2021 | NCI SBIR

INVESTOR INITIATIVES

PORTFOLIO SHOWCASE

NATIONAL CANCER INSTITUTE | SBIR DEVELOPMENT CENTER

INVESTOR | INITIATIVES

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BIOPHARMACEUTICALS

Company	Technology Type	Initial Organ(s)/Indication(s)
Avenzoar Pharmaceuticals	Developing drugs targeting metastasis and chemo-resistance (GSK-3β and HDAC pathways)	Pancreatic, ovarian
BioMimetix	BMX-001, therapeutic for cancer patients receiving radiation and/or chemotherapy	High-grade glioma, head/neck, anal/rectal
Concarlo Holdings	IpY, targeting p27Kip1—leading to the inhibition of CDK4/6 and CDK2 simultaneously	Breast, ovarian, pancreatic
Manzanita Pharmaceuticals	Nerve imaging agent for use in radical prostatectomies	Prostate
NuvOx Pharma	First-in-class oxygen therapeutic	Brain (GBM)
OncoNano Medicine	Ultra pH-sensitive polymeric micelles that encapsulate small molecules and biologics	Various solid cancers
OncoSpherix	Small molecule inhibitors of HIF-1 and HIF-2 transcription factors	Brain (GBM), NSCLC
ProDa BioTech	Protein drug for cancer and chronic liver disease treatment	Pancreatic, breast, lung
Reveal Pharmaceuticals	Gadolinium-free MRI contrast agent	Liver, CNS
Senex Biotechnology	Small molecule CDK8/19 inhibitor	Advanced prostate cancer
Summit Biomedical Imaging	Fluorescent imaging for rapid, point-of-care cancer detection	Oral cancer
Treovir	Oncolytic immunotherapy	Pediatric brain tumors

DRUG DELIVERY PLATFORMS

Company	Technology Type	Initial Organ(s)/Indication(s)
Nami Therapeutics	Nanocarrier platforms for targeted delivery of radiotherapies and chemotherapeutic agents	Ovarian peritoneal metastasis, leukemia, lymphoma
Privo Technologies	Topically administered chemotherapy patch	Oral cancer

DIAGNOSTICS/TOOLS

Company	Technology Type	Initial Organ(s)/Indication(s)
Applikate Technologies	Fully automated tissue processing and digital imaging platform	Prostate, breast, GI, lung, kidney tissues
Creatv MicroTech	Macrophage-like biomarkers for cancer screening and diagnostics	NSCLC
EarlyDiagnostics	Blood-based cfDNA test	Various
Eutropics Pharmaceuticals	First-in-class functional predictive assays	AML
Ferrologix	Ratcheting cell isolation system	Various
JBS Science	Urine-based DNA tests	Liver
Nodexus	Platform for single-cell analysis, sorting, and dispensing	Urothelial carcinoma of the bladder

DEVICES

Company	Technology Type	Initial Organ(s)/Indication(s)
CivaTech Oncology	Targeted radiation therapy devices	Pancreatic, lung, colorectal/pelvic, head/neck, brain, sarcomas
Clarix Imaging	Portable 3D specimen imaging system	Breast
Leuko Labs	White blood cell monitoring device	Chemotherapy-induced febrile neutropenia
NE Scientific	Surgical guidance for tumor ablation	Liver
Rivanna Medical	Ultrasound-based X-ray replacement technologies	Bone marrow biopsies
Veriskin	Non-invasive, handheld device for skin cancer detection	Skin cancer

DIGITAL HEALTH

Company	Technology Type	Initial Organ(s)/Indication(s)
AIQ Solutions	Cloud-based platform for better therapy optimization	Various
Envisagenics	Using AI to develop therapies	RNA splicing diseases
INHERET	Risk assessment and decision support software	Hereditary cancers

SHORT COMPANY SUMMARIES

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

AVENZOAR PHARMACEUTICALS

DEVELOPING DRUGS TARGETING METASTASIS AND CHEMO-RESISTANCE (GSK-3β AND HDAC PATHWAYS)

LOCATION
ENCINITAS, CA

STAGE
PRE-CLINICAL DEVELOPMENT

Avenzoar is a pre-clinical pharmaceutical company founded in 2016 that specializes in developing cancer drugs designed to target and inhibit mechanisms of metastasis and drug resistance. Avenzoar has three drugs in the pipeline so far. The lead drug is AP-001 (Metavert), which is expected to be tested in pancreatic cancer patients in 2022. The anti-cancer drugs developed by Avenzoar target two important pro-cancer pathways regulated by GSK-3β and HDAC. So far, AP-001 and AP-002 have shown strong anti-cancer effects in pancreatic and ovarian cancer, respectively. After performing the mechanistic and efficacy studies in both cancers using multiple animal models, Avenzoar is now in the process of performing the IND-enabling pre-clinical studies (Pharmacokinetics and Tox studies) required for a Phase I clinical trial.

BIOMIMETIX

BMX-001, THERAPEUTIC FOR CANCER PATIENTS RECEIVING RADIATION AND/OR CHEMOTHERAPY

LOCATION
GREENWOOD VILLAGE, CO

STAGE
IN CLINICAL TRIALS: PHASE II

BioMimetix was founded to exploit the therapeutic/commercial potential of the metalloporphyrin drugs. BioMimetix's proprietary drug, BMX-001, is administered to patients receiving radiation therapy (with or without chemotherapy). The drug enhances the anti-cancer benefit of the therapy and, at the same time, reduces the severe, dose-limiting radiation side effects. In the high-grade glioma Phase I/IIa trial, addition of BMX-001 appeared to extend survival by 6–8 months, as recognized by FDA orphan drug and fast track designations. In Phase IIa Head/Neck and Anal/Rectal trials, BMX-001 reduced substantially the radiation side effects of mucositis, xerostomia, and dermatitis. Adverse events are considered minor and manageable. BioMimetix LLC plans to spin off the C-Corp "BMX Oncology," with all related IP, assets, and key personnel, to focus on late-stage clinical development of BMX-001.

CONCARLO HOLDINGS

IPY, TARGETING P27KIP1 AND LEADING TO THE INHIBITION OF CDK4/6 AND CDK2 SIMULTANEOUSLY

LOCATION
BROOKLYN, NY

STAGE
PRE-CLINICAL DEVELOPMENT

Concarlo is exploiting the discovery that an alternate system (p27Kip1) controls CDK4/6 and CDK2 activity and resistance and has developed two technologies to recognize and shut down this pathway. These will be the first technologies based on p27, and they will help to transform the breast cancer space with the hope to develop new therapies that take full advantage of CDKi anti-proliferative properties. The drug, IpY, harnesses the power of biologic targeting using a peptide-liposome formulation, administered by infusion, to specifically inhibit p27 and CDK4 and CDK2. IpY can kill tumor cells and cause regression, as opposed to just slowing tumor growth, which should translate into increased overall survival for patients. IpY is also effective in a wider range of tumor types than CDK4i, including ovarian, pancreatic, and triple negative breast cancer.

MANZANITA PHARMACEUTICALS

NERVE IMAGING AGENT FOR USE IN RADICAL PROSTATECTOMIES

LOCATION
WOODSIDE, CA

STAGE
NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE

Manzanita Pharmaceuticals is developing Nervelight™, a nerve imaging agent that is applied topically, intra-operatively, and is selectively taken up by sensory nerves, thus aiding oncologic surgeons in fluorescence-guided surgery. Nervelight™ is comprised of a commercial near infrared (NIR) fluorescent dye that is attached to a sensory nerve targeting moiety, recombinant human nerve growth factor (rhNGF). Unmodified rhNGF is marketed for topical, ocular use in repeat doses. Manzanita's initial indication is radical prostatectomies. The NIR dye fluoresces in the 800 region, which, like marketed, generic indocyanine green (ICG), can be visualized in existing equipment (99% of ORs are ICG-enabled).

NUVOX PHARMA

FIRST-IN-CLASS OXYGEN THERAPEUTIC

LOCATION
TUCSON, AZ

STAGE
IN CLINICAL TRIALS: PHASE II

NuvOx is developing NanO2 for oxygen delivery, which, when injected intravenously, increases the efficiency of oxygen exchange between blood and tissue. In oncology, the drug increases tumor oxygen levels to make tumors more sensitive to radiotherapy, chemotherapy, and/or immunotherapy. A Phase Ib/II clinical trial in brain cancer demonstrated safety, significant increases in tumor oxygen levels, and evidence consistent with increased survival for the oxygen delivery product. The FDA has allowed an IND for a Phase II clinical trial. NuvOx's NanO2 is the only technology in its class in clinical trials and has shown efficacy in reversing tumor hypoxia. The drug will work for many solid tumor types, but NuvOx is focusing first on the orphan glioblastoma multiforme (GBM) indication.

ONCONANO MEDICINE

ULTRA PH-SENSITIVE POLYMERIC MICELLES THAT ENCAPSULATE SMALL MOLECULES AND BIOLOGICS

LOCATION
SOUTHLAKE, TX

STAGE
IN CLINICAL TRIALS: PHASE II

OncoNano Medicine is developing a new class of products exploiting pH as a simple and ubiquitous biomarker to meet unmet needs of patients and clinicians across the continuum of cancer care. The Company's core technology is based on ultra pH-sensitive polymeric micelles that selectively target cancer for intraoperative imaging and immuno-oncology therapeutics such as tumor-specific drug delivery, cancer immunomodulators, and nanovaccines.

ONCOSPHERIX

SMALL MOLECULE INHIBITORS OF HIF-1 AND HIF-2 TRANSCRIPTION FACTORS

LOCATION
ATLANTA, GA

STAGE
PRE-CLINICAL DEVELOPMENT

OncoSpherix has two distinct drug families that block the adaptive responses that allow cancer cells to survive and spread from regions of hypoxia. The clinical lead candidate blocks the function of the master regulatory proteins HIF-1 and HIF-2, and this in turn prevents tumor cells from surviving and spreading. Efficacy has been shown in pre-clinical models of many types of cancer (brain, lung, breast, ocular melanoma) and the drug can be safely given with other chemotherapy, enhancing responses.

PRODA BIOTECH

PROTEIN DRUG FOR CANCER AND CHRONIC LIVER DISEASE TREATMENT

LOCATION
MARIETTA, GA

STAGE
IN CLINICAL TRIALS: PHASE I

The mission of ProDa is to develop its innovative protein drug, ProAgio, for the clinical market as a cancer (particularly pancreatic and liver cancers) and fibrotic disease treatment drug. For cancer treatment, ProAgio targets the tumor microenvironment, fibrotic stroma, and angiogenic vessels simultaneously. For chronic liver disease treatment, ProAgio directly depletes collagen producing activated hepatic stellate cells and capillarized liver sinusoidal endothelial cells. ProAgio reduces collagen fibril and relieves portal hypertension caused in fibrotic/cirrhotic liver. Effectiveness of ProAgio has been extensively tested in pre-clinical animal models.

REVEAL PHARMACEUTICALS

GADOLINIUM-FREE MRI CONTRAST AGENT

LOCATION
CAMBRIDGE, MA

STAGE
PRE-CLINICAL DEVELOPMENT

Reveal Pharmaceuticals aims to improve safety and deepen insight for MR imaging. Reveal is developing gadolinium-free MRI contrast agents designed to replace gadolinium-based contrast agents (GBCAs), which cause accumulation of the heavy metal in the brain and organs of patients. First-in-class RVP-001 is based on biocompatible manganese and is designed to be a direct substitute for GBCAs. RVP-001 seamlessly fits existing radiology workflows and reimbursement models. Nonclinical data show RVP-001 to be safer than GBCAs, with equivalent imaging efficacy to GBCAs across multiple indications in animal models.

SENEX BIOTECHNOLOGY

TARGETING TRANSCRIPTIONAL REPROGRAMMING FOR CANCER THERAPY

LOCATION
COLUMBIA, SC

STAGE
PRE-CLINICAL DEVELOPMENT

Senex's principal program targets transcription-regulating Mediator kinases CDK8 and CDK19, which mediate changes in cellular gene expression (transcriptional reprogramming) but are not required in adult organisms under homeostatic conditions. CDK8/19-mediated transcriptional reprogramming plays a key role in several types of cancer (prostate, breast, leukemias) and is involved in cancer metastasis and resistance to different types of drugs. In contrast to some other proteins of the CDK family (such as CDK4/6), CDK8/19 are not required for cell division, and long-term CDK8/19 inhibition is very well tolerated in adults. Senex's lead CDK8/19 inhibitor drug candidate is highly potent, selective, and metabolically stable. It is undergoing GMP manufacturing to be followed by preclinical development. The Company's primary disease target is advanced prostate cancer.

SUMMIT BIOMEDICAL IMAGING

FLUORESCENT IMAGING FOR RAPID, POINT-OF-CARE CANCER DETECTION

LOCATION
NEW YORK, NY

STAGE
IN CLINICAL TRIALS: PHASE II

Summit Biomedical Imaging (SBI) seeks to commercialize cancer diagnostics that use PARPi-FL, a fluorescent molecule that targets poly-ADP ribose polymerase (PARP), a DNA repair enzyme. SBI's first target is oral cancer. Oral cancer absorbs PARPi-FL, which, when illuminated, fluoresces. SBI is developing a mouthwash for point-of-care oral cancer detection. Patients swish the mouthwash, spit it out, and a clinician then uses a handheld fluorescence microscope to check for cancer. PARPi-FL has demonstrated high sensitivity and specificity (both 95%+) in ex vivo studies that is supported by results from a Phase I clinical trial (completed 2020).

TREOVIR

ONCOLYTIC THERAPY FOR PEDIATRIC BRAIN TUMORS

LOCATION
PHILADELPHIA, PA

STAGE
IN CLINICAL TRIALS: PHASE I

Treovir is developing G207, an oncolytic HSV virus for the treatment of pediatric brain tumors. G207 is a doubly mutated type-1 herpes simplex virus that is unable to productively infect normal cells that retain normal anti-viral defense mechanisms. Tumor cells, by contrast, are easily infected by G207 and are unable to defeat the oncolytic process of the virus. G207, like most HSVs, is highly immunogenic and elicits a striking immune cell-related infiltration of the infected tumor, resulting in an anti-tumor response. A Phase I clinical trial has been completed demonstrating strong evidence of safety and efficacy.

NAMI THERAPEUTICS

NANOCARRIER PLATFORMS FOR TARGETED DELIVERY OF RADIOTHERAPIES AND CHEMOTHERAPEUTIC AGENTS

LOCATION
STORRS, CT

STAGE
PRE-CLINICAL DEVELOPMENT

Nami Therapeutics Corporation is a specialty nanotechnology platform company developing cutting-edge precision cancer nanotherapies. Nami is focused on developing specifically designed nanocarrier platforms for targeted delivery of radiotherapies and chemotherapeutic agents to tumor cells. Nami nanotechnology can improve the efficacy and reduce the toxicities of therapeutic radiopharmaceuticals and anti-cancer drugs across all tumor types. Current efforts are focused on two lead programs: 1) XLNT-1, radioisotope-loaded nanoparticles with intraperitoneal delivery to treat peritoneal metastases; 2) XLNT-2, nanoparticles containing the chemotherapeutic agents specifically designed to inhibit leukemic stem cells (LSC) to cut the root of treatment resistance and cancer recurrence in leukemias and lymphomas.

PRIVO TECHNOLOGIES

TOPICALLY ADMINISTERED CHEMOTHERAPY PATCH

LOCATION
PEABODY, MA

STAGE
IN CLINICAL TRIALS: PHASE III/PIVOTAL

Privo Technologies is a clinical stage biotech company looking for potential investors to support two pivotal, registration-enabling Phase III trials examining Privo's lead assets, PRV111 and PRV211, in early-stage tongue cancer and oral carcinoma in situ, respectively. PRV111 utilizes Privo's proprietary PRV platform, a transmucosal nano-engineered platform formulated from bio-compatible materials that provides loco-regional delivery of drug products that are typically hindered by dose-limited toxicities. Internally, Privo is currently developing derivatives of the PRV platform for non-viral nucleotide delivery.

APPLIKATE TECHNOLOGIES

FULLY AUTOMATED TISSUE PROCESSING AND DIGITAL IMAGING PLATFORMS

LOCATION
WASHINGTON, DC

STAGE
IN CLINICAL TRIALS: FEASIBILITY/PILOT

Applikate's fully automated tissue processing and digital imaging platform, CHiMP, revolutionizes pathology by eliminating glass slides and directly imaging intact tissue specimens. CHiMP comprises a novel tissue processing method, an associated automated tissue processor, custom disposable cassettes, specialized visualization software, and a purpose-built, ultra-high-speed multiphoton microscope for direct production of digital H&E-like images from intact, formalin-fixed pathology samples. No wax embedding or slicing of tissue is required, and all the tissue is preserved for ancillary studies. CHiMP is a paradigm-shifting technology that eliminates many of the hurdles faced by using physical glass slides and results in high-resolution direct-to-digital pathology that is significantly faster, less costly, and more capable. Unlike all other digital methods, CHiMP does not layer new technology on an inflexible, archaic process.

CREATV MICROTECH

LIQUID BIOPSY FOR CANCER SCREENING, COMPANION DIAGNOSTICS, AND PREDICTION OF TREATMENT RESPONSE

LOCATION
POTOMAC, MD

STAGE
PRE-CLINICAL DEVELOPMENT

Creatv's revolutionary LifeTracDx™ blood tests are applicable for cancer screening, companion diagnostics, prediction of treatment response including immunotherapy, providing prognosis, delivering whole tumor DNA for sequencing, detecting minimal residual disease and early detection of cancer recurrence. The LifeTracDx™ liquid biopsies are applicable to all solid tumors, all stages of cancer, and all therapies. Creatv is setting up a CLIA lab to implement the LifeTracDx™ liquid biopsy.

EARLYDIAGNOSTICS

LIQUID BIOPSY PRODUCTS TO DETECT CANCER EARLY AND PINPOINT ITS LOCATION

LOCATION
LOS ANGELES, CA

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

EarlyDiagnostics (EarlyDx) is devoted to providing accurate, affordable, and non-invasive liquid biopsy products for early cancer diagnosis and precision medicine. EarlyDx's leading product, MethylScan Test, a blood-based cfDNA test combining both an assay technique and machine learning algorithms, can not only detect cancer at early stages but also pinpoint its location. The MethylScan Test has been validated in 479 clinical samples, showing high sensitivity in detecting early stages of cancer.

EUTROPICS PHARMACEUTICALS

FIRST-IN-CLASS FUNCTIONAL PREDICTIVE ASSAYS

LOCATION
CAMBRIDGE, MA

STAGE
NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE

Eutropics is a biomarker discovery, CLIA laboratory advancing personalized medicine by providing a novel functional biomarker driven predictive platform for precision oncology. The Company discovers and develops biomarkers by applying the discovery platform to identify the correct assay readout for predicting the cancer cell response to partners' drugs or drug combinations. 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. The tests recognize unique features of cancer cells from individual patients and a commercial version of the assays is being provided for matching patients with the most effective approved treatments for their indication.

FERROLOGIX

RAPID, HIGH PURITY AND YIELD, LOW-COST ISOLATION OF TARGET CELLS IN SAMPLE PREP AND CELL THERAPY

LOCATION
VALENCIA, CA

STAGE
NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

Cell purification remains a critical need in the development and production of cutting-edge diagnostics and therapeutics. Ferrologix has a unique magnetic-based instrument and disposable cartridge that can transport, filter, and organize single cells for precision analysis or therapeutic manufacture. Pioneering a technique called Digital Magnetic Sorting (aka Ratcheting Cytometry), Ferrologix is developing a suite of tools to assist, accelerate, and scale the development of precision medicine research, next-gen diagnostics, and cellular therapies.

