2018 NCI SBIR
INVESTOR INITIATIVES
COMPANY PROFILES

NATIONAL CANCER INSTITUTE
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Short Summary of Company

One-page Company Overview

7 Hills Pharma

Adhesion activators fo cancer immunotherapy
Location: Houston, TX
Stage: Pre-clinical development

7 Hills Pharma is a pharmaceutical company focused on developing immuno-modulatory drugs. The company's lead drug candidate, 7HP349, is a first-in-class small molecule agonist of integrin cell adhesion molecules. Development is focused on combination therapy to be used with checkpoint blockade, to treat patients with advanced melanoma who have failed single agent therapy. 7HP349 was designed to target integrin cell adhesion molecules α4β1 and αLβ2 on immune cells, as these integrins are clinically validated therapeutic targets (in that inhibitors of these integrins are immuno-suppressive). The company's approach is to activate these integrins to augment the immune response.

AAVogen

Novel gene therapeutic for cancer cachexia
Location: Rockville, MD
Stage: Pre-clinical development

Skeletal and cardiac muscle wasting contributes to the pathogenesis of several disease states including cancer. AVGN7 is a novel gene therapeutic that uses a non-pathogenic adeno-associated virus (AAV) to introduce Smad7 cDNA into muscle. This attenuates processes that normally inhibit muscle growth. By "inhibiting inhibition," muscle growth and function are significantly enhanced and muscle wasting is prevented. Moreover, AVGN7 only affects muscle and avoids off-target effects that have compromised competing technologies. AVGNF is a replacement gene therapeutic for limb-girdle muscular dystrophy 2i (LGMD2i). It replaces a mutated non-functioning FKRP gene with a fully functional gene. This restores muscle structure and function and prevents muscle degeneration.

ADT Pharmaceuticals

Novel anti-tumor inhibitors of Ras and PDE10
Location: Orange Beach, CA
Stage: Pre-clinical development

ADT Pharmaceuticals is focused on discovering novel molecules and methods for inhibiting the growth of Ras-driven tumors. As many as 30% of all human cancers harbor mutant RAS gene that encodes an abnormal Ras protein, which drives the malignant behavior of these tumors. Company technology includes a broad, novel proprietary compound class, comprising two distinct sub-classes that inhibit Ras-mediated signaling or autophagic flux. Several prospective drug development candidates have been identified with strong antitumor activity in preclinical models.

Bexion Pharmaceuticals

First-in-class anti-tumor agent
Location: Covington, KY
Stage: Phase I clinical trials

Bexion Pharmaceuticals, a clinical-stage biopharmaceutical company, is developing BXQ-350, a first in class agent composed of the multifunctional, lysosomal activator protein Saposin C and phosphatidylserine that has demonstrated antitumor effects in vitro and in vivo, particularly in glioma and pancreatic cancer models. BXQ-350's novel mechanism(s) of action, coupled with demonstrated activity in murine models of glioblastoma and pancreatic cancer, suggests the potential for BXQ-350 to fulfill an unmet need in cancer therapy. As such, these data suggest a new mechanism for treating glioblastoma multiforme (GBM) tumors resistant to traditional apoptosis inducing agents.

Cellerant Therapeutics

Antibody drug conjugate therapeutic
Location: San Carlos, CA
Stage: Pre-clinical development

Cellerant Therapeutics is a clinical-stage company developing innovative cell- and antibody-based immunotherapies for hematologic malignancies and other blood-related disorders. The company's lead product, CLT-008 (human Myeloid Progenitor Cells), is a universal cell therapy designed to reduce infection during neutropenia. Neutropenia is a severe side effect of many chemotherapy regimens, particularly for hematologic cancers such as acute myeloid leukemia (AML), and can also result from exposure to acute radiation. Cellerant Therapeutics Phase 2 clinical trial in AML patients showed that CLT-008 significantly reduced infections, use of antimicrobial drugs, and days in hospital.

CerRx

Novel platform for targeting cancer cells via dihydroceramide
Location: Lubbock, TX
Stage: Phase I & Phase II clinical trials

CerRx is a clinical-stage, oncology development company using a novel platform to target toxic intracellular waxes, called `ceramides' and specifically the dihydroceramide pathway. This ceramides-based technology induces high rates of cancer cell death by increasing and manipulating `ceramides' exclusively in cancer cells. Phase I trials of lead agent IV fenretinide have produced multiple sustained complete remissions, partial remissions, and other activity signals in difficult-to-treat cancers, including relapsed T-cell lymphomas, adenocarcinomas of the esophagus and colon, sarcoma, neuroblastoma and others.

Curon Biotech

Small molecules for cancer and heart disease
Location: Cleveland, OH
Stage: Pre-clinical development

Curon's product INV250 is a First in Class Novel Small Molecule to inhibit the cellular metabolism enzyme thioredoxin reductase. Thioredoxin reductase is a metabolic enzyme that appears to be crucial for the growth of a wide range of hematologic malignancies, including acute myelogenous leukemia (AML), a type of aggressive cancer with poor prognosis. INV250 is non-toxic, with differentiation-inducing compounds even in p53 mutant tumor cells. It can be used in combination with the immuno-oncology products like immune checkpoint antibodies and T cell based clinical therapies.

Five Eleven Pharma

PET-based Diagnostic Imaging Agent
Location: Philadelphia, PA
Stage: Phase I clinical trials

Five Eleven Pharma is developing a Positron Emission Tomography (PET)-based diagnostic imaging agent for bone metastases (common in prostate cancer) that does not require the use of a cyclotron produced radionuclide. PET-based imaging with the company's new agent (HBED-BP; P15-041) provides higher resolution images, shorter patient protocol times, and lower patient radiation exposure compared to current standard of care imaging (99mTc-MDP/planar imaging). Moreover, HBED-BP simplifies drug supply and delivery; the agent can be produced at the point of care with commercially available Ge-68/Ga-68 generators, and leverages bisphosphonate (BP) targeted imaging technology that physicians have over 40 years of experience using.

Inhibikase Therapeutics

Gleevec prodrug with superior safety
Location: Atlanta, GA
Stage: Pre-clinical development

Inhibikase Therapeutics is developing small molecule technologies to improve potency and suppress adverse events associated with Abelson kinase inhibitors. Using its proprietary medicinal chemistry design methods, the company developed an esterase-linked prodrug technology that completely suppresses non-hematological adverse events associated with oncology drugs in this class (e.g. Gleevec, Tasigna, etc.). Application of this technology to the anti-cancer agent Gleevec resulted in complete suppression of GI, fatigue and other adverse events that reduce treatment adherence; failure to adhere to Gleevec daily treatment results in treatment failure for up to 1/3 of Chronic Myelogenous Leukemia patients.

Kiromic

Microparticle-based consolidation therapy
Location: Houston, TX
Stage: Pre-clinical development

Using their artificial intelligence-powered disease-specific target identification technology (KAI-BLADE), Kiromic has discovered cancer-associated antigens that can be used to safely direct the immune system to obliterate tumor cells. An example of one such antigen is a peptide representing the T- and B-cell immuno-dominant region of sperm protein 17 (SP17). Kiromic's lead candidate, BSK02-ODP, is an orally-administered microparticle-based formulation ultimately intended as consolidation therapy in patients with triple-negative breast cancer or as first-line therapy for progressed disease. Kiromic's vaccine is capable of activating effector lymphocytes that elicit a vigorous and specific systemic attack against malignant cells expressing distinct surface antigens. Moreover, treatment with BSK02-ODP microparticles containing the SP17 antigen triggers a humoral as well as cellular immune response resulting in retardation of tumor growth.

NuvOx Pharma

Nanotechnology for targeted theranostics
Location: Tucson, AZ
Stage: Pre-clinical development; Phase II clinical trials

NuvOx is a clinical stage biopharma company developing nanotechnology for targeted theranostics for cancer detection, treatment and oxygen delivery. The company's core nanotechnology are microbubbles (MB) and emulsions based upon low molecular weight fluorocarbons ranging from perfluoropropane to perfluoropentane. NuvOx's MB product for pancreatic cancer has targeting ligands that bind to Thy-1 to detect early stage pancreatic cancer. NuvOx has also developed emulsions for oxygen delivery, which, when injected IV, flow through the lungs, pick up oxygen, then deliver oxygen to hypoxic tissues. In oncology, the drug increases tumor oxygen levels in order to make tumors more sensitive to radiation therapy, chemotherapy, and/or immunotherapy.

Oncoceutics

ONC201: Efficacy against H3 K27M mutant glioma
Location: Philadelphia, PA
Stage: Phase II clinical trials

Oncoceutics is a clinical-stage company engaged in the discovery and development of a class of novel compounds for oncology. The company's lead candidate is ONC201, an oral, small molecule that targets potent tumor suppressor pathways by antagonizing dopamine receptor D2 (DRD2), a member of the G-Protein Coupled Receptor (GPCR) superfamily. GPCRs are one of the most exploited targets in drug development, but have never been effectively targeted for oncology. ONC201 exhibits attractive drug-like chemical and physical characteristics: excellent chemical stability, high aqueous solubility at low pH, and high lipophilicity at physiological pH. These attributes enable oral bioavailability that achieves therapeutic concentrations and wide distribution throughout the body to target tissues, including brain, bone marrow and lymph nodes.

OncoImmune

Novel immunomodulatory biopharmaceuticals
Location: Gaithersburg, MD
Stage: Phase II clinical trials

OncoImmune's lead asset, a recombinant CD24/IgG1 fusion protein called CD24Fc, targets a novel checkpoint of disease development and efficiently suppresses diseases such as graft versus host disease (GVHD), multiple sclerosis, and rheumatoid arthritis in animal models. The development of CD24Fc is the company's primary focus and has received FDA approval for clinical testing. A Phase I safety trial in healthy volunteers has been completed, which established safety, PK, and evidence of in-human biological activity. The company has also completed enrollment of a Phase II clinical trial for the prevention of acute GVHD following myeloablative allogeneic hematopoietic stem cell transplant.

Organix

Novel small molecule Id-1 inhibitors
Location: Woburn, MA
Stage: Pre-clinical development

Metastasis of triple-negative breast cancer (TNBC) is a devastating and ultimately fatal condition. A critical barrier in the treatment of TNBC is that few drugs have been developed to specifically target invasion and metastasis. Inhibitor of DNA binding (Id-1) is a key transnational regulator that controls metastatic progression across multiple cancers, including TNBC. Targeting Id-1 results in inhibition of invasion, metastasis, and angiogenesis, and also improves the activity of first-line therapies (e.g. paclitaxel). Organix has developed novel small molecule Id-1 inhibitors that have been shown to inhibit metastatic progression, leading to prolonged survival in multiple mouse models of advanced TNBC.

Pandomedx

Novel AR variants targeted therapy for prostate cancer
Location: Davis, CA
Stage: Phase I & Phase II clinical trials

The androgen-AR signaling pathway is the most critical pathway that drives prostate cancer progression. AR-V7 lacks the androgen binding domain, thus is constitutively active independent of androgen binding, and induces the expression of androgen-induced genes and causes disease progression and treatment resistance. None of the hormonal therapeutic drugs approved by the FDA and used in clinic targets AR-V7. Pandomedx has identified Niclosamide (PDMX1001) as a potent inhibitor of AR-V7. The company is developing Niclosamide (PDMX1001) in combination with abiraterone for the treatment of advanced castration-resistant prostate cancer (CRPC).

Radiomedix

Radiotherapeutic agents targeting glucose-avid cancers
Location: Houston, TX
Stage: Phase I clinical trials

RadioMedix' proprietary 212Pb-AR-RMX (AlphaMedix) has a potential to advance targeted radionuclide therapy and deliver therapeutic alpha particle radiation dose to somatostatin receptor over-expressing cancer cells. It has the potential to circumvent resistance to currently available bet-emitter peptide receptor targeted therapy (PRRT). This new form of alpha-emitter therapy for neuroendocrine-tumors (NETs) is expected to provide lasting benefit that can extend a quality of life for a rapidly increasing number of NETs patients.

SignalRx Pharmaceuticals

Anti-cancer agents blocking pivotal IO-epigenetic-kinase nodes
Location: San Diego, CA
Stage: Pre-clinical development

SignalRx is a pioneer in designing and developing new anticancer drugs that simultaneously inhibit multiple key cancer targets for maximum efficacy with good safety profiles. The company's lead dual PI3K/BRD4 inhibitor, SF2523, is a first-in-class small molecule, providing for the first time a dual mechanism to inhibit the activity of the key cancer promoting transcription factor MYC (both c-MYC and MYCN) by enhancing its degradation (PI3K inhibition) and blocking MYC production via the inhibition of MYC transcription (BRD4 inhibition). MYC plays a key role in up to 70% of cancers but small molecule inhibitors of it have been elusive.

SUMO Biosciences

Small molecule for c-Myc & KRas-driven cancers
Location: Pasadena, CA
Stage: Pre-clinical development

SUMO Biosciences discover and develop small molecule drugs for targeted therapies for c-Myc and KRas-driven cancers, as well as cancer stem cells (CSCs), with a focus on colorectal cancers. The company discovered a mechanism to inhibit the activating enzymes for ubiquitin-like modifications and identified a series of selective, potent inhibitors. The knowledge from the crystal structure of the enzyme-inhibitor complex and over 600 analogs made so far provides a framework for development of molecules targeting E1 enzymes for several ubiquitin-like modifiers to inhibit KRas, c-Myc and CSCs. Their current lead compounds reduce c-Myc levels in c-Myc-dependent cancer cell lines and xenograft models, eradicate CSC population and self-renewal, and inhibit tumor growth in colorectal cancer xenograft and patient-derived xenograft mouse models.

Viewpoint Molecular Targeting

Systemic targeted radiopharmaceutical therapy for cancer
Location: Coralville, IA
Stage: Pre-clinical development

Viewpoint's receptor-targeted radiotherapy for metastatic melanoma (VMT01) is an injectable, tumor-specific radiopharmaceutical that delivers killing alpha-radiation precisely to melanoma tumors via a small peptide molecule that binds to a cell surface receptor that is present on melanoma tumors but not normal cells. Any excess VMT01 is eliminated quickly via the bladder (minimal side effects). The company's companion diagnostic dramatically improves patient selection and personalized care by predicting who will respond and precisely how much of the therapeutic to administer. The companion diagnostic also represents an imaging asset with significant revenue potential.

BioFluidica

Scalable liquid biopsy solution
Location: San Diego, CA
Stage: Phase I clinical trials

BioFluidica, Inc., a diagnostic company that has developed a ground-breaking platform (The Liquid Scan) for vastly improved cancer disease detection from whole blood samples. The technology allows the analysis of extremely rare blood disease biomarkers with unprecedented accuracy and recovery including circulating tumor cells (CTC), circulating leukemic cells (CLC), cell free DNA (cfDNA) and exosomes. The platform has been clinically validated on nine solid tumor cancers, including lung, prostate, bladder, ovarian, breast, colorectal and pancreatic as well as blood born cancers such as Acute Myeloid Leukemia (AML) and Multiple Myeloma (MM) for Minimal Residual Disease (MRD) analysis.

