2020 | NCI SBIR

INVESTOR INITIATIVES

COMPANY PROFILES

NATIONAL CANCER INSTITUTE | SBIR DEVELOPMENT CENTER

INVESTOR | INITIATIVES

NCI SBIR INVESTOR INITIATIVES

There are many ways we work with investors and strategic partners. See below for more information and how to get involved.

PORTFOLIO SHOWCASE PROGRAM

Get an early look at NCI-funded companies as a reviewer

MUTUAL DEAL SOURCE

Share your technology areas of interest to receive a curated portfolio. Support companies in your portfolio with non-dilutive federal funding

EVENTS

Host pitch events or informational sessions for your network to learn more about NCI SBIR funding

MENTORING PROGRAMS

Work with us to identify strategically aligned companies that you can mentor

EMERGING TECHNOLOGY OPPORTUNITIES

Identify emerging areas that require seed-funding

CONTACT

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BIOPHARMACEUTICALS

Company	Technology Type	Indication
Aurora Oncology	Epidermal growth factor-diphtheria toxin-A fusion protein (DT-EGF)	Superficial (non-muscle invasive) bladder cancer
COARE Holdings	CBT-15(h) - humanized mAb that attacks validated tumor stem cell target DCLK1	Pancreatic cancer
Diagnologix	Closed Cell Sorting System Enabled by Targeted Microbubbles	Multiple
FibrosIX	Small molecule therapeutics that inhibit fibrotic disease	Treatment-induced lung fibrosis
GenCirq	Therapeutic gene circuits for cancer therapy	Multiple (1st indication: colorectal cancer metastasized to liver)
IRIA Pharma	Active Tissue Targeting via Anchored ClicK Chemistry (ATTACK)-mertansine conjugate	Triple negative breast cancer (TNBC), ovarian cancer
KeViRx	KVX-053, a highly potent, selective, reversible, allosteric inhibitor of PTP4A phosphatases	Multiple (ovarian, acute myelogenous leukemia)
Metaclipse Therapeutics	Membrex™, personalized cancer immunotherapy platform	Multiple (lead indication: triple negative breast cancer)
Oncoceutics	Small molecule, dopamine receptor D2 (DRD2) antagonist and ClpP agonist	Multiple (gliomas, neuroendocrine tumors, endometrial cancer, CNS tumors, etc.)
OncoNano Medicine	Ultra-PH Sensitive, Micelle-Based Imaging Agents, Therapeutics, & Vaccines	Multiple
Reveal Pharmaceuticals	Gadolinium-Free MRI Contrast Agent	Multiple
StemSynergy	WNT and Notch pathway inhibitors	Multiple
Tensive Controls	Peptide therapeutic to reserve symptoms of proinflammatory cytokines (PICs)	Cancer cachexia

DRUG DELIVERY PLATFORMS

Company	Technology Type	Indication
NanoValent Pharmaceuticals	Targeted nanospheres – non-toxic cancer therapeutics	Multiple (refractory cancers: Ewing's Sarcoma, hepatocellular carcinomas, etc.)
Privo Technologies	Topically administered chemotherapy patch	Oral cancer
TDL Innovations	Foam formulation to deliver sclerosing agent, Talc, to entire pleural space	Malignant Pleural Effusion – complication of advanced cancer

DIAGNOSTICS/TOOLS

Company	Technology Type	Indication
Clara Biotech	Exosome isolation platform for therapeutics	Multiple
Cytoimage	Diagnostic imaging technology to monitor recurrence risk	Multiple (initial indication: leukemia)
Eutropics	Apoptosis phenotyping platform	Multiple (initial indication: acute myeloid leukemia)
Fluent BioSciences	Instrument free single cell RNA sequencing sample prep	Multiple

DEVICES

Company	Technology Type	Indication
CivaTech Oncology	Targeted radiation therapy devices	Multiple (colorectal, pelvic, head and neck, brain, lung/soft tissue sarcomas, pancreatic)
Clarix Imaging	High-resolution specimen imaging device	Multiple (Initial indication: breast cancer)
Lightpoint Medical	Precision-guidance tools for robotic cancer surgery	Multiple (prostate and lung cancer)
MetriTrack	Automated handheld breast ultrasound	Breast cancer
MicroElastic Ultrasound Systems	Handheld ultrasound to precisely measure skin elasticity	Graft-Versus-Host Disease (GVHD)
NE Scientific	Computerized guidance for tumor ablation	Multiple
Simphotek	3D simulation software and hardware system for PDT treatment planning and real-time dosimetry	Solid internal tumors
Surgical Innovation Associates	Bio-absorbable surgical mesh device	Breast reconstruction (other markets: hernia surgery, cosmetic surgery)

DIGITAL HEALTH

Company	Technology Type	Indication
Envisagenics	Using AI to deliver therapies for RNA splicing diseases	Multiple (Initial indication: triple negative breast cancer)
InheRET	SaaS program to identify inherited risk	Multiple
Quantitative Radiology Solutions	Automated analysis of medical images	Multiple

SHORT COMPANY SUMMARIES

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

AURORA ONCOLOGY

TARGETED THERAPIES TO TREAT BLADDER CANCER

LOCATION
AURORA, CO

STAGE
PRE-CLINICAL DEVELOPMENT

Aurora Oncology is an early clinical stage biopharmaceutical company developing targeted therapeutics to treat bladder cancer. Their lead product is an epidermal growth factor-diphtheria toxin-A fusion protein (DT-EGF) for intravesicular treatment of superficial bladder cancer (also known as non-muscle invasive bladder cancer; NIMBC). DT-EGF is poised to enter clinical development. A second product in an earlier stage of development is composed of a gold nanorod-anti-EGFR mAb fluorophore conjugate (Nano-anti-EGFR) with potential to detect and treat superficial bladder cancer, and a third product is being explored for metastatic bladder cancer (AO-201).

COARE

HUMANIZED MAB THAT ATTACKS DCLK1

LOCATION
OKLAHOMA CITY, OK

STAGE
PRE-CLINICAL DEVELOPMENT

COARE is an early-stage biotechnology company focused on the development of novel therapeutic drugs to treat pancreatic cancer and other solid tumors. The Company's strategy is to block the tumor formation ability of cancer cells while simultaneously using the patient's own immune system to eradicate the tumor. The technology is based on targeting the extracellular regions of the tumor stem cell protein doublecortin like kinase 1 (DCLK1). Increased expression of DCLK1 has been associated with poor survival in patients with pancreatic and several other solid tumor cancers. COARE, in collaboration with Panorama Research Inc. (PRI), has developed a humanized therapeutic monoclonal antibody [CBT-15(h)] that binds to DCLK1.

DIAGNOLOGIX

CLOSED CELL SORTING SYSTEM ENABLED BY TARGETED MICROBUBBLES

LOCATION
SAN DIEGO, CA

STAGE
PRE-CLINICAL DEVELOPMENT

Diagnologix is developing a cGMP compliant cell-processing system to process stem cells and immune cells from bulk-volume biological fluids for clinical applications. Diagnologix discovered and applied the lipid shelled perfluorocarbon-filled microbubble (MB), which has been approved by the FDA for use as an ultrasound contrast agent, as a self-driving vehicle for cell separation and as a tunable artificial cell for target-cell regulation. The patented BUBLES (Buoyancy enabled separation) technology has been applied to isolate human hematopoietic stem cells and demonstrated successful engraftment in the immunodeficient mice. Diagnologix recently has accomplished scalable cell isolation through a unique sequential multi-marker cell sorting scheme, designated i(terative)BUBLES, for production of memory stem T (TSCM) cells to overcome cell processing bottlenecks of adoptive cell therapy, including CAR-T cell manufacturing. Compelling evidence indicates that persistence of CAR-T cells in patients is associated with the enrichment of engineered TSCM. A closed CAR-T cell manufacturing system, from isolation of specific T cell types to subsequent cell activation, genetic modification and cell expansion, can be assembled as a single unit. This system has the potential to decentralize CAR-T cell production, therefore benefitting more patients.

FIBROSIX

SMALL MOLECULE THERAPEUTICS THAT INHIBIT FIBROTIC DISEASE

LOCATION
EAST LANSING, MI

STAGE
PRE-CLINICAL DEVELOPMENT

FibrosIX is developing proprietary first-in-class small-molecule therapeutics that inhibit a novel target in a critical signaling pathway that plays a central role in the pathogenesis of fibrotic disease. Fibrotic disorders encompass a wide spectrum of clinical manifestations that includes systemic sclerosis and numerous organ-specific disorders such as radiation-induced, cardiac, pulmonary, liver, and kidney fibrosis. There remains a high unmet medical need for new, more efficacious, and better tolerated drugs to treat fibrotic disease. FibrosIX Inc. received SBIR funding to advance the development of the company's lead drug candidate CCG-257081, and other potential follow-on compounds, for the prevention/treatment of bleomycin-induced lung fibrosis in patients undergoing chemotherapy for Hodgkin's lymphoma and germ cell cancers.

GENCIRQ

THERAPEUTIC GENE CIRCUITS FOR CANCER THERAPY

LOCATION
SAN DIEGO, CA

STAGE
PRE-CLINICAL DEVELOPMENT

GenCirq is developing a novel bacterial platform that enables production and delivery of a wide range of therapeutics at disease sites within the human body. The technology leverages the latest advances in synthetic biology to engineer bacteria for the treatment of disease. GenCirq programs probiotic or clinical bacteria which naturally possess tumor homing capabilities to deliver a variety of therapeutics to tumors and pre-cancerous lesions. The Company's proprietary Synchronized Lysis Circuit (SLC) results in targeted delivery of therapeutics and enhances the safety of bacterial cancer therapy.

IRIA PHARMA

SMALL MOLECULE TARGETING PLATFORM FOR ANTIBODY UNTARGETABLE CANCER TREATMENT

LOCATION
CHAMPAIGN, IL

STAGE
PRE-CLINICAL DEVELOPMENT

IRIA is translating its proprietary cell labeling and targeting technology, Active Tissue Targeting via Anchored ClicK Chemistry (ATTACK), into cancer treatment as its primary focus to develop first-in-class small molecule-based cancer labeling and targeted therapeutics for triple negative breast cancer. IRIA's ATTACK technology is a sugar metabolic labeling platform amendable for targeted disease treatment, diagnosis, and imaging. ATTACK includes two steps: 1) Selective labeling of cancer cells with artificial receptors through unnatural sugar metabolization; 2) Targeted delivery of a payload through recognition of the artificial receptors to achieve targeted treatment. The ATTACK labeling-mediated delivery could target antibody untreatable cancers that do not have known overexpressed receptors.

KEVIRX

A HIGHLY POTENT, SELECTIVE, REVERSIBLE, ALLOSTERIC INHIBITOR OF PTP4A PHOSPHATASES

LOCATION
CHARLOTTESVILLE, VA

STAGE
PRE-CLINICAL DEVELOPMENT

KeViRx seeks to develop a newly discovered class of small molecules that inhibit the activity of one of the most potent cancer-causing protein tyrosine phosphatases, PTP4A3, which is highly expressed in human ovarian cancer and acute myelogenous leukemia as well as in more than 50% of other human malignancies. KeViRx is developing a first-in-class, drug-like, lead compound, JMS-053, which is a highly potent, selective, reversible, allosteric inhibitor of PTP4A phosphatases with documented cellular and preclinical anticancer activity in mice. The cellular actions of JMS-053 require the presence of the target protein, PTP4A3. KeViRx has 65 analogs of JMS-053 as well as a recently developed photoredox flow synthesis that affords low-cost reproducible production of the compounds.

METACLIPSE THERAPEUTICS

MEMBREX™, PERSONALIZED CANCER IMMUNOTHERAPY PLATFORM

LOCATION
ATLANTA, GA

STAGE
PRE-CLINICAL DEVELOPMENT

Metaclipse's core technology comprises membrane-bound biological adjuvants, which Metaclipse is developing for oncology and infectious disease indications. Specific areas of focus include personalized cancer immunotherapies and enhanced vaccines for influenza and SARS-CoV-2 viruses. The lead indication for the personalized cancer immunotherapy platform (Membrex™) is triple negative breast cancer (TNBC), an area of significant unmet medical need with few targeted treatment options. The Membrex™ approach generates a personalized tumor membrane-based immunotherapy capturing the unique antigenic signature of a tumor without the need for sequencing (as in neo-antigen peptide approaches) or the cumbersome, time-consuming act of culturing cells (as required in dendritic cell or CAR-T cell strategies). Competitive approaches take 4–6 months to generate a vaccine and can miss key antigens, while the Metaclipse approach can produce a personalized, cell-free vaccine in just 14 days that covers both mutated/up-regulated proteins and carbohydrates.

ONCOCEUTICS

SMALL MOLECULES THAT SELECTIVELY TARGET G PROTEIN-COUPLED RECEPTORS

LOCATION
PHILADELPHIA, PA

STAGE
IN CLINICAL TRIALS (PHASE II)

Oncoceutics is a clinical-stage drug discovery and development company with a novel class of compounds that selectively target G protein-coupled receptors (GPCRs) for oncology. The first compound to result from this program is ONC201, an orally active dopamine receptor D2 (DRD2) small molecule antagonist that is well-tolerated and effective against advanced cancers. The company has completed a successful Phase I study in solid tumors and is focused on a first approval of ONC201 for patients with H3 K27M-mutant high-grade glioma, an aggressive subtype of brain cancer.

ONCONANO MEDICINE

SMALL MOLECULE TARGETING PLATFORM FOR ANTIBODY UNTARGETABLE CANCER TREATMENT

LOCATION
DALLAS, TX

STAGE
IN CLINICAL TRIALS (PHASE II)

OncoNano has adapted unique, ultra pH-sensitive micelle chemistry to develop an IV injectable, indocyanine green (ICG)-based fluorescent imaging agent, ONM-100, for intraoperative surgical resection of solid tumors, meeting a significant unmet need. Fluorescence is activated by the low pH tumor microenvironment that results from metabolic acid buildup (the Warburg effect) and is a hallmark of all cancers irrespective of their oncogenic phenotype—an attribute that potentially enables ONM-100 to be used to image any solid tumor. Preclinical GLP studies and data from Phase I and an ongoing Phase II clinical trial have shown that ONM-100 is safe (no serious drug-related adverse events) and efficacious for imaging multiple tumor types studied to date, including breast, head and neck, ovarian, colorectal, and prostate cancers.

REVEAL PHARMACEUTICALS

GADOLINIUM-FREE MRI CONTRAST AGENT

LOCATION
CAMBRIDGE, MA

STAGE
PRE-CLINICAL DEVELOPMENT

Reveal Pharmaceuticals aims to improve safety and deepen insights for MR imaging. Contrast-enhanced (CE) MRI is vital for diagnosing, staging, and managing many cancers, but all current MRI contrast agents cause accumulation of the heavy gadolinium (Gd) in the brain and other organs. Gd triggers devastating delayed-onset multi-organ fibrosis in people with chronic kidney disease and is linked to an emerging continuum of adverse effects in patients with normal renal function. Concern is rising about potential late effects, particularly in children, people with kidney disease, and people who need repeat CE-MRI scans for screening, surveillance, management, or clinical trials. Regulators have restricted or suspended Gd-based contrast agenda (GBCAs), but there are no alternatives. Reveal is developing Gd-free MRI contrast agents that are designed to replace GBCAs. The Company's "RVP" technology uses biocompatible manganese and has an innovative cage design enabling high MR signal and high stability.

STEMSYNERGY

WNT AND NOTCH PATHWAY INHIBITORS

LOCATION
MIAMI, FL

STAGE
PRE-CLINICAL DEVELOPMENT

StemSynergy aims to develop drugs that specifically target molecular effectors critical to cancer stem cells, which are fundamental to the initiation and maintenance of tumors. Additionally, these cells are often distinct from the rest of the tumor and often escape or resist current therapies, driving relapse and resistance. The Company's mission is to optimize drug efficacy against developmental pathways that drive cancer recurrence, such as the WNT, Sonic Hedgehog and Notch signaling pathways in order to develop cures for cancer. StemSynergy's lead molecule, SSTN-302, inhibits the growth of Notch-driven cancer cells and xenograft tumors by inhibiting the transcription of Notch gene targets and avoids the dose-limiting toxicity of previous Notch pathway inhibitors. SSTN-302 has extremely favorable in vitro and in vivo ADMET properties and is advancing in IND-enabling studies.

TENSIVE CONTROLS

PEPTIDE THERAPEUTIC TO RESERVE SYMPTOMS OF PROINFLAMMATORY CYTOKINES

LOCATION
COLUMBIA, MO

STAGE
PRE-CLINICAL DEVELOPMENT

Tensive Controls (TCI) was initially focused on developing a melanocortin (MC) peptide drug for reversing cancer cachexia, which then led to the emergence of a technology platform for designing and synthesizing peptide analogs that are more drug-like. The Company has developed a platform technology that makes many small-medium sized peptides drug-like, including active transport across epithelial barriers via OATP1A2, and applied this to the production of an anti-cachexia melanocortin-4 receptor (MC4R) antagonist. This produces transport across the blood-brain barrier. Applying the technology to an MC antagonist pharmacophore produced a drug-like MC antagonist, TCMCB07, which promotes anti-cachexia effects with body mass increases and physical activity enhancement in both small and large animal models with 1X/day dosing. Canine 28-day safety studies showed minimal side effects.

NANOVALENT PHARMACEUTICALS

TARGETED NANOSPHERES – NON-TOXIC CANCER THERAPEUTICS

LOCATION
BOZEMAN, MT

STAGE
PRE-CLINICAL DEVELOPMENT

NanoValent Pharmaceuticals (NVP) is a small biotechnology company that was formed to create much-needed therapeutics for childhood cancers, initially refractory childhood Ewing sarcoma (ES). Out of this mission came a patented Targeted NanoSphere (TNS) platform. TNS is a new generation of antibody-targeted nanoparticles that can encapsulate active therapeutics and enable ADC (antibody drug conjugate) type targeting. True tumor specific targeting with intra-tumoral payload release can potentially increase therapeutic potency and reduce both off-target and long-term toxicity. While the range of potential targets and markets is exciting, NVP's fundamental approach has been to cost effectively develop a small pipeline of proof-in-concept products for partnering with commercial pharmaceutical companies, with a specific lead pediatric oncology application to validate the platform. The chosen lead, NV103, has shown impressive data in ES, utilizing human CD99 antibodies for targeting and the cytotoxic drug irinotecan as the therapeutic payload.

PRIVO TECHNOLOGIES

TOPICALLY ADMINISTERED CHEMOTHERAPY PATCH

LOCATION
PEABODY, MA

STAGE
IN CLINICAL TRIALS (PHASE II)

Privo has developed a nanoparticle-based platform technology to deliver targeted chemotherapeutics locally via topical administration, the initial indication being oral cancer. The 5-year survival rate of oral cancer (OC) remains only 57%, and OC is one of the few cancers increasing in incidence both in the US and worldwide. The treatment (PRV111 patch) is composed of biocompatible polymers and embedded with nanoparticles. Upon contact with tissue, the particles are released and retained by cancer cells to limit systemic toxicity. Privo's local delivery of chemo-loaded nanoparticles is unique in that it can deliver a much higher dose of chemotherapy drug directly to the tumor without the concern of dose-limiting side effects. Elimination of toxic side effects from IV chemo via local delivery and retention has the potential to revolutionize the treatment paradigm of oral cancer and many others. Privo's innovative treatment can be used on precancerous lesions as well as cancerous tumors. The project's platform can be customized per the needs of the patients in terms of permeation depth, drug loading, cancer tumor targeting, muco-adhesives, nano-encapsulation topical or intratumoral delivery.

TDL INNOVATIONS

FOAM FORMULATION TO DELIVER SCLEROSING AGENT, TALC, TO ENTIRE PLEURAL SPACE

LOCATION
PRINCETON, NJ

STAGE
PRE-CLINICAL DEVELOPMENT

Approximately 175,000 new cases of malignant pleural effusion (MPE) occur in the US each year. Although talc pleurodesis is now well recognized as the procedure of choice for the treatment of MPE, the optimal route of talc administration is still debated. Some surgeons prefer thoracoscopic talc poudrage (applied as a powder) during a surgical procedure, whereas others advocate talc slurry instillation through a chest tube because it is an easier, less invasive procedure. TDLI has developed a novel delivery system for talc that employs a unique combination of talc and a foam delivery system. The product is composed of a canister that contains a foam formulation which, when combined with the currently approved aerosol talc drug product, carries talc throughout the pleural space. The liquid in the can undergoes a volume expansion when administered and it becomes a foam, filling the chest cavity, thereby enhancing coverage of the tissue surfaces within the pleural space.

CLARA BIOTECH

EXOSOME ISOLATION PLATFORM FOR THERAPEUTICS

LOCATION
LAWRENCE, KS

STAGE
COMMERCIALLY AVAILABLE

The current gold standard for exosome isolation, ultracentrifugation, involves a 10 continuous cycle by a highly trained technician resulting in inconsistent, low yield (5% to 25% extraction) outputs. This process and other competitive technologies are manual, slow, and limited to low volumes. Sample preparation is the number one issue keeping exosomal applications from moving to patients. Current solutions are not compatible with therapeutic applications. Clara Biotech is enabling tomorrow's medical breakthroughs today through a revolutionary platform that brings exosome sample preparation from research to patient. They have developed a proprietary, patented immunomagnetic bead, making Clara the only option to isolate any species of exosome from any fluid source with applications in diagnostics, therapeutics, and beyond exosomes.