JBS SCIENCE

CFDNA TEST (URINE/BLOOD) FOR CANCER SCREENING AND PRECISION MEDICINE

LOCATION
DOYLESTOWN, PA

STAGE
PRE-CLINICAL DEVELOPMENT

JBS Science is a discovery and development phase cancer diagnostic company focused on the delivery of urine-based DNA tests for cancer screening and precision medicine. The company's mission is to improve early detection of cancer and cancer management by providing diagnostic tools with detection of the most promising cell-free circulating tumor DNA (ctDNA) markers in urine and blood. The JBS Science Urine DNA test is a qPCR-based test that detects small fractions of HCC-derived genetically and epigenetically modified DNA, derived from the circulation and present in the urine of patients with liver cancer. The target population for the test include a clearly defined, high-risk patient population who have chronic liver disease.

NODEXUS

MAKING LIVE SINGLE-CELL ISOLATION 10X FASTER AND 10X LOWER COST

LOCATION
HAYWARD, CA

STAGE
CURRENTLY IN EARLY ACCESS PROGRAM WITH CUSTOMERS

Nodexus is a commercial-stage biotechnology company commercializing the NX One platform to make live single-cell isolation 10X faster and 10X lower cost. The NX One offers a "mainframe-to-PC" transition for live cell isolation through unprecedented walk-up usability and affordability, and Nodexus' patented technology makes automated single-cell isolation widely adoptable across the breadth of biotech, spanning gene editing and drug development to genomics and cancer biology research.

CIVATECH ONCOLOGY

TARGETED RADIATION THERAPY DEVICES

LOCATION
RESEARCH TRIANGLE PARK, NC

STAGE
IN CLINICAL TRIALS: PHASE II/ COMMERCIALLY AVAILABLE

CivaTech Oncology has three commercially available radiation devices to provide therapeutic doses to cancerous tissues in a localized, targeted method. These devices have been shown to significantly reduce the side effects experienced with traditional radiation methods, provide meaningfully higher radiation doses, and enable the delivery of therapeutic radiation doses where only palliative doses were possible. CivaString®, CivaSheet®, and CivaDerm™ are the only polymer-encapsulated implantable radiation devices. These bio-compatible and bio-absorbable products are designed to be easily implemented in the workflow of current cancer care pathways.

CLARIX IMAGING

FDA-CLEARED, PORTABLE 3D SPECIMEN IMAGING SYSTEM

LOCATION
CHICAGO, IL

STAGE
COMMERCIALLY AVAILABLE/FDA 510(K) CLEARED

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 enable accurate margin assessment. The system has 90%+ sensitivity, takes less than four minutes, and requires no change to existing operating room workflow and little training. VSI is estimated to lower re-operations to less than 5%.

LEUKO LABS

WHITE BLOOD CELL MONITORING DEVICE

LOCATION
BOSTON, MA

STAGE
IN CLINICAL TRIALS: PHASE II AND FEASIBILITY/PILOT

Leuko Labs, an MIT spinout, has developed PointCheck™, the first medical device that enables non-invasive, at-home, and frequent WBC monitoring. The monitoring triggers timely interventions by the care team (e.g., prophylactic antibiotics or G-CSFs) that can reduce chemotherapy-induced febrile neutropenia hospital readmissions by 50%. Beyond chemotherapy, Leuko aspires to continue growing to serve the 10 million immunocompromised US patients who could benefit from increased monitoring of their weakened immune systems.

NE SCIENTIFIC

COMPUTERIZED GUIDANCE FOR TUMOR ABLATION

LOCATION
BOSTON, MA

STAGE
PRE-CLINICAL DEVELOPMENT/IN CLINICAL TRIALS

NE Scientific (NES) is addressing a major issue in the percutaneous ablation of tumors: physicians do not have a direct view of tissues and they cannot properly appreciate from the guidance images (CT or Ultrasound) which tissues have been ablated and which not. NES can simulate RF and Microwave ablation physics in real time, a world-first, and is developing a line of products called Accublate™, which uses this simulation capability to account for the delivered energy and for several patient-specific factors, providing a better representation of which tissues are ablated. These simulations are essential, particularly when multiple probes are used concurrently to treat larger tumors. Accrual is complete for a clinical trial for the guidance of liver cancer RF ablation and interim results are promising.

RIVANNA MEDICAL

WORLD-FIRST ULTRASOUND-BASED X-RAY REPLACEMENT TECHNOLOGIES

LOCATION
CHARLOTTESVILLE, VA

STAGE
COMPANY IS COMMERCIAL STAGE/ACCURO 3S IS PRE-CLINICAL

Rivanna Medical (RIVANNA) provides world-first computer automated medical imaging technology that improves health outcomes, clinical workflows, and patient satisfaction. RIVANNA's core technology includes a suite of innovations that produce high-quality bone imaging characteristic of X-ray but by using medical ultrasound combined with computer-automated guidance, detection, and diagnosis. Underpinning these innovations is the Company's patented BoneEnhance® image processing technology that uses a unique beamforming and signal separation approach to isolate and enhance bone structures within ultrasound imaging data. RIVANNA is currently developing its next generation system, Accuro 3S, supported by an NCI SBIR Phase II award. Accuro 3S replaces CT and fluoroscopy with automated bedside imaging for bone marrow biopsy and lumbar puncture procedures.

VERISKIN

NON-INVASIVE, HANDHELD DEVICE FOR SKIN CANCER DETECTION

LOCATION
SAN DIEGO, CA

STAGE
IN CLINICAL TESTING

The Veriskin device (TruScore) is a proprietary, non-invasive, low-cost, handheld unit that aids a non-expert user to rapidly and objectively determine whether a suspect skin lesion is cancerous, thereby reducing the number of false negatives and eliminating unneeded escalation of care and biopsies. The FDA granted TruScore a Breakthrough Device Designation Status in 2020.

AIQ SOLUTIONS

CLOUD-BASED PLATFORM FOR BETTER THERAPY OPTIMIZATION

LOCATION
MADISON, WI

STAGE
IN CLINICAL TRIALS: FEASIBILITY/PILOT

AIQ Solutions has developed a revolutionary software platform to change the way clinicians' approach complex diseases such as metastatic cancer and neurological disorders. The cloud-based platform provides unique, early intelligence to predict both treatment effectiveness and toxicity risk from longitudinal imaging data. AIQ's technology does not diagnose disease; rather, it enables the clinical team to make real-time, patient-specific adjustments to therapy, which helps improve outcomes while reducing healthcare system costs. AIQ's technology has been proven in multiple published studies and is currently being piloted at large cancer centers.

ENVISAGENICS

USING AI TO DEVELOP THERAPIES FOR RNA SPLICING DISEASES

LOCATION
NEW YORK, NY

STAGE
COMMERCIALLY AVAILABLE

Envisagenics is a woman-led, artificial intelligence (AI)-driven biotechnology company focused on discovering novel RNA splicing variants. Its principal technology is the SpliceCore® discovery platform. The platform re-envisions the human genome with a validated exon-centric approach, combined with machine learning algorithms and high-performance computing. SpliceCore® is up to 250 times more likely to discover novel targets than gene-centric discovery tools. Envisagenics accelerates the development of highly specific therapeutics that modulate RNA splicing variants that drive pathogenesis of oncology, neurodegenerative, and metabolic disorders.

INHERET

WEB-BASED FAMILY HISTORY COLLECTION AND DECISION SUPPORT TOOL

LOCATION
ANN ARBOR, MI

STAGE
COMMERCIALLY AVAILABLE

INHERET®, Inc. offers risk assessment and decision support software to identify patients at increased risk for hereditary diseases and creates personalized risk reduction strategies. The web-based family history collection and interpretation tool addresses the time, accuracy, and interpretation of family history barriers faced by clinicians and streamlines the process into easy-to-understand reports with clear next steps for both healthcare providers and patients. INHERET is focused on hereditary cancers with plans to expand to hereditary cardiovascular, endocrine, autoimmune, and neuropsychiatric conditions.

ONE-PAGE COMPANY OVERVIEWS

For an introduction to any of these companies,
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AVENZOAR PHARMACEUTICALS

Developing drugs targeting metastasis and chemo-resistance

Terrance Bruggeman, CEO | tbruggeman@avenzoarpharma.com | 858-736-7354 | avenzoarpharmaceuticals.com

COMPANY OVERVIEW

Avenzoar is a pre-clinical pharmaceutical company founded in 2016 that specializes in developing cancer drugs designed to target and inhibit mechanisms of metastasis and drug resistance. A strong correlation exists between the overexpression of glycogen synthase kinase 3 beta (GSK-3β) and cancer progression in humans. Activation of GSK-3β up-regulates proliferation and increases the resistance to cell death in cancer cells through the activation of pro-survival pathways including the NF-kB pathway. The inhibition of GSK-3β is a potential treatment strategy for many cancers. Histone deacetylases (HDACs) are epigenetic modulators that play a crucial role in carcinogenesis by promoting epithelial to mesenchymal transition (EMT) and cancer stemness. Successful results using HDAC inhibitors ultimately led to clinical trials and FDA-approved treatments for various cancers, such as advanced lymphoma and metastatic cancers. Avenzoar has three drugs in its drug development pipeline so far. The lead drug, AP-001 (aka Metavert), is expected to be tested in pancreatic cancer patients in 2022. The anti-cancer drugs developed by Avenzoar target two important pro-cancer pathways regulated by GSK-3β and HDAC. So far, AP-001 and AP-002 have shown strong anti-cancer effects in pancreatic and ovarian cancer, respectively. After performing the mechanistic and efficacy studies in both cancers using multiple animal models, Avenzoar is now in the process of performing the IND-enabling pre-clinical studies (Pharmacokinetics and Tox studies) required for a phase 1 clinical trial. Avenzoar developed AP-001 as a novel, first-in-class, dual inhibitor compound that inhibits both HDAC and GSK-3β. In addition, the compound can be attached to a cleavable enzyme substrate, such as a magnetic particle or ligand, to direct AP-001 to the tumor cells. Various other NCEs with these same functions have also been developed and are part of the exclusive worldwide license from Cedars-Sinai Medical Center in Los Angeles.

MARKET & COMMERCIALIZATION STRATEGY

Since there are no effective treatments for both pancreatic and ovarian cancers, Avenzoar's patented, small molecule compounds offer the potential to become first-line treatments, and each could be a $1B drug. Avenzoar is working with a group in India to produce the drug substance and drug product, complete the IND-enabling studies and the phase I clinical trial. Avenzoar will grant the India group a royalty-free license for pancreatic cancer in the Indian subcontinent and portions of Southeast Asia. Avenzoar intends to progress AP-001 through the successful completion of the human clinical trials and the sell or license the drug candidate to one of the major pharmaceutical companies with an existing oncology franchise. Avenzoar expects that the sale would result in proceeds of $750M to $1B.

TECHNICAL & COMPETITIVE ADVANTAGE

These are the first drugs developed to mainly prevent metastasis and chemo-resistance, in addition to inducing cancer cell killing. Drugs available in the market target mechanisms that regulate cancer cell division and proliferation. AP-001/002/003 target pathways that regulate EMT and cancer stemness, two important mediators of metastasis and chemo-resistance. In addition, regulation of the glycogen synthesis pathway affects the glucose metabolism pathway and causes a phenotype change of the cancer cells making them acquire a normal-like phenotype.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Avenzoar has been granted orphan drug status for PaCa by the FDA and expects to be granted fast track status. The Company has 3 US patents, 2 international patents and expects to have all worldwide patents issued in 2021.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
12/2021	Completion of IND enabling studies
2/2022	FDA approval for phase 1 clinical trials
12/2022	Completion of phase 1 clinical trial
2/2023	Completion of pre-clinical testing for additional cancers

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016-2019	Seed stage	Friends and family, including Cedars-Sinai	$864K
2019	NIH STTR grant	Competitive grant awarded by National Cancer Institute	$212K

USE OF PROCEEDS

Avenzoar is seeking $6M to complete the IND-enabling pre-clinical studies and obtain FDA approval to initiate phase I trials. In addition, pre-clinical testing in various animal models of cancer will be undertaken for AP-002 and AP-003.

KEY TEAM MEMBERS

Terrance Bruggeman, MBA (CEO) 29 years' experience as Executive Chairman/CEO of life science companies (Diversa, Provasis, Somanta, etc.)

Stephen Pandol, MD (President, CMO, Co-Founder) Director of Basic & Translational Pancreas Research, Cedars-Sinai; Professor of Medicine, UCLA

Mouad Edderkaoui, Ph.D. (CSO & Co-Founder) Associate Professor, UCLA; Research Scientist, Cedars-Sinai

Linda Strause, Ph.D. (VP, Clinical Affairs): Expert in clinical operations; Oncology focused clinical trial consultant; Professor, UCSD

BIOMIMETIX

BMX-001 Therapeutic for Cancer Patients Receiving Radiation and/or Chemotherapy

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COMPANY OVERVIEW

BioMimetix's proprietary drug, BMX-001, is administered to patients receiving radiation therapy (with or without chemotherapy). The drug enhances the anti-cancer benefit of the therapy and, at the same time, reduces the severe, dose-limiting radiation side effects. In the high-grade glioma Phase 1/2A trial, addition of BMX-001 appeared to extend survival by 6-8 months, as recognized by FDA Orphan Drug and Fast Track designations. In Phase 2A Head/Neck and Anal/Rectal trials, BMX-001 reduced substantially the radiation side effects of mucositis, xerostomia, and dermatitis. Adverse events are considered minor and manageable. BioMimetix LLC plans to spin off the C-Corp "BMX Oncology," with all related IP, assets, and key personnel, to focus on late-stage clinical development of BMX-001. The work includes regulatory submissions, manufacturing and CMC, and preparations for market entry.

MARKET & COMMERCIALIZATION STRATEGY

If data continue to support the survival benefit in high-grade glioma (lethal disease with no new medical therapies in >15 years), the company will pursue Breakthrough Status and rapid approval. The preferred plan for market entry is the development of a co-marketing agreement with a CSO or a large pharmaceutical company. Following the first approval, the company will follow up with head/neck and anal/rectal registration trials and other studies to support line extensions to all cancer indications treated with radiation (>600,000 annually in the USA).

TECHNICAL & COMPETITIVE ADVANTAGE

- First/best in class with stability and PK and stability suitable for 14 mg b.i.w. subcutaneous injection.
- Protection derives from IP estate and Orphan Drug designation.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

- Five open INDs; Orphan drug and Fast Track designations based on Phase 1/2A survival benefit in high-grade glioma; pivotal HGG trial fully recruited, will go to FDA under follow-up PBTD based on interim analysis. For HGG, the approvable endpoint is survival benefit; for head/neck and anal/rectal cancer, endpoint is symptom relief.
- IP: US8,618,089 B2; US 9,999,627 B2; WO 2018/187411 A1; WO 2017/118891 A1 plus additional/unpublished or planned submissions that are available under NDA.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q2-Q3 2022	High Grade Glioma Phase 2B (quarterly interim analyses, interim analysis following 84 deaths of 160 enrolled)
Q1 2022	FDA accepts Head/Neck Ph2B IND, enrollment begins
Q2 2022	FDA accepts Anal/Rectal Ph2B IND, enrollment begins
Q2 2022	Completed optimization BMX-001 synthesis

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015-Present	R44CA195749 (Ph1/2 and Ph2 Bridge), HHSN261201500002C, R44CA228694	High Grade Glioma, Head/Neck, Anal/Rectal and other grants from the NIH and other sources. Two other grants are pending with high priority scores	$14M
2013-Present	Multiple small funds and private investors	Received plus commitments, cumulative	$14M

USE OF PROCEEDS

$20–40 million in tranches over three years. BioMimetix LLC will spin off BMX Oncology C-Corp, with all IP and assets, to focus on BMX-001 late-stage development and commercialization. Funding will be used for recruiting and outsourcing key capabilities, manufacturing, CMC, and supply chain, clinical trials in head/neck and anal/rectal cancer, and regulatory clinical trials.

KEY TEAM MEMBERS

James D Crapo, MD (CEO), Chief, Pulmonary & Critical Care Medicine, Duke (1979-1996); Chief of Medicine, National Jewish Health (1996-2004); Principal Investigator COPDGene (2007-Present)

David S Silberstein, Ph.D. (COO), Harvard Medical School (1984-1994); AstraZeneca/MedImmune (1994-2013), supporting science lead for products with aggregate sales >$30B

Shayne Gad, Ph.D. (VP Safety and Regulatory Affairs), 35 years' experience in toxicology and drug development; 96 INDs filed; Director positions at Searle, Synergen, and Becton Dickinson

Sara Penchev (Director of Clinical Operations), Phase I-IV pharmaceutical and NIH studies- management (National Jewish Health, ReSearch Pharmaceutical Services, Sanofi Pasteur)

David A MacLeod, Ph.D. (Director of Information Science and Data Management), Expert in genetics, informatics, artificial intelligence, computational technology (Columbia University)

John Wetzel, PhD (Director of CMC and Manufacturing)

Clinical Investigators at > 12 Academic Institutions

CONCARLO HOLDINGS, LLC

IpY, the first to inhibit p27kip1, a key player of cancer progression and drug-resistance

LisaMarie Casey, Co-Founder and COO | lisamariecasey@concarlo.com | 917-856-9688 | concarlo.com

COMPANY OVERVIEW

Breast cancer remains a significant burden on human health. Almost 250,000 US women will be diagnosed this year, and despite advances in treatment, roughly 40,000 women will die. While combined ER and CDK4-inhibition treatment significantly extends Progression-Free Survival (PFS), those treated eventually develop resistance to the combination and the Overall Survival (OS) of these patients is unchanged, suggesting that we still have not achieved a "cure" and drug resistance remains an unmet need. Concarlo is developing technologies to prevent cancer drug resistance. The product, IpY, targets p27, which is a CDK4 and CDK2 inhibitor, thereby specifically addressing the resistance problem with drugs like Palbociclib and should extend OS of treated patients.

MARKET & COMMERCIALIZATION STRATEGY

Concarlo estimates $13M will be required to take IpY to Phase I trials. With this raise, the Company intends to begin an FIH trial in two years. If Concarlo captures as little as 15% of the drug-resistant breast cancer market, IpY will bring in $2B annual revenue within its first three years on the market.

TECHNICAL & COMPETITIVE ADVANTAGE

Concarlo's drug, IpY, targets the protein p27Kip1, which in turn causes inhibition of CDK4/6 (driver of cancer) AND CDK2 (driver of drug-resistance, and represents the first therapeutic that would inhibit both kinases simultaneously. IpY harnesses the power of biologic targeting: using a peptide-liposome formulation, administered by infusion, to specifically inhibit p27 and CDK4 and CDK2. IpY can kill tumor cells and cause regression, as opposed to just slowing tumor growth, which should translate into increased OS for patients. IpY is also effective in a wider range of tumor types than CDK4i, including ovarian, pancreatic, and Triple Negative breast cancer. This range of tumor types translates into a large addressable market. The Company's Companion Diagnostic will be able to stratify CDK4i-responsive patients and identify those that are eligible for IpY.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Concarlo holds three patent families, two licensed from The SUNY Research Foundation and one filed by Concarlo. The first SUNY patent named "P27 tyrosine phosphorylation as a marker of cdk4 activity and methods of use thereof" has US and foreign office applications outstanding. The second patent family named "Compositions Targeting the Interaction Domain Between p27Kip1 and BRK and Methods of Use Thereof to Inhibit p27 Phosphorylation and CDK4 Activity" had one claim for composition issued on July 7, 2020 and a method composition outstanding.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2020	Proof of concept for the biologic completed. The p27 binding action is specific and selective, the broad inhibition of cell division & tumor growth has no off-target effects, and the lead therapeutic candidate has been identified and formulated for use in humans.
Q2 2021	Preclinical work for the biologic completed. The Company found efficacy in treatment naïve and CDK4i-resistant breast cancer models and pancreatic and ovarian cell line models. No toxicity observed in immunocompetent models.
Q3 2021	Proof of concept for small-molecule almost complete. Proprietary screening for the small molecule generated.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017-2019	Friends and Family rounds		$2.92M
2020-2021	NIH SBIR Phase I		$0.32M
2020-2021	NIH Nanoparticle Characterization Lab	This grant allows for work to be performed without expense	$0.0M
2018-2019	Cavendish Impact Foundation /NYSeed Fund		$0.15M
2019-now	University of Buffalo EDC		$0.15M
2020-now	Seed Round		$1.05M

USE OF PROCEEDS

Concarlo is raising $13M, which will allow the Company to advance IpY and p27 targeting to first in human. They plan to build out their team, begin IpY manufacturing and CMC, ADME/PK, and Phase I FIH.