DiaCarta

Radiotoxicity measurement system
Location: Richmond, CA
Stage: Non-clinical technology in testing stage

The QuantiDNA™ RadTox System is a unique, patented technology that provides a real-time assessment of acute and ongoing chronic radiation toxicity using cell-free DNA from a drop of blood. RadTox will be inexpensive to the end user and to the healthcare system, can be employed on a needle-stick blood drop (eliminating the usual need for tissue biopsy), and will enable minimally invasive blood sample collection longitudinally over time. The technique is expected to provide accurate risk assessment in a central laboratory setting within the first days after irradiation and to continue to supply valuable information on ongoing radiation toxicity for at least weeks after treatment.

ImCare

Diagnostic biomarkers
Location: Doylestown, PA
Stage: Non-clinical technology in full development/testing stage

ImCare's main product, Hepatodetect®, is a diagnostic immunoassay based on a novel biomarker called LC-SPIK, a protein that is expressed uniquely in patients with liver cancer. Based on the company's discovery, their immunoassay has been developed as a sandwich ELISA, which is a laboratory-test conducted using blood sera. A key component in the technology is a monoclonal antibody (IM-CAXX) that is able to specifically bind to the LC-SPIK biomarker. Clinical studies of the ImCare diagnostic system demonstrated a high level of sensitivity and specificity for detecting the liver disease hepatocellular carcinoma (HCC). Moreover, the test can distinguish sera of HCC subjects from those with other liver diseases including chronic hepatitis B/C, liver cirrhosis, as well as those with pancreatitis and healthy test subjects.

KIYATEC

Patient-derived 3D co-cultured micro-tumors
Location: Greenville, SC
Stage: Pivotal trials; Commercially available

KIYATEC's mission is to change the future of cancer care by accurately predicting patient-specific response and non-response before treatment begins. The company utilizes the patient's own living tumor cells to create functional 3D models to test a battery of cancer therapies in their CLIA certified laboratories. KIYATEC's goal is to enable physicians to isolate effective treatments for their patients as quickly as possible - making true personalized medicine a reality.

Medical Discovery Partners

Accurate cancer tissue testing
Location: Sharon, MA
Stage: Ready for commercial development and expanding product line

Medical Discovery Partners' (MDP) new products will be the first system of standardized commercial testing controls and calibrators for over 100 of the most frequently ordered clinical immunohistochemical tests. Immunohistochemical tests detect specific proteins in tissue samples that are removed during surgery. MDP already developed the first products, clinically tested them in customer laboratories, and established cGMP manufacturing.

Morgan and Mendel Genomics

Clinical test technology
Location: New York, NY
Stage: Pre-clinical development

Morgan and Mendel Genomics (MMG) is a start-up genomics technology company that creates and commercializes simple and accurate genetic tests for patient diagnosis and risk assessment using low-cost, novel technologies. The company's flow variant assay (FVA) technology is an innovative, simple, rapid and inexpensive clinical test that will identify with high accuracy those at high risk for breast cancers and other cancers, as well as those with cancer who may be responsive to certain classes of drugs. The novel FVA method measures the response of human blood cells to radiomimetic chemicals that damage DNA in the key double strand break repair (DSB) cyclin-checkpoint and mismatch repair pathways. Currently, there is no comparable test for this type of analysis. The test is faster and more accurate for identifying genetic risks than gene panel sequencing, the current standard.

nanoView Diagnostics

Analytical tools for exosome detection
Location: Boston, MA
Stage: Non-clinical technology in full development/testing stage;
Pre-clinical development

The Extracellular Vesicle (EV) field is rapidly growing. EV-based liquid biopsies are being investigated for early detection, metastasis site prediction, and treatment monitoring. NanoView Diagnostics' ExoView platform is an EV characterization platform that collapses 3 steps into a single high-throughput process by removing the need for purification and combining single EV analysis with specific analyte capture. Furthermore, the ExoView platform allows combined proteomic and nucleic acid co-localization on single EVs. The ExoView platform will expedite EV biomarker research, reveal new data around EV heterogeneity and make-up, and facilitate translation of EV-based diagnostics.

OncoTAb

Targeted radionuclide therapy
Location: Charlotte, NC
Stage: Pre-clinical development

OncoTAb is developing a targeted radionuclide therapy using its patented tumor-specific antibody (TAB004) for Triple Negative Breast Cancers (TNBCs). The TAB004 has been fully humanized (hTAB004) and the company has successfully demonstrated exquisite targeting and treatment with Actinium-225 labeled hTAB004. All treated animals showed regression of tumors and survival. This program is a big step towards fulfilling OncoTAb's vision of offering a continuum of products targeting breast cancer.

Tymora Analytical Operations

Phosphoprotein liquid biopsy biomarkers

Location: West Lafayette, IN

Stage: Non-clinical technology in full development/testing stage
Pre-clinical development

Tymora Analytical Operations has developed a highly efficient method for isolation of extracellular vesicles (EVs) to enable the discovery of cancer-specific phosphoproteins and other molecules in plasma, urine and saliva. EVs are shed by cells into virtually every biological fluid, and provide a good representation of the parent cells. EV-based disease markers can also be identified well before the onset of symptoms or physiological detection of a cancer tumor. Using their new method, the company has been able to identify hundreds of phosphoproteins from EVs from only 1mL of plasma or 10mL of urine, and generate an initial list of the most promising phosphoprotein markers present in bladder cancer EVs, which will enable differentiation of low-grade and high-grade bladder cancer patients from healthy individuals.

American BioOptics

Point-of-care cancer risk screening system
Location: Chicago, IL
Stage: Feasibility/pilot clinical trials

American BioOptics (ABO) is revolutionizing cancer screening with the introduction of its InPointTM System - the first point-of-care, personalized cancer risk assessment tool to provide fast and accurate identification of high-risk patients with pre-cancerous adenomatous adenomas (AA) regardless of their location in the colon. The technology consists of a bedside cart containing a spectrometer, filters, calibrator and computer. A fiber optic cable with a disposable probe tip is introduced into the distal part of the rectum. The screening test lasts roughly 10 minutes and is highly accurate for identification of advanced adenomas. The system provides a cancer risk assessment - high risk patients should be further evaluated by colonoscopy.

CairnSurgical

Breast cancer locator system
Location: Lebanon, NH
Stage: Feasibility/pilot clinical trials

CairnSurgical is developing the Breast Cancer Locator (BCL) system for use in Breast Conserving Surgery (BCS) procedures, also known as lumpectomy procedures. The BCL is an additive manufacturing device that matches the breast surface when the patient is in the supine (and surgical) position and allows the surgeon to place guidance cues on and within the breast at the start of a BCS procedure (i.e., before incision) for accurately localizing and guiding tumor resection during the procedure. The BCL is derived from patient MRI data, using company proprietary software, and it is constructed pre-operatively, sterilized and provided to the surgeon prior to procedure. The BCL is intended to improve both procedure outcomes and procedure economics.

Corvida

Closed system transfer device for chemotherapy
Location: Coralville, IA
Stage: Commercially available

Corvida's innovative Halo Closed System Transfer Device improves safety of preparing and administering chemotherapy. The device is comprised of a patented line of disposable medical devices that attach to standard vials, syringes, and IV sets to prevent spills, vapor leaks, and needle-sticks. The device is used during the drug preparation phase in the pharmacy compounding area as well as at the bedside during drug delivery. Corvida's Halo device is safe, leak proof, and easy to use.

IGI Technologies

Interventional radiology fusion system
Location: College Park, MD
Stage: In clinical trials

IGI Technologies' product, IGT Fusion, is a fusion system that reveals non-contrast CT-invisible tumors in real time during an interventional radiology (IR) procedure, such as a biopsy or an ablation. Currently, no technology exists that assists with guiding an interventional device to difficult-to-visualize masses without the use of manual steps or external tracking technology. IGI's technology achieves this thorough accurate, autonomous real-time registration and fusion of existing diagnostic images (MRI or PET) that show the tumor with intra-procedural that CT does not. Diagnostic scans play an important role in interventional radiology, including the decision to perform a procedure. IGI's proposed technology will enable using them directly for instrument guidance.

Intelligent Optical Systems

Sensor integrated biopsy device
Location: Torrance, CA
Stage: Pre-clinical development

Intelligent Optical Systems, Inc. (IOS) is developing a sensor integrated biopsy device for in-situ and real-time tissue analysis. The sensor integrated biopsy (SIB) needle system enables biopsy teams to measure local tissue metabolism in real time during biopsy procedures, which helps the surgeon place the needle in regions of maximum tumor cellularity within the biopsied region, and guides precise excision of tumor masses. The SIB device is completely compatible with current practice, including imaging systems, which will greatly facilitate its adoption by professionals.

Otomagnetics

Drug delivery technology using magnetic fields
Location: Rockville, MD
Stage: Pre-clinical development

Otomagnetics' patented technology uses magnetic fields to non-invasively deliver therapy to hard-to-reach targets in the body. The technology works like a syringe, but the needle has been replaced by magnetic forces acting on bio-compatible magnetic nano-particles that transports them through tissue barriers to targets that are not reached by current medical care, or that would otherwise require an invasive surgery to reach. The particles can carry drug, protein, or gene therapy. While the magnetic platform has utility for multiple diseases targets, Otomagnetics is currently focusing on delivery to the cochlea to save hearing in pediatric cancer patients receiving platin chemotherapies.

Veriskin

Non-invasive hand-held device for skin cancer detection
Location: San Diego, CA
Stage: Feasibility/pilot clinical trials

The VeriSkin device is a proprietary, non-invasive, low-cost, hand-held unit that aids a non-expert user to rapidly (~ 2 min) and objectively determine whether a suspect skin lesion is cancerous, eliminating unneeded escalation of care and biopsies. The technology works by detecting and analyzing force-induced hemodynamic differences between the normal and malignant skin lesions. VeriSkin has developed a proprietary AI algorithm and protocols to achieve unparalleled screening accuracy in differentiating skin cancer from a variety of benign conditions. The simple-to-use device is intended to be used as a decision support tool during routine physical examines by non-specialists (e.g. nurse practitioners or primary care physicians) and eventually, consumers.

Care Progress

Nurse triage/patient engagement software
Location: Bethesda, MD
Stage: Commercially available

Care Progress' key product is CarePrompter, a cloud-based, nurse triage/patient engagement software platform to improve symptom management of ambulatory patients regardless of their disease state(s). In addition, Care Progress is now building the Caregiver Buddy software technology to assist caregivers to improve care coordination and communication with providers and patients. Caregiver Buddy also seeks to improve Caregiver quality of life and reduce stress. Caregivers download the Caregiver Buddy app on their Smartphones and tablets to directly communicate with clinicians, review care plans, engage in conversations with other caregivers, and help assess symptoms on behalf of patients. CarePrompter and Caregiver Buddy can work as companion technologies or independently.

7 Hills Pharma / Immuno-modulatory Drugs

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Company Overview (Clinical Impact and Value Proposition)

7 Hills Pharma is an immunotherapy company focused on the development of novel tumor-targeting cell adhesion agents for the treatment of cancer and infectious diseases. The lead compound, 7HP349, is a first-in-concept integrin activator that improves solid tumor immune surveillance as a single agent, in addition to having synergistic activity with other immunotherapies. Approximately 60-80% of patients with advanced solid tumors do not respond to checkpoint blockade therapies like aPD(L)-1 inhibitors. Many of the promising intratumoral therapies may be practically useful in only 10-15% of patients with accessible lesions. Safe systemic therapies that can selectively drive tumor inflammation, and reverse drug resistance in a community practice setting are critically needed. We are currently raising our first institutional round of financing of ~$10-15M to activate the 7HP349 Investigational New Drug Application, establish clinical proof of concept in refractory cancer, and complete a licensing transaction within 2 to 3 years, providing a potential early exit. We have an experienced leadership team that has developed products from molecule to market experience, including former presidents of ASCO and AACR.

Market and Commercialization Strategy

The global immune checkpoint inhibitor market is expected to grow from ~$16B in 2018 to $44B in 2024. As the solid tumor indications for aPD(L)-1 drug increase, the incidence and prevalence of the resistant population will commensurately increase. 7HP349 could be simple, potentially universal, and accessible means to reverse immune checkpoint inhibitor resistance. Our licensing business model is based clearly defined developmental and transactional milestones set by 3 of the market leaders. Establishing Phase I safety or pilot efficacy of 7HP349 could be basis of a licensing transaction of >$100 mm upfront, milestone and royalty payments. Interestingly, contemporary intratumoral therapies, which may only address 10 to 15% of accessible resistant patients, have commanded upfront payments of $200 to $554 mm based on phase I milestones.

Technical & Competitive Advantage

7HP349 provides for a first-in-class strategy to synergistically combine with anti-PD-1/PD-L1 or anti-CTLA-4 checkpoint inhibitors. This could improve efficacy and access of existing checkpoint inhibitors, as well as decrease overall treatment costs. Existing options may be ineffective in many solid tumor patients, and ~80% of patients receive no benefit from monotherapy. The competition to convert resistant, non-immunogenic cancers, aka cold tumors to hot, is hypercompetitive with >150 approaches which notably include intratumoral STING and TLR agonists, and oncolytic therapies. Even with image guided instillation, only 10-15% of patients have lesions amenable to such therapies and must be deployed in specialized academic centers. As a systemic therapy that can drive tumor infiltration using an essential mechanism of leukocyte trafficking, 7HP349 could be more broadly used in a PD(L)-1 refractory patients in the community practices setting. Moreover, as an oral small molecule with a relatively short half-life compared to biologics, 7HP349 may have substantive cost and safety advantages that could liberate patients from their infusion chairs.

Regulatory Strategy & Intellectual Property

We anticipate activation of an IND and initiation of a Phase I study within 9 to 12 months in U.S. 7HP349 has received an Orphan Drug Designation and has the potential for accelerated approval and breakthrough status. As 7HP349 improves a critical step in T cell homing to tumors, tissue agonistic biomarker driven pan-solid tumor labeling is possible. We have filed 5 patent applications in 2011, 2015 and 2018 in major PCT countries. Composition of matter, methods to treat, and methods to manufacture for all fields of use outside cardiovascular disease has been licensed by 7 Hills Pharma from the Texas Heart Institute. We plan to protect IP by monitoring the patent landscape of relevant technologies and filing patent applications in the US and abroad.

Key Milestones

Raise 1st institutional round of financing of ~$10 to 15 mm	Q4 2018
7HP349 Investigation New Drug Application Submission and first patient dosed	Q2 2019
License 7HP349 and/or platform to a developmental partner after establishing safety and selecting Phase II dose	Q4 2020

Capitalization History

2016-	Grants	NIH/NCI & NHLBI	$2.6M
2017	Seed Round	Founder & Angel Investors	$3.8M

Use of Proceeds

We are currently raising ~$10 to 15M to file a 7HP349 IND application for solid tumors to establish safety and pilot efficacy, and to complete a licensing transaction. The Phase I clinical trial will be done at University of Chicago and M.D. Anderson Cancer Center.

Key Team Members

Upendra Marathi, Ph.D., M.B.A. - CEO

Dr. Marathi has experience in founding several biotechnology companies, as well as raising over $50M in equity funding.

Lionel Lewis, M.D. - CMO

Dr. Lewis is an experienced oncologist that has led numerous first-in-man studies including the combination of Opdivo and Keytruda.