CYTOIMAGE

DIAGNOSTIC IMAGING TECHNOLOGY TO MONITOR RECURRENCE RISK

LOCATION
PORTLAND, OR

STAGE
PRE-CLINICAL DEVELOPMENT

CytoImage Dx is developing a differentiating technology that addresses a key unmet medical need – to provide personalized information that helps individuals and their doctors to select the optimal drug treatments that eliminate persistent cancer cells and provide durable, cancer-free remission. The CytoScreen technology is a miniaturized imaging platform that uses sensitive, state-of-the-art nanoparticle detection technology to detect the presence of rare drug-resistant cancer cells. The platform provides high-content, high granular screening of an individual's tumor sample, providing information that identifies the drugs that have the best chance of effecting 100% cancer cell kill for each individual's unique cancer, significantly reducing chances of cancer recurrence for that individual following their treatment. The company's unique value proposition is to detect cancer resistance early and to inform selection of treatments appropriate to each individual by providing x100 more drug content testing and x100 more sensitive detection of individual cancer cells.

EUTROPICS

APOPTOSIS PHENOTYPING PLATFORM

LOCATION
CAMBRIDGE, MA

STAGE
IN CLINICAL TRIALS (PHASE III)

Eutropics Pharmaceuticals is an oncology biomarker discovery and clinical diagnostics laboratory that develops novel functional clinical diagnostic tests that recognize unique features of cancer cells from individual patients. The information indicates if a given patient is likely to have a meaningful response to a given apoptosis-inducing drug treatment. These tests are provided to pharmaceutical companies to select patients into clinical trials, and to help oncology physicians select best treatment options for patients. The tests are functional predictive assays that are first in class and are protected by a substantive patent portfolio and have proven utility in prospective phase II clinical trials.

FLUENT BIOSCIENCES

INSTRUMENT FREE SINGLE CELL RNA SEQUENCING SAMPLE PREP

LOCATION
WATERTOWN, MA

STAGE
NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE

Fluent is a platform company developing precision biology tools for the Life Science market. The Company has a worldwide exclusive license to their platform, PIPs (Pre-templated Instant Partitions), a novel method of creating a massive number of uniform reactions without the costs or scaling limitation of microfluidics. The platform works at the pico- to nano-liter physical scale and has a time-independent reaction number from thousands to billions. The power of large numbers of tiny reaction volumes is well understood to improve kinetics massively (i.e., reduce reaction times), eliminate sample waste, reduce costs, and quanta-reactions (i.e., single-molecule, cell, protein). Fluent has demonstrated the development and/or porting of four assays onto the platform: digital PCR, targeted sequencing prep, single-cell whole genome amplification, and single-cell RNA sequencing prep. Each of these applications has unique scaling requirements, i.e., reaction volume and number of reactions. The PIPs technology enables this fast development cycle due to the lack of both application-specific instrumentation and microfluidics.

CIVATECH ONCOLOGY

TARGETED RADIATION THERAPY DEVICES

LOCATION
RESEARCH TRIANGLE PARK, NC

STAGE
IN CLINICAL TRIALS (PHASE II), COMMERCIALLY AVAILABLE

CivaTech Oncology specializes in the development and manufacturing of radiation devices to provide therapeutic doses to cancerous tissues in a localized, targeted delivery method. CivaTech has three product lines—CivaString®, CivaSheet®, and CivaDerm™—that are commercially available. These products were developed, engineered, and now manufactured by CivaTech Oncology. These devices can significantly reduce the side effects experienced with traditional radiation delivery methods. The devices are also able to provide meaningfully higher radiation doses to target tissues. This ability to target radiation delivery in a localized manner is a disruptive technology that opens the possibility of delivering radiation therapy where previously technically and clinically impossible. Also, these devices could enable the delivery of therapeutic radiation doses where only palliative doses are currently possible.

CLARIX IMAGING

HIGH-RESOLUTION SPECIMEN IMAGING DEVICE

LOCATION
CHICAGO, IL

STAGE
COMMERCIALLY AVAILABLE

Clarix Imaging's volumetric specimen imager (VSI) is an FDA-cleared, portable 3D specimen imaging system that can reduce significantly the current 25% reoperation rate of breast-conserving surgery. VSI's unique high-resolution, rapid imaging and advanced software enables accurate margin assessment that fits seamlessly to existing surgical workflow. Immediately following tumor excision, the surgeon can use the compact VSI system to scan the specimen without leaving the OR. Within 5 minutes a fully 3D image of the entire specimen is obtained and shared via network with the radiologist, who can use Clarix software to interpret the image and communicate the findings with OR in real-time, while the patient is still on the table. When VSI shows negative margin, the surgeon can confidently close the wound without randomly shaving additional tissue. When a PM is identified, VSI can direct the surgeon precisely to the location of residual tumor for immediate re-excision, thereby avoiding a separate procedure. This approach helps the surgeon to achieve excellent tumor control while maximally preserving the breast for better patient recovery, improved cosmetic outcomes, and lowered cost.

LIGHTPOINT MEDICAL

PRECISION-GUIDANCE TOOLS FOR ROBOTIC CANCER SURGERY

LOCATION
CAMBRIDGE, MA

STAGE
IN CLINICAL TRIALS (FEASIBILITY/PILOT)

Over recent decades, robots have transformed cancer surgery, growing rapidly to dominate the market. However, despite the technological advances in robotic platforms, surgeons still remain completely dependent on their sight to detect cancer intra-operatively. As a result, surgeons often leave cancer behind or remove more healthy tissue than needed. Residual disease increases the need for further drug treatment, radiotherapy, and surgery. Similarly, removing healthy, functional tissue increases post-surgical complications and escalates healthcare costs. By exploiting advances in miniaturized sensor technologies and the development of cancer-targeted diagnostic imaging agents, Lightpoint is developing miniaturized imaging and sensing tools to accurately detect cancer intra-operatively during robot-assisted surgery. The aims of the tools are to aid surgical decision making, improve patient outcomes and save costs for the healthcare system. The company has two miniaturized robotic probe technologies in development which form a complementary toolset to address the complex challenges and demands of robot-assisted cancer surgery. Although applicable to a wide range of major cancer types, the first commercial focus for the technologies is in prostate cancer surgery.

METRITRACK

AUTOMATED HANDHELD BREAST ULTRASOUND

LOCATION
HILLSIDE, IL

STAGE
IN CLINICAL TRIALS (FEASIBILITY/PILOT)

Breast ultrasound can double the detection rate of small breast cancers in women with dense mammograms, which represent more than half of the women of screening age on the planet. Many small cancers are missed during the initial scanning or at follow-up handheld ultrasound exams. MetriTrack's technology relies on the dynamic mapping of the deforming breast tissue during ultrasound scanning, made possible by actively tacking anatomical references and the ultrasound probe with small electromagnetic sensors enclosed in proprietary body attachment parts. The sensors' output is processed using proprietary algorithms and software to precisely map the breast tissue and guide the operators to obtain complete and optimal exams. MetriTrack's software and sensor-based suite of products is designed to integrate with all existing breast ultrasound systems in use globally.

MICROELASTIC ULTRASOUND SYSTEMS

HANDHELD ULTRASOUND TO PRECISELY MEASURE SKIN ELASTICITY

LOCATION
DURHAM, NC

STAGE
IN CLINICAL TRIALS (FEASIBILITY/PILOT)

For blood cancer care teams who need to track deadly complications of stem-cell transplantation in the skin, MicroElastic's Bullseye™ is a handheld ultrasound system that provides precise measurements of skin elasticity at the touch of a button. Unlike the standard "pinch-and-score" method, which is notoriously variable, Bullseye™ measurements are repeatable and accurate in anyone's hands. MicroElastic's Bullseye™ technology brings ultrasonic precision to tissue elasticity quantification and puts it in a portable package that can be used by any member of the clinical staff with minimal training, enabling doctors to get straight to the data and focus on patient care. The Company's lead application is in supporting the management of chronic Graft-Versus-Host-Disease (cGHVD) in post-stem cell transplant blood cancer patients.

NE SCIENTIFIC

COMPUTERIZED GUIDANCE FOR TUMOR ABLATION

LOCATION
BOSTON, MA

STAGE
PRE-CLINICAL DEVELOPMENT, IN CLINICAL TRIALS (FEASIBILITY/PILOT)

NE Scientific's (NES) goal is to improve precision in the ablation of tumors by providing guidance software similar to what is available in radiotherapy but lacking in radiofrequency ablation (RFA) and microwave ablation (MWA). The Company is focused on a first product for guidance of liver RFA—a procedure where, because of lack of computerized guidance, physicians fail to treat completely the volume of the tumor in 24% of cases for medium tumors (3–5cm) and in 58% of cases for large tumors (>5cm), leading to recurrence after the treatment. The software developed by NES uses a computational core which simulates RFA physics and estimates accurately the volume of the ablation. This volume is shown fused to CT images during the procedure, together with a representation of the tumor volume, so that physicians can visually evaluate whether portions of the tumor are still untreated and immediately treat them if that is the case. NES is currently developing a similar software for MWA.

SIMPHOTEK

3D SIMULATION SOFTWARE AND HARDWARE SYSTEM FOR PDT TREATMENT PLANNING AND REAL-TIME DOSIMETRY

LOCATION
NEWARK, NJ

STAGE
PRE-CLINICAL DEVELOPMENT

Simphotek is developing a software and hardware system (Dosie™) for photodynamic therapy (PDT) treatment planning and real-time dosimetry that controls the applied light intensity and treatment duration to maximize the treatment efficacy. The system guides oncologists in delivering therapeutic dose to the cancer patients helping to arrange lasers, fibers, and spectrometers with light-activated drugs to generate cytotoxic singlet oxygen that actually kills cancer cells. In order to calculate the threshold concentration of cell killing agents, Dosie™ divides the entire tumor shape into millions of voxels and calculates the doses in every one of them. This involves heavy calculations running on a custom-built portable "computer" augmented by a powerful massive-parallel GPU designated for light propagation calculations and multi-core CPU for drug and cancer killing agents' simulations. The major breakthrough is that Dosie™ is capable to run in near real-time. PDT works because excited by light and drug singlet oxygen causes necrosis and apoptosis, triggering membrane rupture and cell death. Initial indications include non-small cell lung cancer and head and neck cancer.

SURGICAL INNOVATION ASSOCIATES

BIO-ABSORBABLE SURGICAL MESH DEVICE

LOCATION
CHICAGO, IL

STAGE
COMMERCIALLY AVAILABLE

Surgical Innovation Associates (SIA) has developed DuraSorb™, an absorbable surgical mesh invented to decrease the cost of breast reconstruction relative to the current standard for women who have had mastectomies, while avoiding the long-term complications that have led to patient harm, complications, and mesh-related lawsuits. SIA has FDA 510(k) clearance and a growing roster of clinicians using the device. DuraSorb™ is "there when you need it, gone when you don't" and was designed to provide temporary soft tissue support, then fully resorb when such support is no longer required, reducing risk of long-term complications that have plagued permanent mesh products. DuraSorb™ was created to address safety, cost, and access issues associated with market-leading products made of animal and human cadaveric tissue. Another major indication for this technology is the $1.2B hernia repair/abdominal wall reconstruction market.

ENVISAGENICS

USING AI TO DELIVER THERAPIES FOR RNA SPLICING DISEASES

LOCATION
NEW YORK, NY

STAGE
NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

Envisagenics' innovative SpliceCore® technology envisions the genome as a collection of exons and leverages proprietary machine learning algorithms to predict the impact of splicing events on the structure and function of gene products and specific points of therapeutic intervention to enable design of anti-sense oligonucleotide (ASO) therapeutics. The company's first therapeutic program is in triple negative breast cancer. In only 8 months, Envisagenics discovered a novel splicing isoform of a key signaling enzyme, which is present in 65% of TNBC patients, and designed an ASO against this target. The SpliceCore-designed ASO has proven to specifically kill almost 80% of TNBC cell lines and is now being tested for efficacy in organoid and preclinical mouse models. While ASO development is a core competency at Envisagenics, the company is growing and diversifying its portfolio to create new partnership opportunities in areas of exceptional commercialization potential and patient need such as Immuno-oncology (IO).

INHERET

SAAS PROGRAM TO IDENTIFY INHERITED RISK

LOCATION
ANN ARBOR, MI

STAGE
INHERET 2.0 IS COMMERCIALLY AVAILABLE, EHR INTEGRATION IN TESTING/PILOT

InheRET 2.0 is an online family health history collection and interpretation program utilizing cognitive programming to accurately identify patients at increased risk for hereditary disease without taking up any clinical time, while providing patients and their healthcare provider with next step recommendations, educational materials, access to genetic counselors and a recommended list of mutations that should be included in any risk panel test ordered.

QUANTITATIVE RADIOLOGY SOLUTIONS

LOCATION
PHILADELPHIA, PA

STAGE
IN CLINICAL TRIALS (FEASIBILITY/PILOT)

Quantitative Radiology Solutions (QRS) helps physicians make better treatment decisions through automated analysis of medical images. The Company offers advanced body-wide analysis of images for applications in radiology, radiation oncology, and medical oncology. QRS's Automatic Anatomy Recognition (AAR) software supports recognition and delineation of anatomical objects and diseased tissue in multiple body regions using MRI, CT, and PET/CT images.

ONE-PAGE COMPANY OVERVIEWS

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

AURORA ONCOLOGY

Targeted Therapeutics for Bladder Cancer

Richard Duke | Richard.duke@cuanschutz.edu | 720-255-5722 | Auroraoncology.com

COMPANY OVERVIEW

Aurora Oncology is focused on novel therapies to treat bladder cancer. The Company's lead product is an epidermal growth factor-diphtheria toxin-A fusion protein (DT-EGF) for intravesicular treatment of superficial bladder cancer (also known as non-muscle invasive bladder cancer; NIMBC). DT-EGF is poised to enter clinical development. A second product in an earlier stage of development is comprised of a gold nanorod-anti-EGFR mAb fluorophore conjugate (Nano-anti-EGFR) with potential to detect and treat superficial bladder cancer. A third product is being explored for metastatic breast cancer (AO-201).

MARKET & COMMERCIALIZATION STRATEGY

More than two million individuals worldwide have bladder cancer with 1.2 million seeking therapy. The market size for Aurora's products is in excess of $1B. In the US, bladder cancer accounts for ~80,000 new cases and ~15,000 deaths annually and is one of the most expensive cancers to care for. Current therapy involves cystoscopic resection and intravesicular BCG administration with recurrence/progression in about 40% of cases that eventually require cystectomy (removal of the bladder) or other aggressive therapy. BCG therapy is >30 years old, involving the use of live, attenuated TB bacteria and is associated with clinically important side effects in a high proportion of patients. Since metastatic disease is incurable and living with a cystectomy can be devastating, it is critical to treat bladder cancer when it is superficial to prevent disease progression. Aurora's products will be developed utilizing published FDA guidelines, covered by Medicare/insurance, and used by urologists in outpatient clinics.

TECHNICAL & COMPETITIVE ADVANTAGE

DT-EGF is a fusion toxin that combines modified diphtheria toxin with EGF; it binds to cancer cells that over-express EGFR and is internalized leading to rapid cell death. DT-EGF is highly efficient as a single molecule of internalized DT is sufficient to kill a cell. Intravesical delivery of DT-EGF via a catheter has been shown to be highly efficacious in preclinical syngeneic and patient derived xenograft models of bladder cancer in mice with the absence of systemic toxicity in these models and in preliminary studies in dogs with bladder cancer. A comparable approach in NMIBC with an antibody-toxin conjugate targeting EpCAM is in phase III development (Vicinium; Sesen Bio). EGFR expression is more common than EpCAM expression, appears to be non-overlapping with EpCAM, and confers higher risk and worse prognosis than EpCAM expression. Immune checkpoint inhibitors are approved to treat late stage metastatic bladder cancer and are being tested in NMIBC in combination with BCG and Vicinium.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

IND enabling studies with GMP product will begin in Q3, 2021. IP consists of:

- US patent number 9,321,820, "Compositions and methods for treating bladder cancer" - filed October 14, 2010
- US Patent number 10,052,393, "Multifunctional nanomaterials for the treatment of cancer" - filed January 25, 2013
- PCT/US20/29396 "Compositions and Methods for Treatment of ..." - Filing Date: April 22, 2020, Priority Date: April 23, 2019

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	Improved construction - Lead Compound declared generating new IP – composition and methods
3/2021	Initiate non-clinical pharmacology and toxicology studies
11/2021	File IND

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
Prior to 2018	SBIR and CO state grants	Early stage funding leading to publication (above) and corporate activities	$0.5M
2019	SPARK grant	Non-GMP manufacturing of potential lead compounds	$0.1 M
2018-Present	SBIR fast-track grant	Enabled lead optimization and will allow completion of IND-enabling studies	$2.3M

USE OF PROCEEDS

Aurora is seeking $15M for all activities to complete clinical Phase II human proof of concept, with a first tranche of $6M needed to complete IND-filing, a Phase Ib/IIa clinical trial in BCG-refractory NMIBC and establishment of a recommended phase 2 dose.

KEY TEAM MEMBERS

Mike Glode, MD, Founder and President, Involved in the clinical development of ONTAK® (DAB-IL-2) and Lupron®
Shawn Zinnen, PhD, CSO, Serial entrepreneur (MBC Pharma, Osteros BioMedica, Zincyte) Ribozyme, Sirna
Rick Duke, PhD, Chairman and Acting CEO, Serial entrepreneur (GlobeImmune, ApopLogic Pharmaceuticals, MenoGeniX)
Tom Flaig, MD, Founder, SAB, Chair, Panel for Bladder Cancer, National Comprehensive Cancer Network (NCCN)
Won Park, PhD, Founder, SAB Member, Professor CU. Expertise: Optics, Nanostructures and Bioengineering
Dan Theodorescu, MD, Founder, SAB Member, Professor Urology and Director, Cedars-Sinai Cancer Center, IOM

COARE HOLDINGS

Humanized mAbs to Treat Pancreatic Cancer

Edwin Bannerman-Menson | Eddie@COAREHOLDINGS.COM | 405-510-6989

COMPANY OVERVIEW

COARE is a pre-clinical stage biotechnology company developing novel therapeutic drugs to treat pancreatic cancer. Currently it focuses on the development of first-in-class therapeutic platform technologies that attack the validated tumor stem cell (TSC) target DCLK1. The underlying technology was licensed to COARE from the University of Oklahoma Health Sciences Center (OUHSC). TSCs, also known as Tumor Initiating Cells or Tumor Stem-Like Cells, represent a small sub population of the bulk tumor mass that starts the cancer growth and are responsible for tumor metastasis. They are often drug and radiotherapy resistant and are largely responsible for tumor recurrence. DCLK1 is a major regulator of tumor initiation, progression and metastasis. It regulates Epithelial Mesenchymal Transition (EMT), and increased DCLK1 is associated with poor overall survival in many solid tumor cancers. Currently, there are no FDA approved drugs or therapies on the market that target TSCs. COARE's lead candidate is CBT-15.

TECHNICAL & COMPETITIVE ADVANTAGE

COARE's technical and competitive advantage is based on targeting the TSC population within the pancreatic cancer mass by inactivation of the tumor promoting protein DCLK1. COARE has identified unique extracellular epitopes on DCLK1 isoforms that are upregulated in PDAC. The lead candidate, CBT-15(h), is a humanized monoclonal antibody (mAb) that binds to these extracellular domains and interrupts pro-oncogenic signals, inhibits EMT, induces tumor suppressor miRNAs, and potentially reactivates host anti- tumor immunity. CBT-15 would be a first-in-class, anti-TSC with the potential single agent use or as adjuvant therapy with other chemotherapeutic strategies including immunotherapy. The targeting of this critical cell type within solid tumors has a therapeutic potential to overcome drug/radiotherapy resistance thereby overcoming one of the major adverse effects of traditional chemotherapy.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

COARE's technology was developed in the Houchen Lab at OUHSC and the Intellectual Property (IP) for this and other related technology is licensed to COARE for further development and commercialization. COARE has retained the services of Foley and Ladner law firm to craft, protect, and expand the IP. Their firm has expertise in biotechnology, biopharmaceutical, diagnostics, regenerative medicine, chemical, pharmaceutical, and nanotechnology. Antoinette F. Konski, partner and intellectual property lawyer, is COARE lead counselor. Ms. Konski works with life science clients, creating and optimizing value in intellectual property portfolios encompassing technologies that include personalized medicine, regenerative and stem cell biology, antibodies, immunology, gene therapy, nanotechnology, diagnostics, small molecules and drug delivery. She represents public and private companies and universities.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
8/2020	Pre-clinical evaluation of target
Now-Q1 2022	DCLK1 mAb ING-Enabling Activities
Q1 2022	IND Filing

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2013-2020	Grant Funding	NIH-NCI (Various awards)	>$3.4M

USE OF PROCEEDS

COARE is currently seeking investors and or strategic partners to accelerate pre-clinical studies and manufacturing required for a successful Investigational New Drug application to the FDA in preparation for Phase 1 clinical trials in patients.