KEY TEAM MEMBERS

Stacy W. Blain, Ph.D. (CSO), Associate Professor, SUNY Downstate Medical Center; 25 years' experience in cell cycle biology and cancer; Trained at Princeton, Columbia, MSKCC; Has received funding from NIH, ACS, Susan G. Komen Breast Cancer Fund

LisaMarie Casey (COO), 30 years' experience in strategic planning and business management; Co-founder of Golden Seeds Angel Group and Morgan eSolutions Investment Banking Team

Jason Mraz (President), 30 years' experience in capital markets and private equity investing; Co-founder and president of Ospraie Management; Serves on the board of The Pandion Fund and Concord Resources

Dominique Bridon, Ph.D. (Therapeutic Development), 30 years' experience in peptide and liposomal discovery; holds leadership positions at Abbott, Ipsen, Redcell, Conjuchem, Epivax Oncology, and Biodesy

MANZANITA PHARMACEUTICALS INC.

Nerve imaging agent (fluorescent dye + rhNGF) given intra-operatively, single dose

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COMPANY OVERVIEW

Manzanita Pharmaceuticals is developing two contrast agents and several therapeutic agents. The sensory nerve imaging agent Nervelight™ is a dye-neurotrophin conjugate which will be given intra-operatively, single dose in radical prostatectomies. There is no commercial nerve imaging agent that gives urologic surgeons a surgical guidance tool. The dye fluoresces in the 800 region (the "indocyanine green (ICG) channel" of 99% of imaging equipment in the Operating Room, OR). The neurotrophin is recombinant human Nerve Growth Factor: 800-rhNGF. In extensive nonclinical studies, the unmodified dye has been shown by third parties to be safe at high systemic doses. Unmodified rhNGF is now approved to treat neurotrophic keratitis when applied topically as repeat dose eye drops.

MARKET & COMMERCIALIZATION STRATEGY

The Company's go-to-market strategy involves three steps: (i) partner with one company (discussions ongoing) as an "IND partner." In IND-enabling studies, the Company is required to demonstrate that Nervelight™, which is novel, can be imaged with an already FDA-approved clinical instrument; (ii) complete GLP toxicology studies, pending grant and private funding decisions in Q3 2021; and (iii) complete clinical Phase 1, where the study design has been preliminarily confirmed by the FDA in its written communication to the preliminary Investigational New Drug (PIND) of July 1, 2021. After completing clinical Phase 1, Manzanita plans to partner out development with the selected "IND partner," who will take primary responsibility for commercializing Nervelight™ worldwide.

TECHNICAL & COMPETITIVE ADVANTAGE

Manzanita's key technical advantages vis-à-vis the competitors, Alume Biosciences, Inc. (San Diego) or Inherent Targeting (Portland), are (i) dose, Manzanita's is single, intra-operative, versus their pre-operatively injected, systemic; (ii) surgical workflow, intra-operative removes some time and costs of pre-operative preparation; (iii) is selective for sensory neurons, and may be combined with the companion Benlight™ (same dye, but attached to rhBDNF to select for motor neurons); and (iv) is cost competitive (90% gross margin at $1,500).

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

For regulatory strategy, Manzanita will show "structural delineation," confirmed by the FDA in the PIND in July 2021. Like ICG, the Company does not have to show "clinical outcomes." Selecting this regulatory path confers at least two important competitive advantages: (i) Manzanita reaches the market sooner, since the main clinical endpoint is day-of-surgery (can view image on OR screens); and (ii) while "clinical outcomes" is technically feasible, such trials must be conducted for a year to show statistical significance of improvement of pre-compared to post-operative incontinence and impotence. For intellectual property (IP), Manzanita has not licensed in any technologies. They filed a patent application for Nervelight™ in October 2020 and received a positive patentability report in December 2020.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
6/2020; 5/2021	Proved Nervelight™ platform (other oncology applications) in vivo; completed efficacy studies; PIND response received
9/2019; 3/2020	Proved drug-conjugate platform (non-opiate pain medication; anti-cancer platform)
8/2022	Complete clinical Phase 1 (n=12, 3 Single Ascending Doses, n=4 per group) – potential to partner out or exit
3/2024	Complete clinical Phase 2/3 (pivotal design per Avelas Biosciences for "cancer paint" 2020)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2007	Founding: private investors	Founded to develop non-opiate pain medication (50% C/S, 50% Conv Prom Note)	$50K
2013-2017	NCI SBIR Phase I/Phase II	Reduce Nervelight™ to practice/Complete efficacy studies for Nervelight™	$288K
2015	DOD US Army	Develop non-opiate pain drug; reduce drug-conjugates, contrast agents to practice	$992K
2017	NCI SBIR Phase II	Complete efficacy studies for Nervelight™	$1.972M
2007-2021	Private investors	Additional capital raised as Convertible Promissory Notes	$413K

USE OF PROCEEDS

Up to $5M Series A from private investors (now 10), including angel groups and early-stage venture funds. Uses: $3M for Nervelight™ (CMC, IND-enabling studies, clinical Phase 1 – see FDA PIND JUL 2021.) Up to $2M will advance other anti-cancer and non-opiate drug conjugates. By mid-October 2021, Manzanita expects to hear from the NCI re: SBIR ($2M) and NExT ($1M value, no funding).

KEY TEAM MEMBERS

Steven B. Kahl, Ph.D. (CSO); Previously, Emeritus, UCSF Vice Chair, Department of Pharmaceutical Chemistry. At UCSF, translated drug discovery for glioma into IND-enabling studies in the US, then into a clinical Phase I in Australia
Constance McKee, MBA (President & CEO); Previously Chief Executive, Cambridge Quantum Fund I; founder i2 Grants Associates; Licensing and M&A, Philips Electronics
Louis Eugene ("Gene") Burton, Ph.D. Previously led or contributed to > 40 BLAs; co-Project Lead at Genentech for CMC, clinical development of unmodified rhNGF injected sub-cutaneously (studied in multiple clinical trials, two Phase 2, one Phase 3)
Aaron Mohs, Ph.D. (Subaward PI); Expert, fluorescent imaging conjugates, University of Nebraska Medical Center
Chad LaGrange, MD (Clinical advisor) Expert, urologic surgeon, dog model, University of Nebraska Medical Center

NUVOX PHARMA

First-in-Class Oxygen Therapeutic to Reduce Tumor Hypoxia

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COMPANY OVERVIEW

NuvOx is developing NanO2 for oxygen delivery, which, when injected IV, increases the efficiency of oxygen exchange between blood and tissue. In oncology, the drug increases tumor oxygen levels to make tumors more sensitive to radiotherapy, chemotherapy, and/or immunotherapy. A Phase Ib/II clinical trial in brain cancer demonstrated safety, significant increases in tumor oxygen levels, and evidence consistent with increased survival for the oxygen delivery product. The FDA has allowed an IND for a Phase II clinical trial. NuvOx's NanO2 is the only technology in its class in clinical trials and has shown efficacy in reversing tumor hypoxia.

MARKET & COMMERCIALIZATION STRATEGY

Potential customers for NanO2 include radiation oncologists, medical oncologists, as well as cancer patients treated with radiotherapy, chemotherapy, and immunotherapy. There are no FDA approved drugs for reversing tumor hypoxia. The drug will work for many solid tumor types, but NuvOx is focusing first on the orphan Glioblastoma multiforme (GBM) indication. NuvOx has created a risk-adjusted NPV model of sales projections for NanO2 for GBM and has validated this model with a potential corporate partner. Revenues of up to $315M are predicted for GBM in the US and $630M worldwide (12,200 patients in the US, $74k per patient, and 35% market penetration). By expanding to more common cancers, the market can increase to $6B/year. The Company's most likely sales strategy will be to partner with pharma companies with established global sales teams. NuvOx could also become vertically integrated to achieve its own sales for selected indications in selected territories.

TECHNICAL & COMPETITIVE ADVANTAGE

NanO2 delivers large amounts of oxygen to hypoxic tissue at very low doses (less than 1/100th), thereby giving it an excellent safety profile. For GBM, the standard of care for newly diagnosed patients is maximum surgical resection followed by radiation therapy, chemotherapy with TMZ, and NovoTTF™ if available. There are many drugs in clinical trials for newly diagnosed GBM, but they would not remove the need for radiation therapy; and NuvOx's drug would likely be complimentary to them. NuvOx's most direct competitor is Diffusion Pharmaceuticals developing trans sodium crocetinate as a radiosensitizer. In animal studies, it appears that the effect on tumor oxygenation of TSC is much smaller than NanO2's (TSC raised tumor pO2 by 40% while NanO2 raised it by > 400%). TSC's Phase Ib/II trial did not validate reversal of tumor hypoxia (unlike NuvOx).

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

NuvOx protects its products through both IP and regulatory exclusivity. The company has two composition of matter patents issued and 12 patent families pending with worldwide prosecution. NanO2 has been granted orphan status for GBM, with potentially up to 7 years' exclusivity. The FDA has also clarified that NanO2 is regulated as a Biologic, presenting opportunity to obtain 12 years of market exclusivity for a first in class indication.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2021	Dose first GBM patient in the Phase II trial for NanO2
Q4 2021	File IND amendment to make the Phase II trial an adaptive design
Q4 2023	Completion of the Phase II portion of study

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
12/2008	Seed Round	Founders	$700k
09/2017	Grants	NIH/NCI, NHLBI, NINDS & State of AZ	$4.77M
2017-2018	Grants	NIH/NCI	$5M
Q4 2017	Series A	Angels	$10M

USE OF PROCEEDS

For NanO2, NuvOX has an IND for a randomized trial in 84 patients that will cost $7M, and $3M will be covered by the NCI leaving $4M required by investors. Assuming NuvOx enrolled an additional 150 patients, that would require roughly $14M in additional funding to support NDA filing. The Company is currently raising a $1.5M Bridge Round leading to a planned $10M financing with goal of closing in the next 12 months.

KEY TEAM MEMBERS

Evan Unger, MD (President, CEO, Co-Founder): Previously founded two other biotechnology companies; Sold first company to DuPont with >20-fold ROI; inventor on 125 issued US patents

Kaitlin Graham, MS (Director of Clinical Science): 5+ years at NuvOx handling regulatory correspondence, filing INDs, and collaborating with project teams to develop clinical studies in several indications

Laurel Watkins de Jong, Ph.D. (Manufacturing Manager): Responsible for the cGMP manufacturing of NanO2, which is done in NuvOx's ISO-5 facility

ONCONANO MEDICINE

Ultra pH-Sensitive Micelle Platform to Encapsulate Small Molecules and Biologics

Marty Driscoll, CEO | mdriscoll@onconanomed.com | 682-285-1444 | OncoNano.com

COMPANY OVERVIEW

OncoNano Medicine is developing a new class of products exploiting pH as a simple and ubiquitous biomarker to meet unmet needs of patients and clinicians across the continuum of cancer care. The Company's ON-BOARD™ product platform includes Pegsitacianine (née ONM-100) currently in Phase II studies for real-time image-guided surgery and therapeutic candidates in preclinical development via two large pharma research collaborations to improve the therapeutic index of proprietary small molecule and biologic actives. ON-BOARD payloads are encapsulated in micelles for systemic administration to specifically target the acidic tumor microenvironment, a hallmark of solid tumors (Warburg effect), while minimizing exposure to normal tissues. Use of pH as a biomarker for cancer enables ON-BOARD to be applied to any solid tumor, regardless of oncogenic phenotype and has been demonstrated in numerous in vivo models and in human clinical trials. OncoNano's OMNI™ product platform features micelles comprised of PC7A polymers that play an active role in an immune response via activation of Stimulator of Interferon Genes (STING) that is different from traditional small molecule STING agonists. OMNI micelles enable delivery of immunotherapeutic actives to the low pH environment of endosomes where the released PC7A and payloads cooperatively and synergistically effect improved trafficking of an innate and adaptive T cell immune response to kill cancer. The OMNI immunotherapeutic product ONM-501 encapsulates and delivers endogenous STING-activating cGAMP that, along with PC7A, provides a complementary and highly differentiated dual activation of STING. ONM-501 preclinical data supports efficacy in multiple tumor types, metastatic disease, an abscopal effect, synergies with checkpoint inhibitors, and preliminary indications of low systemic toxicity.

MARKET & COMMERCIALIZATION STRATEGY

For the Pegsitacianine imaging agent, the >500,000 (US) and ~1.5 million (worldwide) cancer surgeries annually translate to a market of ~$2B. The emerging pan-tumor nature of Pegsitacianine has validated use of the ON-BOARD micelle platform to deliver a variety of small molecule and biologic therapeutic payloads such as IL-2 and OMNI encapsulated cGAMP (ONM-501) representing a substantial multibillion-dollar market. Additionally, OncoNano has two research collaborations with leading pharmaceutical companies using the ON-BOARD platform to deliver proprietary payloads directly to tumors and is seeking additional partnerships to exploit its unique technology to improve the therapeutic index for existing and developmental treatments.

TECHNICAL & COMPETITIVE ADVANTAGE

OncoNano's library of proprietary polymeric based micelles is tunable to encapsulate and release a wide variety of payloads at a specific pH threshold and within a narrow range of 0.2 pH units in these low pH environments (not possible with other conventional pH-based delivery approaches) and can also be modified to play an active role in an immune response by activation of STING. The ultra pH-sensitive micelles ensure targeted delivery of payloads to the point of interest while minimizing systemic exposure 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 ON-BOARD based intraoperative imaging agent Pegsitacianine has potential application to all solid tumor types due to the low pH TME common to all cancer oncogenic phenotypes and utilizes an indocyanine green (ICG) fluorophore compatible with commercial imaging systems and surgical workflows, providing an advantage over competing technologies utilizing limiting receptor-based biomarkers and non-ICG fluorophores. The OMNI-based ONM-501 features PC7A micelles that facilitate transport of cGAMP to the cytosol of dendritic cells and an unprecedented mechanism from dual STING agonists of PC7A polymers and endogenous cGAMP that synergize to activate STING up to 48 hours. This enables orchestration of a superior innate and adaptive immune response that is not possible with current cyclic dinucleotide approaches.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

ON-BOARD and OMNI drug development candidates are in clinical or 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
2022	IND Submission	OMNI Next Generation STING Activation Based Immunomodulator (ONM-501)
2023	NDA Submission	ON-BOARD Intraoperative Imaging Agent (Pegsitacianine)

CAPITALIZATION HISTORY

OncoNano has raised $118M+ to date including private venture financing ($85M) and $33M in grants from the Cancer Prevention Research Institute of Texas (CPRIT) and NCI/NIH SBIR.

USE OF PROCEEDS

OncoNano will use financing for continued development of cancer therapeutic platforms and to support clinical studies of the lead product Pegsitacianine. OncoNano's 2020 award of a third CPRIT grant will be used to advance the Pegsitacianine imaging agent for indications in metastatic disease detection including peritoneal mets. We are seeking partnerships to expand and advance therapeutic application of the ON-BOARD and OMNI platforms to the clinic and advance Pegsitacianine to an NDA.

KEY TEAM MEMBERS

Marty Driscoll (CEO): Highly successful healthcare entrepreneur and executive for 30+ 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, SAB): Prof. Surg. Oncology and ex-EVP, UT MD Anderson; ex-CEO ASCO, ex-CEO City of Hope Hospitals

ONCOSPHERIX, INC

Small molecule inhibitors of HIF-1 and HIF-2 transcription factors for advanced cancer

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COMPANY OVERVIEW

OncoSpherix is developing proprietary first-in-class small molecules that disrupt the function of the transcription factors HIF-1 and HIF-2, thereby crippling the ability of cancer cells to adapt and spread from regions of low oxygen (hypoxia). Many types of cancer utilize both HIF-1 and HIF-2 for their adaptive response to hypoxia, so the dual inhibition of both forms of HIF is advantageous over agents that merely inhibit one form. Regions of hypoxia occur in most solid cancers due to tumor cells growing faster than their blood supply. By blocking the function of both HIFs, the compounds inhibit expression of genes that bring in new blood vessels, drive tumor invasion and metastasis, and aid in tumor cell survival and spread. OncoSpherix drugs show efficacy in multiple mouse models of cancer as single agents (lung cancer, breast cancer, pancreatic cancer, brain cancer, ocular melanoma). They are designed to be given with agents that attack cancer cells in well oxygenated areas of tumors. Safety and synergistic efficacy have been shown in several tumor models (lung cancer, uveal melanoma) and with several classes of drugs (microtubule disruptors; tyrosine kinase inhibitors), with other combinations being explored.

MARKET & COMMERCIALIZATION STRATEGY

The market for the initial indication, glioblastoma multiforme, is projected to reach nearly $1.4B by 2025. Additional indications will follow, including non-small cell lung carcinoma, which had a $6.45B market in the US in 2018 and other solid tumors. OncoSpherix HIF inhibitors are designed to be combined with agents that display synergistic efficacy and manageable toxicity.

TECHNICAL & COMPETITIVE ADVANTAGE

Merck is advancing a selective HIF-2 inhibitor called belzutifan (no effect on HIF-1) that it acquired through the purchase of Peloton Therapeutics for upfront $1.05B in 2019. Belzutifan received FDA approval for its first indication, Von Hippel Lindau-associated cancers, in August 2021. OncoSpherix molecules have an advantage in that they inhibit both HIF-1 and HIF-2, and both HIFs play an important role in tumor survival and spread. Numerous immunotherapies and targeted therapies are of benefit for advanced cancers. OncoSpherix drugs could be combined with these, so they represent opportunities rather than competitors.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Founding technologies were licensed from Emory University and Georgia State University and include novel composition of matter and use. The license includes two issued patents, and the company is working to expand its global patent estate. OncoSpherix completed route scouting and is executing process development studies designed to increase yield and ensure synthetic processes comply with CMC regulatory requirements of the FDA. Once pre-formulation studies are complete, they will begin formulation studies that are accompanied by pharmacokinetic and pharmacodynamic studies to determine optimal delivery route and dosing schedule. Results from the ongoing and planned studies will inform the design of clinical trials and the IND-enabling toxicology studies. OncoSpherix has identified regulatory experts to guide CMC manufacturing, IND-enabling studies, and clinical trial design.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
09/2018	Company Incorporated
07/2019	Licensed technology from Emory and Georgia State Universities
01/2019; 06/2021	Demonstrated synergy with cytotoxic chemo and targeted therapy with two different cancers in mouse xenografts
06/2021	Improved yield of clinical lead more than 10-fold and improved processes for scale-up

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	SBIR Phase I from NCI	Pre-formulation studies for clinical lead and studies testing efficacy and safety of combinations of clinical lead with tyrosine kinase inhibitors in ocular melanoma	$399K
2021	Georgia Research Alliance	Process development for scale-up of clinical lead and additional combination studies	$100K

USE OF PROCEEDS

OncoSpherix is raising $25M to advance lead through phase II clinical testing for the first indication ($5M and 18 months to complete preclinical and IND-enabling studies and file an IND).