Joseph Bailes, M.D. - Director & Advisor

Dr. Bailes is an investor and oncologist. He served as President of ASCO and Executive VP of Clinical Affairs for US Oncology.

AAVogen / Novel Gene Therapeutic for Cancer Cachexia

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Company Overview (Clinical Impact and Value Proposition)

AAVogen is a startup biotech company specializing in gene therapeutics for muscle wasting diseases. The lead asset, AVGN7, uses a non-pathogenic adeno-associated virus (AAV) to introduce Smad7 cDNA into muscle. This attenuates processes that normally inhibit muscle growth. By "inhibiting inhibition", muscle mass and function are greatly enhanced and muscle wasting (cancer cachexia) is prevented. Moreover, AVGN7 only affects muscle and avoids off-target effects that have compromised competing technologies. AAVogen has retained former FDA Medical Officer Dr. Mark Thornton, MD/MPH/PhD and Biologics Consulting to manage clinical development. We are also partnering with the Raymond G. Perelman Center for Cellular and Molecular Therapeutics and the Clinical Vector Core at the Children's Hospital of Philadelphia. This core has over 20 years' manufacturing experience that has been applied safely across an excess of 150 administrations.

Market and Commercialization Strategy

Modeling estimates predict that 1.5% of patients would try AVGN7 in year 1 and that the adoption rate would grow by 5% annually, generating $23.7B over 5 years if multiple markets are exploited simultaneously. Note that cancer cachexia represents 33% of this overall market. AAVogen's marketing plan is strengthened by AVGN7's potential to be adopted as a "backbone combo". In fact, AAVogen is developing combinatorial approaches for different muscular dystrophies that combine AVGN7 with replacement gene therapeutics that are already in clinical trials. Similar strategies will also exploit developed markets for well-established cancer therapeutics.

Technical & Competitive Advantage

AVGN7 is muscle-specific. This is due to the use of a muscle-specific gene promoter and an AAV vector with high tropism for striated muscle. Thus, AVGN7 cannot create the very serious off-target problems (internal bleeding) that have already limited development of competing technologies. Moreover, the payload gene, smad7 cDNA, codes for an intracellular protein with no extracellular target, further enhancing product safety. Such specificity suggests that AVGN7 would work well in combination with other treatments that, for example, target tumors or stabilize muscle structure. Our preclinical studies indicate that AVGN7 works quickly and in different and possibly a broad array of cancer types. It also targets biochemical pathways implicated in a vast array of muscle wasting diseases. Market potential for AVGN7 is, therefore, far greater than that for competing products including those that attenuate myostatin or ActRIIb receptors, those that can only be used with intramuscular injections or those with limited disease indication targets (SARMs).

Regulatory Strategy & Intellectual Property

An international patent covering 7 different composition of matter claims for AAV-based gene therapeutics carrying smad7 cDNA as well as several utility/method claims for different muscle disease states is under review. It was filed by Washington State University (WSU) and Dr. Rodgers, although AAVogen has since obtained an exclusive license for AVGN7 that covers all indications and all geographies. Additional patents for related and novel IP are also being pursued.

Key Milestones

Completed pre/pre- & pre-IND meetings with FDA for AVGN7	Q2 2018
Acquire 1st tranche of Series-A financing for $10M	Q4 2018
Complete GLP/toxicology studies for AVGN7	Q1 2020
File IND application for AVGN7 with the FDA	Q3 2020

Capitalization History

09/2015	Deferment Grant	Kilpatrick Townsend & Stockton, LLP	$25k
05/2016	Grant	Commercialization Gap Fund (Washington State)	$50k
09/2017	Grant	NIH/NCI	$2M

Use of Proceeds

Series-A financing will support CMC design and scale-up, manufacturing for all clinical trials, IND filing and completion of phase 1 clinical trials.

Key Team Members

Buel "Dan" Rodgers, Ph.D. - Founder & CEO

Dr. Rodgers is the founder and former Director of the Washington Center for Muscle Biology and Professor of Molecular Biosciences at Washington State University. He is also the co-discoverer of AVGN7 with 22 years' experience in muscle development research.

Heather Webb Hsu, Ph.D. - CBO

Dr. Hsu has 18 years' experience as a research scientist and Director of business development, preclinical development and safety. She formerly worked for Tularik, Scios, Arête Therapeutics, Calistoga Pharmaceuticals and Gilead Sciences and has authored or co-authored 17 patents.

Peter Korytko, Ph.D., M.B.A. - Director of Preclinical Development

Dr. Korytko has 18 years' industry experience with drug discovery at Pfizer and Amgen. Peter has translated 25 INDs to Phase 1, 11 INDs to Phase 2, 2 bioequivalence/supplements and managed 200+ GLP/toxicology studies.

ADT Pharmaceuticals / Novel Anti-tumor Inhibitors of Ras and PDE10

Michael R. Boyd | mboyd@adtpharma.com | 251-786-4527

Company Overview (Clinical Impact and Value Proposition)

ADT Pharmaceuticals is focused on discovering, developing and securing patent protection for novel molecules that inhibit constitutively activated Ras- or Wnt-mediated signaling pathways that drive the growth of many human cancers. ADT's technology currently comprises a broad, novel proprietary small-molecule class, encompassing at least two distinct mechanistic sub-classes that share a common indene structural core; one subclass blocks Ras-effector interactions to suppress simultaneously MAPK and Akt signaling, thereby preferentially inhibiting the growth of tumor cells harboring hyperactive Ras relative to cells with normal Ras; the other subclass inhibits phosphodiesterase 10A (PDE10), which activates cGMP/PKG signaling to induce β-catenin degradation, thereby suppressing Wnt signaling and tumor cell growth.

Market and Commercialization Strategy

ADT aims to license exclusively all or part(s) of its IP to established firm(s) capable and committed to development of this technology through elucidation of optimal drug development candidate(s), IND-qualifying preclinical R&D, clinical investigations, regulatory approvals and commercialization. Successful development of effective and safe therapies based on ADT's technology will address urgent medical needs and large commercial markets potentially exceeding $1B revenues/yr.

Technical & Competitive Advantage

ADT's compounds have a distinctive constellation of attributes including: 1) non-peptidic, stable, small-molecules of modest MW, 2) physicochemical properties favorable for drug development, 3) readily synthesized and modified, 4) pharmaceutical formulations amenable to cost-efficient, large-scale manufacture, 5) in vivo antitumor activity in preclinical models, 6) diverse active analogs and prodrug formulations, substantially mitigating risks for successful drug development, and 7) strong intellectual property positioning.

Regulatory Strategy & Intellectual Property

Regulatory matters related to IND and NDA filings preferably will be the responsibility of commercial licensee(s) to ADT's technology. ADT's IP is encompassed in the multiple patent applications and patents issued to date. We also have other US and foreign national-phase patent applications based on the PCT's under prosecution.

Key Milestones

Three SBIR Ph1 grants awarded to ADT Pharmaceuticals by the US National Cancer Institute, NIH	2015-17
Identify prospective licensee(s)/investor(s); apply for 4th SBIR Ph1 grant and 1st SBIR Ph2 grant	2017-18
First two US patents issued to ADT Pharmaceuticals, Jan. 1, 2018 and Apr. 3, 2018	2018
Engage licensee(s) and/or investor(s) for ADT technology; continue to build and broaden ADT's IP base	2018

Capitalization History

2014-18	Personal Funds	Co-founder	$650k
2015	Grant	NIH/NCI	$225k
2015	Loan	BB&T	$200k
2016	Grant	NIH/NCI	$300k
2017	Grant	NIH/NCI	$300k

Use of Proceeds

Licensee and/or investor funding of $500,000/yr for 4 yrs would support ADT's continuing R&D and IP capture activities to build and broaden its patent portfolio, further securing an IP base from which valuable commercial product(s) can be developed. For ADT to pursue alone an accelerated, IND-enabling preclinical development program toward at least one IND application in the next 3-4 years, an estimated additional $6M would be needed. ADT alternatively would consider a collaborative consulting and R&D funding opportunity whereby financial support to ADT from an established commercial entity would convey to the entity a ROFN for exclusive license to ADT's technology.

Key Team Members

Michael R. Boyd, M.D., Ph.D. - ADT Co-founder & President

Dr. Boyd has many years of experience in anticancer drug discovery R & D, including three decades at the National Cancer Institute in a variety of senior research and executive administrative positions where he led more than 30 successful IND applications; he was the founding director of the University of South Alabama Mitchell Cancer Institute (USAMCI) in Mobile, AL, in which role he served until 2013, followed by his retirement from academia in 2014, when he co-founded ADT, where he now serves full-time.

Gary A. Piazza, Ph.D. - ADT Co-founder, Consultant, & Chief Scientist

Dr. Piazza is Professor of Oncologic Sciences at the USAMCI; he is a pioneer in the anticancer pharmacology of indene compounds; he has broad experience in drug R&D both in industry and academia; his academic research, which has critically supported the validation of PDE10 as an anticancer target, has received continuous support from NIH for more than 20 years.

Joshua Canzoneri, Ph.D. - SBIR Principal Investigator

Dr. Canzoneri is an experienced biochemical pharmacologist with research focus on Ras and PDE10 inhibition; he is employed full-time as the ADT PI for the NIH-SBIR grants awarded to ADT.

Bexion Pharmaceuticals / First-in-Class Anti-Tumor Agent

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Company Overview (Clinical Impact and Value Proposition)

Bexion Pharmaceuticals, a clinical-stage biopharmaceutical company, is developing BXQ-350 (SapC-DOPS), a first in class agent composed of the multifunctional, lysosomal activator protein Saposin C and phosphatidylserine that has demonstrated antitumor effects in vitro and in vivo, particularly in glioma and pancreatic cancer models. Bexion has completed a multi-site first-in-human, Phase 1a study of BXQ-350 for solid tumors and gliomas, and is currently enrolling patients in an expansion phase. BXQ-350 has a tolerable safety profile with no significant DLT at the highest planned dose, supporting continued monotherapy dose expansion. The FDA has granted Bexion Orphan Drug status for Saposin C, the active ingredient in its proprietary formulation BXQ-350 for the potential treatment of glioblastoma multiforme (GBM). A Pediatric Phase I and Adult Phase II Trials are being planned for late 2018.

Market and Commercialization Strategy

According to the American Cancer Society, in the U.S. alone, an estimated 1.66 million people would be diagnosed with cancer in 2015 and approximately 590,000 will die of the disease. The incidence of malignant glioma has been estimated at 20,000 cases per year. Glioblastoma multiforme (GBM), also known as Grade 4 glioma, has one of the worst prognosis of any cancer, with an average survival of 12 months. The five-year survival rate of GBM is less than 3% and has remained unchanged over the past 30 years. In addition to GBM, we are also evaluating BXQ-350 for other rare solid tumors, which may also qualify for orphan drug exclusivity. According to the NCI, in 2017, approx.. 15,270 children and adolescents ages 0-19 years of age will be diagnosed with cancer and 1,790 will die of the disease in the U.S. In 2018, we plan to conduct clinical studies for pediatric patients, including rare tumor types.

Technical & Competitive Advantage

Current radio- and chemotherapies have low therapeutic indices, incur severe side effects, and display neurotoxicity (in brain tumors). BXQ-350 is expected to avoid debilitating side effects as its mechanism of action is significantly different. The proteolipids recognize aberrantly occurring phosphatidylserine (PS) domains on the surfaces of cancer cells, followed by specific killing via activation of the ceramide pathway. The efficient targeting of brain tumors by BXQ-350 was confirmed in a recent MRI study, in which brain tumors were visualized using paramagnetic Gd-DTPA-BSA/SapC-DOPS vesicles. PS is an anionic lipid normally residing in the inner leaflet of the plasma membrane. It becomes exposed on cancer cells and neovascular cells due, in part, to oxidative stress induced by hypoxia, acidity, and conventional chemo- and radiotherapy. PS is critically involved in immunosuppression. Evidence suggests that PS is potentially a universal tumor target, to which BXQ-350 is directed. Alternative PS-targeted therapeutics have been proposed, but none can bypass the blood brain barrier. BXQ-350's unique targeting and mechanism of action are important “first-in-class” differentiation points against any competitor.

Regulatory Strategy & Intellectual Property

Our patents and applications have been exclusively licensed from Cincinnati Children's Hospital Medical Center, except for the composition in China. The Saposin C-DOPS composition is covered as an anti-tumor agent in two U.S. patents. Methods of treating cancer and delivering agents are also covered.

Key Milestones

Complete Adult Phase I Expansion in GBM and Solid Tumors	Q4 2018
Initiate and Complete Pediatric Phase I in GBM and Solid Tumors	2018-19
Initiate Adult Phase II in GBM	2018

Capitalization History

2006-15	Grants	SBIR, Commonwealth of KY	$6M
2009	Series A	Private Investors	$2.6M
2011-17	Convertible Notes	Private Investors (Converted to equity)	$20.3M
2018	Series B	Private Investors (60% complete)	$15M

Use of Proceeds

Funding will be used for the completion of the expansion Phase I Adult Trial, initiation of a Phase II GBM combo Adult Trial and a Phase I Pediatric Solid Tumor Trial, in addition to drug manufacturing to support the trials.

Key Team Members

Ray Takigiku, Ph.D. - CEO

Dr. Takigiku was part of P&G Pharmaceuticals’ leadership team that developed and marketed the blockbuster osteoporosis drug Actonel and the market leader for ulcerative colitis, Asacol. He was also interim Co-Director of the Genome Research Institute (now UC Metabolic Disease Institute) at University of Cincinnati where he led development of an academic center for drug discovery.

Kevin Xu, M.D., Ph.D., M.B.A. - Vice President

Dr. Xu’s Ph.D. training is in tumor biology from the Mayo Graduate School, and he has experience in healthcare and pharmaceuticals.

Margaret van Gilse, M.B.A. - Vice President of Business Development

Ms. van Gilse has over 25 years of business development, strategic planning, government relations, communications and fund raising experience with entrepreneurial companies in multiple healthcare segments.

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Company Overview (Clinical Impact and Value Proposition)

Cellerant Therapeutics, Inc. is a clinical-stage company developing innovative cell- and antibody-based immunotherapies for hematologic malignancies and other blood-related disorders. Our expertise in hematopoietic stem cell biology has resulted in multiple novel cell-based and antibody-drug conjugate (ADC) product candidates. Our lead product, romyelocel-L (human Myeloid Progenitor Cells), is a universal cell therapy designed to prevent bacterial and fungal infection during prolonged neutropenia. We have completed a randomized controlled Phase 2 clinical trial in acute myeloid leukemia (AML) patients which showed that romyelocel-L significantly reduced infections, days in hospital and use of antimicrobial drugs. We have two ADC product candidates in preclinical development, CLT030 and CSC012-D212 ADC, to treat AML.

Market and Commercialization Strategy

AML is the most common leukemia affecting adults with approx. 21,000 new cases in the U.S. annually. AML is also distinctly a disease of the elderly. The current therapeutic approach to AML—cytotoxic chemotherapy—is non-specific, does not recognize disease heterogeneity, and has not changed substantially in more than 30 years. AML represents an unmet medical need as relapse rates are high (70-80%) and the 5-year overall survival rate of AML patients over 65 years of age is only 5%. Thus, there is a need for therapies that are more specific, less systemically toxic, tolerable in the elderly, and can target the leukemic stem cells (LSC) that is thought to be responsible for the high rate of relapse. Our CSC012-D212 ADC would address this unmet need by targeting LSC, potentially expanding the range of patients that could be treated and providing a durable response.