KEY TEAM MEMBERS

Edwin Bannerman-Menson (Co-founder & CEO/COO), 25+ years' technology and startup experience

Courtney Houchen, MD (Co-founder & CMO), Expert in cancer stem cell biology; 25+ years' experience in gastrointestinal basic and translational research

Frank Griffith Jr. (Co-founder & President), 35+ years' experience in pharmaceutical sales and marketing; Former Senior Executive in sales, marketing and Brand Director at Roche for Hepatitis C Specialty Care Marketing team

Ed Jarbath (CCO), 20 years' experience in biopharmaceuticals

DIAGNOLOGIX, LLC

Closed Cell Sorting System Enabled by Targeted Microbubbles

contact@diagnologix.com | 858-312-6036 | diagnologix.com

COMPANY OVERVIEW

Diagnologix pioneers in cell-processing systems to sort, isolate, and manipulate stem cells, immune cells, and circulating tumor cells in bulk-volume biological fluids (e.g. blood) for research and clinical applications. Diagnologix repurposes the lipid-shelled perfluorocarbon-filled microbubble (MB), which has been approved by the FDA as an ultrasound contrast agent, as a self-driving vehicle for cell separation and as a tunable artificial cell for target-cell regulation. The Company is currently focused on streamlining the workflow for sorting and expanding the naïve T cells to overcome clinical bottlenecks of cell processing and production, including CAR-T cell manufacturing. In two years, Diagnologix will accomplish a scalable and closed-cell manufacturing system (BUBLES), which assembles all cell processing steps including isolation of specific T cell types to subsequent cell activation and expansion in a single unit. This innovation can substantially lower the cost of cell manufacturing and potentially decentralize CAR-T cell production, therefore benefitting more patients.

MARKET & COMMERCIALIZATION STRATEGY

Cancer gene therapies using engineered T lymphocytes will reach over $10 billion in sales by 2021. The stem cell therapy market size is estimated to reach $170 billion by 2020. Stem cell acquisitions are estimated to dominate the market, with revenues estimated at $10.9B. The T-cell therapy market is predicted to be worth USD $25B by 2030, expanding at an annual growth rate of over 101% during this time period. Large-scale cell isolation for clinical use is dominated by magnetic cell sorting technology, and small-scale cell isolation for research is dominated by fluorescence activated cell sorting. Diagnologix's targeted microbubble-based products can fill a market niche of large-scale serial multi-marker sorting to cost-efficiently manufacture a distinctive cell type (e.g. TSCM and lineage-specific stem cells) for cell therapy. Diagnologix has strategically partnered with several industry and academic institutions to collaborate in various manufacturing and research endeavors, including GMP production for clinical implementation.

TECHNICAL & COMPETITIVE ADVANTAGE

A closed CAR-T cell manufacturing system based on BUBLES has the following advantages: 1. Can produce Tscm cells directly by multi-marker serial selection, greatly reducing the cost of biological materials; 2. Eliminates bead removal steps:, simplifying the manufacturing procedures and preserves cell viability; 3. It is a portable and automated device that is easy to operate and decentralizes the cell therapy clinics. Currently, magnetic cell sorting (MACS) techniques, particularly the Miltenyi system, are the main technology for targeted cell isolation in bulk. MACS is mainly used by a single surface marker selection because magnetic particles are difficult to remove. The other new method, Streptamer technology (acquired by Juno in 2015), enables multi-marker selection but requires extensive antibody modifications and bead removals, and consequently will not improve the manufacturing complexity and production cost. There is a clear market need for a multi-maker cell sorting platform for bulk targeted cell isolation.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

- Regulatory: medical device 510(k)
- IP: two series of world-wide patent applications, two US patents and two international patents granted in 2019, multiple pending applications

KEY MILESTONES

DATE/YEAR	DESCRIPTION
12/2020	Anti-CD3/CD28 microbubbles T cell activator ready (meeting QA/QC) for research market
06/2021	Production of GMP-grade microbubbles for clinical applications
12/2021	Completion of a functionally closed automated system for CAR-T cell production

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2012-2019	SBIR phase II contract	SBIR Phase I and II grants/contracts	$5.1M

USE OF PROCEEDS

For next two-three years: Commercialization of RUO kits ~$1.5M, Developments of clinical devices and GMP products ~$5M.

KEY TEAM MEMBERS

Yu-Tsueng Liu, MD. Ph.D. (Acting CEO &Co-founder), 30 years' combined experience in biomedical research and clinical practice, specializing in the research and development of cancer and infectious disease diagnosis and treatment
Guixin Shi, Ph.D. (Chief Scientist), 15+ years' experience in chemical engineering and biomedical research
Mindy Yin, Ph.D. (Chief Operating Officer), 17 years' experience in oncology research and development experience in pharmaceutical industry
Benjamin Carson (Legal Counsel), Expert in M&A; legal counsel for Diagnologix since 2013
Scientific Advisor Board, Dennis Carson, MD, UCSD Moores Cancer Center; Robert Schooley, MD, UCSD Medical School; Sadik Esener, Ph.D., OHSU Knight Cancer Institute

FIBROSIX INC.

Small-molecule Therapeutics for Fibrotic Diseases

Kendell M. Pawelec | ceo@fibrosix.com | 810-220-9307 | fibrosix.com

COMPANY OVERVIEW

FibrosIX is a pre-clinical stage biotechnology start-up, developing proprietary first-in-class small-molecule therapeutics that inhibit fibrotic disease. These drugs modulate a critical signaling pathway that plays a central role in the pathogenesis of fibrotic disease. The lead drug candidate, FBX081, is being developed for the prevention of treatment-induced lung fibrosis in cancer patients, caused by chemotherapy (bleomycin) or radiation therapy.

MARKET & COMMERCIALIZATION STRATEGY

Over 300,000 cancer patients in the US per year are at risk of developing lung fibrosis due to chemotherapy and radiotherapy treatments. Lung fibrosis results in life-long disability with high follow-on healthcare costs and is fatal in 2-5% of the cases. There is a significant unmet clinical need for new drugs to treat this condition and limited competition in the area. This market is driven by the increase in global cancer occurrence. As the Company has learned from clinicians, there is currently no way to predict the development of lung fibrosis during cancer treatment. Therefore, FBX081 is envisioned to be incorporated into standard chemotherapy and radiotherapy for patients in the highest risk groups (>65 years of age, those with comorbidities).

TECHNICAL & COMPETITIVE ADVANTAGE

The FibrosIX lead compound, FBX081, has >50% oral bioavailability, mid-nanomolar potency, and can be dosed once daily, based on its pharmacokinetics. The compounds developed by FibrosIX Inc. inhibit fibrosis through a critical step in the fibrosis pathway: Myocardin-Related Transcription Factor and Serum Response Factor (MRTF/SRF) signaling. Unlike most drugs in the pre-clinical pipeline that target only a single pro-fibrotic signal, MRTF/SRF mediates the majority of fibrotic signals. This is important for complex cancer treatment regimes, which often include both chemotherapy and radiotherapy. Currently, the standard of clinical care is the alleviation of fibrosis symptoms, without treatment of the underlying disease. The drugs in clinical trial (nintedanib and pirfenidone) have thus far reported only mixed efficacy.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

In targeting treatment-induced lung fibrosis, FibrosIX is taking advantage of the translatable animal models available and the feasibility and cost-effectiveness of clinical trials. FibrosIX acquired an exclusive option to license the intellectual property (US 10,662,183), jointly held by the University of Michigan and Michigan State University entitled "Inhibitors of Myocardin-Related Transcription Factor and Serum Response Factor (MRTF/SRF)-Mediated Gene Transcription and Methods for Use of the Same" (priority date: November 7, 2014). This patent encompasses the composition of matter for a novel series of potent small molecule inhibitors (including the lead compound FBX081) of the Rho/MRTF-mediated gene transcription mechanism in fibrosis and cancer. Additional filings for composition of matter are anticipated in late 2020.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
04/2020	Submission of Phase I SBIR: radiation-induced lung fibrosis
12/2020	Completion of Phase I SBIR: bleomycin-induced lung fibrosis
01/2021	Submission of Phase II SBIR: treatment-induced lung fibrosis

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
06/2020	Pre-Seed Funding	Red Cedar Ventures	$10K
08/2018	Phase I SBIR	NCI/NIH: CCG-257081 as a preventive therapy for bleomycin-induced lung fibrosis	$300K
08/2018	Grant Funding	Michigan Emerging Technology fund	$25K
01/2018	Pre-Seed Funding	Red Cedar Ventures	$50K

USE OF PROCEEDS

FibrosIX is seeking $3.5M to take the program through IND submission in Q2/2022. This includes IND-enabling toxicology studies, scale up of the chemistry, and GMP manufacturing. After the submission of the IND, we will solicit for a further $3M to complete Phase I clinical trials to show clinical proof-of-concept.

KEY TEAM MEMBERS

The team has access to the business resources and backing of the University of Michigan Venture Center and Spartan Innovations (Michigan State University Foundation).

Dr. R. Neubig, MD Ph.D. (Co-Founder & President), World-recognized researcher in fibrotic diseases
Dr. S. Larsen, Ph.D. (Co-Founder & VP of Chemistry), Has led interdisciplinary project teams to deliver four drug candidates into clinical development, with 30+ years' experience as a medicinal chemist in academia and the pharmaceutical industry
Dr. K. Pawelec, Ph.D. (CEO), Has led efforts to scale the manufacture of biomedical devices for clinical translation

GENCIRQ, INC.

Engineered Bacteria for Cancer Treatment

GenCirq, Inc. | contact@gencirq.com | gencirq.com

COMPANY OVERVIEW

GenCirq, Inc. is developing a novel class of bacterial therapeutics that leverages the power of genetic circuits within bacteria to treat disease. The Company programs 'tumor-targeting' probiotic bacteria, which naturally possess tumor homing capabilities, with their Synchronized Lysis Circuit (SLC). GenCirq's proprietary SLC technology allows for targeted delivery of therapeutics inside tumors and enhances safety of the bacterial cancer approach. This is a transformative strategy for delivering cancer therapeutics, where drugs can be locally produced by bacteria and delivered within the tumor, additionally providing immunogenic bacterial substrates to prime an immune response. GenCirq is currently in pre-clinical development of our bacterial cancer therapy platform with delivery of an anti-CD47 checkpoint inhibitor as the lead candidate.

MARKET & COMMERCIALIZATION STRATEGY

While this technology can be compatible with any solid tumor patient, the market opportunity for the initial path to market includes colorectal cancer patients presenting with metastatic disease with a focus on liver metastasis. In the US, there are 145,600 new cases of colorectal cancer each year. Roughly, 30,000 (20%) patients develop metastatic disease in the liver. GenCirq pursues strategic partnerships with major pharmaceutical and large biotech companies to co-develop/sub-license SLC technology for different disease indications and anticipates striking multiple upfront and milestone payment deals that will help them advance the lead asset in cancer therapy through clinical trials.

TECHNICAL & COMPETITIVE ADVANTAGE

Several classes of novel immunotherapeutic drugs in development, such as CD47 checkpoint inhibitors, are hampered by immune-related adverse effects and systemic toxicity. These include neutropenia, anemia, and T-cell depletion. To address this, a localized, immune priming, in situ delivery approach is needed. GenCirq's SLC bacteria infiltrate solid tumors and deliver a broad range of therapeutics via synchronized lysis. The lysis is a self-triggering mechanism, activated only when the bacterial population reaches a certain size. Since the bacteria can only survive within the immune-privileged environment within the tumor, the production and release of therapy is localized. In addition, the bacteria are intratumoral 'bioreactors', as the therapy is produced essentially for free. Bacteria are also cheaply manufactured in comparison to traditional antibody production.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

GenCirq is currently pursuing three exclusively licensed patents that relate to the SLC technology and has exclusively licensed the base SLC patent from UCSD, which broadly covers the use of the SLC design to deliver therapeutics. The Company has filed the patent internationally in Europe, China, Japan, and India (claims have already been accepted in Europe and Japan).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	Began early research partnership with a large pharmaceutical company
11/2020	Completion of collaboration with pharma partner

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016	Funding	Founder loan	$500K
2019	SBIR Grants	NIH; NCI and NCATS	$525K

USE OF PROCEEDS

GenCirq's goal is to complete IND-enabling work for their lead product and conduct a 40-patient Phase I study. Funds will cover 15 FTEs over a 4-year time frame. Efforts will cover development of a proprietary anti-human CD47 nanobody, which will be delivered by the SLC bacteria. The manufacturing and CMC will be developed by an experienced bacterial CDMO, which the Company has already engaged, to meet regulatory requirements. Dosing and IND toxicology will also be established prior to human testing. Activities will also include achieving value-inflection milestones of strategic partnerships with established pharmaceutical companies and establishing two other product candidates.

KEY TEAM MEMBERS

Omar Din (Co-founder), Developed the Synchronized Lysis Circuit (SLC) for cancer therapy (Din et al. Nature 2016)
Tal Danino (Co-founder, Synthetic biologist who focuses on programming bacteria as a therapy for cancer; Assistant professor at Columbia University in the Biomedical Engineering Department
Jeff Hasty (Co-founder), Pioneer in the field of synthetic biology with seminal research on the design and construction of gene circuits; Professor at the University of California, San Diego, in Bioengineering and Molecular Biology
Bud Marx (Co-founder), Former Chairman of Gentherm ("NASDAQ"), retired CEO of TMW Enterprises (VC entity), and retired Vice President of Ford Motor Company; Strong expertise in strategic planning and financial forecasting

IRIA PHARMA

Selective cell labeling platform for cancer treatment

Dr. Kaimin Cai | KMCai@iriapharma.com | 217-979-1417 | iriapharma.com

COMPANY OVERVIEW

IRIA Pharma is an Illinois-based, preclinical stage startup dedicated to developing targeted therapeutics and diagnostic solutions to antibody-untargetable disease. IRIA is translating its proprietary cell labeling and targeting technology, Active Tissue Targeting via Anchored Click Chemistry (ATTACK), into cancer treatment as its primary focus to develop first-in-class small molecule-based cancer labeling and targeted therapeutics for untargetable cancer treatment.

MARKET & COMMERCIALIZATION STRATEGY

IRIA's lead product is an ATTACK-mertansine conjugate for triple negative breast cancer (TNBC) and ovarian cancer treatment. In addition to the ATTACK-mertansine product, IRIA is also developing a diverse pipeline with different toxic payloads covering a broad range of oncology indications. The pipeline will provide enormous out-licensing/collaboration/partnership opportunities to support the commercialization of the technology.

TECHNICAL & COMPETITIVE ADVANTAGE

ATTACK technology is a small molecule targeting platform for antibody untargetable cancer treatment. ATTACK includes two steps: 1) Cancer-specific labeling of artificial receptors (azide, N3) on cancer cell surface by proprietary ATTACK-sugar (Sugar-N3). ATTACK- sugar is systemically delivered and metabolized specifically in cancer cells through the novel trigger-responsive design such that cancer cells surface would have enriched artificial receptors than normal cells. 2) Targeted delivery of a dibenzocyclooctynes (DBCO)-containing therapeutic reagent (ATTACK-drug) through highly specific DBCO-N3 Click reaction (specificity of Click reaction resembles antibody-antigen interaction). After the cancer cell surface is modified with the artificial receptor, the antibody-like DBCO can facilitate specific accumulation of therapeutics in the tumors over normal tissues to achieve selective cancer killing. ATTACK inserts artificial receptors on cancer cell surface to achieve targeted delivery of therapeutics in cancer. Therefore, ATTACK can treat cancers without identified overexpressed receptors as opposed to what is required for antibody and antibody-drug conjugate (ADC) targeting.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

IRIA plans to pursue a rare cancer as the first indication for market entry and target recurrent triple negative breast cancer patients following approval of the first indication. The Company expects their lead compound to fall into orphan drug category and will seek for potential accelerated approval after Phase II clinical trial. The ATTACK technology is protected under PCT patent application PCT/US2016/056046 and PCT/US2018/017802. IRIA has obtained exclusive license from University of Illinois at Urbana-Champaign for global rights of the patents. IRIA has also reached a sublicensing deal with Surio Therapeutics Co., Ltd. (China) for developing gastrointestinal (GI) cancer therapeutics in China.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
12/2020	DMPK of lead candidate
12/2020	Series A funding ($4-8M)
12/2021	GMP synthesis and CMC study complete
03/2021	GLP toxicity study complete

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	NSF Phase I SBIR	Development of taxane based ATTACK treatment for triple negative breast cancer	$225K
2019	NIH Phase I SBIR	Development of mertansine based ATTACK treatment for triple negative breast cancer	$300K

USE OF PROCEEDS

IRIA will use funding for lead candidate screening and optimization, IND-enabling studies of lead candidates (CMC, DMPK, toxicology evaluation), pipeline expansion in new indications, and senior team member hiring.

KEY TEAM MEMBERS

Dr. Jianjun Cheng (Cofounder & President),20+ years R&D in biomaterials, nanomedicine, cancer therapeutics
Dr. Kaimin Cai (Cofounder & CTO),10+ years R&D in preclinical therapeutic development
Dr. James Zhang (VP), 10+ years in leading startup development, fund raising, management, and marketing
Ying Sun (COO), 20+ years in drug discovery R&D, corporate management, and IND filing

KEVIRX

Drug Development of Phosphatase Inhibitors

John S. Lazo | jlazo@kevirx.com | 434-422-0179 | kevirx.com

COMPANY OVERVIEW

KeViRx, Inc. is an early stage biotechnology company located in Charlottesville, Virginia. It was co-founded by three professors from the University of Virginia and University of Pittsburgh and seeks to develop newly discovered, first-in-class, small molecules that inhibit the function of one of the most potent cancer-causing protein tyrosine phosphatases, PTP4A3. KeViRx is armed with a drug-like lead compound, **KVX-053**, which is a highly potent (Ki=30 nM), selective, reversible, allosteric inhibitor of PTP4A phosphatases with documented cellular and preclinical anticancer activity in mice. The cellular actions of **KVX-053** require the presence of the target protein, PTP4A3. KeViRx has tested 65 analogs of KVX-053, including chemodegraders, and applies a photoredox flow process that enables a low cost, reproducible production of our target compounds.

MARKET & COMMERCIALIZATION STRATEGY

In the US, ~20,000 women will be diagnosed with ovarian cancer (OvCa) this year and ~14,000 will die; ~21,000 individuals will be informed they have acute myeloid leukemia (AML) and ~11,000 will die. Worldwide >500,000 people will die of these two diseases annually. These deaths dramatically illustrate the significant unmet medical need for a radically new treatment strategy for drug-resistant and refractory OvCa and AML, for which there are currently no effective treatments. KeViRx has focused on employing small molecule inhibitors of PTP4A3 phosphatase for these two orphan diseases, because of its essential role, but our therapeutic approach will have broad applications to many other human cancers. It is estimated that the current total available market (TAM) for OvCa and AML are $2.3B and $731M, respectively. The two initially targeted diseases have anticipated CAGR of 13-17%. KeViRx's commercialization strategy is to complete IND-enabling preclinical studies and Phase I/II clinical trials with the goal of having a large pharmaceutical company successfully complete Phase III and achieve FDA approval to market the drug.

TECHNICAL & COMPETITIVE ADVANTAGE

KeViRx possesses the most potent and selective known inhibitor of PTP4A3 and is collaborating with internationally known OvCa and AML physician-scientists to design and implement preclinical studies. KVX-053 has a novel structure, and we recently developed a photoredox flow synthesis that is adaptable to GMP flow manufacturing platforms. There are no competitive small molecules targeting PTP4A3 in development, and almost no clinical trials focused on protein tyrosine phosphatases. This makes our approach highly innovative.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

U.S. Patent No. 10,308,663 was issued 06/04/2019, and covers composition of matter and method of use for KVX-053 and related analogs. International patents have also been filed and two other US patents are pending. KeViRx has an evaluation and option agreement in place with the University of Virginia and University of Pittsburgh. KeViRx is currently recruiting an individual experienced in Regulatory Affairs to guide the orphan disease focused clinical trials.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
12/2020	Scale up synthesis of lead compound and backup candidates
12/2021	Complete preclinical antitumor studies
07/2021	Initiate GMP synthesis
03/2021	FDA meeting
07/2022	Complete DMPK studies
02/2022	Complete preclinical toxicology studies

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016	Founders	Startup funds	$75K
2016	Ivy Foundation Grant	Funds provided by UVA for IP development	$160K
2019	NIH Grant CA228774	Phase 1 SBIR	<$290K
2020	Commonwealth Research Commercialization Fund	Virginia Center for Innovative Technology grant for start-up companies	$75K

USE OF PROCEEDS

KeViRx will use the funds to accelerate the IND-enabling preclinical antitumor studies, GMP synthesis, and DMPK and toxicology studies.

KEY TEAM MEMBERS

Elizabeth R. Sharlow, Chief Executive Officer**; John S. Lazo**, Chief Scientific Officer**; Peter Wipf**, Chairman, Scientific Advisory Board**; John R. Cornelison**, Senior Scientist (Biological Sciences)

METACLIPSE THERAPEUTICS

Personalized Cancer Immunotherapy

Shaker Reddy | sreddy@metaclipse.com | 404-380-1342 | metaclipse.com

COMPANY OVERVIEW

Metaclipse Therapeutics, founded in 2012, is a late-stage preclinical company licensing the technology out of Emory University. The Company's core technology comprises membrane-bound biological adjuvants, which Metaclipse is developing for oncology and infectious disease indications. Specific areas of focus include personalized cancer immunotherapies and enhanced vaccines for Influenza and SARS-CoV-2 viruses. The lead indication for the personalized cancer immunotherapy platform (Membrex™) is triple negative breast cancer (TNBC), an area of significant unmet medical need with few targeted treatment options.