KEY TEAM MEMBERS

Margaret Offermann, MD, Ph.D. (President & CEO, BOD): Former Deputy National VP, Research-American Cancer Society, Professor, Hematology/Oncology-Emory University; President, Federation of American Societies for Experimental Biology

Russell Medford, MD, Ph.D. (BOD): CEO of Covanos; Former CEO, Atherogenics & a founding Board member, Inhibitex

Kenneth Moch, MBA (Advisor): Expert in building, managing, financing private & public life science companies

Robert Scott, MD (BOD): Former CMO, Abbvie; Created a Center that used predictive analytics and big data for better clinical trials

Erwin G. Van Meir, Ph.D. (CSO, Scientific founder-biology, BOD): Professor of Neurosurgery, University of Alabama at Birmingham; Extensive expertise in molecular basis of tumorigenesis and experimental therapeutics

Binghe Wang, Ph.D. (BOD, Scientific founder-chemistry): Professor, Georgia State; Expert in drug design/delivery, molecular recognition

Kendyle Woodard, MBA (COO): 20+ years' experience in management, marketing, & BD supporting startups, non-profits, manufacturers, and consulting companies; Co-founder, Executive VP, & Corporate Secretary of Innovate Biopharmaceuticals

PRODA BIOTECH LLC

An integrin $\alpha_v\beta_3$ targeting protein drug for cancer and chronic liver disease treatment.

Zhi-Ren Liu, CEO | zliu8@gsu.edu | 404-428-8540

COMPANY OVERVIEW

ProDa is developing an innovative protein drug, ProAgio, for the clinical market as a pancreatic, breast, and lung cancer treatment drug and as a chronic liver diseases treatment drug. For cancer treatment, ProAgio targets tumor microenvironment, fibrotic stroma, and angiogenic vessels simultaneously. For chronic liver disease treatment, ProAgio directly depletes collagen producing activated hepatic stellate cells and capillarized liver sinusoidal endothelial cells. ProAgio reduces collagen fibril and relieves portal hypertension caused in fibrotic/cirrhotic liver. Effectiveness of ProAgio has been extensively tested in pre-clinical animal models. ProDa is seeking partner(s) and/or investors for clinical development of ProAgio.

MARKET & COMMERCIALIZATION STRATEGY

It is anticipated that the market for pancreatic cancer treatment will be more than $1.2B by 2022. The total breast cancer treatment market will be ~$17.8B by 2022, and total market for lung cancer treatment will be ~$26B by 2022. ProDa anticipates that ProAgio will increase the size of the market for targeted therapies for pancreatic, breast, and lung cancers. Treatment drugs for chronic liver disease will have a very large market size. It is anticipated that the NASH market will be ~$24B by 2024, and the total market for alcoholic hepatitis will be around $0.9B by 2023. ProDa anticipates that approval of ProAgio for any one of the oncology indications and/or chronic liver diseases will lead to ProAgio annual sales exceeding $500M/year.

TECHNICAL & COMPETITIVE ADVANTAGE

One important advantage of ProAgio is the high target specific effects due to the unique rationale protein design approach. Another important advantage is that ProAgio acts on multiple disease causative effector cell types at the same time. For cancer treatment, ProAgio acts on tumor microenvironment and fibrotic stroma to overcome cancer treatment resistance. ProAgio simultaneously and specifically depletes both cancer-associated fibroblasts and new blood vessels in tumors. Experiments have proven that this dual targeting strategy provides unique advantages for treating cancer. For chronic liver disease treatment, ProAgio simultaneously depletes collagen-producing activated stellate cells and normalizes the remodeled sinusoids and reduces intrahepatic angiogenesis in diseased liver, which consequentially leads to facilitating liver regeneration and reduction in hepatic inflammation in diseased liver.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

ProDa started a ProAgio single agent phase I trial at the NIH Clinical Center for testing patient tolerability dose escalation. Following this tolerability test, ProAgio will be tested in multiple clinical sites with pancreatic, breast, lung cancer patients in combination with different FDA approved chemotherapies. ProDa will seek approval of ProAgio in combination with Gemzar + Abraxane for pancreatic cancer, ProAgio + Gemzar for breast cancer, and ProAgio standing alone or in combination with cisplatin + Gemzar for lung cancer. Due to unique effect of ProAgio on the tumor microenvironment, ProDa will test ProAgio in combination with immunotherapies in cancer treatment. ProDa will perform clinical studies of ProAgio standing alone for chronic liver disease treatment. Two families of patents that protect ProAgio and its applications in treatment of cancers and chronic liver disease worldwide have been filed (in 16 countries). The IPs are owned by Georgia State University Research Foundation. ProDa entered into an exclusive worldwide license that confers all commercial rights of ProAgio as a cancer and liver diseases therapeutic.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
9/2019	Completion of cGMP manufacture. GMP grade drug is available for both pre-clinical and clinical studies.
10/2020	Completion of pre-clinical TOX, TK, PK studies.
4/2021	US FDA Approval ProAgio IND for solid tumor malignancies
6/2021	NCI IRB approval.
3/2022	Completion of tests of ProAgio single agent patient tolerability or dose escalation

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2012-2021	Private investments		$2.3M
2017-2021	Grants – NIH (NCI)	NCI STTR phase I, phase II, and Phase IIB	$6.17M

USE OF PROCEEDS

$3 – 4M to complete phase I clinical studies of ProAgio for three oncology indications (Pancreatic, breast, lung cancers) by 2023.
$15 – 25M to complete late phase clinical studies of ProAgio in oncology indications hopefully by 2025.
$4 – 5M to complete IND application and initial phase I clinical studies of ProAgio in chronic liver diseases by 2023–2024.
Additional investments for late phase clinical tests of ProAgio in chronic liver disease patients after 2024.

KEY TEAM MEMBERS

Dr. Zhi-Ren Liu (CEO & Founder): Expert in bioscience research and 10 years' experience in small business of drug development.
Dr. Eric Springman (Consultant): 25 years' experience in drug development industries, particularly, in early clinical studies.
Mr. Bill Taylor (Interim executive manager): An experienced executive manager in biopharmaceutical industrial.
Dr. Chakra Ravi Turaga (Research Scientist, CSO): Expert in cancer and bioscience research.
Dr. Yinwei Zhang (Research scientist): 12 years' experience in research in various human diseases related fields.

REVEAL PHARMACEUTICALS

The Gadolinium-Free MRI Contrast Agent

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

COMPANY OVERVIEW

Reveal is a once-in-a-generation opportunity to transform the $2B MRI contrast agent market: deepening insight with precision imaging and improving patient safety for 40M scans/year. First-in-class RVP-001 is an IND-ready gadolinium-free MRI contrast agent that will replace all current MRI contrast agents (GBCAs). All GBCAs cause accumulation of the heavy metal gadolinium in the brain and body of every patient, posing risks of long-term toxicity. Reveal's precision imaging pipeline promises a noninvasive alternative to biopsy 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, GBCAs are used to detect and stage cancer and other diseases, guide treatment, and monitor therapy response -- this is a $2B addressable market. However, 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 multiple 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 serve 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. Adoption by this highly safety sensitive winner-take-most $2B market is 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 GBCAs. RVP-001 seamlessly fits existing radiology workflows and reimbursement models. Nonclinical data show RVP-001 to be safer than GBCAs, with equivalent imaging efficacy to GBCAs across multiple indications in animal models. RVP-001 has completed GLP IND-enabling studies; Phase I clinical trials will start in early 2022. General purpose MRI contrast agents translate readily to the clinic with a 100% FDA success rate to date. Reveal's team are world experts in MRI and precision imaging, with unmatched ability to drive and develop the pipeline.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Reveal is following the 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). Reveal has a worldwide license for two issued patents: i) RVP-001 composition of matter, ii) a broad class of related compounds for the pipeline.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q1 2022	Investigational New Drug application
2022	Phase I clinical trials and clinical proof of concept
2023	Phase II clinical trials

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017-2018	Grants, Accelerators	NIDDK Fast Track SBIR; MassChallenge winner; NHLBI SMARTT; MLSC MassNext Gen	$1.4M
2019	Grant	MLSC Milestone Achievement Program; NCI Fast Track SBIR; continuing NIDDK Fast Track SBIR	$1.2M
2020	Grant	NIDDK Commercialization Readiness Program SBIR; NHLBI SBIR; continuing NCI+ NIDDK SBIRs	$2.3M
2021	Grant	NCI Fast Track SBIR; MassVentures SMART; continuing SBIRs (additional $1M due in 2022)	$2.3M
2016-2021	Founders, Investors	Capped notes [clean cap table; minority of equity]	

USE OF PROCEEDS

$10 - $25M for Phase I/II clinical trials and pipeline development: liver-specific and precision (fibrosis, thrombus, lymph node) agents.

KEY TEAM MEMBERS

Vera Hoffman, MBA (CEO & Co-founder): Expert in business innovation; previous $1B exit
Peter Caravan, Ph.D. (Co-Founder): World leader in MRI contrast agent development; Professor, Harvard; Co-Director, Institute for Innovation in Imaging, Massachusetts General Hospital
Srinivasan Mukundan, MD, Ph.D. (Medical Director): Neuroradiologist; Former MRI Chief, Brigham Health; Professor, Harvard
John Amedio, Ph.D. (Chemistry, Manufacturing, & Controls): 25 years' experience in technical & regulatory CMC
Susan Steward, JD (Regulatory Affairs): 25 years' experience in innovative global regulatory affairs
Thomas Steele, Ph.D. (Nonclinical Pharmacology & Toxicology): 25 years' development & regulatory experience
Christopher Payton, MBA (Finance, Legal, & Administration): 20 years' finance & entrepreneurship experience
Carolyn McGarry, BS (Clinical Operations): 20 years' clinical operations & regulatory affairs experience
Eric Gale, Ph.D. (Co-Founder): Co-Inventor RVP-001; Assistant Professor, Harvard

SENEX BIOTECHNOLOGY, INC.

Targeting transcriptional reprogramming for cancer therapy

Dr. Igor Roninson, President | roninson@senexbio.com | 518-727-5152 | senexbio.com

COMPANY OVERVIEW

Senex Biotechnology is a drug discovery and development company focused on oncology therapeutics. Senex's principal program targets transcription-regulating Mediator kinases CDK8 and CDK19 which mediate changes in cellular gene expression (transcriptional reprogramming) but are not required in adult organisms under homeostatic conditions. CDK8/19-mediated transcriptional reprogramming plays a key role in several types of cancer (prostate, breast, leukemias) and is involved in cancer metastasis and resistance to different types of drugs. In contrast to some other proteins of the CDK family (such as CDK4/6), CDK8/19 are not required for cell division, and long-term CDK8/19 inhibition is very well tolerated in adults. Senex's lead CDK8/19 inhibitor drug candidate is highly potent, selective, and metabolically stable. It is undergoing GMP manufacturing to be followed by preclinical development. The Company's primary disease target is advanced prostate cancer (PCa), where Senex holds issued patents in the US, Europe, and Canada covering the use of any CDK8/19 inhibitors. As PCa progresses to androgen independence, it becomes non-responsive to existing therapies but at the same time it develops sensitivity to CDK8/19-targeting drugs, offering a well-defined patient population for clinical trials. Once approved in PCa or other malignancies where it shows single-agent activity, the drug will be developed for combination therapies in other types of cancer. In addition to its CDK8/19 program, Senex is pursuing small-molecule drug discovery for two other cancer therapeutic targets. CDK8/19 have been implicated in several diseases other than cancer, including inflammation, viral diseases, autoimmune and cardiovascular diseases, and osteoporosis, offering many opportunities for out-licensing or spinoffs.

MARKET & COMMERCIALIZATION STRATEGY

The combined market size of the top three diseases targeted by Senex's drug is ~$30B (2019) and will reach $70B by 2027. Specifically, prostate cancer is a $7B market (2019) and is projected to be $10.6B by 2027. Senex's preferred scenario is to develop its lead CDK8/19 inhibitor drug candidate through clinical proof of concept in Phase I/II trials in prostate cancer, to be followed by out-licensing or acquisition by a major pharmaceutical company.

TECHNICAL & COMPETITIVE ADVANTAGE

CDK8/19 inhibitors suppress the growth and induce disappearance of advanced prostate cancers that are resistant to any other therapies. These compounds are exceptionally well tolerated (up to 300 days of continuous administration). Senex holds issued patents covering the use of any CDK8/19 inhibitors in prostate and breast cancers, blocking the competition.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Senex is planning to carry out IND-enabling preclinical studies and start Phase I/II trials in advanced prostate cancer, where Senex holds issued patents covering the use of any CDK8/19 inhibitors. Senex's current drug candidate and related compounds are covered by pending composition-of-matter patents.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2002-2004	Incorporated, received series A funding and started operations
2011-2012	Identified CDK8/19 as mediators of transcriptional reprogramming and developed first selective inhibitors
2014-2017	First CDK8/19 inhibitor drug candidate licensed to a foreign company that carried out first-in-class Phase I trial
2018-2021	New CDK8/19 inhibitors developed; new clinical candidate validated in animal studies

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2004-2005	Series A	Angel investor	$1.0M
2005-2016	Misc. investments	Various private investors	$0.5M
2011-2015	State investor	SC Launch	$0.5M
2014-2016	Out-licensing and tax credits	3 companies	$2.1M
2006-2021	NIH SBIR and other grants	14 grants total	$6.3M

USE OF PROCEEDS

$10-12M: GMP manufacturing, IND-enabling preclinical studies, Phase I/II studies in prostate cancer to clinical proof-of-concept

KEY TEAM MEMBERS

Igor Roninson, Ph.D. (Founder & President): Expert in cancer biology/pharmacology; 45 issued US patents, 175 articles, H-index 76
George Wilding, MD (CMO): Expert in prostate cancer and clinical trials; Clinical leadership at U Wisc. and MD Anderson
Mengqian Chen, Ph.D. (Director, Research): Expert in CDK8/19 inhibitors/PCa; Inventor of key patents/PI of Phase II SBIR
Karthik Gopalakrishnan, Ph.D. (Head of BD): Expert in business development/licensing; Completed >150 licenses, deal value $250M
Board Members: Dani Bolognesi, Ph.D.; Richard Davidson, Ph.D.; Bob Bonczek

SUMMIT BIOMEDICAL IMAGING

Fluorescent Imaging for Rapid, Point-of-Care Cancer Detection

A. Riley, CEO | rileya@summitbiomedicalimaging.com | 347-752-7197 | summitbiomedicalimaging.com

COMPANY OVERVIEW

Summit Biomedical Imaging is a clinical-stage company developing a mouthwash and fluorescence scope combination for rapid, point of care detection of cancers. Its first target is oral cancer. When diagnosed early, oral cancer interventions have a high success rate and are less expensive. The problem is that almost two-thirds of US patients are diagnosed after their cancer is metastatic, which dramatically reduces five-year survival rates. Summit's product solves this problem by using a fluorescent biomarker that specifically targets cancer for detection, providing significantly improved performance over the current standard of care.

MARKET & COMMERCIALIZATION STRATEGY

Oral cancer diagnostics is over a billion-dollar market in the US. ($5B+ worldwide) and is projected to grow by 7% annually for the next four years. In the US, there are 53,000 new cases of oral cancer annually and more than 50 million oral examinations annually. Summit's beachhead market will be screening of high-risk individuals (alcohol, tobacco, HPV exposure). At the Company's anticipated price point ($20 per exam) and factoring in dentists taking a $7.50 per exam cut, the initial market is a $62,500,000 opportunity for Summit. After launch, the Company's growth strategy is to push into broader screening use and eventually as a biopsy replacement, which will expand the market size significantly. Summit's plan is to use a hybrid sales/distribution model to get product into dentist offices, building their own sales team while also pursuing relationships with larger distributors in the space. The sales efforts will be supported by marketing campaigns, including working with key opinion leaders to spread Summit's messaging through the technical world and other marketing channels, including social media/influencers.

TECHNICAL & COMPETITIVE ADVANTAGE

Summit's product outperforms its competitors because it uses a novel biomarker that specifically looks for oral cancer. Oral cancer over-expresses PARP1, a DNA repair enzyme. Summit's proprietary molecule, PARPi-FL, targets PARP1 and contains a fluorescence tag. Patients swish a mouthwash containing PARPi-FL, spit it out, and a clinician then uses a hand-held fluorescence microscope to look for PARPi-FL fluorescence. PARPi-FL has demonstrated high sensitivity and specificity (both 95%+) in ex vivo studies that is supported by results from a Phase I clinical trial (completed 2020). These levels of sensitivity and specificity outperform current market diagnostic options. The current standard of care, visual inspection, looks for general oral mucosal abnormalities, not cancer. The same goes for adjunctive screening tools, which are used to augment visual inspection. Visual inspection is not much better than a coin flip, and adjunctive screening tools do not reliably improve the predictive capability of visual inspection. The technical advantage over these products is that Summit identifies specific cancerous growths, while they do not.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Informed by interaction with regulatory consultants, Summit believes FDA should consider its product as a device-led combination product. Summit is currently discussing the regulatory path with FDA. Regarding IP, there are three elements to Summit's IP strategy. First, Summit has an exclusive license to a worldwide family of patents covering the class of compounds and their use. Second, Summit has an exclusive option to license patents in the US that cover the Company's compound and its use. Third, Summit has filed patent applications for formulations and additional uses of its compound.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
09/2018	Company begins operations
1/2019, 9/2020	IP licenses procured (exclusive option, exclusive license)
03/2020	Phase I clinical trial completed
05/2020	Phase II clinical trial commenced (ongoing)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Phase I SBIR Grant (NCI/NIH)	Rapid, quantitative and affordable point-of-care diagnostics for oral cancer	$300K
2019	Phase I SBIR Grant (NCI/NIH)	Non-destructive and instant intraoperative margin assessment of high-grade dysplasia and cancer of the cervix and vulva	$300K
2019	Friends & Family Round		$123K
2020	Fast-Track STTR Grant (NCI/NIH)	Non-Invasive Imaging of Oral Cavity Cancer	$1.75M

USE OF PROCEEDS

Summit is currently looking to raise $950,000. These funds will be used to support clinical development, to develop manufacturing processes including focus on hardware optimization, and specialist consultant reimbursement.

KEY TEAM MEMBERS

Andrew Riley (CEO): Leader with experience in project management and pharmaceutical intellectual property
Christian Brand (CSO): Chemist with experience in molecular targeting for diagnostic imaging of cancer
Robert Unnold (Executive Director): Entrepreneur with 35+ years' business development experience

TREOVIR, LLC

Oncolytic therapy for pediatric brain tumors

Michael Christini, CEO | mchristini@treovir.com | treovir.com

COMPANY OVERVIEW

Treovir was established in 2019 to develop and commercialize G207, an oncolytic HSV virus for the treatment of pediatric brain tumors. A Phase I clinical trial has been completed demonstrating strong evidence of safety and efficacy.