Technical & Competitive Advantage

Drug developers have focused on several pathways that have been implicated in AML, including FLT3, Plk, IDH2, IL-3R, CD123 and CD33. Each program has had a certain degree of success in terms of complete responses and improving median overall survival, but little progress has been made in reducing relapse rates and inducing more durable responses in patients. Our CSC012-D212 ADC targets IL1RAP and is designed to eliminate leukemic stem cells, offering the potential of reducing disease progression and providing durable responses. IL1RAP is widely expressed on LSC in patients across all different types of AML, but IL1RAP has little to no expression in normal hematopoietic stem (HSCs) and progenitor cells, while targets such as CD33 or CD123 are expressed in normal HSCs thereby resulting in a safety liability. The use of a DNA binding payload in CSC012-D212 ADC is critical since such a payload enables the killing of both proliferative and quiescent cells. Standard AML chemotherapy cannot kill quiescent cells and LSC often escape treatment by remaining quiescent. Thus, CSC012-D212 ADC is a strong product candidate for the treatment of AML.

Regulatory Strategy & Intellectual Property

Our CSC012-D212 ADC is protected by two issued and one pending patents. The patents and applications have broad antibody claims targeting IL1AP and methods of treating and diagnosing cancer using the antibodies. We also have an issued patent claiming a novel chemical composition (the cytotoxic payload used in CSC012-D212 ADC) and the use of the composition in treating AML.

Key Milestones

Completion of Phase 2 trial for romyelocel-L cell therapy and EOP2 meeting with FDA	Q2 2018
File IND and initiate clinical trial for CLT030 antibody-drug conjugate	Q1 2019
Initiation of Phase 3 trial for romyelocel-L cell therapy	Q3 2019

Capitalization History

2008-12	Series AA and BB	HNW Individuals (Preferred Stock)	$15.7M
2010-18	Contract	BARDA	$166M
2014-17	Convertible Debt	HNW Individuals	$7.7M
2016	Grant	NIH	$1.5M
2017	Grant	Calif Institute for Regenerative Medicine	$6.8M

Use of Proceeds

We are seeking to raise at least $10-15M to fund development of CSC012-D212 ADC to an IND filing, with the funds to be used for preclinical studies, IND-enabling tox studies, and process development and manufacture of ADC product for an initial Phase 1 clinical trial. Ideally, we would raise ~$25M, with the additional funds used to fund a Phase 1 clinical trial of ~20-30 patients.

Key Team Members

Ram Mandalam, Ph.D. - President/CEO

Dr. Mandalam joined Cellerant in 2005 and became CEO in 2008. He has more than 20 years of experience developing stem cell-derived products for various oncology and regenerative medicine applications.

Rodney Young - CFO

Mr. Young has been a CFO for 15 years and previously was an investment banker focused on the biotech and pharmaceutical sectors.

Jagath Junutula, Ph.D. – Vice President, Research and Development

Dr. Junutula is a recognized expert in ADC development and has extensive experience leading cross-functional R&D teams in both ADC and bi-specific antibody-based cancer immunotherapeutic programs.

CerRx / Novel Platform for Targeting Cancer Cells via Dihydroceramide

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Company Overview (Clinical Impact and Value Proposition)

CerRx is using a novel platform to target toxic intracellular waxes called ceramides—specifically the dihydroceramide pathway. This ceramides-based technology induces high rates of cancer cell death by increasing and manipulating `ceramides' exclusively in cancer cells. Phase I trials of lead agent IV fenretinide have produced multiple, sustained complete remissions, partial remissions, and other activity signals in difficult-to-treat cancers, including relapsed T-cell lymphomas, adenocarcinomas of the esophagus and colon, sarcoma, neuroblastoma and others. We are conducting a Phase 2 trial of IV fenretinide for accelerated-approval for patients failing previous therapies with peripheral T-cell Lymphoma (PTCL) under FDA Subpart H. Preclinical models demonstrated a doubling of event-free-survival and may lead to a significant advance in treating CTCL. CerRx' second ceramide-targeting product, IV safingol, further increases the cancer cell killing power of fenretinide by blocking cancer cell death escape mechanisms and increasing variant ceramide waxes at levels minimally toxic to healthy cells. Preclinical combination models with fenretinide showed multi-log/total cell kill in all models tested. An ongoing combination trial is enrolling at dose level 3.

Market and Commercialization Strategy

The prevalence of PTCL is estimated at 42,000 patients in the US and EU with half being relapsed/refractory patients. At first relapse, NCCN guidelines recommend the use of clinical trial over 2nd line agents. Due to limited efficacy, high toxicity, and high pricing ($25-80K/cycle), these products have found limited use in the U.S. and have not been approved in EU. PTCL global base case forecast is ~$300M peak year sales with significant upside if the registration phase II trial yield similar efficacy and safety as seen in Phase I. The NDA is expected to be delivered in late 2019. CTCL markets offer similar opportunities. Safingol + fenretinide forecasts are +$2B, should small cell lung or esophageal indications mimic preclinical models and Phase I results to date.

Technical & Competitive Advantage

Recently approved products in PTCL include romidepsin, pralatrexate, and belinostat. Each product is associated with significant toxicity and limited use due to high rates of treatment discontinuation caused by mucositis, bone marrow suppression, fatal skin reactions and other toxicities. The overall response rate of IV fenretinide in relapsed T-cell lymphomas is impressive with 4 of 12 patients experiencing an ORR and 2 patients experiencing CR lasting >8 years. Another 7 of 12 patients experienced stable disease. This is much higher activity than seen with competitive agents. IV fenretinide has demonstrated a low level of hematologic and non-hematologic toxicity. The dose limiting toxicity was asymptomatic hypertriglyceridemia in a minority of patients which returns to normal levels as soon as the infusion is reduced. Other side effects have been minimal.

Regulatory Strategy & Intellectual Property

CerRx's first indication is anticipated to be in refractory/resistant PTCL as monotherapy. While CerRx has patent protections lasting to 2026, we have secured Orphan Drug Designations (ODD) in the US and Europe in PTCL and CTCL. Second generation ceramide targeting agent has recently secured new composition of matter IP in Europe and pending in the US.

Key Milestones

PTCL first 24 patient go/no go decision	Q4 2018
PTCL sites open in Europe, Korea, Australia	Q1-2 2019
Phase I combination completion	Q1-2 2019
CTCL phase I/II opens	Q2 2019
PTCL NDA	Q2 2021

Capitalization History

2014	Award	State of Texas (CPRIT)	$6M
2014	Grant	NIH/NCI	$1.1M
2014-18	Angel	Angel Investors (3 rounds)	$14.5M
2018	Award	State of Texas (CPRIT)	$11.8M

Use of Proceeds

Our short-term needs are to secure a licensing partner for capital to complete the enrolling phase II for accelerated approval in PTCL and matching the $11.8M CPRIT funding for the phase I/II trial in CTCL. The phase I fenretinide + safingol trial is fully funded.

Key Team Members

Richard Love, M.S. - Executive Chairman

Mr. Love was the founder/CEO of multiple biopharmaceutical companies including Triton Biosciences Inc. and ILEX Oncology Inc., bringing multiple products to market.

William J. Simpson, B.S. - CEO

Mr. Simpson is an executive that lead teams that brought multiple market leader oncology products to market in the US and globally.

C. Patrick Reynolds, M.D., Ph.D. - CSO & Co-founder

Dr. Reynolds is a pediatric oncologist, cancer center director, and professor of cell biology & biochemistry, pediatrics, internal medicine, School of Medicine, Texas Tech University Health Sciences Center.

Curon Biotech

Curon Biotech / Small Molecules for Cancer and Heart Disease

David Wald | dwald@curonbio.com | 216-410-9016

Company Overview (Clinical Impact and Value Proposition)

CuronBiotech is a biopharmaceutical company committed to applying our scientific leadership in the field of drug discovery to transform the lives of patients with cancer and heart disease. Curon has developed a large collection of small molecules based upon the scaffold of the natural product securinine, termed "Curons." These molecules exhibit potent biological activity and demonstrate efficacy in animal models of cancer and heart disease. The cancer curons target cancer cell metabolism leading to the death and differentiation of cancer cells. Our first product Cuon250 is a First in Class, Novel Chemical Entity that inhibits the cellular metabolism enzyme thioredoxin reductase. Curon250 exhibits high activity on blood cancers including Acute Myeloid Leukemia (AML). AML is the most common acute leukemia in adults, yet the prognosis of most patients is still very poor. Curon250 has the potential to make a significant impact in AML therapy. Beyond cancer curons, we have also developed a series of heart disease curons that impair inflammatory responses leading to fibrosis in the heart and subsequent heart failure.

Market and Commercialization Strategy

There is an unmet need for novel therapeutics for AML patients. While there have been a few new agents approved for AML in the last year, they demonstrate only modest improvements in survival and most are targeted for a small subset of patients. Our goal is to raise $10M from institutional investors or partner with pharmaceuticals to continue the development of Curon250 within 3-4 years. The first indication for Curon250 is AML. Curon250 is the only highly specific thioredoxin reductase inhibitor. Our studies have validated thioredoxin reductase as an ideal therapy for AML and demonstrated that Curon250 has efficacy in AML animal models. Our consultants indicate that a therapy like Curon250 can demand $50K+/patient/year for AML treatment. Global sales of Vidaza were $612M in 2014. We model Curon250 to have sales $90M in the first year with 3% penetration in the AML market. With 60,000 patients in the U.S., the global and U.S. AML markets for Curon250 would be approx. $4B+ and $2B+, respectively. After POC studies, Curon plans to license or work through joint venture with pharmaceutical partners to develop Curon250 for combination therapies.

Technical & Competitive Advantage

The field of AML has seen very little progress in drug development. Until recently the only drug to receive FDA approval in the past 30 years (PFE's Mylotarg) was withdrawn following its failure in confirmational studies. While several newer cytotoxics have demonstrated signs of activity in clinical trials, none have hit the mark in terms of statistically significant survival data. In contrast to the vast majority of therapeutics that induce cell death and have high toxicities, our agent has a unique mechanism of action by targeting cancer cell metabolism. Our consultants report that the AML community uses hypomethylating agents such as azacitidine (Vidaza) off-label "all the time" in elderly patients. The composition-of-matter patent for Vidaza and Dacogen has expired and exclusivity in the U.S. protected by its orphan product designation has also expired.

Regulatory Strategy & Intellectual Property

Curon is protected by two major patent applications filed for its work on Curon250 and related products. Curon holds issued and published patents for composition-of-matter, methods of use and formulations claims for Curon250.

Key Milestones

Completion of late preclinical studies	Q4 2019
Completion of IND-enabling Studies	Q4 2020
Initiation of Phase 1 Clinical Trial	Q4 2020

Capitalization History

2011	Grant	NIH/NCI	$844K
2014	Grant	Harrington Foundation	$230K
2018	Grant	NIH/NCI	$220K

Use of Proceeds

We are seeking Series A financing of $3M (2 tranches) to complete pre-IND studies with INV250 and to partner with strategic pharma partners. First tranche of $1.5M in Series A funding in 1Q 2019 will allow us to complete preclinical and IND-enabling studies. The second tranche of $1.5M will allow us to initiate Phase I (POC) study and initiate partnership discussion with pharma partners.

Key Team Members

David Wald, M.D., Ph.D. - CSO/Founder

Dr. Wald is a physician/inventor who developed the IP that forms the basis of Curon's portfolio. He has successfully led multiple drug development efforts that have led to the initiation of 2 cancer clinical trials based upon his work.

Stephen Charles, Ph.D. - Acting CEO

Dr. Charles is a co-founder of multiple companies including SATOR Therapeutics, Lobesity, Diasome Pharmaceuticals, Atalantos Biotechnology, and Kodiak Sciences. He held key roles in various pharmas including Roche's Pegasys and Mircrea, Amgen's Neulasta.

Stanton Gerson, M.D. - Board Member

Dr. Gerson is the director of the Case Comprehensive Cancer Center and president of the American Association of Cancer Institutes. He has extensive expertise in both preclinical research and the initiation of clinical trials for leukemia.

Five Eleven Pharma / PET-based Diagnostic Imaging Agent

David Alexoff | david.alexoff@fiveelevenpharma.com | 215-662-3989

Company Overview (Clinical Impact and Value Proposition)

Five Eleven Pharma, Inc. (511Pharma) is a biotechnology company dedicated to developing new positron-emitting pharmaceuticals that produce 511 keV photons for radiological imaging. 511Pharma is an early-stage drug development company focusing on PET diagnostics for cancer and CNS applications based on Ga-68 and F-18 radionuclides. We are developing a companion drug delivery system for our lead Ga-68 compounds, P15-041 (bone imaging agent) and P16-093 (PSMA-targeting imaging agent). Our strong emphasis is on the development of target-specific imaging agents for diagnosis and monitoring treatment of various human diseases that presently do not benefit from the most sensitive and specific radiotracers, with an initial focus on cancer. The goal of meeting unmet clinical diagnostic and therapeutic needs is the guiding principal for 511Pharma. 511Pharma will leverage certain diagnostic successes to develop therapeutic drugs based on the "theranostics" principle that permits replacement of 511 keV producing radionuclides with alpha or beta emitting (therapeutic) radiometals using the same or similar molecular design.

Market and Commercialization Strategy

511Pharma has estimated the U.S. bone imaging market in cancer to be 0.5-1 million scans/year. It is estimated that > 20 million nuclear medicine scans with 99mTc alone are done in the U.S. (AAAS CSTSP Report, 2013), with an expectation that >25% of these procedures will be replaced by PET by 2030. 511Pharma estimates the world bone scan market size (US, China, Europe, Japan) to be 2 - 4M scans / year, driven primary by bone metastases incidence rates in prostate, breast, lung, kidney, thryoid and bone cancers, with a market value of ~ $600 M ($200/dose) or higher, depending on reimbursement rates and drug costs. 511Pharma expects to fill a niche market providing an alternative to 99mTc-MDP for bone imaging as nuclear medicine moves more and more to higher resolution PET-based agents. Ga-68 P15-041 does not require expensive cyclotron-based infrastructure as other PET radionuclides (F-18), a competitive advantage to F-18 fluoride, another bone imaging agent.

Technical & Competitive Advantage

Current substitutes or competing technologies (FDA-approved) in the U.S. are 99mTc-MDP and 18F-fluoride. High resolution images, lower patient radiation exposures, patient-friendly protocols and simplified drug supply and delivery are possible using Ga-68 P15-041 (HBED-BP) compared to substitutes. The mechanism of accumulation in bone metastases is similar to 99mTc-MDP (both Ga-68 HBED-BP and 99mTc-MDP target bone remodeling using a bisphosphonate pharmacophore), which has been used for bone imaging for more than 40 years. Our product (HBED-BP) will provide high resolution images based on molecular mechanisms familiar to physicians while reducing patent radiation exposure and imaging protocol times. 18F-fluoride is prone to "false positives" that may be in part due to its different molecular mechanisms, although all bone imaging agents have some degree of similar problem. HBED-BP delivers higher resolution imaging with lower patient exposures leveraging 40 years of experience with bisphosphonate imaging.

