Commercial launch of research-scale recombinant antibody purification kits
2026	Commercial launch of fully-automated, closed system for end-to-end autologous cell therapy manufacturing

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015	CoMotion Innovation Fund Grant	Transition technology following the conclusion of academic research grants	$50K
2018	NSF SBIR Phase I Grant	Removing the Purification Bottleneck in Biopharmaceutical Production	$225K
2019	NIH SBIR Phase I Grant	Simple and Effective Method for Cell Enrichment/Cell Depletion During Cell Therapy	$224K
2020	NSF SBIR Phase II Grant	Removing the Purification Bottleneck in Biopharmaceutical Production	$950K
2021	NCI SBIR Phase I Contract	Development a Bench-Scale Prototype for Autologous Cell Therapy Manufacturing	$455K
2022	NIH SBIR Phase II Grant	Simple and Effective Method for Cell Enrichment/Cell Depletion During Cell Therapy	$1.73M

USE OF PROCEEDS

Proteios is seeking $7.5M Series A funding in 2023 to: 1) develop and launch research-scale cell isolation kits, 2) develop and launch research-scale antibody purification kits, 3) gain regulatory approval and launch biopharmaceutical purification for manufacturing, and 4) supplement pending NCI SBIR Phase II contract to develop an at-scale cell therapy manufacturing device.

KEY TEAM MEMBERS

Bob Snyder, PhD, MBA: Co-Founder & Managing Director, 30+ years' experience in life science research and commercialization

François Baneyx, PhD: Co-Founder and Scientific Advisor, Professor of Chemical Engineering, Director of CoMotion, and Vice Provost for Innovation, University of Washington

Alessio Ligabue, PhD: Principal Scientist, Primary focus on cell separation & cell therapy manufacturing

CLARIX IMAGING

Bringing True 3D Clarity to Specimen Imaging

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COMPANY OVERVIEW

Clarix Imaging, a revenue-generating medical technology company, is transforming surgical oncology and pathology by developing the Volumetric Specimen Imaging (VSI) platform, which generates true 3D images of surgical specimens with unprecedented clarity in real-time using unique image reconstruction algorithms. The company is initially targeting breast cancer surgery with the FDA-cleared VSI-360™ for use intraoperatively during lumpectomy, a surgery to remove tumor from the breast, currently associated with high reoperation rates of 25% due to incomplete tumor resection (i.e., positive margin) during the initial surgery. VSI-360™ is portable and estimated to lower reoperation rates to less than 5%. The current gold standard of histopathology identifies positive margins days after the surgery while other intraoperative techniques produce inadequate image quality. The company's clinical data, published in the Annals of Surgical Oncology, demonstrated high correlation of VSI results to post-surgical pathology and superiority over currently used imaging methods. In the future, Clarix Imaging has plans to expand the software to visualize other cancer types. Clarix Imaging is currently raising $30M in a Series A round.

MARKET & COMMERCIALIZATION STRATEGY

Clarix's initial target market is intraoperative breast specimen imaging directly followed by pathology. The company has sold several systems and continues to pursue high-volume clinical users and large academic hospitals that are undergoing clinical evaluations. Clarix plans to exhibit at trade shows for breast surgeons and radiologists to generate new leads by showing demos of the technology, which has been proven to be effective in securing initial customers. Lumpectomy (Surgery): >330,000 lumpectomy surgeries are performed in the US annually. Lumpectomy is associated with a reoperation rate of 25% and utilization of our technology may reduce the rate to <5%. Breast Pathology: 9,000 pathology labs in the US analyze breast specimens. Clarix's technology generates images that can guide gross sampling, which can greatly lower labor cost and improve workflow over current palpation-guided approaches. Immediate Platform Expansions: Prostate cancer (240k+ patients), lung and bronchus cancer (230k+ patients), colorectum cancer (150k+ patients), liver cancer (40k+ patients) in the US with software development using the same core technology.

TECHNICAL & COMPETITIVE ADVANTAGE

Clarix's VSI is uniquely enabled by a breakthrough, Sparse-Data Imaging technology invented at University of Chicago by co-founder Prof. Xiaochuan Pan, a world-renowned imaging scientist with decades of pioneering research experience. Compared with conventional 3D imaging such as micro computed tomography (mCT), 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), prolonged imaging time (mCT), or incompatibility with existing practice (manually operated probes or injected contrast agent). The imaging data can be used to develop new software features that would further strengthen the capabilities of the platform to provide clinical and operational benefits.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

VSI-360™ has received a 510(k) clearance from the FDA to image excised specimens in 2D and 3D. The company will pursue a labeling expansion after successful outcomes from the ongoing 600-patient randomized, controlled study.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
12/2022	Generate >$2M revenue
12/2023	Complete randomized, prospective VIVID study
Q4 2023	Pre-IND Meeting

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
5/2018	Series Seed	$2.2M angel investment and $2.5M non-dilutive NCI SBIR Phase I & II grants	$4.7M
7/2020	Bridge Award	NCI SBIR Phase IIb and new Phase I grant	$4.5M
4/2022	Series Pre-A	Private investors and strategic partners	$7.8M

USE OF PROCEEDS

Clarix is raising a $30M Series A round to fund manufacturing, working capital, marketing/sales, and R&D for pipeline applications.

KEY TEAM MEMBERS

Xiao Han, PhD, Co-founder & CEO, Former University of Chicago Radiology faculty; 17-year R&D and organization-building experiences

Xiaochuan Pan, PhD, Co-founder & CSO, International opinion leader in medical imaging with 30 years' experience; professor at UChicago Radiology

Christian Wietholt, PhD, VP of Product Development, Translational medical imaging scientist with 20+ years' academic and industry experience; PhD in Biomedical Engineering from Marquette; former product manager at FEI, Inc, and Thermo Fisher Scientific

COOLER HEADS

Pioneering cancer side effect management

Kate Dilligan | kate@coolerheads.com | 858-361-9355 | coolerheads.com

COMPANY OVERVIEW

Hair loss (Chemotherapy Induced Alopecia, CIA) is cited as a leading adverse effect of chemotherapy among men and women and is considered among the most distressing problems. A February 2021 review of 27 publications showed that men and women reported the major impact that CIA had on their psychological well-being, quality of life, and body image. Hair loss had a negative impact irrespective of gender, which resulted in feelings of vulnerability and visibility of being a "cancer patient." Scalp cooling is proven to be an effective therapy to reduce CIA, but it is not widely adopted because the legacy systems require the patient to be in an infusion chair for twice the amount of time needed for their actual chemotherapy. Cooler Heads is bringing Amma to market, which is the first FDA cleared, patient administered, and portable device for scalp cooling, which eliminates excessive infusion center overhead for this therapy.