MARKET & COMMERCIALIZATION STRATEGY

Pediatric brain tumors are the most common form of solid tumor in children. More than 3,400 children are diagnosed every year. Outcomes for children with high-grade glioma are poor despite surgery, radiation, and chemotherapy, which produce devastating neurotoxicities in a child's developing brain. There are no FDA-approved therapies for newly diagnosed or r ecurrent/progressive pediatric gliomas and other brain tumors. Treovir/G207 has a significant clinical lead in development of a therapy for pediatric high grade recurrent glioma and plans to initiate a Phase 2 registration study in Q4 2021.

TECHNICAL & COMPETITIVE ADVANTAGE

G207 has proven safe and appears effective in 12 patients treated in a completed Phase I clinical trial. The results were published in NEJM and presented at AACR April 10, 2021:

- A single infusion of G207 plus a 5 Gy dose of radiation is safe and tolerable with only mild (Grade 1) toxicities observed
- Median overall survival of >12 months compares very favorably with 5.6 mOS for historical recurrent glioma children
- Longest surviving patient is >4 years from treatment without any other therapies and 2 patients survived >18 months
- A single G207 infusion into the tumor has resulted in a pronounced and persistent infiltration of immune related cells. Immunologically "cold" tumors turn "hot" to provide an opportunity for anti-tumor immune response.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Treovir will initiate a Phase II trial for G207 in 2H 2021 in collaboration with the Pediatric Brain Tumor Consortium. Thirty pediatric patients with recurrent glioblastoma will be enrolled in the single arm study to compare overall survival (OS) to a historical control group of patients selected by Propensity Score Matching from three Children's Oncology Group (COG) studies. Upon successful completion of the trial, demonstrating safety and improved OS, Treovir will file a BLA for market approval. Treovir owns the G207 regulatory filings and viral and cell materials necessary to manufacture and develop G207. Treovir has received orphan designations for glioblastoma, medulloblastoma, and PNET. Biologics exclusivity would also apply for G207. Finally, Treovir has a significant clinical advantage as the potential first-to-market therapy to treat pediatric brain tumors and could set the bar for subsequent approvals requiring use in combination or at a minimum direct comparator trials requiring years to complete.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
5/2019	Orphan designations granted: glioblastoma, medulloblastoma, PNET
6/2020	Phase I Clinical study of G207 in pediatric patients with recurrent high-grade glioma completed
8/2020	Fast Track Designation granted G207 for pediatric glioma
9/2020	Phase II SBIR for clinical development of G207 awarded ($2 million)
2/2021	Type C meeting with FDA securing agreement on single-arm Phase II trial design
5/2021	Pediatric Brain Tumor Consortium commitment to collaborate on the Phase II clinical trial at up to 20 participating sites

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020	Founder Investments	Convertible Debt	$300K
2020	Phase 2 SBIR	Non-Dilutive Grant for clinical support (2 years)	$2M
2021	Series A	Equity round	TBD

USE OF PROCEEDS

Treovir is seeking up to $20 million Series A equity investment to support Treovir operations ($3 million), Phase II clinical development ($5 million), CMC process development and GMP manufacturing ($3 million) through completion of the Phase II registration trial in mid-2024. Additional funds will be used to extend the G207 development into other pediatric and potentially adult indications: Phase II medulloblastoma study, Phase I/II trials in recurrent and newly diagnosed glioma patients in combination with checkpoint inhibitors. Phase I/II trial evaluating multiple injections of G207 over 6-8 months in newly diagnosed and recurrent patients, phase I trials in children or adults with leptomeningeal disease and low grade astrocytomas.

KEY TEAM MEMBERS

Michael Christini (CEO): 25+ years' biotech operations, regulatory, IP, legal and transactional experience; Previous oncolytic and HSV gene therapy experience with Nurel (sold to Diamyd, Sweden) and Catherex (sold to Amgen)

G. Yancey Gillespie, Ph.D. (CSO): Nearly 30 years' direct research experience with oncolytic HSV and G207; Involved in 3 prior adult trials with G207; Multiple SAB and foundation board positions in the field of brain tumors

Joshua Bernstock, MD, Ph.D. (Advisor): Neurosurgical resident at Brigham and Women's/Boston Children's Hospitals; Postdoctoral work examined role of oHSVs for pediatric brain tumors and was involved with G207 Phase I study at UAB

NAMI THERAPEUTICS CORPORATION

Proving Patient Outcomes Using Nanotherapies

Xiuling Lu, PhD, CEO | lu@namitherapeutics.com | 859-519-0038 | namitherapeutics.com

COMPANY OVERVIEW

Nami Therapeutics Corporation (Nami) is a specialty nanotechnology platform company developing cutting-edge precision cancer nanotherapies. Nami was established in 2018 and is focused on developing specifically designed nanocarrier platforms for targeted delivery of radiotherapies and chemotherapeutic agents to tumor cells. Nami nanotechnology can improve the efficacy and reduce the toxicities of therapeutic radiopharmaceuticals and anti-cancer drugs across all tumor types. Current efforts at Nami are focused on two lead programs: 1) XLNT-1, radioisotope-loaded nanoparticles with intraperitoneal delivery to treat peritoneal metastases; 2) XLNT-2, nanoparticles containing the chemotherapeutic agents specifically designed to inhibit leukemic stem cells (LSC) in order to cut the root of treatment resistance and cancer recurrence in leukemias and lymphomas.

MARKET & COMMERCIALIZATION STRATEGY

The global market for cancer therapies based on nanotechnology is expected to reach $55.4B in the US with a CAGR of 14.9% in 2024. The ovarian cancer market was valued at $1.8B in 2018 across the seven major markets and is expected to grow to $6.7B in the next 10 years with a CAGR of 14.4%. XLNT-1 is an alternative treatment for women with metastatic relapse or resistant ovarian cancer. Initially, XLNT-1 is expected to become the last line of defense against mortality for resistant and recurrent patients. The treatment should expand to pancreatic and colorectal cancer patients that demonstrate poor treatment effectiveness due to abdominal metastasis. The global leukemia therapeutics market increased from $7B in 2012 to $12B in 2017. The cancer stem cell and LSC therapeutics markets are expected to exceed $1.9B and $600M, respectively, by 2022. XLNT-2 will be used as the frontline treatment in combination with regular chemotherapy to treat adult Acute Lymphocytic Leukemia or Acute Myeloid Leukemia.

TECHNICAL & COMPETITIVE ADVANTAGE

Nami's two platform technologies address limited options in relapsed and/or resistant cancer patients and offer another chance for cancer-free life. The platforms allow for developing multiple subsequent products and a rich product portfolio. XLNT-1 comprises a tumor microenvironment targeting strategy with highly tumor-specific internal radiation to treat peritoneal metastasis, showing nearly doubled survival time, limited off-target radiation exposure, and low toxicity in preclinical animal models. The primary indication is ovarian cancer peritoneal metastasis, for which available treatments offer a five-year survival rate of only 28%. The treatment is amenable to various combination therapies and will expand to all types of peritoneal metastases. XLNT-2: These proprietary, biocompatible polymeric nanoparticles can be used to carry a variety of hydrophobic and hydrophilic molecules. The anti-cancer drug doxorubicin, loaded into nanoparticles (XLNT-2), was more effective than small molecule doxorubicin and commercial liposomal doxorubicin in inhibiting leukemic stem cells, with an improved safety profile.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Nami holds exclusive license to a US patent and a pending patent to protect XLNT-1. The product will be a radiopharmaceutical based on a recent pre-request for designation from FDA and will be pursued for fast-track approval. Nami also has exclusive rights to three pending or issued patents for XLNT-2. The drug loaded nanoparticles will be designated as a new drug.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
5/2022	Completion of additional pre-clinical efficacy study
7/2022	Completion of pre-IND application
12/2022	Completion of GMP preparation of nanomaterials and GLP toxicity study for XLNT-1
9/2023	Completion of IDE documentation preparation and submission

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2019	STTR Phase I	NCI grant	$225K

USE OF PROCEEDS

Nami is seeking $5M in convertible debt to further CMC, manufacturing, and operating costs through 2023 and targeting a Series A funding of ~$20M in late 2022 to move one of the two programs to clinical trials.

KEY TEAM MEMBERS

Xiuling Lu, Ph.D. (CEO & Co-founder): 16+ years' experience working in materials science, drug formulation, and nanotechnology

Michael Jay, Ph.D. (CSO): 40+ years' experience in drug development, pharmaceutical formulation, imaging agents; Former director of an FDA-registered cGMP manufacturing facility; Founder of five companies (one currently moving a product to clinical trials)

Ruobing Xia, MBA (CCO): 20+ years' experience in big pharma and repeated success leading product development projects at Eli Lilly and Boehringer Ingelheim; Has managed hundreds of millions of dollars in product launches and promotions

David Worthen, Ph.D., JD (Head of R&D): 20+ years as a senior scientist, project manager, group leader, and PI in the pharmaceutical and consumer products areas in large industry, start-ups, contract research organizations, and academia

Jeffrey C. Miller, MBA (Advisory Board Director): 24+ years' bio/pharmaceutical industry experience with large, mid-size, and small companies in strategic business development

PRIVO TECHNOLOGIES, INC.

Nano-engineered topical mucoadhesive patch technology

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

COMPANY OVERVIEW

Privo Technologies is a clinical stage biotech company, located in Peabody, MA. Privo is looking for potential investors to support two pivotal, registration-enabling Phase III trials examining Privo's lead assets, PRV111 and PRV211, in early-stage tongue cancer and oral carcinoma in situ, respectively. PRV111 utilizes Privo's proprietary PRV platform, a transmucosal nano-engineered platform formulated from bio-compatible materials that provides loco-regional delivery of drug products that are typically hindered by dose-limited toxicities. Internally, Privo is currently developing derivatives of the PRV platform for non-viral nucleotide delivery.

MARKET & COMMERCIALIZATION STRATEGY

Oral cancer (OC) is the 6th most common cancer globally and commonly presents with locally advanced disease, which has a recurrence rate of around 50% even despite aggressive multi-modal treatment regimens. Both conventional treatments and newer immunotherapies suffer from severe side effects, limiting their efficacy. In head and neck cancer alone, the US addressable patient population for PRV111 and PRV211 is approximately 80,000 patients annually, with a US market potential of $900M - $1,000M within five years of launch. PRV111 and PRV211 are effective against all solid tumor types present in mucosal tissue including, but not limited to, cervical, anal, vaginal, penile, and nasal cancer. Following approval in head and neck cancer, the revenue from PRV111/211 will be used to fund additional clinical trials for label expansion. Preliminary market research has already been performed by an independent consultant firm. Results were encouraging, which showed >80% physician adoption and a 95% positive perception of therapies. Privo is interested in out-licensing PRV111 and PRV211 to regional partners and would welcome any conversations with interested partners. There has already been substantial inbound interest from parties interested in licensing PRV111 and PRV211 for different geographic regions and indications.

TECHNICAL & COMPETITIVE ADVANTAGE

The efficacy and safety of PRV111 was evaluated in a Phase I/II trial treating subjects with oral cavity cancer. There was an overall response rate of 87% and over 70% reduction in tumor volume among the responding subjects. The pharmacokinetic profile showed that the drug concentration remained local to the tumor (350x higher than systemic therapy) and locoregional lymph nodes (110x higher than systemic therapy) and did not enter systemic circulation (700x lower than systemic therapy). Although the initial indication for PRV111 and its derivatives is oral cancer, this is a platform technology capable of combination with other therapies useful for several types of cancer, where topical and local treatment can be more effective and much safer. Furthermore, PRV111 demonstrates the ability to make the tumor "hot", suggesting synergy with cancer immunotherapies. Another PRV derivative, PRV211, is a sterilized rapid release chemotherapy patch that can be applied intraoperatively to the tumor bed to reduce the risk of recurrence surgery. PRV211 will be investigated in combination with PRV111 in the planned Phase III tongue cancer study.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The regulatory pathway for PRV111 is an NDA filed via the 505(b)(2) regulatory pathway. This will be approved, marketed, and reimbursed as a new drug, not a generic. Privo has strong intellectual property protection, with a patent life expiring in 2037. Privo has three issued patents (owned solely by Privo), that are sufficiently broad in scope to allow for various APIs and indications.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
11/2017	IND Approval
7/2020	Completion of Phase I/II Clinical Study
10/2020	Successful End-of-Phase II Meetings
6/2021	2021 ASCO Poster Presentation on Phase II Results

CAPITALIZATION HISTORY

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

USE OF PROCEEDS

Privo is looking to raise $43M to help support the initiation of these registration-enabling studies, with $28M allotted for the upcoming Phase III Clinical Trial. $7M is allotted for NDA preparation and filing expenses, and the remainder will be used for internal product pipeline development and label expansion activities.

KEY TEAM MEMBERS

Manijeh Goldberg, Ph.D., MBA, MS (CEO): 25+ years' industry experience; has taken several healthcare products from concept to commercialization, including involvement in five separate startups

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

Sam Goldberger, MD, MBA (Sr. Clinical Monitor): Well-known reconstructive and plastic surgeon practicing since 1991

APPLIKATE TECHNOLOGIES, LLC

Revolutionizing pathology. Reducing medical errors. Lowering costs.

Michael Levene | michael@applikate.com | 607-351-6376 | applikatetechnologies.com

COMPANY OVERVIEW

Just as the digital camera revolutionized photography by eliminating film, Applikate's fully automated tissue processing and digital imaging platform, CHiMP, revolutionizes pathology by eliminating glass slides and directly imaging intact tissue specimens. Preparing slides from tissue typically requires more than 20 manual steps. These steps are done by a diminishing number of expensive histotechnologists, which results in higher costs, delayed diagnosis, and minimal collaboration as physical slides are inaccessible to experts located elsewhere. However, expert consultations reduce medical errors and diagnostic discrepancy rates as high as 50%. Digital slide scanners can produce images from physical slides for sharing but cannot address the problems of slide production. As a result, digital slide scanners add labor and equipment costs, create even more steps, and yield inferior image quality. CHiMP is a paradigm-shifting technology that eliminates these hurdles and results in high-resolution direct-to-digital pathology that is significantly faster, less costly, and more capable. Unlike all other digital methods, CHiMP does not layer new technology on an inflexible, archaic process.

MARKET & COMMERCIALIZATION STRATEGY

Having demonstrated partial integration into the pathology workflow at Yale New Haven Hospital, Applikate will complete and install pre-market devices at three key opinion leader sites (KOLs) for market validation. The company will then target large academic hospital systems as early adopters. These large hospital systems will serve as high-profile market leaders and can demonstrate deployment at remote satellite locations. Applikate's market approach is to have high-volume "use cases" that exemplify the strengths of the CHiMP platform for prostate, breast, GI, lung, and kidney tissues.

TECHNICAL & COMPETITIVE ADVANTAGE

CHiMP produces digital images that surpass even direct observation of physical slides and are superior to digital slide scanners. It creates superior images while achieving complete process automation, in under three hours (compared to 16 or more hours with traditional slide preparation). CHiMP-enabled automation alleviates persistent understaffing at laboratories and significantly reduces labor costs. Rapid turn-around promotes routine same-day diagnosis, giving hospitals a significant market advantage. The non-destructive, 3D-imaging of CHiMP provides superior visualization for improved diagnostic accuracy and preserves tissue for critical DNA analyses. Applikate has strategies for leveraging CHiMP's technical advantages to create massive, unique data libraries for AI system development.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Applikate's proprietary tissue cassettes and automated tissue processors are Class I, 510(k)-exempt. The company will market the microscope as a Class I "fluorescence microscope" device while simultaneously pursuing 510(k) clearance based on Whole Slide Imagers as the predicate device. Applikate plans to use existing CPT codes for reimbursement. The USPTO granted Applikate three US patents in 2020, which cover the tissue processing method, tissue cassettes, and the high-speed multiphoton microscope. Several patent applications under preparation expand upon the tissue processing methods, the cassette, the tissue processor apparatus, and the microscope. Significant trade-secrets in engineering of the microscope and the 3D viewing software provide further barriers to entry for any potential competitors.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2019	Begin clinical validation study and integration into Yale New Haven Hospital workflow for renal samples
Q4 2020	Publication of clinical validation study in prostate

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2014	NIH/NCI SBIR Phase I	Proof-of-principle for CHiMP	$225K
2015	NIH/NIBIB SBIR Phase I	Proof-of-principle for intra-operative version of CHiMP	$216K
2017	NIH/NCI SBIR Phase II	Prototype development for CHiMP	$1.78M
2019	NIH/NCI SBIR Phase I	Custom microscope objective design and application to hematopathology	$224K
2019	NIH/NIDDK Direct-to-Phase II	Clinical validation in renal workflow at Yale New Haven Hospital	$956K
2021	Seed Round	Currently in process of closing over-subscribed round	$2.7M

USE OF PROCEEDS

Funds would be used to finalize the MVP, go-to-market, and collect relevant data and submit a 510(k) application.

KEY TEAM MEMBERS

The founders, **Michael Levene, Ph.D.** and **Richard Torres, M.D.**, are an ideal technical team. Dr. Levene, a former Yale professor, is an expert in optics and microscopy. Dr. Torres is a pathologist who holds a faculty position at Yale. **David Hunt, M.B.A.**, is a serial entrepreneur who has led multiple corporations from inception through exit. He has dedicated 50% of his time, and extensive capital, to assist Applikate.

CREATV MICROTECH

A revolutionary blood test that can transform cancer screening and diagnostics

Cha-Mei Tang, President & CEO | cmtang@creatvmicrotech.com | 301-983-1650 | creatvbio.com

COMPANY OVERVIEW

Creatv is a privately held company with expertise in diagnostics and microfabrication. The convergence of these technologies provided the genesis of the ***CellSieve™*** microfiltration system for liquid cell biopsy that enables the ***LifeTracDx™*** assay. Creatv's mission is to transform cancer screening and diagnostics by accurately detecting and diagnosing cancer at its earliest stages, when it matters most, thus saving and improving lives. The Company's vision is to provide ***LifeTracDx™*** liquid biopsy to screen for cancer when treatment is most effective, to provide companion diagnostics to determine the optimal treatment not requiring tissue biopsy, to monitor treatment response, to provide prognosis, to determine residual disease at the end of therapy, and to detect cancer recurrence earlier than imaging. Creatv is setting up a CLIA lab to implement the ***LifeTracDx™*** liquid biopsy.

MARKET & COMMERCIALIZATION STRATEGY

In the US, 40% of people get cancer in their lifetime. The worldwide market size (a) for cancer diagnostics is >$25 billion, (b) for cancer recurrence is >$35 billion and (c) for cancer screening is >$100 billion. The commercialization strategy is to provide patient testing in a CLIA laboratory and to obtain FDA approvals.