Regulatory Strategy & Intellectual Property

511Pharma has filed 4 patents and has elected to enter the national phase in 10+ countries for P15-041 and P16-093 (PSMA). Our strength is the diverse next generation PET imaging products in oncology and neurology with IP backed by international filings.

Key Milestones

First patient new protocol P16-093 (Ga-68 PSMA) comparing with PSMA-11 in recurrent PCa patients	Q2 2018
FDA Study May Proceed for new IND (proprietary F-18 imaging agent in Alzheimer's Disease patients)	Q1 2018
New IND filing - proprietary F-18 VMAT2 agent for Parkinson disease imaging using PET	Q3 2018
Phase II/III P16-093 protocol start – P16-093 targets PSMA in Prostate Cancer	Q1 2019

Capitalization History

08/2014	Private/Angel	Private	$4M
03/2017	Grant	NIH/NCI	$225k
08/2017	Grant	NIH/NCI	$225k
08/2018	Grant	NIH/NCI	$1.4M

Use of Proceeds

Any partnership would help with clinical Phase 2/3 design and execution.

Key Team Members

Hank Kung, Ph.D. - President & Founder/CSO

Dr. Kung is leading a group of scientists in developing novel diagnostic imaging agents for FDA registration and commercialization. In 2004, He co-founded Avid Radiopharmaceuticals, which was purchased by Eli Lilly and Company in 2010.

David Alexoff, B.S.E. - CEO

Mr. Alexoff brings engineering and technical management experience from his 33 years as a member of the Brookhaven National Laboratory PET group led by Dr. Alfred Wolf and Dr. Joanna Fowler.

Karl Ploessl, Ph.D. - Director of Radiopharmaceutical Chemistry

Dr. Ploessl has expertise in radiochemistry and imaging drug R&D and is responsible for all CMC and drug quality.

Inhibikase Therapeutics / Gleevec Prodrug with Superior Safety

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Company Overview (Clinical Impact and Value Proposition)

Inhibikase is developing small molecule technologies to improve potency and suppress adverse events associated with Abelson kinase inhibitors. We developed an esterase-linked prodrug that completely suppresses non-hematological adverse events associated with oncology drugs in this class (e.g. Gleevec®, Tasigna). Application of this technology to Gleevec resulted in complete suppression of GI, fatigue and other on-dosing adverse events that reduce treatment adherence; failure to adhere to daily regimen results in treatment failure for up to 1/3 of Chronic Myelogenous Leukemia patients. In studies, the NO Adverse Event Level for the Gleevec prodrug (aka 001Pro) increased 13-fold, more than 10-fold in the safety margin for this medication. 001Pro improves the distribution of the active ingredient in the body, reducing metabolic loss on dosing—as a result, Gleevec oral dose can be lowered as much as 22% (validated in cancer xenograft and patient-derived liquid tumor animal models). Since Gleevec oral dose is linearly correlated with adverse event frequency and severity, reducing oral dose is likely to vastly increase the safety of Gleevec. This has remarkable implications for Gleevec-treatable cancers. ~1/3 of Gleevec patients skip doses regularly due to adverse events, even though adherence contributes to primary resistance and treatment failure. Treatment disruption of just five days in the first 12 months is sufficient to reduce success by 25%; failure to adhere to the regimen results in additional cost per patient of up to $100k per year. 001Pro can overcome these burdens. 001Pro could be approved under the 505(b)2 regulation using only a single ascending dose design in 12-24 patients to calibrate the treatment dose—we expect approval by end of 2019 with market entry in 2020.

Market and Commercialization Strategy

Gleevec went generic in 2016 and has earned >$1B USD in the U.S. in each of the last two years, capturing about 3/4 of the branded Gleevec market from Novartis AG. The generic form has only amplified the adherence-related GI issues associated with Gleevec. Thus, a substantial, chronic-treatment market exists for 001Pro. Inhibikase has begun is commercial development strategy in conjunction with director Richard Fante, former commercial head of Astra Zeneca U.S. A differentiated generic of this kind could capture the entire generic market in the U.S. if its safety/experience advantages are seen in patients. Inhibikase presented the opportunity to Sandoz, the generics arm of Novartis, and that created an even larger market opportunity for 001Pro. While branded Gleevec sales would be expected to slowly decline through reimbursement pressures, ~1/3 of Tasigna users begin Tasigna first-line due to Gleevec intolerance; Gleevec-intolerant patients produce $2B in U.S. sales for Tasigna each year. Sandoz viewed 001Pro as a substantial risk to the earnings of Tasgina along with acceleration of sales loss for Gleevec. The combination would be devastating for Sandoz because Novartis would have a strong, unfavorable response while branded sales remain strong for both drugs.

Technical & Competitive Advantage

Competitive advantages include added safety margin, suppression of non-hematological adverse events, and likely suppression of severe adverse events via reduced oral dose. These have been validated in pre-clinical models, including non-human primate.

Regulatory Strategy & Intellectual Property

The Company has compositions of matter protection around the underlying technology for the prodrug, for the prodrug of Gleevec and is prosecuting the intellectual property in Europe, Japan, Canada, Australia, New Zealand.

Key Milestones

Open 001Pro IND	Q4 2018
SAD approval study completion	Q2 2019
NDA filing	Q4 2019

Capitalization History

2008-10	Grants and Loans	Georgia Research Alliance	$460K
2009-17	Grants	NIH	$7.3M
2012-13	Contract	Department of Defense	$7.3M
2017	Grant	Michael J. Fox Foundation	$460K
2017	Loans	Directors	$150K

Use of Proceeds

Inhibikase is seeking strategic investment for its oncology and non-oncology assets as the Company anticipates multiple clinical programs. The Company needs $5M to reach NDA for 001Pro and will seek these dollars aggressively over the next 12 months.

Key Team Members

Milton H. Werner, Ph.D. - Founder/President & CEO

Dr. Werner is internationally recognized with expertise in leukemia, having defined the origin of multiple blood-related cancers during his academic career. After transitioning to business, he rebuilt Celtaxsys from loss of a technology license to raising $18.5M.

Roger Rush, Ph.D. - Preclinical Project Management

Roger has led multiple products through IND-enabling, most recently with Idenix before joining Inhibikase.

Surendra Singh, Ph.D. – Chemistry & Manufacturing Controls

Surendra has run CMC and clinical manufacturing for multiple companies in his career.

Maurizio Chiriva-Internati | mchiriva@kiromic.com | 806-252-5845 | www.kiromic.com

Company Overview (Clinical Impact and Value Proposition)

Kiromic is an immuno-oncology focused biotechnology company, with core technologies are artificial intelligence-powered disease-specific target identification technology (KAI-BLADE), specialized antigen validation platform, and novel drug delivery technologies. Using KAI-BLADE, we have discovered cancer-associated antigens that can be used to safely direct the immune system to obliterate tumor cells; while sparing normal cells and tissues and avoiding side effects of chemo- and radio-therapies. An example is a peptide representing the T- and B-cell immuno-dominant region of sperm protein 17 (SP17). Our lead candidate, BSK02-ODP, is an orally-administered microparticle-based formulation intended as consolidation therapy in patients with triple-negative breast cancer triple negative breast cancer (TNBC) or as first-line therapy for progressed disease. Upon interaction with the gut-associated lymphoid tissue, Kiromic's microparticulate vaccine is capable of activating effector lymphocytes that elicit a vigorous and specific systemic attack against malignant cells expressing distinct surface antigens. Preliminary mouse data suggests that treatment with BSK02-ODP microparticles containing our SP17 antigen triggers a humoral and cellular immune response resulting in slowed tumor growth.

Market and Commercialization Strategy

Breast cancer affects over 3 million women in the US and represents 14.6% of all new cancer cases (1 million new cases worldwide), and 37,000 new TNBC cases are diagnosed annually (200,000 new cases worldwide). TNBC lacks all three targets of major targeted therapies and shows a lower 5-year survival rate compared to all other breast cancer subtypes (55% versus 89%). Global breast cancer therapeutic market was valued at $13B in 2016, with TNBC accounting for $1.1B. The global TNBC therapeutic market is projected to see a 15% CAGR from 2016 to 2023, totaling $3.1B. The BSK02-ODP antigen (SP17) is expressed in 31% of TNBC cases, accounting for 186,000 patients with SP17 positive cancers in the U.S. We anticipate an initial primary-market penetration of 10% with a most likely scenario of 75% penetration due to eligibility criteria and primary indication for treatment. The SP17 antigen has also shown efficacy in ovarian cancer (global market set to jump from $1.2B in 2015 to $5.2B by 2025).

Technical & Competitive Advantage

Current therapeutic treatments for TNBC have failed to effectively and selectively target tumor cells. In addition, the route of administration for these therapeutics leads to challenges related to patient compliance and safety. BSK02-ODP overcomes these issues as an oral therapeutic that selectively targets SP17 positive cancers. There are no oral cancer immunotherapy products are in the market and competitors developing orally administered cancer immunotherapies (Lycera and Vaximm) are not focused on TNBC. Competing technologies rely on stimulation of an immune response that is not tumor-specific and utilize a live bacterium (high manufacturing efficiency and costs). Technologically speaking, BSK02-ODP is a superior therapeutic offering specific targeting, greater manufacturing efficiency, lower production costs, long-term storage, and greater potential for global distribution.

Regulatory Strategy & Intellectual Property

The technology (spray-drying based micro-encapsulation with M-cell targeting compounds) was invented by Dr. D'Souza at Mercer University. A joint patent application with Mercer was published in 2014 with National Stage Entry in 2017. We have an agreement with Mercer for three additional patents. We submitted a provisional application in 2016 with Kiromic as the sole assignee.

Key Milestones

Formulation and physicochemical characterization of anti-TNBC oral microparticles	Q3 2018
Toxicity and efficacy studies	Q4 2018
GLP TK studies and development of a scaled-up manufacturing process	Q3 2019
IND approval	Q4 2019

Capitalization History

2013-	Seed Capital	Individual Investors	$14M
2014-16	Grant	NIH/NCI	$223k
2017-	Grant	NIH/NCI	$225k
2018	Fast Track	NIH	$2.19M

Use of Proceeds

Kiromic anticipates making key connections vital to the attraction of investors to help advance this technology. We look forward to meeting potential collaborators and co-developers that may be interested in this innovative and leading-edge research program.

Key Team Members

Maurizio Chiriva-Internati, Ph.D. - CEO/CSO

Dr. Chiriva-Internati's research has led to the identification of novel cancer testis antigens for the development of immunotherapeutic strategies against solid and non-solid tumors. He is the author of over 149 peer-reviewed publications.

Scott Dahlbeck, M.D., Pharm.D. - COO

Scott has more than 10 years of experience managing operations within healthcare organizations and is an expert in cancer research.

Andrew A. Nat, Jr., M.B.A., Interim CFO

Andrew is a venture capital, finance and corporate development professional with over 30 years of experience.

NuvOx Pharma / Nanotechnology for Targeted Theranostics

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Company Overview (Clinical Impact and Value Proposition)

NuvOx Pharma is developing nanotechnology for targeted theranostics for cancer detection, treatment and oxygen delivery. We have developed microbubbles (MB) and emulsions based on fluorocarbons. NuvOx's MB product for pancreatic cancer has targeting ligands that bind to Thy-1 to detect early stage pancreatic cancer. NuvOx has also developed emulsions for oxygen delivery, which, when injected IV, flow through the lungs, pick up oxygen, then deliver oxygen to hypoxic tissues. The drug increases tumor oxygen levels to make tumors more sensitive to radio-, chemo-, and/or immuno-therapies. 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 dodecafluoropentane emulsion (DDFPe) is the only technology in its class in clinical trials and has shown efficacy in reversing tumor hypoxia.

Market and Commercialization Strategy

Potential customers for Thy-1 MB include gastroenterologists, radiologists, and specialists working on pancreatic ductal adenocarcinoma (PDAC), with potential market of individuals with risk factors for PDAC. The global market for Thy-1 MB is estimated to be >$250M. Potential customers for DDFPe include radiation oncologists, medical oncologists, as well as cancer patients treated with radio-, chemo-, and immuno-therapies. There are no approved drugs for reversing tumor hypoxia. We are focusing first on the orphan Glioblastoma multiforme (GBM) indication. NuvOx has created a risk-adjusted NPV model of sales projections for DDFPe for GBM and has validated it with a potential corporate partner. Revenues of up to $315M are predicted for GBM in the U.S. 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. Our most likely sales strategy will be to partner with pharma companies with global sales teams. NuvOx could also become vertically integrated and to achieve its own sales for selected indications in selected territories.

Technical & Competitive Advantage

Technologies in development seek to detect the presence of pancreatic cancer via blood tests, though these drugs are not able to identify the exact cancer location. NuvOx should have the first diagnostic to determine both the presence and the location of early stage PDAC. DDFPe 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. NuvOx's most direct competitor is Diffusion Pharmaceuticals' trans sodium crocetinate as a radiosensitizer. In animal studies, the effect on tumor oxygenation of TSC was much smaller than NVX-108's (TSC raised tumor pO2 by 40% while NVX-108 raised it by >400%). TSC's Phase Ib/II trial did not validate reversal of tumor hypoxia.

Regulatory Strategy & Intellectual Property

NuvOx has two composition of matter patents issued and 12 patent families pending. One patent is owned by Microvascular Therapeutics, an affiliated company, but we have an agreement to use the technology. We have paid Stanford to license two patent applications covering the Thy-1 product. DDFPe has been granted orphan status for GBM, with potentially up to 7 years' exclusivity. The FDA noted that DDFPe is regulated as a biologic, presenting opportunity for 12 years of exclusivity for a first in class indication.

Key Milestones

Receive Phase II SBIR Funding for Thy-1 Project, commence scale up and IND enabling studies	Q2 2018
Finish read-out for randomized, blinded, placebo-controlled Phase Ib/II trial of DDFPe in stroke	Q3 2018
File IND amendment to make the Phase II trial for DDFPe in GBM have an adaptive design	Q3 2018
Dose first GBM patient in the Phase II trial for DDFPe	Q1 2019

Capitalization History

12/2008	Seed Round	Founders	$700k
2017-18	Grants	NIH/NCI, NHLBI, NINDS & State of AZ	$9.77M
Q4 2017	Series A	Angels	$6.7M

Use of Proceeds

Our trial for DDFPe in 84 patients will cost $7M ($3M from the NCI), and $4M is required by investors. If we enroll 150 more patients, that would require additional ~$14M for NDA filing. NuvOx is raising a $1.5M Bridge round leading to a planned $10M financing.

Key Team Members

Evan Unger, M.D. - President and CEO

Dr. Unger is a co-founder of NuvOx and previously founded two other biotechnology companies. He sold his first company to DuPont with a greater than twenty-fold ROI. He is the inventor on 115 issued US patents.

Gordon Brandt, M.D. - VP of Regulatory Affairs

Dr. Brandt is the former VP of Clinical and Regulatory Affairs at the company that originally developed DDFPe as the ultrasound contrast agent Echogen. He is currently the President of a publicly held biotech company.