MARKET & COMMERCIALIZATION STRATEGY

Medicare released a CPT code with reimbursement of $1,850.50 for scalp cooling on January 1, 2022. Cooler Heads will sell the portable cooling unit to infusion centers for $15,000 as capital equipment and sell the cap system as disposables at $1,000 each. With this business model, infusion centers break even after only 17 patients, and then all dollars generated from this new revenue stream become incremental for them. Additionally, we will rent the devices directly to patients for $2,500. We have applied for a HCPCS code to get DME reimbursement for the direct to patient model.

TECHNICAL & COMPETITIVE ADVANTAGE

Cooler Heads has removed four hurdles that have hindered adoption: 1) cost to the infusion center - overcome by self-administration of cap fitting (cut nursing costs) and portability of station (not tying up valuable chair); 2) hair retention effectiveness - flexible cap eliminates gaps that give uneven hair retention results; 3) cost to patient or payer - $2,500 patient pay and $1,850.50 CPT reimbursement if administered by the infusion center; 4) FDA cleared product broadly available.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Amma is cleared by the FDA as a Class II medical device through the 510(k) process. The company's first patent was issued last year and they filed PCT applications in Mexico, Canada, Europe, China, South Korea, Japan, and Australia. The company has received notice that additional claims in the next patent have been allowed.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
June 2022	First patient using the device
October 2021	FDA cleared
October 2021	Patent issued
January 2021	Phase 1 SBIR awarded

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	Seed Round	Convertible note	$1.4M
2021	Phase 1 SBIR	NCI grant to fund human factors study	$210K
2020-2021	Pitch Awards	WFN winner and MedTech Innovator finalist	$55K
2021	Pre-A	Convertible note	$2.3M

USE OF PROCEEDS

Cooler Heads is raising a $10M Series A for 12% COGS, 39% engineering, 24% sales and marketing and 26% G&A.

KEY TEAM MEMBERS

Kate Dilligan, Founder & CEO, Kate founded Cooler Heads from her personal experience trying to cope with the overwhelming side effects of treatment for breast cancer. When she was diagnosed, Dilligan was an executive at a company she had helped found after graduating from the Stanford Graduate School of Business with her MBA

Ryan Denney, Chief Commercialization Officer, Ryan has built a successful career in the commercialization of medical devices over the past 25 years. His last company, Veran Medical Technologies, was acquired by Olympus for $340M. As the VP of Global Sales at Veran, Ryan was responsible for organizing a domestic and international commercial team

Dan Glazerman, Head of Engineering, Dan has over 25 years' experience in the Medical Device Industry, with proven management and leadership capabilities, and successful experience leading the LEAN and cultural transformation of an organization

LEUKO LABS INC.

Noninvasive white blood cell monitoring

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

COMPANY OVERVIEW

Every year in the US, 850,000 patients begin chemotherapy and 140,000 need to be hospitalized because of febrile neutropenia (FN), a condition where a patient's white blood cells (WBC) are critically low because of their chemotherapy, leaving them more susceptible to severe infections. FN hospitalizations bring negative clinical outcomes (7% mortality) and a total cost of $6.4B ($46k/case) in the US alone. To solve this unmet need, Leuko, an MIT spinout, 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 chemotherapy, Leuko aspires to continue growing to serve the 10 million immunocompromised US patients that could benefit from increased monitoring of their weakened immune system.

MARKET & COMMERCIALIZATION STRATEGY

By reducing FN-related hospitalizations by 50%, the total addressable market (TAM) is $3.2B/year in the US (140k hospitalizations x $46k/case x 50%). Leuko's commercialization strategy, informed by hundreds of customer interviews, focuses on developing partnerships with the 16 largest Integrated Delivery Networks (IDNs) and Accountable Care Organizations (ACOs) in the US, which treat a fourth of all addressable chemotherapy patients, representing a beachhead of $800M/year. These organizations are an ideal target because of their incentives to generate healthcare savings. Leuko projects 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 chemotherapy.

TECHNICAL & COMPETITIVE ADVANTAGE

PointCheckTM 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.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Leuko has worked with regulatory consultants (Hogan Lovells) and submitted a 513(g) request for classification to the FDA which confirmed a Class II De Novo regulatory pathway. The company conducted an in-person pre-submission meeting with the FDA in which they agreed on the intent for use 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. Our IP portfolio includes six patents: three issued, two applications and one provisional, including US and PCT filings. The first 3 patents were developed at MIT with whom the company has an exclusive licensing agreement.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	Pre-marketing & partnerships: Unmet need validation, >100 customer interviews, LOS from 5 hospitals, 1 insurer, 1 medical device distributor and 1 pharma company
2021	Phase II trial: Guided modifications for final device design (self-operated). Usability, safety & efficacy in 154 cancer patients
2022	Series A fundraising
2023	FDA De Novo Clearance

CAPITALIZATION HISTORY

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

USE OF PROCEEDS

Leuko is looking to raise a $5M Series A to support the following value-inflection milestones: Complete pivotal trial and FDA clearance, US commercial launch and label expansion to follow-on indications.