MARKET & COMMERCIALIZATION STRATEGY

Metaclipse has generated robust preclinical data supporting synergy of their immunotherapy approach with immune checkpoint inhibitors (ICIs) in multiple oncology indications. The lead indication, TNBC, has a predicted market size of $4.1B. Additional indications, such as head and neck and lung cancer, have market sizes of $1.4B and $10.9B, respectively. The Company expects their approach to be administered in combination with approved standard of care, which includes chemotherapy and an ICI for TNBC, head and neck, or lung cancer. Strong preclinical data indicate that combination of the Metaclipse approach with an ICI will increase anti-tumor immune responses, leading to increased survival. The Company intends to pursue a strategic partnership with a large pharmaceutical company.

TECHNICAL & COMPETITIVE ADVANTAGE

Although ICIs have revolutionized the field of immunotherapy, they only work for 20-30% of patients. Likely key reasons for this disparity are the requirement for pre-existing immunity and the high variability of tumors. Most advanced tumors are considered "cold-tumors", meaning immune cells cannot infiltrate the tumor. The MembrexTM approach generates a personalized tumor membrane-based immunotherapy capturing the unique antigenic signature of a tumor without the need for sequencing (as in neo- antigen peptide approaches) or the cumbersome, time-consuming act of culturing cells (as required in dendritic cell or CAR-T cell strategies). Competitive approaches take 4-6 months to generate a vaccine and can miss key antigens, while the Metaclipse approach can produce a personalized, cell-free vaccine in just 14 days that covers both mutated/up-regulated proteins and carbohydrates.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Metaclipse conducted a successful pre-IND meeting with the FDA in May 2017 discussing CMC and toxicology plans. An independent GLP toxicology study has been completed and revealed no significant safety concerns. Metaclipse plans on filing an IND in 2Q 2021 and is planning to conduct a phase 1 clinical trial in metastatic TNBC patients at Winship Cancer Center of Emory University in mid-2021. Metaclipse has established a strong IP portfolio surrounding the technology, filing 4 US patents and 1 EU patent. They plan on filing additional patent applications covering manufacturing of key drug substances and the drug product manufacturing process patent in 2020. In addition, the technology is protected by trade secrets.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
04/2021	Complete cGMP manufacturing of drug substances (GPI-protein adjuvants)
06/2021	Initiate Phase 1 clinical trial in metastatic TNBC patients

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2012-2013	GRA Seed Grant	Seed funding from Georgia Research Alliance to develop purification technology	$200K
2013-2014	SBIR Phase I Grant	Preclinical development/proof-of-concept in 4T1 murine TNBC model	$145K
2013-2014	Coulter Foundation Grant	Technology Assessment and Guidance Consulting	$50K
2015-2016	Investment Round	Friends and Family Investment Round	$1M
2016-2021	R01 Academia/Industry Grant	Academia/Industry Partnership with Emory University to translate TNBC vaccine	$2.5M
2017-2019	SBIR Direct Phase II Grant	TNBC Vaccine Product Development	$1.86M
2017-2019	SBIR Phase I Contract Grant	Adjuvant Development for an Influenza Vaccine for the Elderly	$230K
2019-2022	SBIR Phase II Contract Grant	Adjuvant Development for Influenza and COVID-19 Vaccines for the Elderly	$4.2M

USE OF PROCEEDS

Metaclipse is currently raising a Series A funding round of $10M to complete the Phase 1 program.

KEY TEAM MEMBERS

Shaker Reddy, M.S. (President and CEO), Serial entrepreneur and seasoned executive with proven operational experience; **Periasamy Selvaraj, Ph.D. (CSO)**, Professor with extensive publication record in tumor immunology and immunotherapy; **Michael Coleman, Ph.D. (Business Development Consultant)**, 24+ years in biotech development and fundraising; **Kamal Kannan, Ph.D. (VP Product Development)**, Expert in biological product development including IND filings; **Guy T. Clifton, M.D. (Clinical Trial Consultant)**, Extensive experience in breast cancer clinical trials, including TNBC **Christopher Pack, Ph.D. (Director, Preclinical Research)**, Extensive expertise in vaccine design and cancer immunotherapy; **Sampath Ramachandiran, Ph.D. (Director, Product Development)**, Broad experience in protein biochemistry and cancer biology

ONCOCEUTICS

Developing a novel molecule for a subset of gliomas

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COMPANY OVERVIEW

Oncoceutics is a clinical-stage biopharmaceutical company engaged in the discovery and development of a class of novel compounds for oncology. The company's lead candidate is ONC201, an oral, small molecule, dopamine receptor D2 (DRD2) antagonist and ClpP agonist. Results from the Company's clinical trials indicate that ONC201 demonstrates efficacy in several tumor types where the dopamine pathway is dysregulated. In its lead indication, H3 K27M-mutant high-grade glioma, ONC201 has demonstrated an overall response rate by RANO of 30% as a single agent in the recurrent setting where there is currently no effective treatment, and objective responses have not been previously reported. Oncoceutics currently has three ongoing clinical trials in adult and pediatric patients with these gliomas, which represent the pivotal program for its first regulatory approval. The company's additional Phase I and Phase I/II trials include biomarker-enriched indications with dopamine dysregulation where ONC201 has shown early signs of efficacy, including select neuroendocrine tumors and endometrial cancer. Oncoceutics' pipeline includes a number of analogs with distinct molecular targets or target pharmacology that enable efficacy in pre-clinical models in a spectrum of diverse cancers. ONC206, the company's second molecule, is planned to enter Phase I clinical trials for central nervous system tumors in 2020.

MARKET & COMMERCIALIZATION STRATEGY

Oncoceutics is pursuing previously treated H3 K27M–mutant glioma as the lead indication for ONC201. The H3K27M mutation occurs in 70-90% of Diffuse Intrinsic Pontine Gliomas (DIPG), 15-20% of pediatric gliomas, and 8-10% of adult gliomas. Combined, these tumors occur in ~2,100 people per year, including 1,350 adults and 750 pediatric patients. Given the unmet medical need as a WHO Grade IV brain tumor with no effective treatment after first-line radiation, it is anticipated that ONC201 could command pricing similar to other orphan oncology products, leading to a US market opportunity in the range of $500M to $1,000M annually. There is also an opportunity to expand the market for ONC201 to a variety of other indications where the dopamine pathway is dysregulated, including endometrial cancer and neuroendocrine tumors.

TECHNICAL & COMPETITIVE ADVANTAGE

ONC201 is the founding member of the imipridone class, a class of novel small molecules that kill cancer cells by uniquely binding to GPCRs and ClpP. ONC201 exhibits robust drug-like chemical characteristics: excellent chemical stability, high aqueous solubility at low pH, and high lipophilicity at physiological pH. These attributes enable oral bioavailability that achieves therapeutic concentrations and wide distribution throughout the body to target tissues, including brain, bone marrow and lymph nodes. ONC201 kills cancer cells while sparing normal cells by specifically antagonizing DRD2 and agonizing ClpP. ONC201 has exhibited clinical efficacy in recurrent H3 K27M–mutant glioma. There is no treatment that shrinks tumors, reverse neurological symptoms, or prolongs survival for patients with this disease (median 12-18 months). ONC201 has demonstrated a 30% overall response rate that has the potential to support FDA approval of ONC201 via an Accelerated Approval path.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The Company's IP portfolio provides broad coverage of imipridone family and life cycle management opportunity. The company has an extensive patent portfolio for ONC201 in the US covering method of use in various cancers, composition claims for di-salt formulation, and therapeutic combinations for all diseases. The company also has issued patents in Europe, Canada, and Japan covering treatment of brain cancer. The company also issued composition of matter patents for other members of the imipridone family and has multiple pending patents worldwide. Additionally, the company is utilizing a variety of regulatory methods for generating additional market exclusivity. Most notably, ONC201 has received an Orphan Drug Designation for the treatment of glioblastoma and H3 K27M-mutant glioma. Furthermore, ONC201 has received Fast Track Designation for the indication of adult recurrent H3 K27M-mutant high-grade glioma. The company is pursuing an FDA approval of ONC201, potentially via an Accelerated Approval path with its ongoing clinical trials. The company expects ONC201 to gain FDA approval in the next two to three years.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q1 2021	Topline NDA data available
2022	NDA Filing
2022/2023	Expected FDA Approval

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016	Founders	Startup funds	$75K
2016	Ivy Foundation Grant	Funds provided by UVA for IP development	$160K
2019	NIH Grant CA228774	Phase 1 SBIR	<$290K
2020	Commonwealth Research Commercialization Fund	Virginia Center for Innovative Technology grant for start-up companies	$75K

USE OF PROCEEDS

Proceeds will be used for a pivotal program toward approval of ONC201 (CMC, toxicology, pharmacology, and clinical studies) and further development of ONC206 (Phase I/Phase II studies) and ONC212 (IND enabling/Phase I studies).

KEY TEAM MEMBERS

Lee Schalop, MD (CEO); **Martin Stogniew, PhD** (Chief Development Officer); **Joshua Allen, PhD** (Chief Scientific Officer); **Michael Chiarella** (VP Clinical Operations); **Sebastian Franzinger** (VP, Finance & Business Development); **Varun Prabhu, PhD** (VP, R&D)

ONCONANO MEDICINE

Ultra pH- Sensitive Micelle Platform

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COMPANY OVERVIEW

OncoNano has pioneered an ultra pH-sensitive micelle technology that, for the first time, promises to enable selective targeting of a wide range of tumor types. The platform can be used to deliver high-value small molecule and biologic payloads for use across the continuum of cancer care: Diagnosis, Staging, Surgery and Treatment. The technology is comprised of a library of proprietary, ultra pH-sensitive polymeric micelles that selectively identify and target cancerous tumors based on their universal property of acidic pH (the Warburg effect). The imaging program with ONM-100 is in a Phase 2 trial for image-guided surgical tumor resection, and in Phase 1 trials was well-tolerated and identified 100% of all tumors found by standard of care (SOC), and occult disease undetected by SOC in 30% of all patients studied. These results have validated the use of the micelle platform for development of the company's therapeutics program currently in a preclinical phase: (i) ON-BOARD™ for selective delivery of micelle-encapsulated or -conjugated small molecules, antibody fragments, and cytokines (e.g. IL-2) to the tumor microenvironment to improve the therapeutic indexes, and (ii) OMNI™ for antigen-containing micelles that activate T-cell immune responses via the lymph nodes.

MARKET & COMMERCIALIZATION STRATEGY

The emerging pan-tumor nature of ONM-100 has validated the use of the micelle platform to deliver a variety of small molecule and biologic therapeutic payloads such as proprietary ON-BOARD encapsulated IL-2 and OMNI encapsulated antigens representing a multibillion-dollar market. Additionally, OncoNano has two research collaborations with leading pharmaceutical companies using the ON-BOARD platform to deliver proprietary molecules directly to the tumor and is seeking additional partnerships to exploit its unique technology to improve upon existing and developmental treatments. Annually, the ~1 million cancer surgeries in the US and ~5 million cancer surgeries worldwide translate to a market for the ONM-100 imaging agent of ~$2B.

TECHNICAL & COMPETITIVE ADVANTAGE

OncoNano is pioneering the concept of pH as a universal biomarker for tumors and associated low pH-based activation mechanisms that are being leveraged for the ONM-100 imaging agent to trigger fluorescence and to develop micelles such as ON-BOARD and OMNI for therapeutic applications. The core technology is a library of tunable, ultra pH-sensitive micelles that are activated by the low pH nature of the tumor microenvironment compared to that of normal tissue and is applicable to all tumor types regardless of their oncogenic phenotype. This approach ensures targeted delivery of payloads to the point of interest while minimizing systemic exposure for therapeutic payloads as well as associated dose-limiting toxicities – challenges that have been a liability for competitive approaches and provide a significant advantage for OncoNano's platform micelle technology. The company's ON-BOARD and OMNI micelle platforms offer the promise of tumor-specific delivery of cancer therapeutics and next generation STING agonists through either encapsulation or conjugation to the micelles with the potential to improve therapeutic outcomes.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

ON-BOARD and OMNI drug development candidates are in preclinical studies. OncoNano has a broad portfolio of patents covering composition of matter and methods of use for the core micelle technology with patent coverage extending beyond 2031.

KEY MILESTONES

DATE/YEAR	MILESTONE	DESCRIPTION
2021	IND Submission	OMNI Next Generation STING Agonist (ONM-500)
2022	IND Submission	ON-BOARD Cancer Therapeutic (ONM-400)

CAPITALIZATION HISTORY

OncoNano has raised over $58MM to date including private venture financing ($35MM) and grants ($23MM) and is currently raising Series B funding of $50-60MM.

USE OF PROCEEDS

OncoNano will use its financing for continued development of the cancer therapeutic delivery platforms and ongoing Phase 2 study for ONM-100. The company was recently awarded its second grant from the Cancer Prevention and Research Institute of Texas (CPRIT) which will be used to advance the OMNI ONM-500 next generation STING agonist. OncoNano is seeking partnerships to expand the application of the ON-BOARD and OMNI micelle-based platforms to improve the therapeutic window of cancer treatments and advance its lead product, the ONM-100 imaging agent, to an NDA.

KEY TEAM MEMBERS

Ravi Srinivasan, PhD (CEO) Expert in pharma/medical devices, Highly successful healthcare entrepreneur/executive for 15+ years
Matthew Head, MBA (CFO), 20+ years biotech and operational finance; ex-VP, ex-Head of Finance at ZS Pharma and Alcon
Charles Balch, MD (Chair of SAB) Prof. Surgical Oncology, Research, Division of Surgery, The University of Texas MD Anderson; ex-CEO ASCO, ex-CEO City of Hope Hospitals, ex-EVP MD Anderson

REVEAL PHARMACEUTICALS

The Gadolinium-Free MRI Contrast Agent

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COMPANY OVERVIEW

Reveal aims to transform the $2B MRI contrast agent market, deepening insight with precision imaging and improving patient safety. The patented lead product RVP-001 is a first-in-class gadolinium-free, general purpose contrast agent designed to replace all current MRI contrast agents (GBCAs). GBCAs all cause the heavy metal gadolinium to accumulate in the brain and body of all patients, posing long-term risks. Reveal's pipeline of precision imaging agents promises to provide a noninvasive alternative to biopsy that can be used to detect, stage, and monitor treatment response in many cancers and fibrotic diseases such as NASH and heart failure.

MARKET & COMMERCIALIZATION STRATEGY

40 million times each year, gadolinium-based contrast agents (GBCAs) are used to detect and stage cancer and other diseases, guide treatment, and monitor therapy response, representing a $2B addressable market. But all GBCAs cause accumulation of toxic gadolinium in the brain and body of all patients; GBCAs can also trigger devastating fibrosis in people with kidney disease. Those at greatest risk include people who need repeated contrast enhanced (CE) MRI scans, people with kidney disease, and children. Regulators worldwide have suspended or restricted GBCAs but there are no alternatives. Physicians face a dilemma: expose patients to a toxic heavy metal or deny them vital insight from CE-MRI. Reveal's clinical trials will show that RVP-001 is a safe gadolinium-free alternative to GBCAs and provides the same vital diagnostic information. Reveal will first target patients particularly vulnerable to GBCAs. All radiology practices have vulnerable patients: once in the formulary, radiologists will choose the safest contrast agent for every patient. This is a highly safety sensitive winner-take-most market, as borne out by demonstrated market dynamics. Reveal's precision imaging pipeline will leverage RVP technology to create new markets by solving unmet problems in lymph node staging, thrombus detection, detecting and staging tissue fibrosis (NASH, renal, cardiac), with multi-billion-dollar market potential.

TECHNICAL & COMPETITIVE ADVANTAGE

First-in-class RVP-001 is based on biocompatible manganese and is designed to be a direct substitute for general purpose GBCAs. RVP-001 seamlessly fits existing radiology workflows and will take advantage of an established reimbursement model. Nonclinical data demonstrate RVP-001 to be safer than GBCAs, with equivalent imaging efficacy to GBCAs across a range of indications in animal models. Contrast agents translate readily to the clinic. RVP-001 is completing GLP IND-enabling studies, with Phase 1 clinical trials to start in early 2021. Reveal's team are world experts in MRI and precision imaging, with unmatched ability to drive the pipeline.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Reveal is following the well-established regulatory path used by all approved general-purpose MRI contrast agents. The first indication for RVP-001 is CNS imaging (50% of total market), followed by additional indications (e.g. breast, pediatric). RVP-001 is patented in major markets worldwide; a second patent covers a broad class of related compounds for the pipeline.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2021	Investigational New Drug application
2021	Phase 1 clinical trials and clinical proof of concept)
2022	Phase 2 clinical trials

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017	Grant, Accelerator	Fast Track SBIR ($1.6M), MassChallenge winner ($50k)	$1.65M
2018	Accelerator, Grant	Massachusetts Life Sciences Center (MLSC) MassNextGen ($62k), SBIR ($160k)	$0.22M
2019	Grant	MLSC Milestone Achievement Program ($200k); Fast Track SBIR ($2.24M)	$2.44M
2020	Grant	Commercialization Readiness Program SBIR	$1.00M
2016 - 2020	Founders, Private investors	Notes [clean cap table; <10% of equity]	CONFIDENTIAL

USE OF PROCEEDS

Capital will support an IND and clinical trials for Reveal's lead product, the first-in-class gadolinium-free MRI contrast agent RVP 001. Additional proceeds will be used for pipeline development: liver-specific and precision (fibrosis, thrombus, lymph node) agents.

KEY TEAM MEMBERS

Vera Hoffman, MBA (CEO & co-founder), Business innovation, $1B exit; **Peter Caravan, PhD** (World leader in MRI contrast), Professor, Harvard Medical School; **Eric Gale, PhD** (Co-Inventor RVP-001), Asst. Professor, Harvard Medical School; **Srinivasan Mukundan, MD, PhD** (Clinical Director, Neuroradiologist), Medical Director of MRI, BrighamHealth; **John Amedio, PhD** (Chemistry, Manufacturing & Controls), 25 years technical & regulatory CMC; **Tom Steele, PhD** (Non-clinical Toxicology & Pharmacology), 25 years development & regulatory exp.; **Scott Reeder, MD, PhD** (Professor, V.Chair Research, Chief of MRI), University of Wisconsin Madison; **Gregory Sorensen, MD** (CEO DeepHealth, Executive Chair Imris), Former CEO, Siemens Health N. America; **Michael Tweedle, PhD** (GBCA inventor, led Bracco Research USA), Professor, the Ohio State University

STEMSYNERGY THERAPEUTICS

Innovative, Targeted Cancer Therapeutics

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COMPANY OVERVIEW

StemSynergy Therapeutics (SSTI) specializes in the discovery and development of novel therapeutics that target mechanisms and pathways fundamental to cancer. The Company's approach is to identify drug targetable biology within these pathways to provide greater efficacy with minimal toxicity over current therapies or for cancers with no approved therapeutics. SSTI has a robust preclinical pipeline with seven innovative therapeutics under development and has recently partnered with Exelixis, Inc. to develop a lead candidate WNT pathway inhibitor for clinical evaluation.

MARKET & COMMERCIALIZATION STRATEGY

SSTI's next generation of cancer therapeutics has the potential to impact the lives of millions of cancer patients worldwide, representing a considerable market opportunity. An estimated 1.8 million Americans will be diagnosed with cancer in 2020, and more than 600,000 will die of their disease. Many patients continue to have dismal five-year survival, a point which illustrates the largely unmet need for better cancer treatments which safely and efficaciously target tumors and prevent recurrence and metastasis. Inhibition of WNT and Notch signaling, particularly, present attractive opportunities to significantly impact clinical outcomes in colorectal, breast, esophageal, lung, sarcoma, and other cancers.

TECHNICAL & COMPETITIVE ADVANTAGE

SSTI therapeutics target biology central to tumor growth and recurrence at innovative nodes within crucial oncogenic signaling pathways. In addition to pursuing novel mechanisms of action, this approach confers increased specificity for individual oncogenes required for cancer growth and survival, and with greater therapeutic indices, allows for the avoidance of challenging toxicities.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

SSTI has several active programs in their pipeline targeting Notch and WNT pathway biology with patent protection in place. The Company's goal is to partner or license these assets with pharma companies for clinical development, or alternatively, to capitalize and develop their assets for an IPO with subsequent commercialization. SSTI has also received Orphan Drug Designation and exclusivity for the development of a clinical therapeutic for the treatment of Familial Adenomatous Polyposis (FAP).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
06/2020	Generate additional lead compounds through structure activity relationships and in silico scaffold hopping
12/2020	GMP bulk synthesis, API validation
06/2021	IND-enabling rat safety studies
12/2021	IND-enabling large animal safety studies

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2008	Angel	Initial Angel investment	$200K
2010-2020	NCI SBIR Phase I/II Grants	Various Phase I/Phase NCI Grants, including Phase IIB Bridge Award	$10.609M
2016	NIGMS SBIR	Phase I grant – Development of WNT inhibitors for regenerative burn healing	$225K
2017	SBIR match - Exelixis, Inc.	Licensing agreement deal with a match for Phase IIb SBIR grant	$3M
2018	Exelixis, Inc.	Expansion of partnership for WNT therapeutic program	Undisclosed

USE OF PROCEEDS

StemSynergy currently has no revenue. All additional funding is reinvested into developing the pipeline. SSTI is interested in partnering their Notch inhibitor program with Pharma partners that can propel development and progression through clinical trials for Notch-dependent cancers. The Company is progressing their Notch inhibitors through IND-enabling studies and will soon be ready for large animal safety studies. This would be an appropriate timepoint to develop a partnership with a clinical-stage partner. SSTI has successfully partnered one program with Exelixis and have incorporated this experience and insights into developing the other programs and making them more attractive/de-risked for future partnerships.