Betty Weaver, CPA - CFO

Ms. Weaver is a financial expert providing early/expansion-stage life sciences companies with planning, analysis, and CFO services.

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Company Overview (Clinical Impact and Value Proposition)

Oncoceutics, Inc. is a clinical-stage drug discovery and development company with a novel class of compounds that selectively target G protein-coupled receptors (GPCRs). The first lead compound from this program is ONC201, an orally active small molecule antagonist of dopamine receptor D2 (DRD2) that has shown efficacy against gliomas with the H3 K27 mutation. This mutation confers a poor prognosis, even worse than that of other high-grade gliomas. Currently, there are no therapies available that benefit patients, and the median survival is 12-18 months. Patients with this mutation who have been treated with ONC201 have shown dramatic radiographic regressions, including complete, durable tumor regressions lasting over 24 months, with significant improvements in clinical symptoms. We have three ongoing clinical trials in adult and pediatric patients with this mutation, which have the potential to support FDA approval of ONC201 via an Accelerated Approval path. We have also completed two Phase Is in 2015, and we are conducting 11 Phase I/II and Phase II trials across a variety of solid and liquid tumors. Early results indicate ONC201's efficacy in tumor types where dopamine is dysregulated, beyond the dramatic efficacy signal in H3 K27-mutant gliomas.

Market and Commercialization Strategy

Oncoceutics is pursuing H3 K27M gliomas as the lead indication for ONC201. H3 K27M mutation occurs in 70-90% of Diffuse Intrinsic Pontine Gliomas, 15-20% of pediatric gliomas, and 8-10% of adult gliomas. Combined, these tumors occur in ~2,100 people per year. Given the unmet need, ONC201 could command similar pricing as other orphan oncology products, leading to a market of hundreds of millions of dollars annually. Opportunities exist to expand the market to other indications where the dopamine pathway is dysregulated, including neuroendocrine tumors like pheochromocytoma/paraganglioma, endometrial cancer, and small cell lung cancer. A study in neuroendocrine tumors is enrolling at The Cleveland Clinic, and three studies in endometrial cancer are underway. We continue to investigate additional indications of ONC201, including studies in leukemia and lymphoma, supported by an alliance with The MD Anderson Cancer Center and two studies in multiple myeloma: FDA-supported one in combination with dexamethasone and another in combination with ixazomib, jointly with Takeda.

Technical & Competitive Advantage

ONC201 hits a novel target (DRD2), by inducing known anti-cancer pathways including integrated stress response and Ras signaling. The involvement of downstream members of the PI3K/Akt and EGFR signaling pathways via a novel mechanism of induction allows for activity in cancer cells that are resistant to other targeted therapies. ONC201, as well as our other drug candidates with a common core structure with ONC201 (called imipridones), work by binding to GPCRs. Despite the focus of GPCRs for drug developers and the frequent dysregulation of the receptors and their signaling mediators that control pro-survival and stress signaling pathways that are important in cancer, no GPCR-targeting cancer drugs have been developed. The ability to target GPCRs safely without cytotoxic effects to normal cells represents an opportunity that contrasts with existing chemotherapies and targeted agents.

Regulatory Strategy & Intellectual Property

Oncoceutics' IP portfolio provides broad coverage of imipridone family and life cycle management opportunity. We have eight issued patents in the U.S. and an issued patent in Japan covering all cancers. ONC201 has received an orphan drug designation for the treatment of glioblastoma, providing seven years of market exclusivity in that indication from the date of approval.

Key Milestones

FDA meeting re H3 K27M development pathway	Q3 2018
Initial read-out from dedicated H3 K27M mutant glioma trials in adults and pediatric patients	Q4 2018
Initiation of pivotal trial, or expansion of existing trials to serve as registration study in H3 K27M	Q1 2019
NDA Filing for ONC201	2021

Capitalization History

2013-2018	Grants	NIH/NCI; U.S. FDA; Pennsylvania Department of Health; The Musella Foundation	$9M
10/2014	Seed Round	Led by Spring Mountain Capital	n/a
2015-17	Series A1/A2	Led by Spring Mountain Capital (A1 in 2015; A2 in 2017)	n/a

Use of Proceeds

Oncoceutics is interested in partnership to enable a pivotal program for our lead molecule ONC201. Any proceeds will be used to fund the approval of ONC201 and explore the potential of additional imipridones in future clinical trials.

Key Team Members

Wolfgang Oster, M.D., Ph.D. - CEO/Co-founder

Dr. Oster is a hematologist/oncologist, an accomplished entrepreneur, and industry executive with expertise in drug development.

Lee Schalop, M.D. - CBO/Co-founder

Dr. Schalop is a successful Wall Street executive and life science venture capitalist with experience in fund raising and trade sales.

Martin Stogniew, Ph.D. - CDO

Dr. Stogniew served in senior management of Yaupon Therapeutics and played a key role in developing a proprietary gel formulation of Valchor. Drs. Oster and Stogniew have a combined experience that includes 12+ successful NDAs.

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Company Overview (Clinical Impact and Value Proposition)

OncoImmune is developing novel immunomodulatory biopharmaceuticals for the treatment of autoimmunity and cancer. We have a pipeline of clinical and pre-clinical assets with a focus on immunotherapy, solid tumor targeting monoclonal antibodies, and cancer vaccines. The founders have identified a novel checkpoint of disease development and have designed a large molecule compound, CD24Fc. It regulates host inflammatory response to tissue injuries and has broad implications in the pathogenesis of autoimmune diseases, cancer, and graft-versus-host disease (GvHD). CD24Fc is our primary focus and is in Phase II clinical testing for the prophylaxis of acute GvHD following myeloablative allogeneic hematopoietic stem cell transplantation (HSCT). Data indicates that CD24Fc improves Grade III-IV acute GvHD (aGvHD)/relapse free survival at day 180 compared to placebo or historical controls. We also have programs that we aim to transition into pre-clinical testing, including an anti-CTLA4 antibodies with reduced toxicity. Our lead antibody, ONC-392, is as or more effective but dramatically less toxic than Ipilimumab when used with anti-PD-1.

Market and Commercialization Strategy

CD24Fc is being developed for the prevention of aGvHD in leukemia patients undergoing allogeneic myeloablative HSCT, which is a high unmet need. Allogeneic HSCT is the only established curative therapy for refractory leukemia in adults. However, aGvHD is the principle contributor to transplant-related mortality and occurs in ~ 60-80% of recipients receiving unrelated donor HSCT. Allogeneic HSCT is performed in ~30,000 patients worldwide each year (>8000 per year in the U.S.) and is expected to increase at a CAGR of 2.92% in the U.S. (2013-2023) due to growing number of hematologic malignancies associated with aging population. The diagnosed incidence cases of aGvHD in the U.S. is expected to increase at a CAGR of 4.14% (2013-2023).

Technical & Competitive Advantage

aGvHD results from an immunologically-mediated cascade that starts with injury to host tissues, which is usually related to the myeloablative regimen administered to the patient prior to receiving the transplant. CD24Fc is different from other approaches in that it specifically targets the disease-causing tissue damage that occurs before and during transplantation. The drug will be administered without the need for long-term administration because it is expected to be active at time of transplantation. Treatment/prevention of GvHD focuses on pharmacologic inhibition or depletion of T cells to limit the expansion of alloreactive T cells that mediate GvHD. Non-selective T-cell depleting strategies are efficacious in preventing aGvHD and extensive chronic GvHD, but they do not improve survival. More selective inhibition by targeting single pro-inflammatory cytokines has not shown clinical benefit in treating GvHD. CD24Fc does not cause general immune suppression, which suggests that it will not likely increase the risk of infection. Our data also shows that CD24Fc prevents GvHD but preserves GVL, making it an ideal GvHD prophylaxis drug.

Regulatory Strategy & Intellectual Property

The CD24Fc portfolio consists of several families. The “400” Patent Family represents the key IP related to CD24Fc as claims cover the drug product compositions of matter and methods for treating immune-mediated tissue damage. In addition, there are families related to methods of use of CD24. We have obtained Orphan designation for CD24Fc for GVHD prophylaxis in the U.S. and Europe.

Key Milestones

Filing for Breakthrough Designation for GvHD prophylaxis	Q2 2018
Initiation of the Phase IIb trial for GvHD prophylaxis	Q3 2018
IND filing and initiation of a Phase II trial for the prevention of prediabetes	Q3 2018
Initial Public Offering	2019

Capitalization History

04/2016	Private Equity	Angel Investor (Amount Undisclosed)	n/a
09/2016	Strategic Partner	Pfizer (Amount Undisclosed)	n/a
01/2017	Series A	3E Bioventures & Others	$10M
09/2017	Grant	NIH/NCI	$2M

Use of Proceeds

We aim to raise $30M+ to support development of CD24Fc through Phase IIb and move earlier stage programs into clinical testing.

Key Team Members

Yang Liu, Ph.D. - CEO/Chief Scientist

Dr. Liu is a professor and director at Division of Immunotherapy, Institute of Human Virology at University of Maryland Baltimore. He is recognized for his research on immune recognition of cancer and activation of lymphocytes, with nearly 200 published articles.

Pan Zheng, M.D., Ph.D. - CMO

Dr. Zheng has an academic appointment at the University of Maryland Baltimore as Professor, Division of Immunotherapy, Institute of Human Virology. He is an expert on the mechanism of tumor evasion of host immunity and has published numerous papers.

Martin Devenport, Ph.D. - COO

Dr. Devenport was Vice President of Business Strategy at Amplimmune, Inc. and was an integral member of the business development team that led to its successful sale to MedImmune in 2013.

Organix / Novel Small Molecule Id-1 Inhibitors

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Company Overview (Clinical Impact and Value Proposition)

Organix has developed novel small molecule Id-1 inhibitors that have been shown to inhibit metastatic progression leading to prolonged survival in multiple mouse models of advanced triple negative breast cancer (TNBC). Id-1 is a key transcriptional regulator that controls metastatic progression across multiple cancers, including TNBC. Targeting Id-1 results in inhibition of invasion, metastasis, and angiogenesis, and improves the activity of first-line therapies (e.g. paclitaxel). The market value for TNBC therapeutics is expected to increase more than fourfold, from $1.45B in 2013 to an estimated $6.12B by 2023; hence, the value of the IP of our technology is substantial. We expect to leverage the valuable IP that is being created from the Phase II SBIR grant as well as other research activities to lead to financially attractive licensing deals with large pharmaceutical companies or the creation of a start-up focused on our core technology. As a part of these agreements, we will expect to receive up-front payments and to have funded in-house research programs that will expedite the licensing company's efforts to bring our inventions to market.

Market and Commercialization Strategy

In a survey by the Mattson Jack Group, oncology key opinion leaders (KOLs) identified TNBC as the biggest unmet need in treatment of metastatic breast cancer. TNBC patients typically have relatively shorter survival (~2 y). KOLs describe the treatment field as "wide open" and the development of an efficacious treatment as "a welcome addition." TNBC lacking tumor specific receptors do not respond well to targeted therapies such as Tamoxifen or Herceptin and are frequently resistant to standard chemotherapeutic regimens. Currently, cytotoxics are the primary treatment. Studies using human biopsies clearly demonstrated that many types of aggressive cancers, including TNBCs, expressed high levels of Id-1 protein; and Id-1 is not expressed in normal tissues. Our preclinical data demonstrated that our lead inhibitor of Id-1 expression was effective at inhibiting TNBC progression in advanced stages of the disease. American Cancer Society estimates that 30,325 breast cancer patients will be diagnosed with TNBC per year. None of the currently approved therapies for metastatic breast cancer work by inhibition of Id-1 expression, the method by which our lead compounds work. The specificity of this process will allow development of more selective treatments with reduced toxic side effects.

Technical & Competitive Advantage

Antibodies directed at Id proteins have been developed, however, they have limited usefulness since Id proteins are transcriptional regulators located intracellularly. Therapeutic antibodies do not efficiently cross the cell membrane, whereas our small molecules are lipophilic and readily cross the cell membrane. Id protein mimics have been developed but demonstrate low potency and have not been shown to have in vivo activity. Angiogenex has a small molecule Id-1 inhibitor (AGX-51) in early preclinical development. However, the patent does not present any data for this drug as an inhibitor of Id proteins. We are also the only group to date to show that small molecule inhibitors of Id-1 expression could prolong survival in an advanced model of TNBC metastasis.

Regulatory Strategy & Intellectual Property

Organix and California Pacific Medical Center are joint inventors on the patents for inhibitors of Id-1 expression based on the resorcinol template and licensing agreements are already in place. The patents cover composition of matter around our lead compounds, as well as treatment of disease (aggressive cancers). Our patent also covers combination therapy of Id inhibitors.

Key Milestones

Evaluation of leads for antimetastatic activity alone and in combination with first-line agents	Q4 2018
Evaluation of leads in TNBC PDX model that expresses our target gene Id-1	Q4 2018
Testing of leads using the DOX-TNBC resistant cell line (MDA-MB231/DOX)	Q2 2019
Evaluation of the most active lead in acute and repeated dose range finding studies	Q3 2019

Capitalization History

2009-14	Grant	NIH/NCI	$1.4M
2010-14	Grant	Susan G. Komen Foundation	$460K
2013-14	Grant	NIH/NCI	$290K
2016-19	Grant	NIH/NCI	$1.73M

Use of Proceeds

We are currently seeking additional funds to scale up our lead compound to 1 kg for detailed pre-clinical studies to support the IND application over 2 years. Estimated cost for these studies is $3M.

Key Team Members

Anu Mahadevan, Ph.D. - CEO

Dr. Mahadevan received her Ph.D. from Purdue University under Professor Fuchs. She has been with Organix since 1997 and has since rose to her current position.

Paul Blundell, Ph. D. - President

Dr. Blundell had done research under Nobel Laureate Sir Derek H. R. Barton at TexasA&M. He has been with Organix since 1993.

Howard Sard, Ph. D. - Vice President

Dr. Sard co-founded Organix. After receiving Ph.D. from MIT, he did his post-doc and was a Group Leader at SISA.

Pandomedx

Pandomedx / Novel AR Variants Targeted Therapy for Prostate Cancer

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Company Overview (Clinical Impact and Value Proposition)

Pandomedx is developing a novel therapy to overcome resistance and improve the treatment outcomes of advanced prostate cancer. When prostate cancer (CaP) becomes resistant to the first-line androgen deprivation therapy, it is called castration-resistant prostate cancer (CRPC), which is treated with FDA-approved drugs enzalutamide and abiraterone. However, resistance is the most common cause of treatment failure. Androgen receptor variant 7 (AR-V7) is known as the key mechanism to cause resistance to abiraterone and enzalutamide treatment. We have found that niclosamide targets AR-V7, overcomes resistance to abiraterone and enzalutamide, and synergizes with these two drugs. Niclosamide (PDMX1001) was approved by the FDA to treat tapeworm infection and is not available in the U.S. We have so far developed a clinical trial protocol and consent form, conducted a cGMP formulation, and finished the CMC section, received FDA IND approval, and finished a Phase I clinical trial with promising safety and efficacy data. A Phase II clinical trial of PDMX1001 plus abiraterone is currently undergoing in patients with enzalutamide resistant CRPC.