TECHNICAL & COMPETITIVE ADVANTAGE

Creatv discovered and analyzed a type of giant cell in the blood of cancer patients. They are macrophages engulfed tumor cells from the tumor site then entered the blood stream. They are found in the blood of >30 types of solid tumors analyzed and found even in high percentages in Stage 1. The unique properties of this macrophage-like biomarker enable a spectrum of applications.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Creatv intends to file for FDA approval for many clinical applications. The first one is to predict immunotherapy treatment response for non-small cell lung cancer (NSCLC) after chemoradiation.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2010-2011	Developed ***CellSieve™*** microfilter by photolithography with uniform pore sizes, low auto fluorescence background
2011	Demonstrated ***CellSieve™*** filtration collects circulating tumor cells (CTCs)
2012	Developed ***LifeTracDx™*** liquid biopsy
2013	Discovered circulating cancer associated macrophage-like (CAML) cells and showed that they come from tumor site
2016	Discovered CTC in mitosis indicate very aggressive cancer with short progression free survival (PFS) and overall survival (OS)
2017	Developed immunotherapy companion diagnostic by a blood test, not requiring tissue biopsy
2018	Discovered presence of just one CAML with size ≥50 microns from 7.5 mL of blood indicates short PFS and OS
2018	Demonstrated CAMLs deliver many copies of whole tumor DNA for sequencing
2019	Demonstrated ability to predict treatment response based on the changes of CAML size
2016-2021	Demonstrated CAMLs very suitable for screening for single cancer or pan cancers
9/2021	Unblinding 900 breast cancer patient CAML study after mammography with BIRAD4A-B for breast cancer screening
11/2021	Complete setting up CLIA lab
1/2022	Start FDA clinical trial to predict immunotherapy treatment response for NSCLC

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016-2022	U01CA214183	Breast cancer detection consortium (subcontractor)	$498K
2018-2022	W81XWH1810197	CAML cells to enhance detection of early-stage lung cancer and relapse after definitive treatment	$625K
2019-2024	U01CA239141	MRI imaging and biomarkers for early detection of aggressive prostate cancer (subcontractor)	$75.8K
2020-2024	R01EB028829-01	A soft x-ray phase-based microscope for biomedical Application (subcontractor)	$505K
2000-2021	Angel funding	Family, employees, friends	$9.4M

USE OF PROCEEDS

Series A: $20 million for (i) CLIA lab, (ii) automation of blood processing instrument, (iii) AI software to read slides and identify CTCs and CAMLs, and (iv) FDA clinical trial to predict immunotherapy treatment response for NSCLC.

KEY TEAM MEMBERS

Cha-Mei Tang, Sc.D., (Founder, President and CEO): BS, MS, Ph.D. from MIT; 180+ journal publications; Most outstanding woman scientist in the Federal Government by Women in Science and Engineering (1992)

Platte (Pete) T Amstutz III, CFA (CFO): BS & MS from MIT; Worked on Wall Street and in corporate finance

Ronald Baker (Business Development): Experience in business, operations and services in healthcare and the life sciences

Daniel Adams (Director of Clinical R&D): Discovered the cancer associated macrophage-like cell (CAMLs) biomarker

EARLYDIAGNOSITCS INC.

Detecting and Locating Cancer Early

Xiaohui Ni, CTO | xiaohui.ni@earlydx.com | 617-283-9982 | earlydx.com

COMPANY OVERVIEW

EarlyDx is a seed-stage company co-founded in 2017 by professors of UCLA and Stanford University. The company is devoted to providing accurate, affordable, and non-invasive liquid biopsy products for early cancer diagnosis and precision medicine. EarlyDx's leading product, *MethylScan* Test, a blood-based cfDNA test combining both an assay technique and machine learning algorithms, can not only detect cancer at early stages but also pinpoint its location. The ***MethylScan*** Test has been validated in 479 clinical samples, showing high sensitivity in detecting early stages of cancer.

MARKET & COMMERCIALIZATION STRATEGY

The global cancer diagnosis market is projected to grow at a CAGR of 7.0% and reach $249 billion by 2026. The Early Diagnosis market is experiencing the fastest growth but largely remains unaddressed. EarlyDx will penetrate the market through decentralized testing; the company will provide reagent kits to its own or partner's CLIA-certificated labs for performing the ***MethylScan*** assay and provide a cloud computing platform for cancer classification. The ***MethylScan*** Test targets a billion-dollar market, but as a new test, the Company expects it will take time for initial market penetration and clinical adoption. EarlyDx's reagent kits and cloud-computing platform alone can bring incremental revenue by splitting shares from current players in the space and provide needed data for regulatory application.

TECHNICAL & COMPETITIVE ADVANTAGE

EarlyDx provides sample-to-result testing and differentiates itself from its direct competitors through four advantages: 1) EarlyDx provides a proprietary easy-to-use assay for enriching informative cfDNA fragments. This assay will also be distributed to other molecular diagnostic labs to reach more customers; 2) EarlyDx's proprietary CancerLocator/CancerDetector algorithms maximize the information obtained from methylation patterns and provide a more accurate test; 3) EarlyDx's ***MethylScan*** assay can simultaneously provide multiple epigenomic and genomic features that may otherwise be unattainable; 4) The genome-wide data collected by the ***MethylScan*** test have additional data mining uses, ensuring EarlyDx's continuous growth from a decentralized cancer screening testing provider to a big data analytics company.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Multi-cancer detection tests represent a breakthrough technique for which no approved or cleared alternatives exist. Fortunately, billions of dollars have been spent by competitors to pave regulatory pathways. FDA recognizes the importance of this type of test and has granted a few Breakthrough Device Designations in the field. The CMS issued a proposed rule to expedite Breakthrough Devices coverage. As an early-stage company, EarlyDx is focusing on providing evidence for the clinical validity of its test. EarlyDx is in the process of submitting a request for breakthrough device designation for its ***MethylScan*** Test. EarlyDx owns IPs on both assay technology and computational algorithms. Currently, EarlyDx has five PCT applications and a few provisional patent applications. The freedom to operate assessment has been performed by EarlyDx's patent attorney.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2021	First reagent kit sale
Q2 2022	Publication of collaborative clinical study data of ***MethylScan*** Test
Q2 2022	Launch laboratory developed test
Q1 2023	IVD application

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Pre-seed round	Angel investor / Venture capital	$2M
2020	Grant	SBIR Phase I	$351K
2020	Seed round	Venture capital	$5M

USE OF PROCEEDS

EarlyDx plans to raise $10M to support new product development, expand the MethylScan test to cover multiple cancer types, build its own CLIA and GMP facilities, conduct a multi-center clinical trial, and establish partnerships to launch LDT, IVD application.

KEY TEAM MEMBERS

EarlyDx is currently under the direction of its interim CEO and co-founders. EarlyDx has 5 full-time employees focusing on R&D, and a consulting team focusing on business development and regulatory affairs. In the leadership team, **Dr. Xianghong Zhou**, the cofounder and interim CEO, is a Professor of Pathology and Lab Medicine at UCLA. The co-founder, **Dr. Wing Hung Wong**, is the Stephen R. Pierce Family Goldman Sachs Professor at Stanford University and is the co-founder of Bina Biotechnologies which was acquired by Roche. The CTO, **Dr. Xiaohui Ni**, has extensive experience in assay development and previously successfully developed a blood-based FISH test for early cancer detection. The VP of Cloud Computing, **Dr. Chun-Chi Liu**, has over 15 years of experience in bioinformatics and machine learning.

EUTROPICS

Novel functional clinical diagnostic tests for use in oncology

Michael Cardone, CEO | mcardone@eutropics.com | 617-803-1511 | eutropics.com

COMPANY OVERVIEW

Eutropics is a biomarker discovery, CLIA laboratory advancing personalized medicine by providing a novel functional biomarker driven predictive platform for precision oncology. The Company discovers and develops biomarkers by applying the discovery platform to identify the correct assay readout for predicting the cancer cell response to partners' drugs or drug combinations. 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. The tests recognize unique features of cancer cells from individual patients and a commercial version of the assays is being provided for matching patients with the most effective approved treatments for their indication.

MARKET & COMMERCIALIZATION STRATEGY

Targeted markets are in AML and Multiple Myeloma (MM) patients with potential addressable markets for predictive diagnostics in the US of 160K global / 32K U.S. and 125K global / 20K U.S. patients, and $200M and $120M in U.S. revenues per annum respectively. The next iteration of the platform is being developed with support from large pharma partner for use in breast cancer and small cell lung cancer, which are potential U.S. Markets of $200M and $100M respectively. Strategy consists of a combination of Commercial Dx and licensing of the novel CDx platform to pharma for guiding cancer therapies. A revenue stream from CLIA services support assay development efforts. Partnering occurs in discovery, development, and licensing stages.

TECHNICAL & COMPETITIVE ADVANTAGE

The platform provides functional surrogate readout that has unique predictive utility filling biomarker need unfilled by currently marketed genomics or high-resolution proteomics platforms. With a few exceptions, these competing tests are not sufficiently sensitive to add needed improvement in response or survival rates patients. 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.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Eutropics relies on issued patents covering iterations of the Company's PraediCare Dx and PrimAb platforms. These are both being developed as laboratory developed tests (LDTs) under CLIA with the intention of following with PMA approval from the FDA if pharma partner intends to develop an on-label CDx. Stand-alone tests can be run as CLIA-LDT or PMA approved tests. Intellectual property covers a mitochondrial-based liposome binding and release assay, various antibodies (binding heterodimers of Mcl-1/Bim, Bcl-2/Bim, and Bcl-xL/Bim), Concerns BH3 profiling diagnostics; Covers various diagnostic and therapeutic compounds in small molecule program.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2014	POC for PraediCare Dx in AML clinical data published with collaborators and patents filed
2016	Prospective selection of patients into phase 2 clinical trials, IP filed, licensing deal with pharma partner
2018	Next generation test developed, IP issued, POC data generated and presented at major meetings
2021	Agreements to established utility of next generation tests in AML and solid tumors with two large pharma partners

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2008-2016	Grants, Phase 1 and 2	Develop Technology platform, including BH3 mimetic class of drugs	$7.375M
2016-2020	Mass Ventures / NCI SBIR	Commercialization of predictive diagnostic platform	$3.895M
2005-2020	PE	Development and commercialization of platform	$1.243M
2016-press	Partnering revenue	Assay development and implementation with pharma partners	$4.113M

USE OF PROCEEDS

Eutropics is seeking additional seed funding of $5.5M to capitalize on short-term marketing opportunity of $25mm to $40mm through clinical trials service and CDx test development agreements with current and new pharma clients. Funds will be used for commercial team buildout, hiring of key leadership personnel, developing commercial strategic plan including cost benefit of Cdx/ Pharmacoeconomics Science team buildout.

KEY TEAM MEMBERS

Michael Cardone, Ph.D. (President, CEO, & Founder): 15+ years' experience in scientific and business management at early-/mid-stage biotech companies; Founder of Merrimack Pharmaceuticals

Steve Lyle M.D., Ph.D. (CLIA lab Director and strategic advisor) Former VP of Clinical Services at the KEW Group, Associate Professor of Cell Molecular and Cancer Biology at U Mass Medical School

Jason Walsh, MBA (Business Advisor) 20 years of leadership experience in life science companies as CFO/COO

Rema Al Hazem (CLIA Lab Manager) Over 10 years of lab management experience and CLIA regulated labs

Michael Andreff, M.D., Ph.D. (Founding Scientific Advisor) Professor at MDACC

FERROLOGIX INC.

Rapid, high purity & yield, low-cost isolation of target cells in sample prep & cell therapy

Tim Tiemann, CEO | TTiemann@Ferrologix.com | 661-513-8710 | Ferrologix.com

COMPANY OVERVIEW

Ferrologix is a pre-revenue company with more than $5M in support, targeting high value applications in cell isolation for downstream processing & analytics. Cell purification remains a critical need in the development and production of cutting-edge diagnostics and therapeutics. Ferrologix has a unique magnetic-based instrument & disposable cartridge that can transport, filter, and organize single cells for precision analysis or therapeutic manufacture. Pioneering a technique called Digital Magnetic Sorting (aka Ratcheting Cytometry), Ferrologix is developing a suite of tools to assist, accelerate, and scale the development of precision medicine research, next gen diagnostics, and cellular therapies.

MARKET & COMMERCIALIZATION STRATEGY

Market interviews have identified a progression of applications with unmet needs regarding MACS and FACS separations. The Company is undertaking a series of beta tests with their MVP in KOL labs with a goal of developing publications/endorsements via a select installed base. Product development continues to reduce COG and increase input/output cell number.

TECHNICAL & COMPETITIVE ADVANTAGE

Ferrologix's ratcheting cell isolation system allows for the simultaneous isolation of two target populations from a sample in under 30 minutes and higher purity/yield for rare cell isolation than competing products. The closed system enables aseptic handling, and the technology breaks down into two components: (1) a rotating magnetic field supplied by a benchtop instrument and (2) disposable cartridges containing arrays of ferromagnetic microstructures.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Regulatory strategy is initially for RUO, later developed as both front-end sample prep, and at scale as a cell therapy manufacturing module. Conversation with FDA confirmed ISO 13485 pathway is acceptable for therapeutic cell manufacture, Provisional patent filed.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	Transition of chip manufacturing to commercial partner (GE Global Research)
2021	Filing foundational patent
2021	Beta testing rare cell isolation system with 5 laboratories across the US
2022	3 Posters/technical presentations at target conferences
2022	Freeze design for larger scale Cell therapy separation device

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017-2020	SBIR Grants & Contracts	NIH – NCI, NCATS, NIAID, NHLBI	$4.9M
2021	Subcontract _DOD	Universal Sample Preparation of Pathogens	$500K

USE OF PROCEEDS

SBIR contracts and grants provide justification to develop RUO units targeting select applications. Cartridges and instruments function with all existing bead manufacturers, so Customer Discovery in the Research-scale cell isolation market with individual labs and Flow Cytometry core facilities has been the priority. Funds would be used to (1) hire a small sales team, (2) transfer manufacturing to higher scale/lower cost methods, and (3) complete design of larger volume Cell Therapy product.

KEY TEAM MEMBERS

Tim Tiemann (CEO)

Responsible for Corporate and Business Development; graduate degrees in Business and Immunology from the University of Rochester; Has led Business unit functions at Bayer, Motorola, and several life science start-ups; Holds a series 7 and 63 license in Investment Banking; Led the Life Science licensing and commercialization effort at USC for several years.

Dr. Coleman Murray (COO)

Lead inventor of the Ferrologix system and leads the Research and Operation functions of the company; Background in lab automation and applying microelectromechanical systems (MEMS) towards healthcare products; Ph.D. in 2015 under the mentorship of Professor Dino Di Carlo where he developed the ratcheting cytometry platform which formed Ferrologix's core technology.

JBS SCIENCE INC.

cfDNA test (urine/blood) for cancer screening and precision medicine

Ying-Hsiu Su, CSO | ysu@jbs-science.com | 610-888-3740 | jbs-science.com

COMPANY OVERVIEW

JBS Science Inc. is a discovery and development phase cancer diagnostic company focused on the delivery of urine-based DNA tests for cancer screening and precision medicine. The company's mission is to improve early detection of cancer and cancer management by providing diagnostic tools with detection of the most promising cell-free circulating tumor DNA (ctDNA) markers in urine and blood. The team includes experts in biomarker research, sample preparation, clinical oncology, and the diagnostics industry. The Company's innovative technologies robustly isolate cfDNA, detect primary and recurrent cancers, and provide cancer genetics for precision medicine.

MARKET & COMMERCIALIZATION STRATEGY

The market for JBS's hepatocellular carcinoma (HCC) DNA test is the in-vitro diagnostic market. The target population would be high-risk individuals including individuals that have HBV and HCV infections (500 million people worldwide and 2 million in the USA). These individuals would be screened every six months for primary liver cancer and every three months for monitoring HCC recurrence. The JBS HCC test will identify the necessary patients in need of more sophisticated imaging diagnostic tests, such as MRI or CT scan. JBS Science plans to obtain CLIA certification for the test from the State of Pennsylvania. Patient samples will be sent to the JBS Science laboratory in Doylestown, PA. After analysis, a report will be sent to the ordering physician. JBS Science will market the test to hepatologists. Peer reviewed publications, presentations at medical meetings and professional societies will be the highlights of the Company's marketing strategy. Price for the test is expected to be $500, which is the current reimbursement for a similar DNA cancer screening assay.

TECHNICAL & COMPETITIVE ADVANTAGE

The cost, sensitivity, specificity, and patient compliancy significantly impact a screening test. The cost effectiveness of lives saved is the ultimate criterion. JBS's urine DNA test is to replace the AFP and ultrasound (US) test as a screening test. Currently, AFP and US are the standard screening methods, but they miss ~50% of HCC. CT and MRI are primarily for diagnosis and are not used for screening due to the expensive cost of the test. JBS's HCC test is a DNA test that can detect 60% AFP-negative HCC, together, almost 80% HCC at 90% specificity. As compared to MRI and CT, the cost effectiveness of JBS's HCC urine test allows more sensitive screenings to be performed more frequently and can be combined with a more sophisticated diagnostic test on a less frequent basis to decrease cost while increasing efficiency of detection. Furthermore, the cost-effective nature of the HCC test incentivizes insurance providers to utilize this HCC screening test to minimize costs in HCC treatment.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The HCC test, JBS's first cancer screening test, will be commercialized in the US as a CLIA-certified LDT for HCC screening of at-risk population, with proper CPT codes for reimbursement. To commercialize the test in Asia, the Company plans to start a clinical trial in China for HCC screening for CFDA approval in 2022 and for other countries after.

IP: 1. Detection of a panel of urine DNA markers for HCC screening and disease management (US Patent 9,598,735); 2. Detection of hepatitis B virus (HBV) DNA and methylated HBV DNA in urine of patients with HBV-associated hepatocellular carcinoma (US 9,840,742); 3. Kit and Method for detecting mutations in CTNNB1 and hTERT and use thereof in HCC detection and disease management (US 10,689,709); 4. Quantitative measurement of hepatitis B virus cccDNA assay (US 10,422,013).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
7/2022	To obtain 80% sensitivity at 90% specificity in a multi-center blinded validation study
6/2022	To obtain breakthrough device designation from the FDA for the JBS HCC screening test
11/2022	To obtain/ identify a CPT code for a panel of cfDNA assays as JBS HCC screening test
12/2022	To obtain CLIA certification for JBS cfDNA assays

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2012-2021	SBIR phase I and II	NIH	$7.5M
2019	Series A round	Series A Investors	$1.7M
2020	Series A round (continued)	Series A Investors	$0.6M

USE OF PROCEEDS

JBS seeks $6M to commercialize JBS HCC urine test. This includes CLIA certification, CPT code and launch to the clinic, including clinical trial in Asia (2022) for CFDA.

KEY TEAM MEMBERS

Wei Song, MD Ph.D. (CEO/Director of The Board); Board-certified hematologist and medical oncologist; trained at The Temple/Fox Chase Cancer Center program focusing on liver cancer.

Ying-Hsiu Su, Ph.D. (CSO); Pioneer in trans-renal DNA technology for cancer detection; joined team to take the technology to clinic.

Selena Lin, Ph.D. (COO); 12+ years' experience in developing PCR-based assays for detecting circulating tumor-related DNA (ctDNA) modifications for cancer diagnostics

NODEXUS INC.

"Mainframe-to-PC" tools that democratize and unlock access to biology

Karthik Balakrishnan, CEO | karthik@nodexus.com | 510-397-0641 | nodexus.com

COMPANY OVERVIEW

Nodexus is a commercial-stage biotechnology company commercializing the NX One platform to make live single-cell isolation 10X faster and 10X lower cost. The NX One offers a "mainframe-to-PC" transition for live cell isolation through unprecedented walk-up usability and affordability, and Nodexus' patented technology makes automated single-cell isolation widely adoptable across the breadth of biotech, spanning gene editing and drug development to genomics and cancer biology research.

MARKET & COMMERCIALIZATION STRATEGY

There is tremendous demand for access to live single cells for the quickest growing sectors in biotech, including bioprocessing, gene editing, and genomics (>$17B customer market potential), and current solutions cause critical bottlenecks. While there is broad potential for deployment into industrial (spanning small startups to large biotech), clinical research, and academic (Core facility and individual) sites, Nodexus' focused strategy is modeled off successful scaling in adjacent companies. Early beachhead customers are the tens of thousands of small/medium biotech sites, as >90% of these customers lack automated cell-isolation in-house and rely on manual processes or Core facilities (extremely inefficient, compromise cell viability, cause contamination). The unprecedented pricing of the NX One enables accelerated purchasing (Nodexus has even received POs through virtual interactions), and robust design enables low-cost dropship deployment. Typically, sites break even on an NX One purchase in less than six months. Moving forward, Nodexus will more broadly enter larger biotechs (potential multi-system sales) and academic/clinical sites. Nodexus estimates instrument placement potential to be >50,000 (based on adjacent market comparables), and long-term value is driven by significant recurring revenue (razor/razor-blade model) through disposable cartridges, software licenses, and service contracts. Nodexus projects an addressable market size (not including pipeline products) of more than $3B and five-year revenues of more than $100M.