KEY TEAM MEMBERS

Anthony J. Capobianco, Ph.D., President, University of Miami School of Medicine
William A. Weiss M.D., Ph.D., University of California at San Francisco
Ethan Lee, M.D., Ph.D., Vanderbilt University Medical School
David J. Robbins, Ph.D., University of Miami School of Medicine

TENSIVE CONTROLS, INC.

Peptide Therapeutic to Reverse Symptoms of PICs

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COMPANY OVERVIEW

There is a significant unmet medical need for a safe and effective drug to reverse the symptoms produced by proinflammatory cytokines (PICs) in many diseases including cancer, renal failure, COPD, heart failure, chronic infections (e.g. Covid-19), and trauma. Tensive Controls (TCI) is developing a peptide therapeutic (TCMCB07) that can reverse many of the symptoms of PICs. TCMCB07 is a first-in-class melanocortin-4 receptor (MC4R) antagonist, originally developed as new standard of care for cancer cachexia patients. Cachexia, including lean body mass wasting leading to multiorgan failure and cytokine sickness behavior, is increasingly recognized as a condition produced by the CNS effects of elevated PICs. In pre-clinical studies, TCMCB07 improved lean body mass and quality of life, while reducing hypothalamic inflammation in cancer models. In a veterinary hospital canine cachexia trial, TCMCB07 demonstrated safety and efficacy in cachectic dogs on treatment for a year.

MARKET & COMMERCIALIZATION STRATEGY

While TCMCB07 has demonstrated efficacy and safety in multiple pre-clinical models, the initial target indication will be for cancer cachexia. The market for a cancer cachexia therapeutic is $2.3 Billion in the US, $50 Billion worldwide. TCI is working with a leading drug development regulatory company to finalize pre-clinical development and plan clinical trials. An IND is anticipated in early-mid-2021. cGMP drug has been produced in large quantities at an acceptable COGS. Partners for toxicology studies and clinical trials have been identified, and final studies to support the IND are underway. TCI anticipates licensing TCMCB07 after the Phase 1 trials. TCI continues to fund the advancement of its platform technology in peptide therapeutics. Several therapeutic targets are being explored to broaden TCI's pipeline as well as creating next generation cachexia therapeutics.

TECHNICAL & COMPETITIVE ADVANTAGE

TCI designed a novel platform technology that imparts drug-like activity to many small-medium sized peptides. To accomplish this, the Company searched the scientific literature to find examples of peptides with unexplained drug-like activity. These peptides were incorporated into a drug-like peptide library, allowing recognition of common derivatizations that can be easily applied to many small-medium sized natural peptides. The result was peptides with oral activity, blood brain barrier (BBB) transport, and enhanced in vivo half-life.; i.e., predictable pharmacokinetics. This approach produced a series of drug-like peptides, including a MC4R antagonist to treat elevated PICs and cachexia, and an angiotensin1-7 analog with enhanced anticancer properties.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

TCMCB07 is in the late stages of preclinical development and TCI is planning their request for a pre-IND meeting with the assistance of Premier Research. With FDA concurrence, TCI will begin the final safety toxicology studies and plans to submit an IND application in the Q1 of 2021. TCI plans to perform Phase 1 and 2 clinical trials in head and neck squamous carcinoma patients at MD Anderson Cancer Center's Radiation Oncology Department. TCI's platform technology is protected by multiple patents.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Sept. 2020 submission	Development of critical questions for pre-IND meeting request with FDA (with Premier Research CRO)
4th Q 2020	Initiation of final IND safety-toxicology studies
1st Q 2021	Completion of negotiations with MD Anderson Cancer Center for Phased Clinical Trials
1st-2nd Q 2021	Completing development of documents for IND package and submission to FDA
2nd Q 2021	Initiation of Phase 1 clinical trial of TCMCB07 in head and neck squamous cell carcinoma patients

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2010-2016	NCI SBIR (Phase I/II/Fast Track), USDA SBIR (Phase I)	SBIR Phase I, Phase II, Fast Track	$4,263,436
2010	IRS Qualifying Therapeutic Discovery Project Award	Matching funds	$63,986
2014, 2016	Missouri Technology Corp. (Angel Round) Potterfield Family Investments, LLC	Convertible note and SAFE Agreement	$175K, $1.5M
2014, 2016	Centennial Investors, Private Investor	Convertible notes	$552K

USE OF PROCEEDS

TCI is raising an A round ($3-5M) to fund final IND safety-toxicology studies. A B-round is anticipated in 2021 for Phase 1 trials.

KEY TEAM MEMBERS

Mr. Russell Potterfield (Executive Chair), Entrepreneur with product design, business startup and exit experiences; Leads 511 Capital; **Kenneth A Gruber, B.A., Ph.D.** (President & CSO), Former Director of Research, California State Polytechnic University, and former Chief of the Chronic Diseases Branch at NIH; Expert in peptide research, including the design of melanocortin peptides; **Bobby Sandage, Ph.D.** (Board Member), President/CEO of Euclises Pharmaceuticals, Inc.; former President and CEO of Coronado Biosciences, VP of Covidien Pharmaceuticals' oncology R&D program, CSO and EVP of R&D at Indevus Pharmaceuticals

NANOVALENT

Targeted NanoSpheres - Nontoxic Cancer Therapeutics

Timothy L Enns, President & CEO | time@nanovalent.com

COMPANY OVERVIEW

NanoValent is developing an innovative technology that could have a broad impact on refractory cancers and form the basis for a scalable business. The Company was formed to create much needed therapeutics for childhood cancers (initially refractory childhood Ewing's sarcoma), hepatocellular carcinomas, and other urgent medical needs. Out of this mission came a patented Targeted NanoSphere (TNS) platform. TNS is a new generation of antibody-targeted nanoparticles that can encapsulate active therapeutics and enable ADC (antibody drug conjugate) type targeting. True tumor-specific targeting with intra-tumoral payload release can potentially increase therapeutic potency and reduce both off-target and long-term toxicity. While the range of potential targets and markets is exciting, the Company's fundamental approach has been to cost effectively develop a small pipeline of proof-in-concept products for partnering with commercial pharmaceutical companies, with a specific lead pediatric oncology application to validate the platform. Significant executive management was added in 2016 and 2017 to drive financing and commercialization. The lead cancer program is moving through GMP production and the secondary program in surgical adhesion treatment has achieved POC in lead optimization.

MARKET & COMMERCIALIZATION STRATEGY

By developing a specific therapeutic for the small Ewing's market (incidence 2000+ US) and demonstrating efficacy in a larger market of hepatocellular carcinoma HCC (500,000 + WW) a sale to a commercial pharmaceutical company would be possible with phase 2a data. The secondary surgical adhesion program could be partnered at IND due the novelty and multibillion-dollar market size.

TECHNICAL & COMPETITIVE ADVANTAGE

By combining proven therapeutic moieties of antibodies for targeting, small improved, patented liposomes for encapsulation and proven chemotherapeutics as a payload, a nontoxic therapy for Ewing's sarcoma and HCC patients should be able to deliver a significantly improved therapeutic for patients worldwide. The same improved liposomal properties are used in NanoValent's surgical adhesion product and benefiting from the manufacturing synergies of common GMP ingredients.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Standard CMC and BLA regulatory approach were discussed in an informal FDA meeting for the cancer program. Phase 1 trials would then be conducted to support a phase 2 program in Ewing's sarcoma. Intellectual property has been granted in the US for the core nanoparticle and additional jurisdictions are under review.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4/2021	Complete GMP Production of NV103
Q2/2022	Complete GLP Toxicology programs for Ewing's sarcoma & HCC
Q4/2022	File BLA for Ewing's sarcoma
Q4/2024	Complete Phase 1 & phase 2 Ewing's sarcoma studies

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2012 & 13	NSF SBIR Phase 1 & 2	Targeted Nanoparticle Delivery Agent for Treatment of Adult Leukemia	$649,848
2012 & 13	NIH STTR (2x)	Nanoparticle Delivery for EWS & Targeted Polymerized Microbubbles	$479,478
2016 & 18	Phase 1 & 2 State Grants	Montana SBIR/STTR Matching Funds Program	$60,000
2017	Seed and Convertible Notes	Management, Legal Representation, Licensees and Angel Investors	$392,044
2018	NIH SBIR Phase 2	Targeted PS Microbubbles to Image and Treat Surgical Adhesions	$1,597,000
2018	NIHSBIR Fast Track	NV103: Antibody Conjugated Nanoparticle for ES Targeted Therapy	$2,381,000
2020	State Grant	Montana Coronavirus Relief Business Stabilization & Innovation Grants	$35,000

USE OF PROCEEDS

An $8 million dollar raise followed by matching SBIR phase 2B funds would allow the company to advance NV103 through phase 2a clinical studies, sell the asset, and provide investor a return on their investment.

KEY TEAM MEMBERS

Timothy L Enns (President & CEO), 35+ years in leadership roles within Pharmaceutical cancer-focused companies from start up through launch, partnering and investor exits; **Jon Nagy, Ph.D.** (Co-founder &CSO) Joined Lawrence Berkeley National Laboratory, with a Ph.D. in synthetic organic chemistry from Iowa State University and doctoral training at UC Berkeley, generating seven issued patents and 15 scientific publications; **Timothy Triche MD, Ph.D.** (Co-founder & acting CMO) Board-certified pathologist; Children's Hospital Los Angeles Co-Director of Center for Personalized Medicine Program; Mark Lewis (Head of International Business Operations) 30+ years' experience in international leadership for pharmaceutical companies

PRIVO TECHNOLOGIES

Nano-engineered Local Cancer Treatment

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

COMPANY OVERVIEW (CLINICAL IMPACT AND VALUE PROPOSITION)

Privo is a private oncology company that has developed a nanoparticle-based platform technology for intramucosal chemotherapy, and its initial indication is oral cancer. The treatment (PRV111 patch) is composed of biocompatible polymers and embedded with nanoparticles. Upon contact with tissue, the particles are rapidly taken up by cancer cells to limit washing off and systemic toxicity. Epithelium cancers can significantly benefit from high concentration of topical and local treatment with negligible toxicity.

MARKET & COMMERCIALIZATION STRATEGY

The five-year survival rate of oral cancer (OC) remains only 57%, and OC is one of the few cancers increasing in incidence both in the US and worldwide. The annual incidence has increased over 30% in the past 5 years, and annually has increased approximately 37%. Privo's strategy has been based on the reformulating already FDA approved drugs with well-known toxicity profiles (For oral cancer, Privo uses the drug cisplatin), ensuring that all other excipients are FDA Generally Recognized as Safe (GRAS) to minimize regulatory and testing costs, and using a nanoparticle synthesis method which eliminates any chemical changes to FDA approved ingredients which would increase regulatory scrutiny, and targeting a disease which qualifies for FDA's Orphan Designation.

TECHNICAL & COMPETITIVE ADVANTAGE

PRV111 is a 2cm x 2cm polymeric patch that contains nanoparticles loaded with chemotherapy designed to only permeate cancerous tissue and preserve healthy areas of the mouth. When placed on a tumor, it adheres to the surface and releases and retains the nanoparticles directly into the tissue. The nanoparticles are then taken up by cells and degrade to release their drug. This treatment is customizable to the tumor/lesion size and one or more patches can be used to fully cover larger tumors in multiple locations. PRV111 application takes only 10 minutes, allowing for multiple applications per visit if higher dosing is needed. This is in contrast to the greater than 6 hours of IV chemotherapy. PRV111 has shown no systemic toxicity and no dose limiting toxicity, and on average has reduced visible tumor volume by over 70% in one week in over 85% of the patients in its phase 2 clinical trial. PRV111 can reduce the need for intense clinical management and postponing or eliminating the need for disfiguring surgeries or reconstructive surgery.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Privo's technology is from MIT's Langer lab, which is globally recognized for its translational science. Privo has 3 issued U.S. patents for this technology. In addition to the US, patents have been filed in several countries. Privo has 7 pending applications combined into one omnibus submission. Privo has obtained orphan designation for PRV111 and is currently discussing the design of its phase 3 study with the FDA.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	Complete Phase II Clinical Trial
2019	Large Pharma Partnership
2020	Begin Pivotal Phase III Trial
2020	Negotiate Product Licensing/Acquisition

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015	Grant Funding	NSF Phase I SBIR	$180K
2015	Angel	Private Investment	$3M
2016	Grant Funding	NIH-NIDCR Phase II SBIR	$2M
2016	Grant Funding	NIH-NCI Fast-track SBIR	$2.3M
2018	Grant Funding	NIH-NCI Bridge Award	$3M
2019	Grant Funding	FDA Orphan Disease R01	$2M

USE OF PROCEEDS

Privo is currently seeking $60M for its Phase 3 pivotal study, a large pharma company partner, or a combination thereof.

KEY TEAM MEMBERS

Manijeh Goldberg, PhD, MBA, MS (CEO), 25+ years industry experience; Founder of 5 medical startups; Expertise in nanotechnology developed at MIT's Langer Lab; **Dan Geffken (CFO),** 30+ years' experience in Financial deals specializing in life sciences. Dan has an MBA from Harvard Business school; **Joanna Ward** (Director of GMP Manufacturing), 30+ years of chemistry experience in FDA regulatory submissions, chemical/manufacturing control strategy and method validation; **Jesse Hall, MD, FACP** (Chief Medical Officer), 20+ years' experience in biopharma, oncology drug development, and strategic clinical planning/management; **Ruthanna Castello, MS, BS** (Clinical Operations), 30+ years' experience managing clinical trials for large institutions (Sanofi, Novartis, etc.)

TDL INNOVATIONS, LLC

Developing Technology Driven, Life Saving Innovations

Glenn W. Laub, MD | glenn.laub@tdlinnovations.com | 609-712-7972 | tdlinnovations.com

COMPANY OVERVIEW

Malignant Pleural Effusion (MPE) is a frequent and devastating complication of advanced cancer. The standard treatment of MPE is usually palliative, initially managed by drainage of the fluid, followed by pleurodesis, a procedure by which a sclerosing agent is used to obliterate the space between the lung and chest wall in order to prevent fluid accumulation. Talc is the only FDA-approved sclerosing agent used in this procedure. Talc can be applied during surgery as a powder "poudrage" or at the bedside mixed with saline as "talc slurry." Both techniques are suboptimal due to insufficient and non-uniform delivery of talc onto the pleural surfaces, which can result in recurring fluid buildup and repeat interventions. TDLI has developed a unique foam formulation, Pleurafoam, that improves coverage, regardless as to whether the procedure is performed in the operating room or bedside. The product has been designed to cover the entire pleural space, which will provide more complete delivery of the active ingredient and may lead to fewer procedural failures and a lower reoperation rate.

MARKET & COMMERCIALIZATION STRATEGY

MPE occurs in approximately 175,000 patients in the US each year, affecting between approximately 7% to 15% of all cancer patients. The total market for Pleurafoam is $112 million. The addressable market is $61 million, based on the number of patients that undergo pleurodesis with talc.

TECHNICAL & COMPETITIVE ADVANTAGE

TDLI has developed a unique foam formulation, Pleurafoam, to improve delivery of the active agent to the tissues regardless as to whether the procedure is performed in the operating room or bedside. There have been no new approved pharmaceutical treatments for this condition for over 50 years.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

TDLI has discussed the appropriate regulatory path with FDA and the Agency agreed that Pleurafoam is a combination product and the lead review division will be CDER. The next step is to submit a pre-IND application to confirm that a 505(b)(2) application is appropriate. The company has one issued patent and several pending, filed patent applications covering the delivery method and the foam composition. As developments arise, new patent applications may be filed. The founders have extensive experience in inventing, filing and prosecuting patent applications.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	Finalize formulation
2020	FDA Pre-IND meeting
2021	FDA approval of IND
2022	Clinical study interim analysis for futility
2023	Clinical study readout
2024	FDA approval

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017	Grant	NCI NIH Phase I SBIR Grant	$224,516
2018-2020	Private Equity round		$1M
2019	Grant	NCI Phase II SBIR Grant	$1,890,220

USE OF PROCEEDS

The company will conduct a Phase 3 clinical study for its lead candidate, Pleurafoam, the results of which will be submitted in an NDA to the FDA for product approval.

KEY TEAM MEMBERS

Glenn W. Laub, CEO, Founder, Practicing academic cardiothoracic surgeon, engineer and entrepreneur with more than 100 peer reviewed publications and patents; **James Wilkie, COO,** 33 years' experience in the life sciences industry developing both drugs and devices; former VP of New Enterprise Development at LJPC and former COO of Pluromed, Inc., until the sale of the company in 2012 to Sanofi, which provided a 6x return to seed investors and a 4.7x return to Series A shareholders; **Karen Laub, President,** Seasoned serial entrepreneur with extensive experience in creating and managing consumer and medical startups; experienced cardiac nurse; Previously started a medical device company that developed a novel ultrasonic peripheral blood flow monitor from concept to an FDA approved and marketed product

CLARA BIOTECH

Breakthrough Exosome Isolation Platform for Therapeutics

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COMPANY OVERVIEW

Clara Biotech is enabling tomorrow's medical breakthroughs today through a revolutionary platform that brings exosome sample preparation from research to patient. The Company has a proprietary, patented immunomagnetic bead which currently provides the only option to isolate any species of exosome from any fluid source with applications in diagnostics, therapeutics, and beyond exosomes. Clara is currently working with and growing the number of paying customers including Pfizer, Allergan, and AbbVie. The biggest impacts from this technology will be around combating aging with organ and tissue regeneration, cancer therapies, targeted drug delivery, and diagnostics.

MARKET & COMMERCIALIZATION STRATEGY

Clara's technology solves many of the concerns around quality manufacturing and scalability. The exosome isolation kit research space is a $1.9B market today growing at CAGR 18.8%. One of the benefits of the isolation platform is how universal it is. The same product has value to several different customer segments including: **Therapeutics** - Exosome biologics for cancer immunotherapy, tissue regeneration, targeted drug delivery and more; **Diagnostics** - Saliva, urine, and blood liquid biopsy for cancer, Alzheimer's Disease, viruses, and more; **Research** - Looking for biomarker discovery, mechanism of action, exosome networking and other fundamental research. Commercialization is staged around product milestones. In 2019, Clara launched their exosome isolation lab as a service while IP was being developed to validate market needs and recruit early customers. In July 2020, the Company is launching an Exosome Isolation Kit enabling the technology in customer labs directly. In the future Clara will be providing exosomes for targeted therapeutic delivery.

TECHNICAL & COMPETITIVE ADVANTAGE

Sample preparation is the No. 1 issue keeping exosomal applications from moving to patients. Current solutions are not compatible with therapeutic end use applications. The quality of Clara's unique exosome isolation process, coupled with the ability to scale and subtype exosomes, positions them as the platform that meets the manufacturing, regulatory, and quality needed for exosome therapeutic development. The Company has three main competitive advantages: 1) Purity: Unlike other purification options based on size or density, Clara leaves all the noise behind allowing for the isolation of the customer's active ingredient; 2) Subtyping: While most filtration processes are bulk filtration, Clara's platform enables companies to select for and differentiate between specific types of exosomes, even within a single cell population; 3) Scalability: Current methods are difficult to scale. Clara has several pathways to provide for and expand scalable isolation at both small and industrial levels.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Clara Biotech as a platform technology does not have significant regulatory risk. They plan to work towards FDA requirements, Good Manufacturing Practices (cGMP), and Good Laboratory Practices (GLP). Clara maintains a growing IP portfolio (2 patents awarded, 4 currently in development) to protect methods, processes, and technologies around the immuno-isolation platform. The Company has an exclusive license agreement from the University of Kansa and trade secrets around some of the manufacturing processes.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
06/2020	Accepted to MassChallenge Boston 2020 Cohort
Q3 2020	Launch of early access exosome isolation kit to 20+ customers
Q4 2021	Complete GMP and ISO-13485 / Complete Lab Tool Automation MVP

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	NIH/NCI SBIR + I-Corps	Phase 1 SBIR + I-Corps Grant for customer development	$305k
2019	Pre-Seed Funding Round	Investment from Angel Investor	$300K

USE OF PROCEEDS

Funds will be used for early CMC work developing scalability of production, applying for future SBIR grants (4+), securing 1 significant long-term customer, setting up distribution, launching Commercial Exosome Isolation Kit, and maintaining and expanding patent portfolio.