Market and Commercialization Strategy

Our product is priced competitively at about $2,000/month, compared to enzalutamide at >$11k/month, abiraterone at >$10k /month, and cabazitaxel at $5,598 per cycle. The patient population in the U.S. eligible for enzalutamide is approximately 50,000 to 60,000 per year. PDMX1001 synergizes with abiraterone and ADT, and we will use PDMX1001/abiraterone after resistance to enzalutamide in the current project, and we assume that the response rate will be 40%. Prostate Cancer Working Group 2 Guidelines advises that patients should not switch to another therapy during the first three months even with rising prostate-specific antigen (PSA) since patients can have rising PSA during the treatment period. Market size for these 60% of non-responders will be $200M and $528M for the remaining 40% responders. Therefore, the total market size will be $728M in the U.S. and $2.2B globally. Based on our Phase I clinical trial data, the combination of PDMX1001/abiraterone is well tolerated. Therefore, some physicians will prescribe this combination even when patients have not been treated with enzalutamide. In this case, the duration of treatment will be much longer and the market size will be much larger.

Technical & Competitive Advantage

PDMX1001 will be combined with current hormonal therapeutic agents. The combination therapy delays the development of resistance and prolongs the use of both PDMX1001 and the partner drug. The only potential competitor is other AR-V7 inhibitors. Galeterone claims to “target” AR-V7; but a Phase III trial comparing galeterone to enzalutamide in treatment-naïve CRPC expressing AR-V7 has been terminated because the trial is unlikely to meet its primary endpoint of improvement of radiologic progression-free survival. Key advantages of PDMX1001 over other newly developed AR-V7 inhibitors are the timeline and cost of development. The total cost of developing PDMX1001 for CaP will be less than $50M, a fraction of $2.6B needed for a new prescription drug. We expect to obtain FDA approval for PDMX1001 within the next 6-7 years.

Regulatory Strategy & Intellectual Property

The patent of using PDMX1001 in the treatment of prostate cancer has been filed through UC Davis. Pandomedx has signed an exclusive license from UC Davis for developing PDMX1001 for the treatment of CaP.

Key Milestones

Finish accrual for a Phase II clinical trial	Q3 2019
The objective response rate, progression-free survival time, overall survival and toxicity are assessed	Q1 2020
Sample collection and molecular correlative analysis are performed	Q2 2020

Capitalization History

2016	Grant	NIH/NCI	$300k
2018	Grant	NIH/NCI	$1.5M

Use of Proceeds

Pandomedx will require ~$50M to hire core staff, secure IP licensing, establish office space, and preform two clinical trials, including the Phase III clinical trial that will lead to FDA approval. For the final year of the approval period, we will require an additional $10M in VC funding to support launching activities. We can also consider joining another company to sell PDMX1001.

Key Team Members

Allen Gao, M.D., Ph.D. - Chairman

Dr. Gao has more than 25 years of research in CaP and works at UC Davis Comprehensive Cancer Center. One of his research focuses is to study the mechanisms of drug resistance and develop novel therapy to improve the treatment outcomes of CaP.

Chengfei Liu, M.D., Ph.D. - Chief Scientist

Dr. Liu has more than 10 years of experience in cancer research; he has participated and contributed to all aspects of developmental programs, including clinical epidemiology, preclinical drug testing, clinical testing and basic scientific research.

Chong-Xian Pan, M.D., Ph.D. - Co-founder

Dr. Pan has more than 10 years of experience in medical oncology and drug development including preclinical and clinical drug testing. Dr. Pan works at UC Davis Comprehensive Cancer Center and serves as a co-leader of Therapeutic Program.

RadioMedix / Radiotheranostic Drug Targeting Neuroendocrine Tumors

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Company Overview (Clinical Impact and Value Proposition)

RadioMedix, Inc. is a clinical stage biotechnology company focused on innovative targeted radiopharmaceuticals for diagnosis, monitoring and therapy of cancer. RadioMedix has established two service facilities for academic and industrial partners: cGMP Manufacturing Suite for clinical trials and Molecular Imaging Facility for evaluation of agents in animal models. RadioMedix is an US-exclusive distributor of ITG GmbH (Germany) products (68Ga/68Ga generators, Ac^{225}/Bi^{122} generators, DOTATOC kit peptide and PSMA-targeting agents) and Trasis SA automated modules for radiolabeling (Belgium). RadioMedix serves also as a contract research project organization for partners interested in development of radio labeled probes. These research contracts and clinical activities provide a revenue that will support commercialization of radiotherapeutic agents, designed to precisely target 1) neuroendocrine tumors (NETs) AlphaMedixTM (radiotherapeutic drug) and NETMedixTM (diagnostic drug); 2) glucose-avid aggressive tumors (GlucoMedixTM). RadioMedix signed a collaboration agreement with ORANO Med, company specializing in the development of innovative alpha-emitter-based therapies to fight cancer. Our company serves as a co-sponsor and collaborator on Phase I/II and Phase III clinical studies of radiolabeled drugs. Currently, we are expanding our facility by addition of a new state of art site for commercial manufacturing of the radiolabeled drugs (RadioMedix Spica Center).

Market and Commercialization Strategy

The radiotherapeutic market is expected to grow 26% annually by 2030. The approval of Xofigo and Lutathera should help in the introduction of new drugs to market and approval by FDA. The alpha therapy agents are considered the next generation of targeted radionuclide therapy, and the promise of extremely energetic alpha particles causing double-strand DNA damage, making "cure of cancer" enticing. There are no commercially available alpha-emitter tagged drugs that target somatostatin receptor overexpressing NETs. RadioMedix product will target the same market segment as Lutathera (Novartis), however will provide a more effective treatment option for cancer patients who do not respond and develop resistance to targeted radiotherapy and Lutathera.

Technical & Competitive Advantage

Current approaches to cancer treatment are largely ineffective once the tumor has metastasized and tumor cells are disseminated. An additional problem is the high systemic cytotoxicity of chemotherapy, or lack of response or resistance to beta-emitter radiotherapy. Alpha-emitter labeled agents such as AlphaMedix may address these critical needs. Alpha-particle emitters (e.g. 212Pb) have higher potency and specificity than beta-particle emitters (e.g. 177Lu). The high energy emission of the alpha-particle used for targeted therapy produces clustered double-strand DNA breaks and the rapid death of cancer cells. The effective range of targeted therapy using alpha-emitters is only 50-I00 µm (diameter of 2-3 cancer cells) that decreases the cytotoxic effect on surrounding normal tissue, providing strength and rationale for using alpha-particle emitting radionuclides for cancer therapy.

Regulatory Strategy & Intellectual Property

RadioMedix submitted the Orphan Drug Application for AlphaMedix in Q3 of 2018. We have a pending patent for the composition, kit, and method of production of AlphaMedix, and a granted trademark for its name. RadioMedix has also two patents in the IP portfolio covering the composition of the GlucoMedix and a pending patent for the kidney protective composition, AminoMedix.

Key Milestones

Determination safety and preliminary efficacy of AlphaMedix™ in Phase I dose escalation studies	Q2 2019
Completion of Phase II/III clinical studies of AlphaMedix™	Q4 2022
Pre-NDA meeting with FDA	Q2 2022

Capitalization History

2008	Grant	DoD	$300k
2011	Grant	Texas Emerging Tech fund	$2.4M
2014	Grant	NIH/NCI	$160k
2015	Contract	NIH/NCI	$74k
2016	Contract	NIH/NCI	$300k

Use of Proceeds

We are seeking $30M for the Phase II study, and preparation of the multi-center NDA-enabling clinical studies of AlphaMedix.

Key Team Members

Ebrahim S. Delpassand, M.D. - Founder/CEO

Ebrahim is an American College of Nuclear Medicine Fellow. He founded Excel Diagnostics and Nuclear Oncology Center and has 30+ years' experience. He has served as PI and Medical Director on the multiple clinical studies of radiotheranostics targeting NETs.

Azar Delpassand, RN - Founder/Board Member/President

Ms. Delpassand has 20 years of experience as an entrepreneur in healthcare industry and has co-founded three additional start-ups, including Infinity Infusion Care and Infinity Care (named in 1997 as one of the 100 fastest growing businesses in Houston).

Izabela Tworowska, Ph.D. - CSO

Dr. Tworowska has multi-disciplined background with 20+ years' experience in clinical pharmacy and oncology research. She leads the AlphaMedix' project and is responsible for its clinical development and securing funds supporting commercialization.

Guillermo A. Morales | morales@signalrx.com | 520-777-9609 | www.signalrx.com

Company Overview (Clinical Impact and Value Proposition)

SignalRx Pharmaceuticals, Inc. is a clinical-stage company developing novel small-molecules therapeutics. We use our patented thienopyranone molecular scaffold and in silico molecular design/modeling process to inhibit key cancer-driving targets with single small molecules that are efficacious in preclinical mouse models, safer than combining 2 single inhibitors (no animal deaths), and proven to cause synthetic lethality in cancer cells. Our agents also target cancer-resistance signaling networks, allow for simpler and faster clinical development (1 drug=1 PK/PD/tox profile), and development of more sophisticated combinations. Our R&D pipeline includes: PI3K/BRD4, CDK4-6/BRD4/PI3K, BTK/BRD4/PI3K, HDAC6/PI3K/BRD4, PARP/PI3K. ~70% of all cancers are driven by the transcription factor MYC. Our PI3K, HDAC, and/or CDK chemotypes have been shown to function as checkpoint inhibitors and enhance immune-therapeutics, while BRD4 inhibition has been shown to block tumor-specific super-enhancers activating the innate and adaptive immune response. Our first-in-class lead dual PI3K/BRD4 inhibitor, SF2523, also inhibits MYC activity by enhancing MYC degradation (via PI3K inhibition) and blocking MYC production via inhibition of MYC transcription (via BRD4 inhibition).

Market and Commercialization Strategy

SF2523 can be commercialized in 3 cancer areas for which we have experience:
(1) Hepatocellular Carcinoma (HCC): While Sorafenib is FDA-approved for advanced HCC, it is not well tolerated, and survival benefit is limited to ~3 months. PI3K is activated in 30-50% of HCC and c-MYC is overexpressed in up to 70% of alcohol-related and viral HCC, making it ideal for dual PI3K/BRD4 therapy. Sorafenib's global sales in 2017 were $946M and are set to grow to $1.4B by 2019.
(2) HPV+ Squamous Cell Carcinoma of Head & Neck Cancer: 50% of HPV+ SCCHN are PIK3CA mutated. BRD4 inhibitors block HPV infectivity. SF2523 can address the disease via the two mechanisms. Head & neck cancer market is expected to reach $2.8B by 2026.
(3) Pediatric Medulloblastoma (MB) and Neuroblastoma (NB): 20-40% of MB/NB are MYCN dependent. Upon completing SF2523 Phase Is, we plan to test SF2523 in this orphan-drug population with patient selection driven by a MYCN biomarker strategy.

Technical & Competitive Advantage

There are no PI3K/BRD4 inhibitors in clinical development. SF2523 can also maximally disrupt MYC in turn down regulating PDL1 and CD47 immuno-oncology receptors. We have demonstrated that combining a BRD4i with a PI3Ki is more toxic in vivo than single agent SF2523. SF2523 can also enable the evaluation of more complex drug combinations in early clinical trials expanding the patient population and markets (i.e., SF2523 and Sorafenib in HCC). SF2523 is a small molecule, not a conjugate linking a BRD4i with a PI3Ki, that acts like 2 drugs in 1, safer in vivo, with 1 PK/PD/tox profile to streamline clinical development.

Regulatory Strategy & Intellectual Property

SignalRx has strong IP protection for the PI3K/BRD4 program and SF2523 with patents granted. Dr. Tom Webster, former senior patent attorney at Eli Lilly, works with us for patent strategy and filing.

Key Milestones

Scale up of dual PI3K/BRD4 inhibitor SF2523 (route evaluation/scalability/stability) prior to GMP synthesis	Q3 2018
Optimize oral formulation suitable for IND-enabling studies and Phase I trials	Q4 2018
Dose ranging tox/optimal tumor type determination/optimal dose schedule (final PK/PD studies)	Q1 2019
Run IND enabling studies and then file IND	Q4 2019

Capitalization History

Pre-2012	Semafore Pharma Acquisition	Indiana angels and boutique venture groups/grants + Semafore assets	$30M
2012	Angels & Individuals	Founders	$200k
2015-17	Grant	NIH/NCI	$2.17M
2016	Grant	NIH/NCI	$300k
2018	Grant	NIH/NCI	$300k

Use of Proceeds

We seek $2M for IND-required toxicity studies and IND submission. We will pursue Series A-type round in 2019 for at least $4M to start Phase I human clinical trials. We also seek partnering opportunities to accelerate the development of our early assets.

Key Team Members

Donald Durden, M.D., Ph.D. - Founder/Senior Science Advisor

Dr. Durden is an expert in PTEN/PI3K signaling, tumor/immune compartment cancer biology, and small molecule inhibitor discovery. He is a board-certified pediatric hematologist-oncologist at UCSD.

Joseph Garlich, Ph.D. - CSO

Dr. Garlich is a medicinal chemistry expert and the inventor on 27 U.S. patents. In his 33 years of R&D career, he has served as CSO, CEO, and president of Semafore Pharmaceuticals, successfully raising ~$30M.

Guillermo Morales, M.B.A., Ph.D. - CBO/Director of R&D

Dr. Morales has 23 years of small molecule drug development experience from idea to IND-ready status. He is an expert in medicinal chemistry, chemoinformatics, and computer-aided drug design. He is the inventor on 12 patents.

SUMO Biosciences / Small Molecule for c-Myc & KRas-driven Cancers

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Company Overview (Clinical Impact and Value Proposition)

SUMO Biosciences focuses on small molecule drugs for targeted therapies for c-Myc and KRas-driven cancers, as well as cancer stem cells (CSC), with a focus on colorectal cancers. c-Myc and KRas contribute to more than 70% of all human cancers. However, there have not been targeted therapies for cancers driven by these oncogenes. CSC also present a major obstacle to effective therapy. These small populations of cells can seed tumor regrowth at either the original or distant sites, resulting in tumor relapse and metastasis. Standard chemotherapy and radiation therapy have few inhibitory effects on CSCs. Signaling pathways controlled by post-translational modifications by ubiquitin-like modifications are important for c-Myc and KRas oncogenic functions. Inhibiting some of these pathways can selectively eliminate cancer cells that depend on hyperactivated c-Myc or KRas activities and dramatically inhibits CSC maintenance and self-renewal. We discovered an allosteric, covalent mechanism to inhibit the activating enzymes for ubiquitin-like modifications and identified a series of highly selective, very potent inhibitors. The extensive knowledge from the crystal structure of the enzyme-inhibitor complex and over 700 analogs of several chemotypes made so far provides a framework for development of molecules targeting E1 enzymes for several ubiquitin-like modifiers to inhibit KRas, c-Myc, and CSCs. Our lead compounds reduce c-Myc levels in c-Myc-dependent cancer cell lines and xenograft models, eradicate CSC population and self-renewal, and inhibit tumor growth in colorectal cancer xenograft and patient-derived xenograft mouse models.