KEY TEAM MEMBERS

Carlos Castro-Gonzalez, PhD (Co-founder & Chief Executive Officer), >10-year experience in biomedical engineering. Innovation & entrepreneurship training at MIT. Prior med device startup experience

Ian Butterworth, MSc (Co-founder & Chief Technology Officer), >10-year experience in hardware prototyping, electronics and coding. MIT research engineer. Prior med device startup experience

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

MADORRA

Restoring Postmenopausal Quality of Life

Holly Rockweiler | holly@madorra.com | 314-239-3059 | madorra.com

COMPANY OVERVIEW

Madorra is developing devices to replace pharmaceuticals with better, safer solutions for unmet needs in women's health. Madorra's first product is a revolutionary treatment for vaginal atrophy with FDA Breakthrough Designation. The patented, prescription medical device will empower 9.5 million postmenopausal women and cancer survivors ($13B SAM) to improve their sexual health and quality of life by providing a solution that can treat their condition without the side effects and risks of hormone therapy (today's gold standard treatment). Madorra is building a foundation of clinical evidence including a year-long, sham-controlled trial that has demonstrated encouraging efficacy, safety, and patient engagement.

MARKET & COMMERCIALIZATION STRATEGY

Breast cancer survivors (BCS) have the largest unmet need and therefore represent Madorra's first target customer. The only effective treatment options for vaginal atrophy available today are hormone-based; yet hormone use is contraindicated for BCS because of the risk of cancer recurrence. BCS represent a large market segment in that there are 1.8 million breast cancer survivors in the US alone suffering from vaginal dryness ($2B market opportunity). After meeting the needs of the beachhead market, Madorra will expand into other market opportunities with postmenopausal women who are looking to avoid hormones. Madorra will commercialize the product as prescription from the gynecologist and will focus on clinical evidence generation and scientific presentations to create awareness and excitement. They will also do a limited amount of direct-to-consumer marketing to create a patient pull for the product and will utilize a small direct sales force to execute in-office and virtual detailing and follow up.

TECHNICAL & COMPETITIVE ADVANTAGE

The Madorra therapy is patented ultrasound technology with strong clinical data, and the company is working towards FDA clearance—three things that no other home-use device offers. Madorra also has first mover advantage and has strong advantages over the pharmaceutical companies making hormone-replacement therapies (e.g., Pfizer) and the lubricant and moisturizer manufacturers (e.g., K-Y, Replens brands). The solution will be more effective (with a better user experience) than lubricants and moisturizers. Emerging technologies in the "vaginal rejuvenation" space (laser and RF ablation, e.g., MonaLisa Touch) and other home-use products (e.g., Joylux, AVeta) are not FDA approved, lack robust clinical effectiveness data, and are not reimbursed.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Madorra has an FDA Breakthrough Device Designation and will pursue a De Novo clearance from the FDA. The company has significantly de-risked this pathway via three pre-sub meetings and by obtaining IDE approval to commence a Pivotal Trial in the US. Madorra has two granted patents and five pending. The Madorra name is also trademarked.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2022	Complete Pilot Study #2 & Raise Series B
Q4 2022	Commence pivotal trial planning
Q1 2023	Publish Pilot Study #1 in a peer-reviewed journal

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2014-15	Grants	Stanford, NSF, Other	$1M
2015+2017	2 seed rounds	Angel investors	$1.5M
2019	Series A	Priced round led by OneVentures and syndicated with micro VCs	$6.7M
2018	Grant	NIH SBIR Fast Track	$2.3M

USE OF PROCEEDS

Madorra is raising a $26M Series B to fund the pivotal trial and the company for 2.5 years. This funding will take the company through De Novo submission to the FDA, after which the company plans for a Series C or a partnership/acquisition.

KEY TEAM MEMBERS

Holly Rockweiler: CEO & Co-Founder, Extensive experience in medical device development, user-centric design, and feasibility research from her prior work at Boston Scientific and as a Stanford Biodesign Fellow; 15+ patents in the cardiovascular and women's health fields

Stephanie Kaplan, MBA: COO, Industrial engineer who helps companies transition from early-stage R&D to advanced manufacturing; 30+ years' experience in medical device/high-tech industries; prior leadership roles at Intuitive Surgical, Ardian, PowerVision, Sadra, Fox Hollow, and TyRx

Bryan Flaherty, PhD: CTO, 15 years' experience leading product development at start up medical device companies; 30+ years' experience in the industry and has held R&D leadership roles at successful medical device companies including Natus, Apieron, and Earlens

MALCOVA

Patient-Specific 3-D Breast Imaging

Peymon Ghazi, Ph.D. | peymon.ghazi@malcova.com | 916-835-0130 | malcova.com

COMPANY OVERVIEW

MALCOVA Inc. develops technologies for enhanced breast cancer detection to overcome the largest challenge in the field — reliable cancer detection and diagnostics in women with dense breast tissue (nearly half of the female population in the US). MALCOVA's technology is poised to solve this problem as the first safe and comfortable 3-D x-ray-based high quality imaging platform available to the breast cancer radiology market.

MARKET & COMMERCIALIZATION STRATEGY

MALCOVA's technology is needed in both major segments of Breast cancer radiology, Screening and Diagnostics, where women with dense breasts are highly underserved. Diagnostics, with a shorter regulatory pathway and high patient need, will be the company's entry point. MRI is the only high-quality 3-D option presently available for dense-breast imaging in this space. Comparatively, MALCOVA's technology requires a small fraction of the space and infrastructure, allows for 4x the patient throughput, provides a more comfortable imaging experience, and will be priced at an order of magnitude less. The company's peer-reviewed and published studies (simulation and phantom) validate the diagnostic performance of the technology. MALCOVA will conduct a pilot patient study (2024) at a partner hospital to evaluate the technology's performance. This will be followed by a small-scale clinical trial (2025). At the Radiological Society of North America (RSNA) in Q4 of 2026, the company plans to launch Sales.