KEY TEAM MEMBERS

Mei He, PhD (Chief Science Officer): Since 2015 has served as a principal investigator and been leading a career in translational medicine involving cutting-edge microfluidic technology, 3D bioprinting, nano-biomaterials, and exosomes. In February 2019 was published in Nature Biomedical Engineering detecting ovarian cancer through exosomal markers
Mr. Jim West, MS (CEO): Building life science companies since earning his MS in biomedical product development from the University of Kansas (2011), and a Master's Certificate in Entrepreneurship from Nanyang Technological University in Singapore (2009)
Tom Krol, PharmD (Chief Development Officer): Has worked in large pharma companies like Pfizer and Sanofi in both R&D and commercial roles, in start-ups, and as an investor and holds a PharmD from the University of Utah

CYTOIMAGE, INC.

Tools for Visualizing Cancer Recurrence

Ann Bunnenberg, CEO | ann@cytoimagedx.com | 503-810-4063 | cytoimagedx.com

COMPANY OVERVIEW

Preventing the recurrence of cancer following initial treatment is a fundamental goal for cancer drug development and in-patient care. Despite major progress in initial treatment response, recurrence remains common for most cancer types -- even very small numbers of vigorous "survivor" cancer cells post-treatment can drive it. CytoImage is developing a novel diagnostic imaging technology, CytoScreen™, with a specific focus on monitoring recurrence risk. This proprietary platform allows single cell imaging and functional assessment of rapidly proliferating cancer cells even where the concentrations of the cells of interest are very low.

MARKET & COMMERCIALIZATION STRATEGY

CytoImage plans to develop assays as drug evaluation tools focusing on combination and immuno-oncological therapies. Over time, the Company plans to expand to blood cancers and apply the initial assays in personalized medicine. They plan to provide proprietary assay results to academic researchers and others engaged in drug evaluation with sale of the Cytoscreen system an option for the future. Initially, the team will target the drug development market in leukemia, leveraging strong relationships with the Knight Cancer Center and BD (partner) to demonstrate the unique clinical yield provided by CytoScreen. The current market for leukemia drugs is estimated at 12.3B with a 10% CAGR (markets and markets,2020). Reoccurrence in this market is a key challenge with AML (45% reoccurrence/<11% survival). CytoImage plans to seek out 2-3 pilot customers (other leukemia programs, CROs, and biotechs).

TECHNICAL & COMPETITIVE ADVANTAGE

The CytoScreen™ platform is a miniaturized imaging platform that uses sensitive, state-of-the-art molecular digitized detection technology and multiplexed fluorescent dye methods to detect the presence of rare drug-resistant cancer or other rapidly multiplying cells of interest. The platform provides high-content, high granular screening of an individual's tumor or blood sample, providing information that identifies the drugs that have the best chance of effecting 100% cancer cell kill for each individual's unique cancer or other disease, significantly reducing chances of cancer recurrence for that individual following treatment. CytoScreen™ technology offers important improvements over existing tools for assessing minimum residual disease such as Flow Cytometry and PCR, including sensitivity to very low cell counts, small volume of sample needed per test (allows more drug combination conditions to be tested), and the ability to assess the functional status of remaining cancer cells.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

CytoImage has two issued US patents and one pending patent application, which protect methods of counting, the apparatuses, and quantification of proteins using fluorescent nanoparticle and other discrete dye molecules. CytoImage holds the exclusive option to license these patents from OHSU. The Company's first regulatory goal will be to clear the CytoScreen™ platform as a Class 2 IVD device and the initial assays will be targeted at monitoring for the recurrence of cancer rather than screening resulting in a lower risk classification. The Company expects to pursue CLIA certification so they can perform the assays on a contract basis.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
December 2020	Pilot initial assay (leukemia) with 2-3 target customers (proof of market)
Early 2021/June 2021	Raise 1.5M & Refine CytoScreen platform for commercial efficiency
December 2021	Standardize first assay and scale for commercial production

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2019	Oregon Inc.	Commercialization Grant Funding	$50K
2019	Phase I SBIR – NCI (NIH)	Grant Number: 1R43CA235940-01A1	$300K
2020	Conversion Round	Small private investment round to fund OHSU option fees and Inc organization	$25K

USE OF PROCEEDS

CytoImage is planning on launching a seed round in early 2021 to fund the commercialization of its initial assay (leukemia), the refinement of its CytoScreen platform and conduct continuing validation studies. Additional goals include deepening the management, commercialization, and scientific teams.

KEY TEAM MEMBERS

Ann Bunnenberg, Ph.D., JD (CEO), Experienced medical device/bioscience executive; took Electrical Geodesics Inc. public in 2013 and sold it to Phillips Healthcare in 2017; Various leadership/board roles (Synergic Medical Technologies, Wellrythms, Invivo Biosciences, and AdvaMed); **Tania Vu, Ph.D.** (Founder, CytoScreen inventor and CSO), Biomedical engineer on faculty at OHSU and Knight Cancer Institute with extensive expertise in optical imaging and nanomaterials; **Lynn Stevenson, Ph.D.** (Director), Extensive experience in running early stage companies (CEO of Heska, CEO of DesignMedix, and Board Member of Sedia); **Thomas Jacob, Pd.D.** (VP of R&D), 20 years' experience in protein detection assay development in academic and industry settings

EUTROPICS

Novel, Predictive Diagnostic Tests to Accurately Guide Treatment

Michael Cardone | mcardone@eutropics.com

COMPANY OVERVIEW

Eutropics Pharmaceuticals is an oncology biomarker discovery and clinical diagnostics laboratory that develops novel functional clinical diagnostic tests that recognize unique features of cancer cells from individual patients. The test result indicates if a given patient is likely to have a meaningful response to a given apoptosis-inducing drug treatment. These tests are provided to pharmaceutical companies to select patients into clinical trials, and to help oncology physicians select best treatment options for patients. The tests are first-in-class functional predictive assays and are protected by a substantive patent portfolio and have proven utility in prospective clinical trials. Eutropics is currently in three such trials investigating utility of novel treatments for acute myeloid leukemia (AML) and has completed one trial that allowed rapid advance of a novel AML treatment to the pivotal clinical study.

MARKET & COMMERCIALIZATION STRATEGY

Eutropics' partnering model consists of a combination of fee-for-service and licensing. The platform is applied to several classes of liquid and solid cancer therapies. Eutropics prioritizes partnerships according to market potential and impact on patient outcomes. The Company discovers and develops biomarkers by applying the discovery platform to identify the correct assay readout for predicting the cancer cell response to the partner's drug or drug combinations. The next phase is assay development in retrospective studies. This establishes the cut points, clinical utility, and basis for clinical trial design. During this research phase, the work is sponsored under a fee-for-service agreement at a profit to Eutropics. Once the data is validated in second-tier studies and IP protection is filed, the assay system can be transferred to the partner, or to a third-party diagnostics company for distribution. The collaboration transitions into a licensing-agreement with associated milestones and royalty payments. Appropriate trigger language is written into the initial agreements. The biomarker platform is owned exclusively by Eutropics.

TECHNICAL & COMPETITIVE ADVANTAGE

PraediCare Dx™ is a proven clinical diagnostic assay used to predict patient response to specific chemotherapies. Unlike existing assays, PraediCare Dx™ predicts response to specific chemotherapies by direct evaluation of cancer cells' potential to enter an apoptotic state following exposure to therapy. PraediCare Dx™ has the potential to provide actionable data for guiding the use of available treatment options in numerous cancers. The current iteration of the PraediCare Dx™ test measures the functionality of the mitochondria, the key energy providers within the cell and disruption in their function to signal impacts susceptibility to chemotherapy induced cell death. The mitochondria also play an essential role in innate and adaptive immunity making them key regulators of viral infection. Understanding the functionality of these organelles could have importance in future treatments for COVID-19 as well and Eutropics is currently working with academic and pharmaceutical collaborators to investigate this.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The laboratory developed tests (LDTs) are run as RUO or investigational use only (IUO) stages under CLIA certification. There are several options for regulatory strategies, including to approach the FDA for pre-submission of data, before any FDA regulatory decisions are made and adherence is required. These activities are executed with direction and participation of the pharmaceutical partner. Initial discussions with the FDA are both at the CDER and the CDRH. Initiation of the of the approval process occurs at a pre-submission meeting which, when completed guides the co-development of the guiding test, Companion Diagnostic, and the therapeutic. Individual patents for selecting patients most likely to respond to each therapy being tested are filed, prosecuted, and owned by Eutropics. In some cases, when overseas studies are required, Eutropics will transfer of the assay to a third-party under a licensing agreement. Such transfers result in transfer milestone payments and residuals from the third-party diagnostic companies. Eutropics holds 8 issued patents and is prosecuting multiple applications.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2020	Deliver predictive biomarker readouts in next partnered biomarker clinical study in AML or MM
Q2 2021	Deliver predictive biomarker readouts with next generation platform reagents in solid tumor indication
Q3 2021	Conclude 3 way partnering and licensing payout for next AML or MM predicative biomarker test
Q3 2022	Achieve Milestones for PIVOTAL, FDA approval of CDx for Alvocidib in AML

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2010	Debt	Mass Life Science Center Accelerator Award (loan)	$500K
2005-2015	Angel Investments	Friends and Family	$1.4M
2007-2020	SBIR Funding	2 phase-2 grants , 2 phase-2 contracts, Bridge Award	$12.5M
2015-2020	Revenue	Licensing up front and milestones, fee for service	$3.1M
2016-2020	Investment	Achieve Milestones for PIVOTAL, FDA approval of CDx for Alvocidib in AML	$800K

USE OF PROCEEDS

Accelerate revenue, execute licensing, prosecute IP, expand business, clinical and discovery operations, purchase equipment

KEY TEAM MEMBERS

Michael Cardone, Ph.D. (CEO); **Anne Assmus, Ph.D.** (VP business Development); **Stephen Lyle, MD, Ph.D.** (Clinical Lab Director); **Kristen Gumz** (CLIA Lab Manager); **Andrew Kinloch, Ph.D.** (Director of Assay Development); **Alan D'Andrea** (Scientific Co-founder)

FLUENT BIOSCIENCES INC.

Scalable Precision Biology

Sepehr Kiani | skiani@fluentbio.com | 857-600-0736 | fluentbio.com

COMPANY OVERVIEW

Fluent BioSciences is an early stage startup developing cutting edge lifescience tools for ultra-sensitive genomic analysis providing reagents, and services for the research market. The Company has a worldwide exclusive license to this platform, PIPs (Pre-templated Instant Partitions), a novel method of creating a massive number of uniform reactions without the costs or scaling limitation of microfluidics. The platform works at the pico- to nano-liter physical scale and has a time-independent reaction number from thousands to billions. The power of large numbers of tiny reaction volumes is well understood to improve kinetics massively (i.e., reduce reaction times), eliminate sample waste, reduce costs, and quanta-reactions (i.e., single-molecule, cell, protein, etc.).

MARKET & COMMERCIALIZATION STRATEGY

Fluent is pilot testing the single cell analysis platform with lead pharmaceutical and academic researchers to validate the performance and hone the configuration of the Company's offerings. Fluent's launch focus will be on those unmet needs in both commercial and academic markets. The SAM of those unmet needs that we address are north of $300M with high annual growth rates. The recent situation with Covid-19 has turned into demand for Fluent's solution in the virology space. Upon completion of the pilot program, we intend to move into Beta and product launch in early 2021. The Company is early in the process of laying that commercial foundation.

TECHNICAL & COMPETITIVE ADVANTAGE

Fluent's novel "PIPs™" technology applies to biological experiments and diagnostics application where high sensitivity is required. Unlike competing approaches, Fluent's micro self-assembly process can directly scale from the smallest to the largest application without the need of complex equipment or microfluidics. Fluent is also free from the cost and scale limitations as they apply to the product development process, vastly improving Fluent's overall velocity.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Fluent initial focus in life sciences is not subject to regulatory hurdles. The Company's valuable IP portfolio is at the heart of their platform. Fluent's IP portfolio has been to start with some of the best counsel in the world, including WSGR and Brown Rudnick. They exclusively license in core and application specific IP where advantageous, along with aggressively filing supporting patents

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q1/2020	Mark 2.0 chemistry/software, beginning of pilot program
04/2021	Launch of benchtop scRNA product
11/2021	Beta fully automated scRNA product

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Pre-Seed funding	Founders, friends and family	$400K
2019	Phase I/Fast Track SBIR	Head and neck cancer diagnostic from blood/Single cell drug dose response	$2.7M
2019	Venture backing	Illumina Ventures LLC	$1.5M
2020	Phase 1 SBIR	Extreme single cell sequencing (NIH/NIGMS)	$399K

USE OF PROCEEDS

Fluent will use proceeds to develop core platform, develop two distinct applications, begin pilot program, and lay foundation for commercialization.

KEY TEAM MEMBERS

Sepehr Kiani, Ph.D. (Co-Founder & CEO), 24+ years' experience in building startups (+$100M exit & IPO) and large mature enterprises; 35+ issued/actively pending patents; **Kristina Fontanez, Ph.D.** (VP Biology), Harvard University, postdoc MIT; Expert in molecular biology and microbiology; **Gary Zwieger, Ph.D.** (Co-Founder and Business Development), Expert in genomics business development; **Adam Abate, Ph.D.** (Co-Founder and BOD), World-renowned researcher in area of high-throughput biological assays; Several companies founded on his cutting-edge microfluidics; **Bill Hyun, Ph.D.** (Co-Founder and BOD), Partner at Genoa Ventures; Expert in developing commercially successful cytometric and genomic instrumentation; **Robert Meltzer, Ph.D.** (Director of Advanced Projects); **Wouter Meuleman, Ph.D., BOD** (Illumina Ventures, Partner); **Mike Dybbs, Ph.D. BOD.** (Samsara BioCapital, Partner); **Tony Godfrey, Ph.D., SAB** (Boston University, Professor)

CIVATECH ONCOLOGY®

Targeted Radiation Therapy Devices

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COMPANY OVERVIEW

CivaTech Oncology has developed three commercially available radiation devices to provide therapeutic doses to cancerous tissues in a localized, targeted, one-time delivery method. Clinical trials prove efficacy and significantly reduced side effects compared to traditional radiation delivery methods while providing meaningfully higher radiation doses to target tissues and enabling delivery of therapeutic radiation doses where only palliative doses had been possible. The platform technology is manufactured by CivaTech Oncology in an ISO 13485 certified facility. CivaString®, CivaSheet® and CivaDermTM (CivaSheet that is used to treat skin cancer) are the only polymer-encapsulated radiation devices. These bio-compatible and bio-absorbable products have been designed to be easily implemented in the workflow of the current cancer care pathways and through less invasive techniques. The products are being used in clinics in the US including several major designated cancer centers.

MARKET & COMMERCIALIZATION STRATEGY

CivaSheet has a large market potential because it provides an opportunity to deliver radiation therapy in patient populations where (1) external beam radiation is difficult to use and/or (2) the patients have already received the external beam radiation limit. CivaSheet adds a revenue stream for hospitals to offer patients an option to receive a clinically beneficial dose of radiation therapy in a onetime implant during surgery. CivaSheet has a target market potential of treating the 250,000 cases of cancer in the US. For ~50,000 cases of cancer recurrence, a second course of radiation is not currently prescribed because one round of external beam therapy is the limit to surrounding organs and tissues but CivaSheet can address this problem and treat the margins. The total US market is estimated to be over $2Bn. Primary indications include colorectal and pelvic region, head and neck, brain, lung and soft tissue sarcomas and pancreatic cancers. CivaString's initial indication is focused on prostate cancer. Products have unique brachytherapy reimbursement (payment) codes issued by CMS.

TECHNICAL & COMPETITIVE ADVANTAGE

CivaSheet is the only unidirectional, permanently implantable radiation device cleared for sale in the US. The shielded radiation source allows for delivery of radiation to the targeted tissue in a localized and directed approach. The device minimizes radiation damage to neighboring tissues. In the current radiation therapy paradigm, the dose to healthy tissues limits the total amount of radiation to the cancerous tissue. CivaSheet delivers very high doses of radiation locally to the cancerous tissue and almost no dose to surrounding tissues, sparing unnecessary and unfortunate side effects. Patient studies are demonstrating improved efficacy.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

5 US patents issued (7,686,756; 8,323,172; 9,180,310; 9,358,377) and 1 pending (13/594,214); Notice of Issuance of International Patents. CivaTech Oncology fully owns all patents and trademarks. Patents protect the methods of polymer encapsulation and proprietary manufacturing techniques and methods.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2017-2019	Expanding sales of CivaSheet through technical publications beginning with American Brachytherapy Society, ASTRO
2018-2020	Excellent Outcome data for pancreatic and other cancers
2018-2019	Scale up manufacturing to meet growth projections

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2007-12	Initial private funding	(R&D Phase)	$6M
2015-2020	Convertible Notes and Series E	Private (Scale/Commercial)	$7M
2016-20	NIH/NCI Fast Track Grants	Government Grant (Clinical Commercialization)	$4.6M

USE OF PROCEEDS

CivaTech is currently seeking $10-15M to provide working capital, fund post market studies, and to expand sales and corporate infrastructure. Sales are projected to be $5M in 2021.

KEY TEAM MEMBERS

Suzanne Babcock, BA (CEO), Diverse business development and technical capabilities to foster creative talent, develop novel radiation devices, build infrastructure and achieve numerous approval processes, positioning the Company to commercialize.
Kristy Perez, Ph.D. (Vice President, Clinical Programs), Ph.D in Medical Physics; leads the team in translating the products from research and development to the clinic, including managing product testing and development, writing applications for regulatory clearances, and educating clinics on the use of the products.
Greg Briley, BA (CFO), Co-Founder of Etix, an international web-based service provider that was the largest independent ticketing provider in North America.
Randy Harrison, MS (National Sales Manager) Previously held sales roles with Hologic, Ethicon, and Rita Medical.

CLARIX IMAGING

Point-of-Care Precision Imaging for Surgical Oncology

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

COMPANY OVERVIEW

Clarix Imaging, a University of Chicago startup company, is developing a suite of cloud-connected precision tools enabling the future of surgical oncology, streamlining cross-disciplinary workflows in surgery, radiology, and pathology. Clarix's first product, VSI, is a high-resolution specimen imaging device that lowers current high re-operation rate of breast cancer surgery by enabling real-time surgery-radiology collaboration for accurate intra-operative margin assessment. VSI has received FDA 510(k) clearance, is reimbursable with an existing CPT code, and is ready to ship.

MARKET & COMMERCIALIZATION STRATEGY

Clarix Imaging aims at disrupting the $150B global market of surgical oncology with a three-step strategy. Step 1 is an immediate entry into the breast cancer surgery market, which has $750M market in the US and $3B worldwide, with our FDA cleared VSI product, existing CPT reimbursement, and virtually no change required from existing clinical practice. Step 2 is to expand in 1-2 years to the anatomic pathology market covering all body organs with a $40B global market, with a VSI-plus device and software automating pathology workflow. Step 3 is to further expand in 2-3 years to the $100B robotic surgery market with an in-vivo imaging device and software for surgical planning, guidance, and verification.

TECHNICAL & COMPETITIVE ADVANTAGE

Based on decades of world-leading research at U Chicago, Clarix Imaging's core technology uniquely enables the highest quality volumetric (i.e., fully-3D) imaging with the least amount of scan time and radiation dose, thus making high-performance imaging available for point of care physicians with unprecedented accessibility and clinical adoptability. Moreover, Clarix's product ecosystem is driven by built-in cloud connectivity that enables real-time remote collaboration on clinical tasks requiring multi-specialty physicians. For example, current standard of care breast lumpectomy requiring 20-30 minutes for intraoperative margin assessment has 15%-25% re-operations, Clarix's VSI takes less than 4 minutes, while reducing re-operations to below 5%.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Clarix Imaging's regulatory strategy is optimized for time and capital efficiency. We start with a product posing the lowest regulatory risk and obtained FDA clearance in 2019. Through the process, Clarix established regulatory-compliant design & manufacture controls and processes. With products in the market generating revenue, we continue to work with the FDA and foreign agencies to seek approval for expanded indications and geolocations, and for products & features with gradually increased risk levels. Clarix is the exclusive licensee to the core patents owned by Univ of Chicago, which protects the fundamental enabling technologies and novel system designs. Meanwhile, Clarix is aggressively growing its own IP portfolio for protecting product-specific functionalities and features covering a multitude of existing and new clinical use-case scenarios.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
4/2019	Installation at two leading cancer centers for evaluation
12/2019	FDA 510(K) clearance
12/2019	Product launch at RSNA
5/2020 (delayed by COVID)	First commercial product ship

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Angel	Independent angel investors (closed)	$2.2M
2019	SBIR Awards	Phase II and multiple Phase I awards (awarded)	$2.7M
2020	SBIR Bridge Award	Matching grant (awarded)	$4M

USE OF PROCEEDS

Clarix is looking to raise $4M investment to match with the $4M NCI bridge award for a total of $8M series A investment. Over the next 2 years, approximately $2.5M will be used for scaled manufacturing, $2.5M for continued R&D including expansion to pathology markets, $1.5M for marketing & sales, $800K for IP & legal expenses and $700K for operation expenses.