TECHNICAL & COMPETITIVE ADVANTAGE

The NX One leverages patented microfluidics and instrument development, proprietary design and manufacturing processes, and trade secret software algorithms to enable key value propositions including: 1) affordable price points for widespread adoption (closely mimicking Accuri Cytometers' $30-50K model for successful scaling to >500 units within two years of launch prior to acquisition by BD Biosciences for >10X revenue), 2) preservation of cell viability through microfluidics for <40X pressure on cells, 3) a "one-click" walk-up usable approach without needing a dedicated technician, 4) active multi-parametric detection and isolation, 5) the ability to process a wide variety of samples (e.g. large cell sizes, small cell number inputs), and 6) contamination-free operation. No existing cell sorter meets the financial, workflow, and personnel limitations of sites that rely on Core facilities and dedicated technicians – the NX One platform addresses these key needs and enables universal deployment into every biological site.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Over the past decade of development, a robust IP portfolio was built both from UC Berkeley as well as work within Nodexus since inception to surround the core innovations including characterization and fractionation of samples, detection of cells of interest, and integrated isolation of single particles. Nodexus has established an exclusive licensing agreement with UC Berkeley to obtain a portfolio covering broad fields of use, while the algorithms/electronics for detection and enhanced sensitivity are kept as trade-secrets. None of Nodexus' initial markets require any regulatory approval for entry.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2021	Purchase orders for 100% of Early Access system inventory
2020-2021	Translated to high-margin (>80%) manufacturing (e.g., injection molding) for cartridges and instrument
2015-Present	Investment from life science venture capital firms
2014-Present	Exclusively licensed (granted and PCT-phase patents) and internally developed/filed IP

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015	Pre-Seed	Life science VC, Angel investors, and Biotech Executives	>$1M
2015-2020	Grant	Multiple awarded federal SBIR grants (NIH, USDA, NIST)	$800K
2018	Seed	Led by life science-focused VC (Grey Sky Venture Partners)	>$1M

USE OF PROCEEDS

To date, all sales were made with $0 marketing spend. The next stage of growth for Nodexus is focused on manufacturing scale-up to meet market demand of the NX One, as well as expansion of the commercial and R&D teams within Nodexus. Nodexus has identified significant adjacent opportunities (e.g., new cartridge offerings) that do not require extensive development, and this will be the focus of pipeline product development. Nodexus is raising $6M for the above with a 24-month runway.

KEY TEAM MEMBERS

CEO: Karthik Balakrishnan, PhD (UC Berkeley, Caltech), **Chief Strategy Officer:** Anand Kesavaraju (startups, St. Jude Medical, UC Berkeley, Northwestern), **VP, Eng:** Hany Nassef, PhD (>decade at Fluidigm developing, selling, and marketing products, USC, UCLA)
Advisory Board: Bill Rhodes, Dr. Ashraf Hanna; Dr. Diether Recktenwald; Dr. Joseph Keegan

CIVATECH ONCOLOGY®/TARGETED RADIATION THERAPY DEVICES

Suzanne Babcock | sbabcock@civatechoncology.com | 919-314-5515 | civatechoncology.com

COMPANY OVERVIEW

CivaTech Oncology has three commercially available radiation devices to provide therapeutic doses to cancerous tissues in a localized, targeted method. These devices have been shown to significantly reduce the side effects experienced with traditional radiation methods, provide meaningfully higher radiation doses, and enable the delivery of therapeutic radiation doses where only palliative doses were possible. The patented platform technology was developed, engineered, and is manufactured by CivaTech in their ISO 13485 certified facility. CivaString®, CivaSheet® and CivaDerm™ are the only polymer-encapsulated implantable radiation devices. These bio-compatible and bio-absorbable products are designed to be easily implemented in the workflow of current cancer care pathways. CivaTech products have dedicated brachytherapy reimbursement (payment) codes.

MARKET & COMMERCIALIZATION STRATEGY

CivaSheet has a large market potential because it provides a unique way to deliver radiation therapy to 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 give patients an immediate, clinically beneficial dose of radiation therapy. CivaSheet can address the multi-billion dollar markets in the US and internationally. For cancer recurrence in the margin, a second course of radiation is generally not administered because one round of external beam is the limit. CivaSheet will be used immediately to treat ~50,000 cases of recurrence, 15,000 of pancreatic cancer and early detected lung cancers. Primary indications for use also include cancers of the colorectal and pelvic region, head and neck, brain, sarcomas, and more. Clinical evidence indicates that patients receive their entire radiation therapy at the time of surgery with a hotter dose that is customized to treat the cancer type and tissue type. The increased dose is improving outcomes without the usual radiation toxicities. A new model of CivaSheet (CivaDerm™) is cleared by the FDA to treat non-melanoma skin cancers and keloids, etc. It can replace surgery and will be worn as a bandage to treat the 3 million cases of non-melanoma skin cancer in the US, alone.

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 to a targeted tissue in a localized and directional approach that minimizes radiation damage to surrounding tissues. In the current radiation therapy paradigm, the radiation 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 with almost no dose to surrounding tissues, sparing unnecessary side effects. It is customizable in the OR and delivered in custom strengths. CivaSheet is implanted in a single ~15-20 minute procedure during the patient's initial surgical resection and the patient will not have to return for weeks of repeated external beam treatments. This provides cost savings to both the patient and the hospital.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

CivaTech Oncology has developed its own IP and trademarks protecting the methods of polymer encapsulation and the manufacturing techniques. Eight patents relate to the directionality of the radiation distribution and the method of encapsulation.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2017-2020	Expanding sales of CivaSheet through technical publications and clinical trials
2021	Excellent Outcome data for pancreatic and other cancers, Three FDA cleared products, over 200 patients treated with remarkable results

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2007-2012	Series A-D	Private (R&D Phase)	$6M
2012-2015	NIH/NCI Phase II development	Government Contract & Private funding	$3M
2017	Notes and Govt grants	Private funding (scaling 1st Product) and clinical grants	$8M
2018-2020	Convertible Notes	Private (Commercializing 2nd Product and scaling)	$3M

USE OF PROCEEDS

Seeking $15M for expansion of manufacturing capacity, to fund continued post-market clinical trials, and to invest in sales and customer support infrastructure.

KEY TEAM MEMBERS

Suzanne Babcock (CEO): BA, NCSU; Founder with diverse business development and tech. capabilities to foster creative talent, develop novel radiation devices, build infrastructure, navigate numerous approval processes through to commercialization
Kristy Perez, Ph.D. (VP, Clinical Programs/COO): Medical Physics, Duke; Led team in translating CivaSheet from R&D to clinic
Greg Briley (CFO): BA, NCSU; previously Co-Founder of Etix, an international web-based ticketing provider, largest in N. America.
George Paschal, MD (CMO): Wake Forest University; 44+ years' experience as a general surgeon
Mark Rivard, PhD (CSO): World-renowned medical physics expert in brachytherapy and radiation therapy
Randy Harrison, MS (Natl. Sales Manager.): WFU; 30 years experience in radiation and medical device sales

CLARIX IMAGING

Real-time 3D Imaging Platform for Point-of-Care Surgical Oncology

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

COMPANY OVERVIEW

Clarix Imaging looks to transform surgical oncology by providing a real-time 3D imaging platform and software with unsurpassed resolution and intuitive workflow, thus providing point-of-care precision assessment and guidance for cancer surgery and pathology. The Clarix Imaging Volumetric Specimen Imager (VSI) is an FDA-cleared, portable, hardware-software integrated cabinet X-ray computed tomography (CT) system that generates 3D images of surgically excised tumor specimens directly in the operating room or pathology lab.

MARKET & COMMERCIALIZATION STRATEGY

Breast-conserving surgery has a high re-operation rate of 25%-38% due to inadequate assessment of margins during the initial surgery. Unaddressed positive margins have increased cancer recurrence rates and lead to poorer outcomes. Pathology assessment misses 30%-40% of positive margins because only 0.1% of tissue, which is subjectively and randomly selected, undergoes microscopic examination. Each year, 333,000 breast-conserving surgeries are performed in the US, and globally >2 million new breast cancers are diagnosed. Clarix sells directly and through distributors to 7,000 surgical sites in hospitals and surgical centers and to 9,000 pathology labs. $40B global TAM for VSI (includes immediate software expansion into lung, colorectal, prostate, liver, and kidney), and >$100B pipeline market for tumor AI and ecosystem products and services.

TECHNICAL & COMPETITIVE ADVANTAGE

VSI has 10X higher resolution than diagnostic CT systems, and is 10X faster than a CT procedure, enabled by breakthrough imaging system design & algorithms invented by founders. Additional software capabilities such as intuitive 3D image navigation, cloud-based remote collaboration, and AI-powered automated analysis, provide surgeons and pathologists with real-time actionable information in a streamlined clinical workflow at point of care. The initial application is for breast cancer surgery and pathology; however, the underlying technology is easily scalable to other tumor types through expanded software modules with the same hardware.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Clarix Imaging has received FDA 510(K) clearance for the initial VSI product. Additional FDA applications for expanded indications are planned for late 2021. Clarix is the exclusive licensee to the core patents owned by U. Chicago. Clarix is also 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
12/2019	US FDA 510(k) clearance
5/2021	200-case multi-center study completed, and results presented at American Society of Breast Surgeons Conference
6/2021	Manufacture transfer completed and the first commercial installation

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
5/2018	Series Seed	Angel investment ($2.2M) + non-dilutive NCI SBIR grants ($2.5M)	$4.7M
7/2020	Grant	NCI SBIR Phase I & Bridge Award	$4.5M
8/2021	Series Pre-A investment		$5M

USE OF PROCEEDS

Clarix Imaging is looking to raise a $15M Series A round as growth capital to accelerate manufacturing & product sales in US and Europe, and to fund development of new software features and tumor AI systems.

KEY TEAM MEMBERS

Xiao Han, Ph.D. (CEO & Co-founder): Former University of Chicago radiology faculty; 15 years R&D experience in medical imaging; Led system design, $9M fundraising, and successful regulatory clearance

Xiaochuan Pan, Ph.D. (CSO & Co-founder): World-leading medical physicist and pioneer in tomographic imaging algorithm with 30+ years of track record of disruptive innovation

Christian Wietholt, Ph.D. (VP Product Dev): Former manager at ThermoFisher Scientific with 20 years' experience in 3D imaging and AI

Sathya Kovour, (Architect), Former chief systems architect of Siemens Healthineers with 28 years' industry experience

Marc Orloff, (Engineering & Manufacturing Lead): Former manager at Xerox & Fischer Imaging with 20+ years' regulated medical device design and manufacturing experience

Richard Fine, MD, (Clinical Advisor): National leader in breast care and former President of American Society of Breast Surgeons

Scott Peairs, MBA, (Business Dev Advisor): Former VP of Marketing & Sales at Faxitron (acquired by Hologic, Inc.) with 30+ years' experience in commercializing and selling surgical imaging devices and software.

LEUKO LABS INC.

Noninvasive white blood cell monitoring to improve cancer chemotherapy outcomes

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

COMPANY OVERVIEW

850,000 patients start chemotherapy every year in the US and 140,000 need to be hospitalized because of febrile neutropenia (FN), an infection that occurs while the patient's WBCs are critically low because of their chemotherapy. FN hospitalizations bring negative clinical outcomes (7% mortality) and a total cost of $4.2B ($30k/case) in the US alone. To solve this unmet need, Leuko, an MIT spinout, has developed PointCheck™, the first medical device that enables non-invasive, at-home, and frequent WBC monitoring. The monitoring triggers timely interventions by the care team (e.g., prophylactic antibiotics or G-CSFs) that can reduce FN hospital readmissions by 50%. Beyond chemotherapy, Leuko aspires to continue growing to serve the 10 million immunocompromised US patients that could benefit from increased monitoring of their weakened immune systems.

MARKET & COMMERCIALIZATION STRATEGY

By saving 50% of FN-related hospitalizations, the total addressable market is $2.1B/year in the US (140k hospitalizations x $30k/case x 50%). Leuko's commercialization strategy, informed by the Company's customer interviews, focuses on developing partnerships with the 16 largest Integrated Delivery Networks (IDNs) and Accountable Care Organizations (ACOs) in the US which treat 1/3 of all addressable chemotherapy patients, representing a beachhead of $700M/year. These organizations are an ideal target because of their incentives to generate healthcare savings. Leuko projects initial revenue to come from a value-based leasing model that will be implemented following FDA approval. Expansion to fee-for-service providers will follow through reimbursement as a Durable Medical Equipment (DME) supplemented by remote patient monitoring (RPM) CPT codes. Future commercial applications include expansion to Europe and globally, and to other therapeutic markets beyond chemotherapy.

TECHNICAL & COMPETITIVE ADVANTAGE

PointCheck™ is the first noninvasive, portable self-test to monitor WBC levels at home. All existing technologies require visits to the clinic, blood draws, healthcare staff, reagents, and biohazard disposal, and thus cannot be easily performed at home and daily.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

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

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2018	Phase I trial: Clinical proof of concept of prototype device (nurse-operated) in >40 cancer patients.
2019	FDA pre-submission: Class II De Novo classification, finalized pivotal trial (Phase III) design and intended use.
2020	Pre-marketing & partnerships: Unmet need validation, >100 customer interviews, LOIs from 5 hospitals, 1 insurer, 1 medical device distributor and 1 pharma company.
2021	Phase II trial: Guided modifications for final device design (self-operated). Usability, safety & efficacy in >80 cancer patients.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Awards	MassChallenge HealthTech, MIT 100k, Rice Business Plan Competition, etc.	$200k
2018 & 2020	Grant	NIH SBIR Phase I & Phase II	$2.225M
2019	Funding Round	Seed round led by Good Growth Capital, Pegasus Tech Ventures and Nina Capital	$2M

USE OF PROCEEDS

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

KEY TEAM MEMBERS

Carlos Castro-Gonzalez, Ph.D. (Co-founder & Chief Executive Officer) 10+ years' experience in biomedical engineering; Innovation & entrepreneurship training at MIT; Prior med device startup experience

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

Aurelien Bourquard, Ph.D. (Co-founder & Chief Data Scientist) 10 years' experience developing AI and computer vision algorithms; EPFL and MIT trained scientist

Alvaro Sanchez-Ferro, MD, Ph.D. (Co-founder & Chief Medical Officer) 15 years' experience in medical practice, clinical studies and biostatistics; MIT training; Prior med device startup experience

Partha Paul, MBA (VP, Business Development) 20 years' experience in medical device commercialization at Philips and GE

NE SCIENTIFIC

Surgical guidance for tumor ablation

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

COMPANY OVERVIEW

NE Scientific (NES) is addressing a major issue in the percutaneous ablation of tumors: physicians do not have a direct view of tissues (ablation probes are inserted through the skin) and they cannot properly appreciate from the guidance images (CT or Ultrasound) which tissues have been ablated and which not. Consequently, in 24% of cases for medium tumors (3-5cm) and in 58% of cases for large tumors (>5cm) the procedure is terminated early leaving behind untreated malignant tissues, a situation that leads to recurrence. The problem is well-known in Interventional Radiology and a tidal transformative change is occurring, where software is used to overlay to intraoperative images an indication of which tissues have been ablated and which not. Currently, the vast majority of procedures are still conducted without the support of software, but physicians are aware that software can help them, and are actively demanding it. Early guidance software implementations are appearing on the market and are based on a fixed representation of the ablation "footprint" which is estimated from animal studies and understood to be a very approximate representation of the true ablation footprint. NES can simulate RF and Microwave ablation physics in real-time, a world-first, and is developing a line of products called Accublate™ which use this simulation capability to account for the delivered energy and for a number of patient-specific factors providing a better representation of which tissues are ablated. These simulations are essential particularly when multiple probes are used concurrently to treat larger tumors. Accrual is complete for a clinical trial for the guidance of liver cancer RF ablation and interim results are promising. It is expected that a significant reduction in the recurrence will be shown, thanks to the software, as physicians can better judge whether tissues are completely treated.

MARKET & COMMERCIALIZATION STRATEGY

NES intends to form commercialization partnerships with manufacturers of ablation systems, such NeuWave (Johnson & Johnson), Medtronic, AngioDynamics, and Boston Scientific. Microwave and RF ablation are mature technologies and differentiation between ablation systems is limited. A significant competitive role will be played by the software that systems are provided with. NES can offer a technology that is unique, something that would take years to develop from scratch. If it is deployed timely, the technology can contribute significantly to the success of a vendor. NES has developed a relationship with a key player in this market with the goal of licensing the technology, and entered a contract for a small scale clinical validation of Microwave ablation guidance.

TECHNICAL & COMPETITIVE ADVANTAGE

NES has been the first organization to show the ability to simulate in real-time RF ablation physics (2014) and Microwave ablation physics (2020). This ability is essential in permitting use of simulations during the procedures, as until recently these simulations took more than one hour. As of March 2021, the Microwave simulation technology developed by NES has been evaluated to be 20 times faster than competitors - a performance gap that separates a clinically useful technology from a non-useful one.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

NES is pursuing the development of three versions of Accublate™, a 510(k) for a first and simplified version of Accublate will be filed around October 2021. Filing for the two other versions of the product is expected in 2022. NES has filed several patent applications to protect specific aspects of its approaches.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2014-2015	Achieved real-time simulation of RF ablation, bench-top and animal validation of algorithms
12/2019	Started clinical trial for guidance of RF liver cancer ablation at the Dartmouth Hitchcock Medical Center
6/2020	Achieved real-time speed for Microwave ablation simulation, enabling clinical use of this technology
2020-2021	Developed a relationship with a leading medical devices manufacturer

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2014-2015	NCI SBIR Phase I	Initial grant which permitted the development of the core technology for RF ablation	$220K
2017-2021	NCI SBIR Phase II	Clinical trial for liver RF ablation, dev. of AI technologies related to the application	$1.6M
2019	J&J Quick Fire Challenge	Johnson & Johnson prize for lung cancer prevention or treatment innovation	$250K

USE OF PROCEEDS

NES is looking to raise $2M to support a clinical validation study for Microwave ablation guidance (the ongoing trial is for guidance of RF ablation) and the regulatory pipeline. If NES does not close a deal with the strategic partner by Q1-2022, the Company would like to go to market with the main aim to generate interest in the products and stimulate relationships with multiple strategics.

KEY TEAM MEMBERS

Andrea Borsic (CEO): Former Eng. Faculty at Dartmouth
Dave Dlesk & Eric Evans (Advisors): Seasoned executives and entrepreneurs
Rick Hoffer (Advisor): Director, Interventional Radiology at Dartmouth Hitchcock Medical Center

RIVANNA®

World-first ultrasound-based X-ray replacement technologies

F. William Mauldin, Jr., CEO | wmauldin@rivannamedical.com | 800-645-7508 | rivannamedical.com

COMPANY OVERVIEW

X-ray is ubiquitous in healthcare, but in numerous clinical indications, drawbacks limit utility and increase cost of care. RIVANNA is creating new standards of care with its innovative bone imaging technology coupled to AI-based clinician assistance software. Together these technologies enable high-performance diagnostic and interventional bone imaging that is bedside capable and does not exhibit ionizing radiation. The company operates an FDA-registered and ISO 13485:2016 certified manufacturing facility and is scaling sales and marketing for its flagship product Accuro. RIVANNA aims to disrupt and significantly expand an addressable market of $4B with clinician indications in anesthesia, neurology, oncology, and emergency medicine.