TECHNICAL & COMPETITIVE ADVANTAGE

MALCOVA's proprietary solution is a patient-specific breast cancer imaging platform, and the auxiliary suite of tools for its optimal operation and QC. The output of a typical patient scan are high-quality 3D breast images. A scan is performed in a few seconds and without the need for contrast – rendering it several times faster (and for some women safer) than MRI. Images are acquired with the same low level of radiation dose as Mammography, but without any need for breast compression or pain.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

In communications with the FDA, MALCOVA has been notified that a small-scale PMA path is anticipated for entry to the diagnostic market. The clinical trial phase will be conducted at two different sites during Q1 2025 and Q1 2026, with an anticipated receipt of approval in Q3 of 2026. MALCOVA's technology is protected by 3 patents (2 issued, 1 pending) and is fully owned by MALCOVA.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2021	Scanner MVP completion and characterization
Q2 2022	Phantom MVP completion and characterization
Q2 2024	Pilot Validation Study in Patients
Q1 2025	Clinical Trial for Regulatory Pathway

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	NSF SBIR Phase I grant	(2014351) Narrow-beam breast computed tomography	$275K
2021	NIH SBIR Phase I contract	(75N91020C00055) Anthropomorphic breast phantoms for use in CT	$400K
2021	NIH SBIR Phase I grant	(R43CA261381) Patient-specific narrow-beam CT	$450K

USE OF PROCEEDS

MALCOVA aims to secure $7M by Q2 2023 and an additional $3-4M by Q1 2024. Initial funds will support expansion of the team, development of the scanner beta prototype, production of design files under design control, and contract manufacturing costs. Later funds will be used in support of all regulatory pathway, pilot and clinical trial expenses.

KEY TEAM MEMBERS

Peymon Ghazi, PhD: CO-Founder & CEO, Doctoral dissertation in breast cancer radiology; Deep expertise and long experience in the development of x-ray based medical imaging devices; Prior to launching MALCOVA, Dr. Ghazi worked in the medical devices industry in Silicon Valley

Tara Ghazi, PhD: Co-Founder & COO, Doctoral dissertation on human attention and short-term memory of spatial information; Experimental data scientist by training, she is re-envisioning the radiologist image viewing experience; Spend more than a decade in the Service sector, acquiring extensive management experience

Lynda Ikejimba, PhD: Director of R&D, Expert in medical physics; Worked in imaging regulatory sector of the FDA as a scientist and reviewer with specific experience in the regulation of Devices for Radiological applications; Experience in virtual clinical trial and project management

NAVIGATION SCIENCES, INC.

Real-Time Margin Measurement for Precision Cancer Surgery

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

COMPANY OVERVIEW

Navigation Sciences™ is a clinical-stage company developing the NaviSci™ System for the tissue conserving removal of lung cancer and other soft tissue tumors. The system integrates Augmented Reality (AR) 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

There are approximately 450,000 soft tissue cancer cases per year in the U.S., where Navigation's technology may provide benefits. These cancers include lung, liver, head and neck, thyroid, and brain, as well as breast cancer. The addressable U.S. market for Navigation's technology, including both systems and consumables is estimated at approximately $1.26 Billion. The company's lead application is lung cancer, where the potential to improve outcomes with early-stage detection and removal is particularly high, and the impact of delayed treatment on morbidity and mortality is severe. There are more than 76,000 cases of early-stage lung cancer in the U.S. annually. Although the total number of lung cancer patients has been decreasing, the number of early-stage diagnoses is growing annually and is expected to increase further because of the expanded use of CT X-ray screening and favorable CMS reimbursement coverage for high-risk 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 relationship to the surgical instrumentation and recommend where to excise the tumor. The system is the first to measure surgical margins in real-time enabling significantly enhanced precision in tissue resection.

The system consists of:

- An active fiducial marker (called a J-Bar) placed next to the tumor to localize and track its position as well as identify the shortest route of entry from the lung surface to the tumor nodule
- A surgical cutting instrument with a second position sensor
- Proprietary software that links the sensors on the J-Bar and cutting instruments and provides visual as well as quantitative information to measure tumor margins in real-time. The real-time measurements permit resection with a sufficient margin of lung tissue surrounding the tumor.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The NaviSci System is undergoing a 25-patient prospective clinical trial, initiated in Fall 2021, for treating early-stage lung cancer. The study is designed to support a Class II 510(k) submission to the FDA for US market clearance. The company has three issued patents and nonprovisional applications, securing seven exclusive features of the NaviSci System.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2022	Workflow enhancements based on the clinical feasibility trial & bronchoscope-based tissue marker
Q4 2022	User interface optimization and software development
Q1 2023	FDA 510k regulatory application

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Pre-Seed	Co-founders	$75K
2019-2021	Seed-Series B	Family Funds	$4.4M
2021	Grant	NIH (NCI) Phase I STTR	$324K

USE OF PROCEEDS

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

KEY TEAM MEMBERS

Alan Lucas: Co-Founder, CEO, Director 25+ years' experience in senior business development and marketing positions for MedTech companies

Raphael Bueno, MD: Co-Founder, Director, SAB Chair Chief of thoracic surgery at Brigham & Women's Hospital; Professor of Surgery, Harvard Medical School

Jayender Jagadeesan, PhD: Co-Founder, SAB Member Associate Professor of Radiology, Harvard Medical School; Research Associate, Brigham & Women's Hospital

SAVAGE MEDICAL

Novel device alternative to temporary diverting ostomies

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COMPANY OVERVIEW

Savage Medical, Inc is focused on colonic protection and founded by highly experienced medical device entrepreneurs. When the colon is damaged from disease (e.g., inflammation) or surgery (e.g., surgical resection and anastomosis), stool flowing within the damaged segment of bowel can further degrade tissues or lead to severe infections and even death. To prevent these issues, surgeons currently divert a proximal segment of bowel to the skin to form a protective ostomy, bypassing stool into an attached bag on the patient's abdomen. However, protective ostomies and ostomy reversal surgeries are associated with very high morbidity (>50%), significant mortality (1-2%), and drastic reductions in quality of life for patients. The ColoSeal™ ICD System eliminates the need for most protective ostomy surgeries by providing a simple, safe, and easily reversible device solution for fecal diversion. The initial indication for this device is rectal cancer, the most common form of colon cancer.