KEY TEAM MEMBERS

Xiaochuan Pan, Ph.D. (Co-Founder & CSO), Professor at U Chicago; World authority on medical imaging with 30 years of experiences; **Xiao Han, Ph.D.** (Co-Founder & CEO), 15 years of experience in medical and industrial imaging; former PhD student of Co-Founder; **Christian Wietholt, Ph.D.** (VP Product Dev), 20 years of biomedical R&D and product management experiences at FEI/Thermo Fisher; **Sathya Kovour** (Director of Software), Former chief architect at Siemens Healthineers with 24 years of architecting & dev experience; **Kirti Kulkarni, MD** (Clinical Advisor), Breast radiologist at U Chicago with 14 years of clinical experience; **Arthur Lerner, MD** (Clinical Advisor), Founder of the American Society of Breast Surgeons & former board member of Hologic

LIGHTPOINT MEDICAL

Precision-guidance Tools for Robotic Cancer Surgery

Dr. David Tuch | david.tuch@lightpointmedical.com | 857-234-2414 | lightpointmedical.com

COMPANY OVERVIEW

Lightpoint is developing miniaturized sensing and imaging tools for robot-assisted cancer surgery. The company has two robotic probe technologies in development which aim to aid surgical decision making, improve patient outcomes, and save costs for healthcare systems. Although applicable to a wide range of major cancer types, the first commercial focus is prostate cancer surgery. Lightpoint has secured over $17M in non-dilutive grants and $10M in private investment with early commercial sales in the UK, Netherlands, and Germany. Lightpoint has offices in Cambridge, Massachusetts; the UK; and the Netherlands.

MARKET & COMMERCIALIZATION STRATEGY

Lightpoint's probe technologies exploit recent advances in miniaturized sensors and cancer-targeted diagnostic imaging drugs. The first probe, SENSEI®, is designed to confirm metastases deep in lymph nodes. The second, Surface Probe, is designed to detect disease spread on the surface of tissue, for example in the nerve bundle surrounding the prostate. The probes integrate with surgical robotic platforms. The surgical robotics market is expanding rapidly. The recurring purchase of instruments and accessories for every procedure is significantly boosting demand for consumables. The total addressable market for Lightpoint's probe technologies in prostate cancer surgery alone within the initial target territories of the US, EU, Japan, and China is estimated at $1.16B. The miniaturized probes work with cancer-targeted radiopharmaceuticals already developed for diagnostic imaging. Lightpoint is at term-sheet stage to license drugs for use with the probes in prostate and lung cancer surgery.

TECHNICAL & COMPETITIVE ADVANTAGE

Currently there are no widely used tools to detect cancer during surgery. Most surgeons use only their sense of touch and naked eye. The rise of robotic surgery reduces the potential for even touch. One method used in a handful of academic hospitals is frozen section analysis (FSA). FSA, however, suffers from several critical weaknesses, including adding operating time, high cost, and poor performance. Another emerging method is targeted fluorescence imaging using a cancer-targeted fluorescence drug. However, despite decades of development and investment, the technique has not entered Phase 3 clinical trials. The main barrier is the hundreds of millions of dollars needed to gain approval for a new drug, along with other critical technical hurdles. Lightpoint bypasses this barrier by repurposing validated imaging drugs already approved or close to approval.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

SENSEI® has undergone thorough usability testing and pre-clinical validation. Patient recruitment for clinical validation is due to commence in Q3 2020. The regulatory route for SENSEI® is FDA 510k Class II De Novo combination product (2025). In the EU the route is CE Mark Class IIa (2023). The Surface Probe has been validated pre-clinically. The next phase of work is to miniaturize the probe with a novel miniature sensor. A miniaturized prototype will be ready in Q2 2021. The regulatory route for the Surface Probe is FDA 510k Class II De Novo (2025). In the EU, Class IIa (2025). Lightpoint wholly owns the IP for the probe technologies.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	SENSEI® clinical study to initiate; License agreed for prostate cancer drug.
2021	Surface Probe miniaturized prototype complete; License agreed for lung cancer drug.
2023	CE Mark for SENSEI®

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2013-2014	Seed-Series A1	Oxford Technology, Angels	$2.93
2015	Series A3	Cambridge Capital Group, SyndicateRoom, Follow-on Investors, Management	$1.15M
2018	Series B	Coutts, Venture Founders, Envestors, Follow-on Investors, Management	$6.70M

USE OF PROCEEDS

The company currently has an open C1 fundraising round with a target of $6M. $3.7M of the total has already been committed. This round will be used for clinical trials and market development in the first target indication of prostate cancer surgery.

KEY TEAM MEMBERS

David Tuch, Ph.D. (CEO), More than 15 years' experience in the medical imaging and pharmaceutical sectors; Former Head of Research Alliances at GE Healthcare and Head of Clinical Imaging at Novartis
Claire Woodthorpe, LLD (COO), More than 10 years' experience in commercial operations, including medtech.
Simon McCoy, ACA (Finance Director), 30 years' experience in blue chip international companies, including life sciences and healthcare.
Board of Directors: David Ford, MBA; Nadim Yared; Elizabeth Usher, MBA; Martin Jamieson.

METRITRACK, INC.

Automated Breast Ultrasound

Calin Caluser | calin@metritrack.com | 630-498-3578 | metritrack.com

COMPANY OVERVIEW

MetriTrack is a medical device company incorporated in 2014 and headquartered in Hillside, IL. MetriTrack's first FDA cleared product, the Breast Volume Navigator (BVN) G-1000, automates lesion localization and has been successfully tested in clinical conditions. The company's next product under development, the BVN G-2000, in addition to including all the features of the first product is also designed to facilitate optimal breast tissue scanning to prevent radiologists and surgeons from missing small tumors.

MARKET & COMMERCIALIZATION STRATEGY

Breast cancer is the most frequent cancer among women and impacts 2.1 million women every year. Ultrasound screening combined with x-ray mammography in women with dense breasts became the standard of care to detect small cancers that would otherwise be missed. The global market for automated breast ultrasound systems is growing >20% CAGR and will exceed USD $2 billion by 2024. The global and domestic total addressable market is estimated at $6 and $2 billion respectively. While developing beta sites, MetriTrack plans to establish strategic partnerships with breast ultrasound imaging industry leaders for licensing and sales support. MetriTrack will support its solution and partners with a complete digital marketing and PR campaign that focuses initially on breast imaging radiologists, surgeons, ultrasound technologists, and eventually on patient education.

TECHNICAL & COMPETITIVE ADVANTAGE

Metritrack's innovative technology, based on its proprietary dynamic mapping solution, addresses the limitations of alternative solutions. The automated mapping and precise re-localization of small lesions in the breast and axilla combined with the confident coverage of the entire breast volume enables radiologists and surgeons to avoid missing cancers as small as 3 mm and provides the needed diagnostic and guidance confidence to find even more small cancers than currently possible. The BVN G-2000 system is designed to easily integrate with the existing workflows, ultrasound machines, and PACS systems. Furthermore, the ability to localize breast lesions as small as 3mm to within <10 mm, combined with the ability to precisely re-localize a lesion using multi-modality imaging, is unmatched by any existing product. The automated mapping technology can soon be applied to automate the mapping of other body regions like the thyroid or other neck structures, a capability not present in other automated ultrasound systems.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

MetriTrack has 8 granted patents in the US, Canada, Europe, and China, and >10 pending patents for materials and methods used for its unique anatomical landmark and software mapping advancements. The company's intention is to complete the development of the commercial product and clinically validate its efficacy and efficiency. The company already obtained the 510(k) FDA clearance for its first product, the BVN G-1000, which is used in clinical research projects. The experience gained with the first product is applied to the development of BVN G-2000, and Metritrack anticipates no significant obstacles in obtaining 510(k) FDA clearance. The first prototype of BVN G-2000 passed the feasibility phase and, after testing by a third-party laboratory for compliance with recognized consensus standards for safety, the company will start the clinical validation and submit for 510(k) FDA clearance. The product can be added to existing and new ultrasound machines and the exams can be billed under the existing CMS codes.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
5/2021	FDA clearance for the new product BVN G-2000
10/2021	Clinical validation for the detection of more lesions than with current ultrasound technologies
12/2021	Install 10 BVN G-2000 units

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016	Funding	Convertible debt	$300K
2019	Funding	Seed series preferred shares	$1.5M
2019	Grant	SBIR phase 1 grant	$149K

USE OF PROCEEDS

Funding will be used for R&D activities to complete the development of the commercial product, operating expenses, regulatory and marketing consultants, FDA clearance, and outsourcing to a design firm to incorporate design changes for the final product. The funding will also support further commercialization (contract manufacturing and sales and marketing expenses).

KEY TEAM MEMBERS

Dr. Calin Caluser is the company founder, technology inventor and CEO, with 20+ years' clinical experience.
Ms. Mirela Wohlford is the Director of Operations and Compliance with more than 10 years' experience in implementing regulatory compliance strategies for medical device startup companies.
Michael Cannizzaro, Chairman of the Board of Directors, brings significant knowledge and business experience, as he held top executive positions at several successful medical device companies.

MICROELASTIC ULTRASOUND SYSTEMS

Skin Elasticity Quantification for GVHD

Peter Hollender | Peter.Hollender@microelastic.com | 440-532-0087

COMPANY OVERVIEW

For blood cancer care teams who need to track deadly complications of stem-cell transplantation, MicroElastic's Bullseye™ is a handheld ultrasound system that provides precise measurements of skin elasticity at the touch of a button. Unlike the standard "pinch-and-score" method, which is notoriously variable, Bullseye™ measurements are repeatable and accurate in anyone's hands. MicroElastic believes that Bullseye™ will empower clinicians to identify and connect more transplant recipients with earlier interventions, select the right therapy at the right time, and optimize long-term treatment plans.

MARKET & COMMERCIALIZATION STRATEGY

There are 200,000+ patients living in the US post-transplant and at risk for Graft-Versus-Host Disease (GVHD), and this prevalence is expected to grow to more than 500,000 by 2030 due to the expansion of stem cell transplants to higher-risk patients. Because these patients typically receive care at the 70 NCI-Designated Cancer Centers, accessing a large portion of the target population at risk is feasible. From conversations with specialists about the ideal frequency of measurements, and the cost of $100/scan (deemed reasonable against $1500/day of prophylactic antifungal/antivirals), the Company estimates a TAM of $260M by 2025 and $351M by 2030. MicroElastic sees this as an attractive beachhead market because of the limited points of sale, high cost of ongoing care, access to the target population, and an established but imprecise method that the GVHD community urgently seeks to improve.

TECHNICAL & COMPETITIVE ADVANTAGE

The clinical "standard" is the pinch-and-score, but its inter-operator agreement is quite poor, so the true gold standard remains biopsy, which is impractical for long-term monitoring. Because the dermis is only a few mm thick, fully distinguishing dermal elasticity from subcutaneous tissues by hand is impossible. Highly sclerotic skin can be easily felt as stiff but waiting for the tissue to be palpably damaged risks missing the window of effective intervention. Courage and Khazaka's Cutometer is a standalone product designed to measure skin elasticity and is the most direct competitor. It uses a suction tube and measures deformation and, while this removes user judgement, it fails to isolate dermal elasticity and is subject to high interoperator variability from the angle and applied pressure. MicroElastic's technology uses a sterile standoff to maintain proper alignment without deforming the skin, giving the same measurements in anyone's hands. Additionally, whereas other ultrasound technologies are used to image the skin, none are capable of measuring elasticity.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The device will be a class II regulated medical device. It will fall under a 510(k) clearance with a predicate of K123806. The Company expects it to be regulated as Ultrasonic Pulsed Echo Imaging 21 CFR §892.1560 IYO System and Diagnostic Ultrasonic Transducer 21 CFR §892.1570 1 ITX. MicroElastic is working with Duke Dermatology to establish which existing CPT code could be used for reimbursement and currently contracts a design and development firm experienced in preparing medical devices and diagnostics for regulatory clearance. The technology is based on three patents licensed exclusively from Duke University, covering the unique hardware configuration enabling portability of MicroElastic's first product, the algorithm used to extract elasticity from the signals recorded by that device, and a class of algorithms claimed by the unique configuration but more broadly applicable, particularly in the context of potential competitors or alternative solutions. They expect to continue to grow the patent portfolio as they develop advanced algorithms for multiparametric estimation and obtain design patents on the device and the single use disposable.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
03/2020	GVHD Clinical Study
06/2020	Design Lock
04/2021	FDA 510(k) and GVHD launch
10/2021	General dermatology launch

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016	Grant	Duke Coulter	$270K
2017, 2019	Grants	STTR Phase I, STTR Phase II (NIH, NCI)	$1.65M
2018	Revenue	Commercial Research Agreement	$1.5M
2019	Loan	NC Biotech Center	$150K

USE OF PROCEEDS

MicroElastic is seeking a Series Seed round of $2.1M in dilutive financing to reach FDA clearance for the first product.

KEY TEAM MEMBERS

Peter Hollender (CEO) Elasticity imaging expert and inventor - PhD BME, Duke, 2015; **Kyle Langdell, MBA** (Chief Business Officer) 5+ years medical device clinical, sales, and marketing experience; **Steve Grenon** (Product Director) 30+ years of medical device product development and regulatory expertise; **Rich McGivney, CPA** (CFO) 30+ years finance, accounting, and corporate governance experience

NE SCIENTIFIC

Computerized Guidance for Tumor Ablation

Andrea Borsic | aborsic@ne-scientific.com | 857-200-7259 | ne-scientific.com

COMPANY OVERVIEW

NE Scientific (NES) develops software that guides oncological ablations, with the goal of ensuring the complete eradication of the tumor, a goal which is missed in 24% of cases for medium sized tumors in the current practice, where no software is used. Accublate™ is a platform that supports multiple ablation technologies, multiple ablation systems, and multiple tumor indications. Commercialization for a first and simplified version of the product is anticipated to start in H1 2021. A clinical trial for a more sophisticated second-generation product is undergoing at the Dartmouth Hitchcock Medical Center, Lebanon, NH. The company is a recipient of SBIR Phase I and Phase II awards from the National Cancer Institute and of the QuickFire Lung Cancer Innovation Challenge from Johnson & Johnson (J&J). NES is based in Boston and has a desk at JLABS Shanghai, as part of the J&J award.

MARKET & COMMERCIALIZATION STRATEGY

NES is evaluating two commercialization strategies. A first commercialization strategy is based on forming partnerships with industry strategics, which, for us, are the manufactures of ablation systems and of CT scanners. Currently NES has entered an NDA and is under due diligence with a potential strategic partner. A second strategy is a direct commercialization strategy, where NES would offer Accublate as Software as a Service (SaaS) based on a monthly subscription. As the company is an early stage startup, and as the field is rapidly evolving, NES is continuously evaluating the two strategies. Data points arising from the ongoing partnering efforts and from a commercial pilot planned for 2021 will inform in the medium term the optimal strategy for the company.

TECHNICAL & COMPETITIVE ADVANTAGE

The possibility of using computer simulations of an ablation process to guide physicians has been envisioned since approximately 2005. For years however the idea has been unfeasible as in the past simulations were taking excessive time to be compatible with the clinical use. NES has been the first entity world-wide to show real-time simulation for Radiofrequency ablation physics (2014), to the best of our knowledge we are also the first to have implemented this technology in a clinical trial (Dec 2019) which is designed to assess the local recurrence rate under the use of the guidance software. As of July 2020, 18 patients been recruited to the trial (target 52), no local recurrence has been observed in these patients to date. Real-time ablation simulation performance for Microwave ablation has been achieved in June 2020. To the best of the Company's knowledge this is also a world-first result.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

NES is developing three versions of the Accublate software. A basic version, which indicates the ablation zone overlaid to CT images based on the information provided by the manufacturer of the system, and two advanced versions based on the simulation of physics respectively for RF and for Microwave ablation. NES aims to file a 510K for a first version of the software in September 2020, to file a 510K the second version of the product in Q1-2021, and to file a 510K for the third version of the software around Q4-2021. NES has filed 3 patent applications, and two new patent applications are in preparation.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
06/2020	Developed accelerated simulation of MW ablation physics achieving real-time performance (Accublate "3.0")
09/2020	File a 510k for first version of Accublate
02/2021	File a 510K for an advanced version of Accublate based on the simulation of RF physics
12/2021	File a 510K for an advanced version of Accublate based on the simulation of Microwave physics

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2014-2015	SBIR Phase I – NIH/NCI	Initial development of the idea and animal validation	$200K
2017-Ongoing	SBIR Phase II – NIH/NCI	Full development of the idea and clinical validation	$1.4M
2019	J&J QuickFire Lung Cancer Innovation Challenge	Highly competitive award from J&J consisting in a monetary prize and access to the JLABS incubation program. NES currently associated with JLABS @ Shanghai.	$250K

USE OF PROCEEDS

Proceeds will be used for supporting the clinical validation of the third generation of Accublate (advanced Microwave ablation guidance) and to start a small-scale commercialization pilot.

KEY TEAM MEMBERS

Andrea Borsic, PhD (CEO, Co-Founder), former biomedical engineering faculty at Dartmouth, 20 years' experience in R&D.
Eric Hoffer, MD, CMO (Co-Founder), Director of Vascular and Interventional Radiology at Dartmouth.
Neeharika Sinha, PhD (Senior Scientist & Software Developer), 10 years' experience in R&D.
Elia Attardo, PhD (Senior Software Developer (part-time)), 10 years of experience in R&D.
David Dlesk (Senior Advisor Business Development), 30 years of experience in executive roles in the medical devices industry.
Keith Paulsen, PhD (Senior Scientific Advisor), Professor of Biomed. Eng. at Dartmouth and Entrepreneur.

SIMPHOTEK, INC

Eliminating solid tumors with light by guided PDT

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COMPANY OVERVIEW

Simphotek is creating breakthrough personalized medical products to treat solid internal tumors. The Company's technology utilizes Photodynamic therapy (PDT) and Photoimmunotherapy (PIT) with a drug-light system that not only directly kills cancer cells without damaging healthy cells, but also releases tumor antigens activating both the innate and adaptive immune systems. Combination therapy of PDT and checkpoint inhibitors shows additional immunotherapy enhancement. Simphotek's product is an advanced 3D simulation software and hardware system for PDT treatment planning and real-time dosimetry that guides oncologists in delivering the required therapeutic dose to cancer patients, helping to optimally arrange lasers, fibers, spectrometers with light-activated drugs to effectively kill cancer cells.

MARKET & COMMERCIALIZATION STRATEGY

Simphotek's product pipeline includes Dosie™, a real-time computational device to optimize light power and treatment times, and Intelli, an integrated system that includes Dosie, feedback-enabled hardware, lasers, light-activated drugs, and necessary delivery accessories. The Company assumes a price tag of $120K for Dosie™ and $500K for Intelli with the hardware and software components. The market for Dosie is about $170M US and about $1.9B worldwide. For Intelli, the numbers rise to $0.7B US and $8B worldwide. The Company will be paid by clinics/hospitals for the hardware/software, and by insurance plans for the drug/accessories. Simphotek plans to sell direct through a major medical device company that has reach to hospitals and plans to enter the clinic with Dosie, post-510(k) clearance in 2021, which will establish initial users of the technology and support the development and launch of the integrated Intelli system.

TECHNICAL & COMPETITIVE ADVANTAGE

The product is a turn-key system for light-based cancer treatment planning, real-time monitoring and treatment modifications, and feedback that controls the light intensity, light duration while at the same time estimating PS concentration, photobleaching, oxygen concentration, light-dose, PDT-dose and singlet oxygen-dose in near real-time to maximize the treatment efficacy. Currently, there is a lack of computational mastery of how the many variables must be combined to have repeatable successful treatments. Simphotek provides a way to properly dose the light and drug to reach a threshold level of cytotoxic agents capable of killing cancer cells. Dosie also runs in near real-time, unlike other technologies that can take hours.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Simphotek has prominent advisers from the NIH SEED office and has hired an acclaimed FDA consultant who is a former director of the FDA's Office of Device Evaluation and serves on the board of advisors for the Medical Technology Leadership Forum. Simphotek plans to apply for 510(k) clearance for Dosie. The technology is protected by two issued patents and has two additional patents filed and one provisionally filed.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2H/2020	Complete patent provisional for DOSIE, licensing deals with Penn, Roswell Park for IP; investigate/develop relationships with strategic partners
1H/2021	Hire C-level business management; complete DOSIE pre-clinical work; secure funding and develop a protocol for PDT Phase I pilot clinical study that uses DOSIE, initiate/complete FDA clearance for DOSIE, initiate prototype of INTELLI
2H/2021	Complete Phase I pilot clinical study; raise $3.5M; file and license additional IP, complete working prototype of INTELLI, work with FDA for approval of INTELLI
2022	Raise $20M to complete INTELLI and start PDT clinical trials for the designated indications, data analysis for FDA.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2014-2018	SBIR Phase I/II Grants	NIH/NCI Funding	$3.749M
2020	R01	Industrial academic partnership (PEDSY) – admin. pending	$3.019M

USE OF PROCEEDS

Simphotek is raising $3.5M to hire experienced C-level business management, complete licensing deals for IP, build out the working prototype of INTELLI system and commercial DOSIE prototype, submit IP (including CPT) on the method and computer visualization, perform Phase I clinical trial of DOSIE, support Phase II clinical trials with collaborators, and for FDA contacts and initial arrangements.