MARKET & COMMERCIALIZATION STRATEGY

The Company delivers its products and services to market through a global network of distribution partners, which is supported by a dedicated in-house marketing and sales team. Sales offerings include a mix of capital equipment, consumables, and product servicing. RIVANNA's initial product, Accuro® has generated over $3.8M in revenue to date with accelerating sales.

TECHNICAL & COMPETITIVE ADVANTAGE

RIVANNA's core technology includes a suite of innovations that produce X-ray-like images of bone anatomy using safe, portable, low-cost medical ultrasound combined with computer-automated guidance, detection, and diagnosis. The company's trademarks and patents provide substantial competitive advantages. Compared to X-ray based competition, the Accuro product line is technologically advanced as it can provide both 3D and real-time 2D imaging simultaneously, is a lower cost with bedside portability, and does not exhibit ionizing radiation.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The Company's products follow well-defined regulatory pathways for FDA 510(k) clearance of medical ultrasound equipment. RIVANNA has filed over 35 patents (15 issued) and holds 40 globally registered trademarks.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2015	FDA 510(k) clearance of the Accuro handheld spinal navigation system
2019	First Accuro RCT trial published
2019	Distribution alliance established with B.Braun (France, Japan, Mexico)
2020	Accuro® 2nd generation product launch with thoracic epidural guidance presetting
2021	USA distribution alliance established with Tri-anim
Pending	Federal government contract with BARDA to develop and commercialize Accuro XV rapid fracture triage system
2023	Accuro 3S fluoroscopy-replacement product 510(k) clearance
2025	Accuro XV rapid fracture triage product 510(k) clearance

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2011	Funding Round	Family and friends seed investment (equity)	$150K
2011	Funding Round	Center for Innovative Technology seed investment (convertible debt)	$50,000
2012-2020	Grant	NIH Grants (NIBIB, NIAMS SBIR Phase Is/NIBIB, NIGMS, NCI Phase IIs)	$6.27M
2013	Grant	NSF SBIR Phase I and Phase II	$1.56M
2013	Funding Round	Angel investor investment (Class B preferred equity)	$500K
2015	Funding Round	Angel investor investment (Class B preferred equity)	$1.5M
2016	Funding Round	Angel investor investment (Class B preferred equity)	$3.5M
2020	Grant	VA Catalyst award	$800K

USE OF PROCEEDS

RIVANNA is raising $10M to launch Accuro 3S and accelerate sales and marketing of its Accuro product line. These activities will include onboarding additional account manager, marketing, and business development staff.

KEY TEAM MEMBERS

Will Mauldin, Ph.D. (CEO): Expert in R&D, QMS, and business development; Developed/launched handheld Accuro product

Adam Dixon, Ph.D. (VP Engineering): Expert in R&D and manufacturing; Previously of GE Healthcare where he led/co-developed several image processing algorithms that have been implemented on clinically available platforms

Danielle Faulk (Director of North American Sales): Expert in medical sales; Previously of Terason Ultrasound

Vicki Brothers (Director of Global Marketing): Expert in healthcare marketing

Operations & Manufacturing: **Robert Rickel, MS** (Production Manager) & **Taisiya Novopachennaia** (Operations Manager)

VERISKIN, INC.

Non-Invasive, Hand-Held Device for Skin Cancer Detection

Mirianas Chachisvilis, CEO/CTO | mirianas@veriskin.com | 858-722-0657 | veriskin.com

COMPANY OVERVIEW

Skin cancer is the most common form of cancer in the US, accounting for just under half of all cancers or >5 million diagnoses annually. Unfortunately, all of these cancers are very difficult for the non-specialist (e.g., primary care physicians) to diagnose and distinguish from non-cancerous skin abnormalities. Uncertainty in this initial assessment leads to: (I) failure to detect cancer at an early, more treatable stage, and loss of lives (27,000+ in the US), (II) hundreds of malpractice claims due to false negative diagnoses and, (III) many unnecessary referrals and biopsies. Overall, the lack of an accurate, objective assessment tool for frontline caregivers leads to preventable loss of lives and costs the US healthcare system over $3B each year, monies that are unnecessarily wasted. The Veriskin device (TruScore) is a proprietary, non-invasive, low-cost, hand-held unit that aids a non-expert user to rapidly and objectively determine whether a suspect skin lesion is cancerous, thereby reducing the number of false negatives and eliminating unneeded escalation of care and biopsies. The FDA granted TruScore a Breakthrough Device Designation Status in 2020.

MARKET & COMMERCIALIZATION STRATEGY

Veriskin will focus on distribution to the frontline caregivers (e.g., PCPs, PAs and nurses) as well as dermatologists through a combination of device (~$1,000/unit) and per-use fee (~$50/test) sales (razor/virtual razorblade model). CMS issued a final rule mandating automatic Medicare coverage for all devices with FDA's Breakthrough Device designation. The total US market is estimated at $2.4B, while worldwide TAM is $7.7B. Apart from skin cancer, other potential market uses include in pre-emergent and post-emergent wound healing, diabetes, skin flaps in cosmetic surgery, and endothelial dysfunction.

TECHNICAL & COMPETITIVE ADVANTAGE

Other devices and approaches (imaging, elastic and inelastic light scattering, electric impedance, smartphone apps) have only shown nominal benefits in clinical effectiveness because they are either of too low sensitivity or specificity. In contrast, VeriSkin technology is based on a novel, orthogonal approach – active perturbative hemodynamic measurements with a proprietary machine-learning algorithm and is applicable to screening of both pigmented and non-pigmented skin lesions. Veriskin detects both structural and functional vascular abnormalities associated with pathological angiogenesis, which is a well-established, early hallmark of cancer. Inherently higher diagnostic information content from such measurements (as compared to competitor surface imaging-based technologies) coupled with AI-assisted analysis of the force-induced hemodynamic response provides for rapid, quantitative answers with outstanding sensitivity AND specificity. Pilot clinical studies have demonstrated sensitivity of >99% and specificity of >94% in screening for skin cancer (>125 biopsy-verified lesions).

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

All IP has been created in-house and is owned by Veriskin. The Company's IP strategy is developed and prosecuted by Wilson Sonsini Goodrich & Rosati. Broad patents claim the method and devices of the core technology, as well as potential uses. Veriskin received allowance for the key patent from the USPTO in 2021 and has one issued patent in Australia (2018).

KEY MILESTONES

DATE/YEAR	DESCRIPTION
7/2020	FDA grants Breakthrough Device Designation Status
3/2021	US Patent Allowed
7/2021	Initiated multi-site clinical study
Projected Q3 2022	FDA pivotal clinical trial

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2016	NIH/NCI	SBIR Phase II, Development of hand-held device and clinical validation.	$1.87M
2020	NIH/NCI	SBIR Phase II, Clinical Data Collection for algorithm training.	$1.99M
2021	Seed-1 Round	Preparation to FDA pivotal clinical trial	$1.04M

USE OF PROCEEDS

The Company is seeking $2.5M to conduct FDA pivotal clinical trial and to obtain FDA clearance (expected 2023). The Company is applying for additional funding via Phase IIb program from the NCI ($2.5M in matching funds).

KEY TEAM MEMBERS

Mirianas Chachisvilis, Ph.D. (CEO/CTO) Mirianas is an experienced scientist and consultant to early-stage technology companies.

Carl Edman, Ph.D. (Co-founder) Carl is an experienced early-stage medical device executive, co-founder of Corventis (acquired by Medtronics $200M+),

Eugene Tu, MS (Co-founder) Eugene was a founding team member of multiple biotech startups (Nanogen, Genoptix, Nanomix, Omniome).

Autumn Lang, Ph.D. (Director of Clinical Affairs)

Monica Alfaro Welling, MBA (VP of Commercialization): (Dermtech, Allergan, Novo Nordisk)

AIQ SOLUTIONS

Improving clinical outcomes for complex diseases through better therapy optimization

Eric Horler, President & CEO | eric.horler@aiq-solutions.com | 608-268-9684 | aiq-solutions.com

COMPANY OVERVIEW

AIQ Solutions has developed a revolutionary software platform to change the way clinicians' approach complex diseases such as metastatic cancer and neurological disorders. The cloud-based platform provides unique, early intelligence to predict both treatment effectiveness and toxicity risk from longitudinal imaging data. AIQ's technology does not diagnosis disease; rather, it enables the clinical team to make real-time, patient-specific adjustments to therapy, which helps improve outcomes while reducing healthcare system costs. AIQ's technology has been proven in multiple published studies and is currently being piloted at large cancer centers.

MARKET & COMMERCIALIZATION STRATEGY

AIQ will market its technology, the TRAQinform IQ system, to hospital systems in the US and internationally using a SaaS business model. Within a hospital, AIQ will target oncologists as clinical champions, focusing messaging on clinical and health economic evidence. Five parallel initiatives comprise AIQ's commercialization strategy: generate clinical evidence, demonstrate health economic value proposition, build physician advocacy base, secure reimbursement, and establish distribution partnerships.

TECHNICAL & COMPETITIVE ADVANTAGE

No other technology can quantify treatment response at the individual lesion level, nor can they accurately predict both ultimate treatment effectiveness and toxicity risk. Unlike treatment response technologies based on non-imaging biomarkers, the TRAQinform IQ system quantifies both temporal and spatial heterogeneity of response; spatial information is critical to make the information actionable. AIQ's technology is protected by a portfolio of patents and trade secrets.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

The primary functionality of the TRAQinform IQ technology has already received 510(k) clearance. However, AIQ is also pursuing breakthrough device status for the technology's advanced features. In parallel, AIQ is actively working towards approval in the EU and Australia. The company has three issued patents as well as three pending patent applications.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
7/2018	US FDA 510(k) clearance
1/2019	First employees hired
8/2019	Initial financing closed
6/2021	Start of first pilot at a major cancer center

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2019	Series A	Equity financing from VC funds	$3.8M
2019	Loan	Economic development loan from Wisconsin Economic Development Corp	$500K
2020	SBIR Phase I	NCI (NIH) grant	$388K
2021	EIDL and PPP	Non-dilutive funding related to COVID-19 pandemic	$471K

USE OF PROCEEDS

AIQ is currently raising a $10M Series A-1 to fund two years of additional runway and commercialization activities. The company has built and validated its product, secured FDA clearance, and initiated pilots with beachhead customers. AIQ will use the Series A-1 for market access activities—in particular, clinical trials to support reimbursement and market adoption ($5M)—as well as additional product development ($4.25M) and business operations.

KEY TEAM MEMBERS

Eric Horler, MBA, President and Chief Executive Officer
Previously general manager of a $220M global business for GE Healthcare, then CEO of Swallow Solutions, a medical device startup company. He brings >15 years of experience in medical product development, marketing, sales, and general management.

Robert Jeraj, PhD, Co-Founder and Chief Scientific Officer
Globally recognized expert in medical physics, director of the Wisconsin Oncology Network of Imaging Excellence

Glenn Liu, MD, Co-Founder and Chief Medical Officer
Medical oncologist and key opinion leader in genitourinary oncology

Guy Starbuck, Chief Technical Officer
Software executive with more than a decade managing the development of software in regulated industries

Sean Houshmandi, PhD, Vice President of Business Development and Strategic Alliances
Over a decade selling advanced medical technologies for companies including HTG Molecular Diagnostics and Becton Dickinson

ENVISAGENICS

Using AI to develop therapies for RNA splicing diseases

Maria Luisa Pineda, CEO | marialpineda@envisagenics.com | 516-847-5585 | envisagenics.com

COMPANY OVERVIEW

Envisagenics is a woman-led, Artificial Intelligence (AI)-driven biotechnology company focused on discovering novel RNA splicing variants. Its principal technology is the SpliceCore® discovery platform. The platform re-envisions the human genome with a validated exon-centric approach, combined with machine learning algorithms and high-performance computing. SpliceCore® is up to 250 times more likely to discover novel targets than gene-centric discovery tools. Envisagenics accelerates the development of highly specific therapeutics that modulate RNA splicing variants that drive pathogenesis of oncology, neurodegenerative, and metabolic disorders. Envisagenics partners with biopharmaceutical companies and academic institutions to advance their drug discovery capabilities. To date, Envisagenics has commercial partnerships with Biogen and the Lung Cancer Initiative at Johnson & Johnson. In addition, Envisagenics has its own internally developed RNA therapeutic programs.

MARKET & COMMERCIALIZATION STRATEGY

There are 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%. The company intends to expand the application of SpliceCore® to other indications through internal R&D programs and research collaborations with pharmaceutical partners and capture specific therapeutic markets as well.

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 6 million are novel. Envisagenics has developed several proprietary ML algorithms to identify novel splicing derived targets amenable for specific modalities, including RNA therapeutics, antibodies, and small molecules. The discoveries made by SpliceCore® are further qualified experimentally in cell lines, primary disease tissues, and validated using RNA therapeutics to confirm the modulation of any splicing event.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

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
2018	Winner of Johnson & Johnson AI for Drug Discovery QuickFire Challenge & became resident company at JLABS@NYC
2018	Winner of Innovate.AI challenge sponsored by M12 and Madrona Venture Group
2019	Launched in-house TNBC therapeutic program
2020	Research program agreement with the Lung Cancer Initiative at Johnson & Johnson
2021	Research collaboration agreement with Biogen

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015	Pre-seed	Investment from Accelerate Long Island and the Long Island Emerging Technologies Fund	$100k
2015	Grant	Phase I SBIR grant from NIGMS for the development of SpliceCore	$225k
2017	Seed Round	Investment from Third Kind Venture Capital, Cosine, Dynamk Capital, Dolby Family Ventures, NY Empire State Development, SV Angel	$2.35M
2018	Seed Round	Investment from M12 (formerly Microsoft Ventures) and Madrona Venture Group	$1M
2018	Grant	Phase II SBIR from NIGMS for continued development of SpliceCore	$1.5M
2019	Seed+ Round	Follow on investment from existing and new investors	
2019	Grant	Phase I SBIR grant from NCI for expansion of SpliceCore for IO therapeutic development	$300k
2020	Seed+ Round	Follow on investment from existing and new investors	$2M
2021	Seed+ Round	Investment from new investors	$525k

USE OF PROCEEDS

Envisagenics is raising a Series A round to scale application of the SpliceCore® software platform for target discovery in other indications with strong evidence of splicing dysregulation and to secure additional co-development partnerships 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 advisors: Omar Abdel-Wahab, M.D.; Sudhir Agrawal, D. Phil, FRSC; Adrian Krainer, Ph.D.; Kalpana Merchant, Ph.D.; Michael Zhang, Ph.D.; **Business advisors:** Michael Grissinger, M.B.A.; Alan Roemer, M.B.A, M.P.H., Ofer Nemirovsky, M.B.A.

INHERET, INC.

Web-based family history collection and decision support tool

David F. Keren, MD, CEO | dkeren@inheret.com | 866-464-3738 x701 | inheret.com

COMPANY OVERVIEW

INHERET®, Inc. offers risk assessment and decision support software to identify patients at increased risk for hereditary diseases and creates personalized risk reduction strategies. The web-based family history collection and interpretation tool addresses the time, accuracy, and interpretation of family history barriers faced by clinicians and streamlines the process into easy-to-understand reports with clear next steps for both healthcare providers and patients. INHERET is focused on hereditary cancers with plans to expand to hereditary cardiovascular, endocrine, autoimmune, and neuropsychiatric conditions.

MARKET & COMMERCIALIZATION STRATEGY

INHERET provides value across multiple market segments: Healthcare providers and as an Employee Benefit.

Healthcare Providers: INHERET recently commercialized and has a contract with a major health system. The Company is also in negotiations with two additional health systems, a national tele-genetics company, and several reference laboratories to provide INHERET as a service to their clients. **Employers:** Working through benefit brokers focused on large, self-insured clients, INHERET will be an innovative offering with the potential to save the employer millions of dollars in cancer treatment costs through prevention and early detection strategies. INHERET is entering the massive employee benefit market by approaching Benefit Brokers who are looking for innovative offerings for their employer clients. The Company has begun to test the market and the feedback has been "this is a very powerful tool" and "I suggest getting this in the hands of Brokers immediately." With no competition in this space, the Company intends to put immediate focus and resources into bringing this offering to market by Fall of 2021. Providers who manage the lives of the participating members will be contacted and offered licenses to facilitate genetic testing and the use of the decision support tools.

TECHNICAL & COMPETITIVE ADVANTAGE

There are multiple small companies that collect personal and family health history, but none offer the comprehensive list of guidelines nor automatic annual reviews against updates like INHERET.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Determined by the FDA to be a non-regulated product. US Patent pending and Foreign Filing NHRT 100-A and NHRT 100-B submitted. IP licensed from University of Michigan for InheRET1.0. Subsequent IP owned by INHERET. Name and Mark are registered.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
5/2018	Company Incorporated
5/2019	INHERET2.0 launched
12/2020	1ST Commercial Contract
12/2020	Full Patent Filed
6/2021	INHERET 3.0 launched, Foreign protections filed

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2018	Founder Investment	Founder Investments	$100K
2019 & 2020	Grants	STTR Phase I/STTR Phase II & MEDC Emerging Technologies Fund, PPP (forgiven)	$2.54M
2019-20	Conv. Debt	Angel Investor, Founder	$425K

USE OF PROCEEDS

INHERET is looking to raise a minimum of $1M and up to $2M, which may be matched with an SBIR Phase IIB grant in 2022. Funds will be used to expand the technical, sales, and marketing teams, enhance the product, increase strategic partnerships with laboratories, genetic counseling providers, and complimentary health system targets and move into the lucrative employer benefits market. With a full raise, INHERET will also add additional hereditary disease states (cardiovascular, endocrine, prenatal, ocular and neuropsychiatric conditions).

KEY TEAM MEMBERS

David Keren, MD – Founder and CEO with 22 years as the CEO and CLIA Director for Warde Medical Laboratory

Lynn McCain, MSHA (COO), has more than 25 years of finance and administration experience in Healthcare, IT, and Insurance

Amanda Cook, BA VP Product Marketing, has over 25 years of experience in sales, marketing, and medical insurance.

Kelly Hall, MBA (VP Business Development); 20 years in Oncology administration and 8 years in sales in the genetics market

Sofia Merajver, MD, Ph.D. (CSO); Expert in cancer genetics, prevention, and translational science; Serves on the National Comprehensive Cancer Network Committee devoted to creating guidelines for Cancer Risk Reduction.

Lee Schroeder, MD, Ph.D. (CAO); Expert in the interface of clinical informatics and health services research

Kara Milliron, MS, CGC (Genetics Specialist); Board-certified genetic counselor; 20+ years' experience counseling patients who are at risk for inherited susceptibility to cancer.

THANK YOU

TO THE 2021 NCI SBIR INVESTOR INITIATIVES REVIEWER COMMITTEE FOR YOUR HELP IN SCORING APPLICATIONS AND PARTICIPATING IN THE REVIEW CALLS. WE CANNOT RUN THIS PROGRAM WITHOUT YOU!

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David Heenan
Martin Heidecker
John Hopper
Charlotte Hubbert
Daniel Jacobs
Noel Jee
Curt Johnson
Avnish Kapoor
Jamie Kasuboski
Oliver Keown
Dave Kereiakes
Fran Kern
Andrew Koopman
Olga Koper
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