MARKET & COMMERCIALIZATION STRATEGY

Protection of the colon from fecal contamination is an under-appreciated whitespace with a more than $6 Billion worldwide market. The initial beachhead market targeted by the Savage ICD Device is patients with rectal cancer resection and primary anastomosis, an addressable annual US market of $318 million and $2.4 billion worldwide. Overall, the number of rectal cancer cases are increasing, with data from the WHO projecting an annual increase in incidence of 2.6% a year through 2025. Rectal cancer resections represent only one of many potential indications for the Savage Medical ICD Device. Savage's initial focus will be on colorectal surgeons at major cancer centers. The company anticipates that the study sites will become the initial commercial sites once FDA clearance is reached. Modelling shows revenue of $3M/sales rep averaging 50 devices/account. ASP $6K, gross margin of 95%. The system utilizes existing DRG's, NTAP application, ICD-PCS coding. The company has validated interest from strategics in this area.

TECHNICAL & COMPETITIVE ADVANTAGE

Other emerging technologies have two major shortcomings, poor anchoring consistency and/or traumatic anchoring that can lead to devastating complications. The Savage Medical technology overcomes all these obstacles with incredibly reliable and strong anchoring within the bowel that is completely safe and atraumatic. The technology uses a combination of novel seals, low negative pressure (<100mmHg), and specialized friction interface to create immovable anchoring that is both air and fluid tight. Protection can last up to 21 days (enough time for the bowel to heal itself) and device removal is easily performed in the clinic during routine follow-up. Currently, after low colon resections, most patients get a protective ostomy. By using the Savage device, these patients will no longer require an ostomy, eliminating the cost and complications associated with an ostomy and ostomy reversal surgeries. Payers save on average $65K per patient treated with this technology. Because of the safety profile, ease of use, and ability to be placed using a colonoscope without laparoscopy or laparotomy, this device has a wide range of other indications where colon protection is critical such as interventional/high-risk colonoscopies, diverticulitis, and Inflammatory bowel disease.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Savage is in discussion with FDA on the De Novo vs PMA pathway as they prepare the IDE submission. The company has been granted US and International patents for novel atraumatic anchoring mechanism and multiple additional patents for sealing mechanisms and delivery system have been submitted.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2022	Validation in over 31 Pigs, GLP Studies & Completed all DV Testing for 24 Mo Shelf-life, Ready for IDE Submission
Q1 2023	First In Human, Sites UCSF, Cleveland Clinic Florida, HCA Houston

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017	Seed Round		$500K
2020-2021	SBIR Phase I NSF	NSF SBIR Phase I & Phase II / NCI SBIR Phase I	$1.5M
2022	SBIR Phase II NIH	Pending for Clinical Trial	$2M

USE OF PROCEEDS

Savage is raising $8M to fund acceleration of US clinical trial timelines, OUS clinical trials, and Regulatory Approvals and to set up Pivotal RCT Trial.

KEY TEAM MEMBERS

Kenton D. Fong, MD: CEO, 15 years' experience in medical device startups as a C-level executive

Jeffrey Etter: VP Engineering, >25 years' experience in medical device R&D and manufacturing; numerous products

Grace Carlson, MD, VP Clinical and Regulatory, >20 years' experience in medical device regulatory; multiple FDA clearances including PMAs

CAREVIVE SYSTEMS, INC.

Improving the Treatment Experience

info@carevive.com | 800-460-3790 | carevive.com

COMPANY OVERVIEW

Carevive Systems, Inc. is an oncology-focused health technology company centered on understanding and improving the experience of patients with cancer. The platform enables clinicians to monitor and manage their patients remotely, which improves clinical outcomes and patient quality of life. Use of Carevive in the clinic unlocks critical data on the real-world experience of patients with cancer, that is aggregated into analytic databases and available for licensure to all cancer stakeholders to continuously improve patient care and advance cancer drug development.

MARKET & COMMERCIALIZATION STRATEGY

Carevive is a two-sided business, with a provider sales team that sells care management technology, currently 40 academic and community cancer programs, to enable care teams to provide care planning and home-based symptom management services to patients (>450 providers and 70,000 patients under contract). These enhanced patient services are required for participation in CMS' new value-based Enhancing Oncology Model. The data sales team licenses numerous registries to life sciences, with four leading oncology pharmaceutical companies currently in multi-year licenses.

TECHNICAL & COMPETITIVE ADVANTAGE

Carevive uniquely supports a comprehensive patient experience platform that is deeply embedded into provider EHR workflows. This extends from treatment diagnosis, with patient assessment surveys; through active treatment, with personalized treatment care plans and remote patient symptom monitoring and management (computerized symptom pathways); through survivorship, with tailored survivorship plans for patients and primary care physicians. Carevive's platform is centered on the company's proprietary Clinical Intelligence System, an algorithm-based engine that combines EHR data, evidence-based guidelines, and patient-reported outcomes into one solution. This combined data is processed to power the company's cancer patient care plans and home-based symptom management solutions that improve patient outcomes, reduce avoidable care utilization, and increase revenue. Carevive is the most holistic cancer care management platform, known for the scientific rigor (NCI- funded) and implementation science expertise.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Carevive holds two product trademarks (Carevive Prompt and Carevive OPT-IN) and one copyright (CLARA).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
5/2022	Sale of Managed Care Services to Existing Customers
9/2022	Payer-Provider Partnership
1/2023	Commercialization of STaIRs
3/2023	Commercialization of Data Service Offering to Providers and Life Sciences

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2013	Series A	Friends & Family	$.750M
2016	Series B	HLM Venture Partners, LRV Health, Cerner Capital, Madelyn Herzfeld	$7.5M
2020	Series C	Debiopharm, Philips, Our Crowd Qure	$18M
2018, 2020	NIH/NCI Contracts	Phase I and Phase II NCI SBIR Contracts	$225K, $1.5M

USE OF PROCEEDS

Carevive is currently raising a Series D to continue to build their provider network, collect patient data at scale, create an economic engine with life sciences, and enter the payer market.