KEY TEAM MEMBERS

Dr. M. Potasek, Ph.D. (CSO), More than 22 years' experience in molecular models, nanotechnology, biophotonics, and photo medicine; led projects and product development at AT&T Bell Labs; Fellow SPIE, Senior Member OSA, IEEE, Phi Beta Kappa
Dr. E. Parilov, Ph.D. (CTO), Expert in GPGPU, computer modeling, computational dosimetry, computer vision
Dr. K. Beeson, Ph.D. (EVP), Expert in biophysics; 69 patents issued

SURGICAL INNOVATION ASSOCIATES, INC.

Bio-Absorbable Surgical Mesh Device

Alexei Mlodinow, MD, MBA | Alexei@sia.health | 626-372-4884 | sia.health

COMPANY OVERVIEW

Surgical Innovation Associates (SIA) is a Northwestern University spin-out medical device manufacturer pioneering innovative products for reconstructive and plastic surgery. The Company's first device, DuraSorb™, is an absorbable surgical mesh invented to decrease the cost of breast reconstruction relative to the current standard for women who have had mastectomies, while avoiding short- and long-term complications, patient harm, and mesh-related lawsuits. **The company has FDA 510(k) clearance, a growing roster of clinicians using the device, and is increasing sales revenue** with large academic institutions such as University of Michigan.

MARKET & COMMERCIALIZATION STRATEGY

SIA's initial US FDA clearance permitted the company to begin marketing DuraSorb® into the $1.2B hernia surgery market (>500K addressable US procedures) and the cosmetic surgery market (>100K addressable US procedures). They are also planning to expand their indication to enter the breast reconstruction market, a $500M US addressable market comprised of >100K procedures and rapidly growing at 18% year over year. SIA's business model is to generate recurring revenues on high margin disposables. Their absorbable mesh is clinically superior but priced below the market leading biologic mesh, offering significant cost savings. Low material costs and lean manufacturing processes keep COGS under $350/sheet compared to a price of $3,500/sheet, allowing SIA to maintain a >90% gross margin while delivering significant savings to customers.

TECHNICAL & COMPETITIVE ADVANTAGE

SIA's competition is from manufacturers of mesh material derived from biologic sources such as human or porcine dermis, including LifeCell (recently acquired), MTF (formerly distributed by J&J), Novadaq, and RTI. Another source of competition is from manufacturers of synthetic meshes that carry disadvantages, including Ethicon (J&J), Allergan, C.R. Bard and Tepha. They have major drawbacks related to absorption profile and material composition that compromise the balance of long-term safety and long-term effectiveness. DuraSorb™ provides temporary soft tissue support, then fully resorbs when such support is no longer required, reducing the risk of long-term complications that have plagued permanent mesh products.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

SIA was **Awarded US FDA 510(k) Clearance** for DuraSorb™ indicated for use in the $1.2 Billion U.S. hernia market and recently **received CE Mark**. SIA's regulatory strategy is to expand the indications to become the first and only mesh clinically indicated for breast reconstruction. The Company also secured a favorable exclusive license on an issued US patent with Northwestern University and has since created a strong patent position with multiple issued patents and several additional US and PCT patents pending.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2021	Grow Sales to >$3M annually via direct sales in the US as well as distributor sales OUS
Q1 2022	Complete IDE Clinical Study in pursuit of expanded indication as the "first and only" mesh with label for breast recon.
Q4 2022	Grow Sales to >$10M annually positioning the company for strategic acquisition in the 2023 timeframe

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017-2018	Seed I/II Financing	Common Stock Seed I/II Financing	$2.3M
2019	Series A Financing	Series A Preferred Stock Financing; 1x liquidation preference; $20M post-money	$4.0M
2019	NCI SBIR Phase II Grant	National Cancer Institute (NCI) SBIR Direct to Phase II Grant Award	$2.0M
2020	Convertible Note Bridge Round	Convertible Note Bridge Financing; 20% discount to Series B	$2.0M

USE OF PROCEEDS

SIA is seeking a **Series B up to $10M by Q1 2021** to increase sales revenue, recruit additional talent, and to expand the indications for use to become the first and only mesh clinically indicated for breast reconstruction. Comparable acquisitions range $96M (pre-revenue; Seri by Allergan) to $2.9B (6x sales; LifeCell by Allergan), reinforcing the opportunity for an attractive ROI.

KEY TEAM MEMBERS

Alexei Mlodinow, MD, MBA (CEO/Co-Founder), Author of 25+ peer-reviewed publications, presentations and abstracts in plastic and reconstructive surgery; member of the 2019 Forbes 30 under 30; **Todd Cruikshank, MBA** (COO), Formerly of Baxter Healthcare and Baxalta (Acquired by Shire) for nearly a decade; **John Slump** (CFO), Co-founder of three medical device startups; two have FDA clearance & scaling sales; one is a PMA in the clinic; **Jason O'Hearn** (CCO), 20+ years' plastic surgical device experience; Previous VP/General Manager, Aesthetics at Sientra (joined pre-IPO and saw through to current position as third largest breast implant manufacturer in the world); **John Kim, MD** (Co-Founder), Professor of Plastic Surgery at the Feinberg School of Medicine; editorial board member for the Journal of Plastic and Reconstructive Surgery; previous invention secured multi-million-dollar licensure by Stryker Corporation

ENVISAGENICS

Using AI to deliver therapies for RNA splicing diseases

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COMPANY OVERVIEW

Envisagenics is an Artificial Intelligence (AI)-driven biotechnology company focused on discovering novel RNA splicing variants. Its SpliceCore® software platform employs a proprietary, exon-centric approach to RNA-sequencing analysis, and the company uses validated machine learning (ML) to accelerate the identification and development of highly specific therapeutics to treat cancer and other genetic diseases. Envisagenics is developing an internally discovered RNA therapeutic, ENV-0205, for triple negative breast cancer (TNBC). ENV-0205 targets a novel splicing isoform of a key signaling enzyme, which is present in 65% of TNBC patients. The SpliceCore-designed antisense oligonucleotide (ASO) has been proven to reduce viability of TNBC cell lines and is now undergoing preclinical studies. Envisagenics also partners with biopharmaceutical companies and recently announced an oncology partnership with The Lung Cancer Initiative at Johnson & Johnson.

MARKET & COMMERCIALIZATION STRATEGY

There is a growing number of biopharmaceutical companies developing AI/ML technologies towards novel therapeutic discovery and development. Applications of AI for drug discovery holds 35% of the rapidly emerging AI in Healthcare market, which is projected to reach $22.2B globally by 2023 at a CAGR of 48.7%. Envisagenics' first therapeutic program is in TNBC, which affects 40,000 patients in the United States each year. The global TNBC market is projected to reach $720M by 2026. The company intends to expand the application of SpliceCore to other indications with strong evidence of splicing dysregulation as drivers of the disease through its internal R&D programs and research collaborations with pharmaceutical partners.

TECHNICAL & COMPETITIVE ADVANTAGE

Envisagenics' SpliceCore software platform utilizes an exon-centric approach to analyzing RNA splicing events. This approach results in a deeper search space for therapeutic targets compared to the traditional gene-centric approach and allows for distributed and scalable computing to accelerate target discovery. Envisagenics has developed a proprietary and stratified reference database, TXdb, with approximately 7 million unique splicing events, of which 4.5 million are novel. Envisagenics has also developed proprietary ML algorithms which generate biological insight to infer mRNA stability and translatability, and to identify points of intervention. The discoveries made by SpliceCore are further qualified experimentally in cell lines, primary disease tissues and validated using an ASO to confirm the modulation of any splicing event. In 8 months, the platform has been successfully leveraged in-house for the development of Envisagenics' first therapeutic program in TNBC.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Envisagenics' TNBC program is currently undergoing preclinical studies. The company plans to initiate IND-enabling studies in Q2 of 2021 and to file for first in human studies in Q4 2021. Envisagenics is a spin out of Cold Spring Harbor Laboratory and was granted an exclusive, global, and royalty-free license to the algorithms and databases. Envisagenics has filed two Patent Cooperation Treaty applications. These applications, together with additional pending provisional filings, cover the software platform itself and cancer- related novel splicing variants and potential splicing-modulating therapeutics that are discovered by the platform.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2014	Company founded
Q2 2020	Secure new co-development deal with biopharma partner
Q4 2020	Complete IND enabling studies for TNBC program
Q4 2020	Complete development of commercially ready SpliceIO platform
Q4 2021	IND filing for TNBC program

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015	Pre-seed	Investment from Accelerate Long Island and the Long Island Emerging Technologies Fund	$100k
2015	Grant	Phase I SBIR grant from NIGMS for the development of SpliceCore	$225k
2017	Seed Round	Investment from Third Kind Venture Capital, Cosine, Dynamk Capital, Dolby Family Ventures, NY Empire State Dev., SV Angel	$2.35M
2018	Seed Round	Investment from M12 (formerly Microsoft Ventures) and Madrona Venture Group	$1M
2018	Grant	Phase II SBIR from NIGMS for continued development of SpliceCore	$1.5M
2019	Grant	Phase I SBIR grant from NCI for expansion of SpliceCore for IO therapeutic development	$300k

USE OF PROCEEDS

Envisagenics is raising a $20M Series A round which will fund the company's lead asset through Phase Ib and to secure additional co-development projects with pharmaceutical companies to discover and accelerate the development of novel therapeutics.

KEY TEAM MEMBERS

Founders: Maria Luisa Pineda, Ph.D. – CEO; Martin Akerman, Ph.D. – CTO; **Scientific Advisory Board:** Omar Abdel-Wahab, M.D.; Sudhir Agrawal, D. Phil, FRSC; Adrian Krainer, Ph.D.; Michael Zhang, Ph.D.; **Business Advisory Board:** Michael Grissinger, M.B.A.; Alan Roemer, M.B.A, M.P.H.

INHERET

Inherited Risk Evaluation Tool, a SaaS program

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COMPANY OVERVIEW

InheRET, Inc. offers a SaaS program to identify people at increased risk for hereditary diseases enabling risk reduction efforts prior to disease onset. Clinical pilot testing is completed and InheRET 2.0 is now commercially available with a feature-rich InheRET 3.0 beginning clinical pilot testing within six months. Currently focused on hereditary cancer (with other disease modules in process), InheRET identifies the 1 in 5 Americans who are at increased risk for hereditary cancer, but among whom fewer than 10% are aware of their risk. InheRET addresses the time, accuracy, and interpretation of family health history barriers faced by clinicians and streamlines the process delivering easy-to-understand reports based on National Comprehensive Cancer Network Guidelines (NCCN; licensed) and others, for both healthcare providers and patients.

MARKET & COMMERCIALIZATION STRATEGY

The US market is >$1B annually with 1,223 health systems/large hospitals, 400,000 primary care providers, >10,000 oncologists, and 5,700 genetic counselors. Hundreds of thousands of cardiologists, endocrinologists, surgeons, psychiatrists, and other mental health professionals, audiologists, pediatricians, and other providers will find InheRET's future other hereditary disease modules very attractive. The global health IT market continues to expand with Europe holding a significant position. Asia Pacific is forecast to experience the highest level of growth, with other regions continuing to expand. InheRET has segmented the United States market into 8 regions with the home region being the Great Lakes Region (GLR) where marketing efforts have begun. The GLR is home to 46,360 active primary care providers, 1,950 genetic counselors and 97 health systems with 544 hospitals employing 75,100 physicians. The Company plans to expand as finances allow.

TECHNICAL & COMPETITIVE ADVANTAGE

There are several competitive products that offer some, but not all, features of InheRET. InheRET is set apart by: 1) written at a fourth grade reading level, reducing literacy barriers; 2) web-enabled device compatibility from computers to smartphones; 3) patients complete at home, accessible to underserved populations; 4) fully transparent recommendations, with the specific guideline criteria met; 5) NCCN tested with results accuracy verified; 6) full-color 7 generation pedigree; 7) resource library with a directory of genetics clinics and educational materials; 8) Customizable reports; 9) Automatic annual updates for avoiding obsolescence, customizable by clinic preference. InheRET 3.0 will also offer proprietary risk model to guide care decisions, recommended genes for testing linked to a test ordering portal, customizable database for provider use, templates for generating letters to insurance, family members and patients, patient navigation module to support patient needs.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

FDA regulation review in 2018 and 2019 determined InheRET is a non-regulated product. The initial 2018 IP was licensed from the University of Michigan with all updates and revisions belonging solely to InheRET, Inc. InheRET received US registered trademark protection and filed for patent protection in June 2020.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
12/2020	Sales reach $1.5M
04/2021	InheRET 3.0 ready for pilot testing
09/2021	InheRET 3.0 launch/InheRET-CNS (Clinical Neurosciences) ready for pilot testing

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Founder Investment	Convertible Debt	$100K
2019	Angel Investment	Convertible Debt	$200K
2019	Grant	NIH STTR Phase I, SBIR MEDC, SPARK Ann Arbor	$339K
2020	Investment	Convertible Debt ($25k Founder, $50k Angel)	$75K
2020	Grants	PPP, EIDL Grant, MI SBA Emergency Relief, Washtenaw City Emergency Relief	$66.8K

USE OF PROCEEDS

InheRET is looking for $2M in external funding in 2020 to expand sales, customer support teams, and product offering.

KEY TEAM MEMBERS

David Keren, MD (CEO) 22 years as CEO of Warde Medical Laboratory; expert in clinical laboratory testing
Sofia Merajver, MD, Ph.D. (CSO) Expert in cancer genetics, prevention, translational science; NCCN cancer risk guidelines committee member
Lynn McCain, MSHA (COO) 25 years' finance/administration experience in Healthcare, IT, and Insurance
Kara Milliron, MS, CGC (Genetic Counselor) 20 years' experience in inherited cancer risk genetic counseling
Lee Schroeder, MD, Ph.D. (CAO) Expert in clinical informatics, health services research, data analytics, and modeling
Amanda M. Cook (Director of Business Development) 25 years' experience in sales, marketing, and medical insurance

QUANTITATIVE RADIOLOGY SOLUTIONS

Automated Analysis of Medical Images

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COMPANY OVERVIEW

Quantitative Radiology Solutions (QRS) helps physicians make better treatment decisions through automated analysis of medical images. The Company's Automatic Anatomy Recognition (AAR) software supports analysis of anatomical structures and diseased tissue using MRI, CT, and PET/CT images for applications in treatment planning and monitoring. The first application aims to reduce side effects from unnecessary radiation exposure for cancer patients undergoing radiation therapy. AAR is used to delineate "organs at risk" and reduce radiation received by anatomical structures. QRS's solution allows physicians to increase accuracy of planning while reducing treatment planning time, and re-plan to account for anatomical changes that occur during treatment.

MARKET & COMMERCIALIZATION STRATEGY

QRS participates in the $1B U.S. market for automated analysis of imaging in cancer care. There are currently over 2,200 sites in the U.S. that provide radiation therapy, and our initial target market segment is academic medical centers and integrated delivery networks that offer specialized radiation treatments such as proton therapy and stereotactic body radiotherapy. QRS's software-as-a-service (SaaS) platform delivers an automated solution for contouring organs at risk, and will be promoted through a direct sales approach. The Company estimates the market for this initial solution to be $250MM.

TECHNICAL & COMPETITIVE ADVANTAGE

The basic premise of AAR is that, to successfully automatically contour anatomic structures on a CT or MR image of a body region, a significant amount of prior information is needed about structures and the subject-to-subject variation of their layout. AAR divides contouring into 2 actions: locating the structure in the image, process of defining the precise boundary of the structure in the image. AAR offers 3 advantages when compared to existing automatic contouring approaches: 1) higher accuracy obviating the need for manual editing; 2) contouring of all anatomical structures in a body region, and 3) scalable performance using parallel processing and cloud-based computing resources to reduce contouring times.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Discussions with FDA indicate that AAR is a Class II medical device with an identified predicate device. The Company anticipates a 510(k) submission to the FDA by 8/31/2020 and 4-month regulatory approval process. QRS has an agreement with the University of Pennsylvania that grants the company an exclusive, world-wide license to patent rights for automatic body region recognition, and copyright for software for automatic localization of anatomical structures using fuzzy models. In addition, QRS has retained the rights to over 1000 clinical cases to use as data for product development.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
10/2020	Completion of clinical evaluation
12/2020	Receive FDA clearance for marketing of AAR in radiation treatment planning
12/2020	Initial customer revenue
12/2021	Expansion of functionality to accommodate prostate radiation treatment

CAPITALIZATION HISTORY

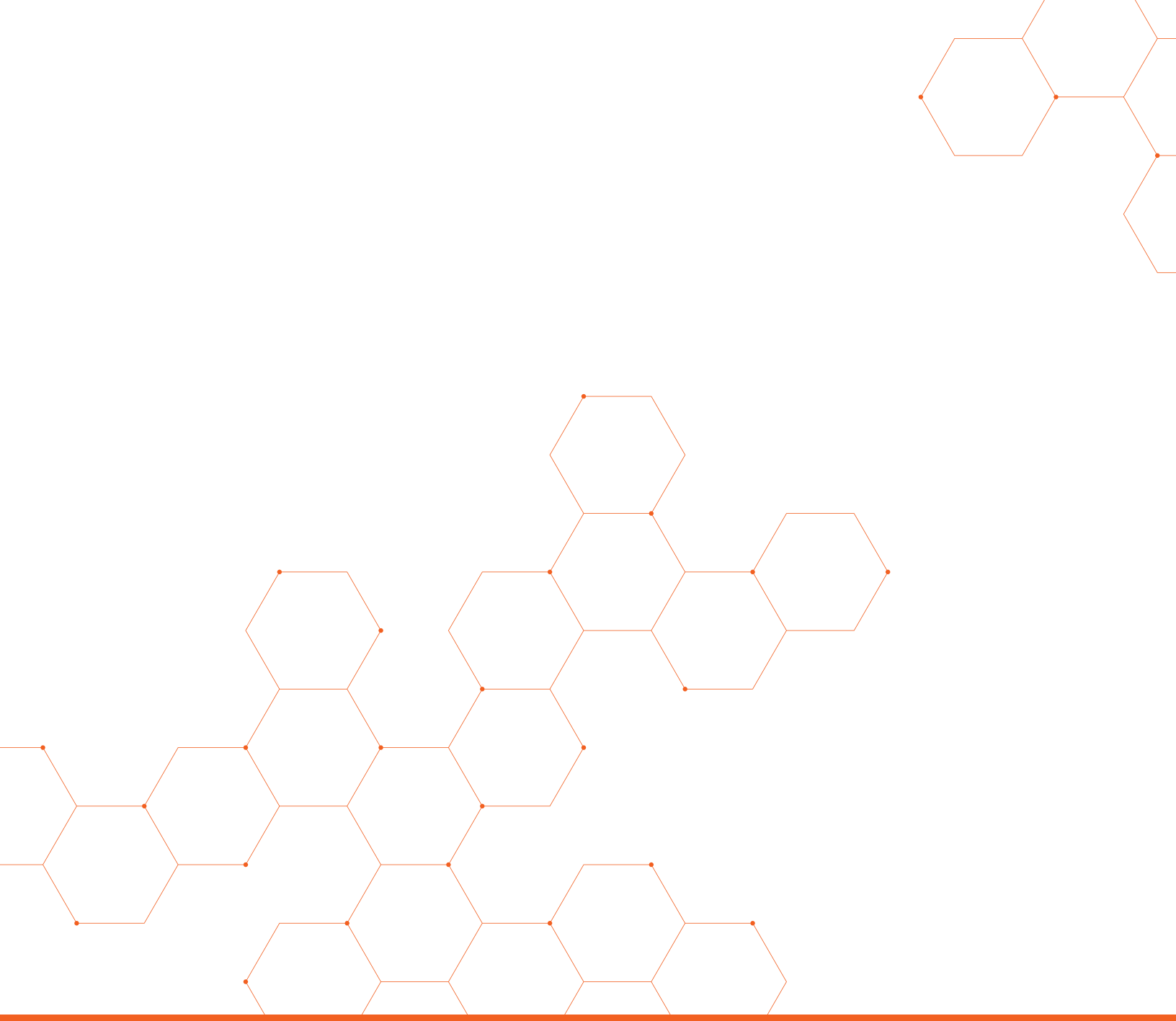
YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016	Grant	NSF STTR Phase I and Phase Ib	$270K
2016	Grant	NIH STTR Phase I	$255K
2016	Seed Round	Convertible note from Phase 1 Ventures	$213K
2018	Seed Round	Convertible note from Ben Franklin Technology Partners	$50K
2018	Grant	NIH STTR Phase II	$2M
2019	Seed Round	Convertible note from Phase 1 Ventures	$230K

USE OF PROCEEDS

QRS is raising $1.8M to support product launch of AAR in the radiation treatment planning market. Expenses for sales and marketing account for $1.4M of the raise and include support for business development personnel (2 FTE's) and marketing spend. The remaining $400K will be used to develop end user training and support, and further improve integration of the cloud-based solution into the clinical workflow.

KEY TEAM MEMBERS

Joe Camaratta, President and CEO, 30 years' experience in commercialization of medical technologies that impact patient care; Built businesses for GE Healthcare and Siemens Healthcare in medical imaging, cardiology, and oncology
Steve Owens, Chief Technology Officer and Chief Operating Officer, 30+ years' development experience, and a track record of leading people to transform cutting edge technology into innovative products; Built software development organizations for Siemens Healthcare, RadPharm, and Forest Laboratories



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