KEY TEAM MEMBERS

Bruno Lempernesse: CEO, 25 years' experience in the life sciences industry; Expert in healthcare technology solutions, data science and analytics, at a global level; Pioneered the Real-World Evidence & Real-World Data, and healthcare big data domain with the early development of collection and utilization of Longitudinal Patient Data sourced from Electronic Medical Records (EMR), in Europe and the US

Madelyn Trupkin Herzfeld: Founder and Vice Chair, Founder and former CEO of Carevive, and Founder & CEO of IMER, a leader in accredited oncology education, sold to United BioSource (now Express Scripts); Began career at Bear, Stearns & Co. in the healthcare services/pharmaceutical investment banking division after earning dual degrees from University of Pennsylvania's Wharton School/School of Nursing

Stan Norton: CTO, A recognized expert in the extraction, transport, management and analysis of Clinical and Claims Health Care Data for Provider, Employer, Payor and Life Science Communities; Former CTO of Humedica and Optum Analytics; Creator of a continuously updated and normalized 80 million+ Patient Data Repository from hundreds of disparate EMRs

ELIMU INFORMATICS

Advanced Cancer Symptom Management

David Lobach | dlobach@elimu.io | 919-438-2346 | elimu.io

COMPANY OVERVIEW

Elimu Informatics is focused on developing clinical decision support solutions, enabling electronic health records (EHR) integration using Fast Healthcare Interoperability Resource (FHIR®) standards, and facilitating semantic normalization of data. Products include EHR-integrated applications for managing cancer-related symptoms, depression, hypertension, post-operative opioid use, hypertensive disorders of pregnancy postpartum, and SARS-CoV-2 infected patients monitoring at home. CDS-Sx is designed to collect symptom severity data directly from cancer patients and combine it with the patients' EHR information for processing through symptom management algorithms prepared from evidence-based guidelines to generate explicit, actionable recommendations.

MARKET & COMMERCIALIZATION STRATEGY

Elimu's target market is health systems and oncology clinics that are operating under value-based care. Elimu has included two potential customers for technical integration proof-of-concept implementations as part of their SBIR Phase II contract, identified future clients with interest in the product from among current customers, and is considering self-funding commercialization for CDS-Sx. They anticipate successful technical integration of CDS-Sx will position them to obtain additional customers. Elimu is looking for a partner to co-market CDS-Sx and is in discussions with one prospect. Elimu is pursuing strategic alliances by joining Epic's App Orchard and Cerner's App Gallery to offer CDS-Sx and is pursuing partnerships with knowledge marketplace platform vendors.

TECHNICAL & COMPETITIVE ADVANTAGE

Elimu's cancer symptom management product offers innovative features and functions. Specifically, CDS-Sx is superior to the competition because it: 1) Utilizes evidence-based cancer symptom management algorithms developed by clinicians at a renowned cancer center and informed by national consensus guidelines; 2) Engages patients through secure SMS with no app to download or patient portal to navigate; 3) Combines in-depth patient reported and extensive EHR data to generate recommendations; 4) Enables clinicians to review and verify these data; and 5) Provides explicit, actionable, detailed, patient-tailored clinical guidance for simultaneous symptom management for nine cancer symptoms through the EHR at the point of action.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

CDS-Sx deliberately involved an oncology clinician as a learned intermediary in the decision process, so the product is exempt from regulation by the FDA. The IP produced through this project includes the symptom management algorithms and the technologic design of CDS-Sx. The algorithms developed with the Dana Farber Cancer Institute will be protected as trade secrets. Confidentiality and non-disclosure clauses will be used in customer contracts. All screen designs will be protected by copyright. Elimu plans to register a trademark for Sapphire CDS-Sx (or eventual brand name) with USPTO. Elimu has been granted the trademark registration for Sapphire and has two patent applications filed.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Sept/Dec 2022	Creation of management algorithms for 9 common cancer patient symptoms & Completion of fully functional CDS-Sx product
March 2023	Technical integration of CDS-Sx at Dana-Farber Cancer Institute
June 2023	Technical integration of CDS-Sx at Medical U of South Carolina & Signed contract with commercial partner for comarketing

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018-2020	SBIR Phase I Contract from NCI	SBIR Phase I & II Contracts from NCI	$1.7M

USE OF PROCEEDS

The proceeds from investment will be used to conduct 2-3 clinical pilots to measure the improved outcomes from symptom management and to support sales and marketing of the CDS-Sx app.

KEY TEAM MEMBERS

David Lobach, MD, PhD, MS: VP for Health Informatics Research/Principal Investigator, Former Chief of the Division of Clinical Informatics at Duke University Medical Center; Developed multiple applications for decision support and population health that were used by Duke Medical Center and North Carolina Medicaid

Aziz Boxwala, MD, PhD: President, 25+ years' experience in health IT; Founded Meliorix in 2012; Former Director of Medical Informatics at Eclipsys Corporation (now part of Allscripts)

James Shalaby, PharmD: CEO, A leader in clinical terminology, knowledge management and clinical information models with 25+ years' experience; Founded PSMI Consulting in 2005; Held informatics positions at Kaiser Permanente, GE, and First DataBank

MELAX TECHNOLOGIES, INC

Clinical and Biomedical Sciences Natural Language Processing

Frank J. Manion | frank.manion@melaxtech.com | 734-276-0111 | melaxtech.com

COMPANY OVERVIEW

Melax Tech empowers healthcare and life sciences organizations to use natural language processing (NLP) coupled with AI methods to solve real-world problems. Melax Tech has been profitable since day one, has no debt, has doubled revenues year over year, and has over 30 paying clients including several large bi-pharma and leading health systems. Melax's business is a SaaS-based model plus service contracts with their target audience: BioPharma, CROs, Big Data/Health IT vendors, and Healthcare systems. The company's major NLP-based products include: 1) CLAMP, the flagship NLP platform which provides the foundation for other NLP tools; 2) MERIC, a subscription-based SaaS system providing real time NLP services for clinical text; 3) LANN, a tool for intelligent annotation of text for use in NLP model development; 4) AILA, an advanced tool for systematic literature review targeted at drug development; 5) VITAL, a chart review and cohort analysis tool; and 6) SELENA, social media analysis tool. Together, these applications and tools have been deployed at leading research and medical facilities with more than 5,000 current users.

MARKET & COMMERCIALIZATION STRATEGY

Melax has had success selling into the areas of hospitals/academic medicine, biopharma, and health IT companies and has several $1B+ companies among as clients. The global Healthcare Analytics Market is estimated at USD $14 billion in 2019 and projected to grow at a CAGR of 28.3% to reach USD $50.5 billion by 2024. Melax already has a successful marketing and commercialization strategy with their existing products. This includes advertising both online and at conferences and trade shows. The company's online presence includes a website and targeted ads through search engines and social media. Melax is working at community development and partnership activities that they hope to begin exploiting in late 2022.

TECHNICAL & COMPETITIVE ADVANTAGE

Melax Tech advantages include: 1) High quality, state-of-the-art NLP performance specifically tuned for texts from biomedical sources; 2) Excellent accuracy in normalizing clinical concepts against normative clinical vocabularies such as SNOMED-CT; 3) Customizability and hybrid approaches allow for the best accuracy/performance; 4) Best-in-class performance for clinical text, per performance rankings in NIH and professional society NLP competitions; 5) Ranked first in a dozen international NLP challenges

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

These products are not currently in an FDA-regulated area. Melax maintains strict HIPAA controls. The company is in the process of being SOC-2 certified. The principal IP is the product listed above, as well as specific NLP modules that are "trained" with machine or deep learning and reusable for multiple use cases. The software and these models are either wholly owned by Melax or they substantively extend unrestricted open-source work. Melax has the right to use, sell, distribute, incorporate into other works, and otherwise exploit the products and any derivatives and to authorize others to do so for any lawful purpose.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
3/1/2023	MERIC - Subscription based clinical NLP service similar to Amazon Comprehend Medical
6/1/2023	CLAMP Web - Cloud-based version of flagship CLAMP product
7/1/2023	Intelligent clinical trial design system based on inclusion/exclusion criteria
9/1/2023	DeepMed - Product for training deep-learning NLP models from annotated corpora
3/1/2024	Improve CLAMP pipelines and scale to 50 modules in total & Sign 10 large cap Biopharma clients

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018-2021	SBIR Contracts	NIH (NCI, NIAID)	$1.3M
2020	SBIR Grant	NIH (NCATS)	$1M

USE OF PROCEEDS

Melax is looking to raise $5M million dollars to evolve CLAMP from a stand-alone application into an integrated platform-based architecture. This will allow them to expand their base by allowing them to rapidly incorporate new AI and NLP methods, as well as build targeted applications for the Pharmaceutical and healthcare domains.

KEY TEAM MEMBERS

Hua Xu, Ph.D.: Founder, Professor, School of Biomedical Informatics at UTHealth and directs Center for Computational Biomedicine

Andre Pontin: CEO, Expert in finance and banking; has successfully developed other early phase startups with two exits in the digital health space

Frank Manion, Ph.D.: VP of Innovation, Expert in biomedical informatics, ontology engineering, and has led informatics and technology initiatives for major academic medical centers and NCI-designated cancer centers

RAPID

Precision medicine for radiopharmaceutical therapy

Jennifer Mecchella | jmecchella@rapiddosimetry.com | 321-759-7523 | rapiddosimetry.com

COMPANY OVERVIEW

Rapid develops evidence-based precision dosimetry software to optimize dosing of radiopharmaceutical therapies. The company is developing a comprehensive, cloud-based software for RPT dosimetry that enables remote, multi-disciplinary collaboration. Rapid also provides comprehensive expert services related to quantitative imaging, and dosimetry, in support of pre-clinical and clinical studies needed for regulatory approval and the effective and safe clinical implementation of radiopharmaceuticals.

MARKET & COMMERCIALIZATION STRATEGY

Rapid aims at engaging with RPT developers from early stages of development to clinical use. The team developed a business model for commercializing the technology in harmony with the fast-growing RPT market. Rapid offers pre-clinical and clinical services to RPT developers, including quantitative imaging services, developing imaging protocols, and dosimetry services. Rapid develops web and cloud-based software applications for RPT dosimetry that enables this kind of "precision medicine" approach for RPT. The ability to use a web-based platform that enables remote collaboration with experts is essential both for clinical trials investigating these precision dosing methods and their clinical application. Projections for the precision medicine software market estimate a value of $2 billion by 2024 from $1.2 billion in 2019 at a CAGR of 11.5%.

TECHNICAL & COMPETITIVE ADVANTAGE

Current products in the market have multiple technical limitations, especially for alpha particle dosimetry. Some have an antiquated user interface and lack multi-user, management and data organization, access management, and collaboration features of 3D-RD-S. Other products require a capital equipment commitment in the $40 to $150k range. The result is that competitors' products are purchased almost exclusively by large academic centers. None of the packages support alpha emitters, combined XRT/RPT dosimetry, or incorporate radiobiological metrics. The packages from the imaging system vendors (GE/Philips/Siemens) provide quantitative reconstruction capabilities, but not for most therapeutic radionuclides or alpha emitters. Rapid also uses a cloud-based system which has many benefits. Licensing, upgrades, and distribution are simplified, reducing costs.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

IP Portfolio (JHU issued patents and software) based on 40+ years of NIH funded research:

- Method and System for Administering Radiopharmaceutical Therapy (Patent No. US9757084B2)
- Methods for Determining Absorbed Dose Information (Patent No. US9387344B2)
- Methods and software to transform 3D radioactivity distributions in the body into metrics (Patent No. 8693629 Method and system for administering internal radionuclide therapy (IRT) and external radiation therapy (XRT))

Rapid's regulatory strategy is comprehensive and led by Nadine Bonds, Rapids Director of Quality Assurance.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
8/15/22	Expected 510(k) approval of first SAAS Product – 3D-RD-S
3/2023	510(k) submission for 3D-RD-S+ application

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016-2022	SBIR Contracts	NIH	$4.6M
2016-2022	SBIR Grants	NIH	$2.9M
2016-2022	Revenue	Service and Consulting	$1.35M
2018	Convertible Note	TEDCO, MD	$150K

USE OF PROCEEDS

Based upon contracts already signed, discussions with current vendors, and business expansion efforts, Rapid anticipates a revenue stream from the service business of $700-$1,000k per year for the next two years. To date, Rapid has not raised external funds besides the revenue from the service business, federal grants, contracts, and loans from the owners. Raised funds will enable Rapid to complete at least near-release versions of a suite of dosimetry and quantitative imaging tools.

KEY TEAM MEMBERS

George Sgouros, PhD: CEO, World-recognized expert in dosimetry for radiopharmaceutical therapy
Eric Frey, PhD: CSO, Recognized expert in quantitative SPECT, especially with applications to RPT
Michael Ghaly, PhD: Chief Operating and Technology Officer, Expert in SPECT reconstruction and dosimetry

VOXIMETRY

VOXIMETRY Fighting cancer. Making it personal.

Sue Wallace, PhD | swallace@voximetry.com | 262-751-6441 | voximetry.com

COMPANY OVERVIEW

Of the 190,000 men diagnosed with prostate cancer in the US every year, 25% will not achieve cure with surgery, conventional radiation therapy or chemo. For these men, targeted Radiopharmaceutical Therapy (RPT) is their last hope. Studies show that RPT radiation dose to critical organs can vary up to 10-fold between patients and 100-fold between tumors. Yet the standard of care remains one-size-fits-all. This results in outcomes ranging from excellent therapy response to poor response and/or treatment-related toxicity. RPT clinicians are looking for a solution to personalize patient treatment plans, increase tumor control (cure), and reduce risk to critical organs. The Solution: Dosimetry-Guided RPT (DG-RPT). Voximetry's Torch™ software application makes RPT safer and more effective. Torch analyzes pre-treatment Nuclear Medicine (NM) scans to model each patient's unique drug interaction and estimate the optimal number of therapy cycles and dose to administer per cycle. Patient-specific treatments have been shown to increase tumor response by 71% and overall survival by 16 months.

MARKET & COMMERCIALIZATION STRATEGY

The RPT market is growing at a rate of 39% annually, driven by new therapeutic drug approvals and ongoing investment in new drugs, three of which recently announced successful Phase II trials. Within this $7B market opportunity, there is a $1B global market for personalized treatment planning. Torch will be marketed as an annual software subscription with additional per-use fees, deployed locally on user-provided hardware. There are existing treatment planning codes and defined CMS payments for radiation treatment plannings. Total cost of Torch subscription plus use fees will be <30% of the incremental revenue they generate. Torch will be distributed through imaging company OEMs with existing relationships to NM and Radiation Oncology clinics. These companies will integrate Torch into their existing software solutions. Talks with the top two imaging companies are underway and progressing quickly. Voximetry will maintain the right to distribute the stand-alone Torch solution direct-to-market.

TECHNICAL & COMPETITIVE ADVANTAGE

Torch demonstrates extreme accuracy and lightning speed of the therapeutic dose calculation using ideas borrowed from the gaming industry. As the only GPU-accelerated solution on the market, Torch increases compute power by 5 orders of magnitude to reduce calc times (hours to seconds), facilitating extreme accuracy in the clinic for the first time. Competitors run on CPUs and are limited to less accurate models. Competitors do not have equal depth of physics expertise and cannot provide comparable models. The smart workflow of the Torch application was based on optimized therapy workflows in Radiation Therapy treatment planning. Competitors' workflows are expanded from diagnostic image analysis platforms and are not well-suited to therapy.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Voximetry has a two-step regulatory strategy for this Class II device: 1) Torch Dose Assessment (retrospective analysis of dose that was delivered during therapy) is under review by the FDA and market clearance is anticipated by Q4 2022. 2) Torch Treatment Planning (prospective analysis of optimal personalized plan per patient before therapy) will be submitted in 2024 for De Novo review. Torch has a strong system patent licensed from University of Wisconsin-Madison where it was developed by the founders that includes generation of RPT treatment plans and RPT plans combined with External Beam Radiation Therapy treatment plans.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2022	FDA Market Clearance & Commercial Launch – Torch 1.0
Q4 2023	MDR Audit, CE Mark and EU Launch & First $2M annual revenue (software subscription based)
June 2024	FDA Market Clearance (De Novo) – Torch 2.0

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018 & 2021	Grants	Wisconsin Economic Development Corporation (WEDC) Phase I & Phase IIs	$450K
2018-2022	NIH Grants	NIH NCI SBIR Phase I & II Grants & Phase I Contract	$2.6M

USE OF PROCEEDS

Voximetry is raising $1.5M in seed funds to cover one year of operations. During that year the company may be awarded two additional grants, giving the company $5.5M total and three years of running room. If grants are not secured, the round will be followed by a Series A. Funds will be used for commercial launch of Torch 1.0. in Q4 2022 and on-going product development.

KEY TEAM MEMBERS

Sue Wallace, PhD: CEO, Strong KOL network, record of growing share; Formerly of GE, Cardinal Health, Philips, Accuray

Paul Wickre, MS: CTO & Co-Founder, Strong commercial SW development experience; Formerly of Philips, Standard Imaging

Joe Grudzinksi, PhD: Chief Innovation Officer & Co-Founder, Strong RPT drug development network; deep technology and application insight; Formerly of Philips, Cellectar, UW-Madison

THANK YOU

TO THE 2022 NCI SBIR INVESTOR INITIATIVES REVIEWER COMMITTEE FOR YOUR HELP IN SCORING APPLICATIONS AND PARTICIPATING IN THE REVIEW CALLS. WE CANNOT RUN THIS PROGRAM WITHOUT YOU!

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Alexander (Sasha) Naydich
Andrew Koopman
Anna Turetsky
Anne DeGheest
Anton Gopka
Anton Xavier
Armen Shanafelt
Ben Nahir
Bill Hyun
Bob Crutchfield
Daniel Jacobs
Dave Kereiakes
Dee Dao
Diana Saraceni
Douglas Munsey
Elizabeth Cho-Fertikh
Evan Caplan
Fei Shen
Ian McAlexander
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