Market and Commercialization Strategy

The chance of developing cancer is 1 in 3 for women and 1 in 2 for men in the U.S. The current market for anticancer drugs exceeds $121B. Despite progress made to date, it is still not possible to inhibit major oncogenes, e.g. c-Myc, that contribute to most cancers. For example, colorectal cancer, to which c-Myc nearly always contributes, continues to be the third leading cause of cancer death in the U.S. There are 10 different agents for the treatment of metastatic colorectal cancer, but improvements in overall survival have been modest with median survival of 20-30 months. Recently-developed immune checkpoint inhibitors benefit approx. 4% of colorectal cancer patients. Clinical data suggest that further variations on currently approved drugs are not likely to result in additional improvements in patients' outcomes. Therefore, developing novel drugs that address new targets that are essential, for tumor growth will be critical to further improve the outlook for patients with colorectal or other c-Myc- and KRas- driven cancers.

Technical & Competitive Advantage

Companies including Takeda, SuniQ, Mercachem/UbiQ, and Forma are pursuing SUMOylation inhibitors but are in preclinical stage. The SUMOylation inhibitors developed by Takeda target the ATP binding site of the E1 enzymes, which is very different from our approach. The approaches taken by other companies are not yet available. Our inhibitor targets an allosteric site and uses a covalent mechanism. A bromo-domain-containing protein, BRD4, could be an indirect target to inhibit c-Myc. Although this program is already in clinical trials, the outcome is not clear. Inhibition of SUMOylation and other ubiquitin-like modification targets address different cellular pathways from that of BRD4, and thus may synergize with BRD4 inhibition. Mirna Therapeutics is developing methods to directly deliver anti-tumor microRNA to suppress c-Myc, but delivery of RNA to cells may be inefficient and costly compared to small molecules. Kura Oncology is developing small molecule covalent inhibitor targeting KRas-G12C mutant-driven cancers. Our approach is not limited to this particular KRas activating mutation and can be used for other KRas activating mutations.

Regulatory Strategy & Intellectual Property

Patents covering two chemotypes of small molecule inhibitors of SUMOylation identified by the Chen laboratory was filed by the Beckman Research Institute of City of Hope and licensed to SUMO Biosciences.

Key Milestones

File IND	2019
Phase I or pilot clinical trial	Q4 2019

Capitalization History

2014	Grant	City of Hope	$345k
2014-15	Grant	NIH/NCI	$2.25M
2017	Grant	California Institute of Regenerative Medicine (jointly with City of Hope)	$1.8M

Use of Proceeds

We are seeking $4M to accelerate the progress of our current NIH-funded program and to go towards matching funds for SBIR Phase IIB Bridge Award. We would also like to add additional targets and generate the necessary preliminary data for new funding.

Key Team Members

Yuan Chen, Ph.D. - CEO

Dr. Chen is a faculty member and dean of transdisciplinary research at City of Hope. He is a pioneer and key player in the field.

Shawn Ouyang, Ph.D. - Principal Scientist

Dr. Ouyang has 10 years' experience in medicinal chemistry. He has designed and synthesized VEGFR2 kinase inhibitor AMG706.

Ted Judd, Ph.D. - Principal Scientist

Dr. Judd has > 2 years' experience in all aspects of medicinal chemistry, cross-functional collaboration, and in process development.

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Company Overview (Clinical Impact and Value Proposition)

Viewpoint Molecular Targeting, Inc. is developing targeted radiopharmaceutical therapies and companion products for cancer, with an initial focus on metastatic melanoma. Viewpoint's innovative receptor-targeted radiotherapy for metastatic melanoma (VMT01) is an injectable, tumor-specific radiopharmaceutical that delivers killing alpha-radiation precisely to melanoma tumors via a small peptide molecule that binds to a cell surface receptor that is present on melanoma tumors but not normal cells. Any excess VMT01 is eliminated quickly via the bladder (minimal side effects). Our companion diagnostic dramatically improves patient selection and personalized care by predicting who will respond and precisely how much of the therapeutic to administer. The companion diagnostic also represents an imaging asset with significant revenue potential. Viewpoint's image-guided therapy has significantly extended survival relative to the current standard of care in pre-clinical melanoma models using implanted human melanoma tumors in mice. Pharm/Tox studies are complete. Company is entering clinical development.

Market and Commercialization Strategy

The total market for metastatic melanoma drugs exceeded $1.6B annually in 2013 (CAGR of 15.5% through 2024). Sales estimates of the two dominant metastatic melanoma drugs suggest between $9 and $13B by 2023. Melanoma incidence is growing faster than that of any other cancer (132,000 new cases annually worldwide). Despite improved treatments, metastatic melanoma is recurrence is almost inevitable and the 5 yr survival is <20% (U.S. death toll >11,000). Metastatic melanoma has precedence for Orphan Drug designation, which Viewpoint is pursuing. Medical Oncologist interviews revealed enthusiasm to prescribe VMT01 with expectation of a 6-mon. survival improvement for patients who have failed all current therapies and expansion to combinations with melanoma drugs for front line therapy. Viewpoint has platform radionuclide-chelator and radiopharmaceutical manufacturing technologies under development that will be serve unmet needs and expand company revenue potential.

Technical & Competitive Advantage

The melanoma market is dominated by two major groups of therapeutics including kinase inhibitors and immunotherapies. External beam radiation therapy is considered palliative. Since the introduction of immunotherapies and kinase inhibitors in 2012, the use of chemotherapies has diminished. Combinations of these treatments yield incremental improvements in survival (months). Relapse is the rule, with less than 10% achieving a durable complete response – recurrence is the rule. Recent introductions do not introduce new targets of therapy. There is still a growing unmet need for a new approach that will provide meaningful medium- to long-term progression-free survival. Viewpoint's receptor-targeted alpha-radiation therapy overcomes melanoma resistance pathways by directing killing alpha-radiation precisely to melanoma tumors.

Regulatory Strategy & Intellectual Property

Viewpoint's therapeutic is protected by 6 Patents and 4 other filings (full-exclusive licenses) that extend the IP globally. The freedom to operate and intellectual property position in the U.S. is strengthened by Orphan status of metastatic melanoma (7 y market exclusivity upon approval).

Key Milestones

IND Phase 0/I Clinical Safety Trial for Diagnostic/ Orphan Drug Status Expected	Q1 2019
Commence Phase 0/1 Safety trial for Diagnostic	Q2 2019
IND Phase 0/I Safety for Therapeutic	Q4 2019

Capitalization History

2013	Awards & Loans	State of IA & Wellmark Foundation Loan	$100k
2015	Grants	NIH/NCI & State of IA Awards	$280k
2016	Grants &Loans	NIH/NCI & Wellmark Foundation Loan	$425k
2017	Grant	NIH/NCI	$2M

Use of Proceeds

Viewpoint is seeking $15M to complete Phase 1 clinical trials of its diagnostic and therapeutic products ($6M in the form of Phase II SBIR).

Key Team Members

Michael Schultz, Ph.D. - Founder and CSO

Dr. Schultz is a radiopharmaceutical and cancer biology expert. He led the submission of a successful IND for the first gallium-68 radiolabeled peptide in the U.S. He consulted for Algeta ASA for FDA approval of Xofigo.

Frances Johnson, M.D. - Founder and CMO

Dr. Johnson has 20 years of experience in clinical trials and in commercialization of biotech discoveries. She was an inventor and co-founder of biotech startup (Stanford spinout) now publicly traded as CareDx®, a molecular diagnostics company.

Heyward Coleman, M.S., M.B.A. - Founder and CEO

Mr. Coleman is a nuclear physicist with an MBA from Harvard. He founded and built the largest privately-owned radiochemistry company in the U.S., General Engineering Laboratories and is leading two other medical technology startup enterprises.

BioFluidica / Scalable Liquid Biopsy Solution

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Company Overview (Clinical Impact and Value Proposition)

BioFluidica, Inc. has developed a platform (The Liquid Scan) for vastly improved cancer detection from whole blood samples. Our technology allows the analysis of extremely rare blood disease biomarkers with unprecedented accuracy and recovery including circulating tumor cells (CTC), circulating leukemic cells, cell free DNA (cfDNA) and exosomes. The platform has been clinically validated on nine solid tumor cancers, as well as blood born cancers such as Acute Myeloid Leukemia (AML) and Multiple Myeloma for Minimal Residual Disease (MRD). Biofluidica's complete liquid biopsy solution reduces the loss of even the rarest biomarkers from collection through analysis. Innovation in instrument and software design allows instant scalability of the process while injection-molded production of plastic microfluidic capture chips enable mass production. The platform technology is commercially ready for cell-based analysis and is expandable to cfDNA and exosome analysis. We have shown the ability to replace bone marrow biopsies through a simple blood test for AML patients and are currently conducting an NIH-sponsored clinical trial.

Market and Commercialization Strategy

Liquid biopsy in the U.S. was set to grow to $33.1B and BioFluidica's technology can serve the entire market. In cell-based liquid biopsy, the only FDA-cleared technology in the U.S. for CTC selection is the Veridex CellSearch System by Menarini. However, this system has limitations including modest recovery and clinical sensitivity, limited specificity, high test cost, and low purity of the CTC selected fraction. Compared to CellSearch, our platform generates higher rare CTC recovery and lower test cost and high purity. We are integrating the Liquid Scan platform for the isolation of cfDNA and exosomes, providing an unprecedented capability of performing a complete liquid biopsy from a single blood sample using a fully automated platform. The platform can also be used for MRD applications such as blood cancers or for isolating fetal cells in maternal blood.

Technical & Competitive Advantage

Our system can be tailored to rapidly process the large input blood volumes needed to enumerate target cells with a high statistical confidence. No other device comes close to the speed and reproducibility of Biofluidica's biomarker capture. We also offer a simple workflow; no centrifuging, staining, or other preparation is required prior to the chip processing—reducing potential loss of rare cancer cells or contamination. With our system, time from patient blood sampling to results can be a few of hours instead of days. BioFluidica significantly reduces the cost per assay by employing low-cost, injection molded polymer cartridges. We have integrated and automated the process, eliminating the need for highly specialized technicians. Our second-generation benchtop instrument opens the technology to a decentralized distribution system in point-of-care testing, a larger customer pool, and more flexible use.

Regulatory Strategy & Intellectual Property

BioFluidica obtained platform technologies through exclusive license agreements with UNC-Chapel Hill, LSU, and Cornell University. Our patent portfolio includes four issued U.S. patents, and 14 pending U.S. and foreign patent applications. Our patent strategies focus on ensuring that the portfolio covers its Liquid Scan commercial products and liquid biopsy diagnostic pipeline.

Key Milestones

Develop small table top end-user instrument to commercial product	2018
Operating 3 US core facilities processing over 10,000 patient samples per year	2019
Establish the infrastructure and supply chain to process >100,000 samples per year	2019
Advance one disease indication sample to answer diagnostic test towards FDA approval	2019

Capitalization History

2013-17	Grants	NIH/NCI & NIBIB ($4.6M) Diverse Sources ($6M)	$10.6M
2016	Loan	NCBC	$250K
2016	Series A	Private Placement	$2M
2017	Series B	Private Placement	$5M

Use of Proceeds

We will open next round of financing of $20M within the next 3-4 months to expand core facility operations, grow business development infrastructure, complete prototype instrument for decentralized sale to end users and prepare for global operations.

Key Team Members

Rolf Muller, Ph.D. - CEO

Dr. Muller has founded many companies, including Biomatrica, a company that commercialized products for the diagnostic field. His background as a molecular biologist and inventor are strong support to building a commercially viable diagnostic company.

Judy Muller, Ph.D. - COO

MR. Muller has more than 25 years commercializing life science products. Most notably, Judy founded and served as CEO of Biomatrica. She brings expertise in discovery, operations, and manufacturing to building BioFluidica's commercial strategy.

Paul Diaz, Ph.D. - Director Commercial Development

Under the direction of Dr. Diaz, the commercial development team continues to benefit from the research of the scientific founders and move the processes into a commercially viable phase of the company.

Company Overview (Clinical Impact and Value Proposition)

DiaCarta's QuantiDNA™ RadTox System is a unique, patented technology that measures tissue damage shortly following radiation-induced injury using cell-free DNA from a drop of blood. Premised on murine and primate studies showing that circulating DNA is logarithmically increased with whole-body radiation dose, RadTox has the potential to overcome many of the species-specific challenges faced by biodosimetry panels. Two clinical studies have confirmed that peak RadTox levels occur in the first week and that the integral dose and bladder dose correlate with the average, peak, and day-2 RadTox levels. We expect, for the first time, to subcategorize patients into personalized risk groups and to provide a general method of real-time assessment of acute and progressive chronic radiotoxicity. RadTox will be inexpensive, can be employed on a needle-stick blood drop, and will enable minimally invasive blood collection longitudinally over time. The technique should provide accurate risk assessment in a local laboratory setting within the first days after irradiation and continue to supply valuable information for ongoing radiotoxicity for weeks after treatment. This simple measurement of total DNA in the circulation requires minimal specimen processing and can be easily deployed with a commercially available, conventional microplate luminometer platform.

Market and Commercialization Strategy

The International Agency for Research on Cancer reports 14 million new cases of cancer worldwide, with 50% of patients receiving radiotherapy during their illness, and radiotherapy contributing to 40% of curative treatment for cancer. The radiotherapy market is expected to reach $7.5B USD by 2020 from $5.6B in 2015 at a compound annual growth rate of 6.2%. The key market drivers underpinning this growth include technological advancements and increasing incidence of cancer in an aging population. DiaCarta foresees three initial pipeline products following clearance of RadTox: (1) organ and tumor-specific circulating biomarkers that can be combined with RadTox to distinguish the amount of organ damage and degree of tumor response; (2) a portable assay to measure effects of industrial exposure to radiation; and (3) a tool to measure mass exposure to radiation.

Technical & Competitive Advantage

RadTox has many advantages over existing and emerging biodosimetry technologies. Specimen collection does not involve PCR and can be performed in various environments on instrumentation available in a CLIA laboratory. This advantage is further strengthened by our patented DNA markers. The RadTox System is very likely to become the gold standard in assessing localized, individual patient sensitivities to irradiation, as existing gold-standard biodosimetry approaches have significant limitations that make them unsuitable predictors of localized radiotoxicity. RadTox has the flexibility to be multiplexed with additional DNA or RNA markers, providing data on patient sensitivities specific to organs or infections. DxTerity Diagnostics' REDI-Dx biodosimetry test is a close competitor, but we believe the current RADIANT 700-patient clinical trial has design weaknesses that are likely to limit success of that study.

Regulatory Strategy & Intellectual Property

DiaCarta is protected by 18 issued patent applications (US and PCT) for its work on bDNA and related products. DiaCarta completed license agreements with Siemens for exclusive rights to patent families and licenses in patents related to bDNA and measurement of free circulating Alu. DiaCarta has a trademark for the name "RadTox" and holds exclusive rights to xenonucleic acid detection.

Key Milestones

Scale-up and documentation of cGMP-manufactured RadTox kits and commercial reagents.	Q1 2019
Design, perform, and analyze multi-institutional clinical trial to evaluate RadTox clinical utility.	Q3 2021
Administrative coordination with US FDA, USPHS, NIH/NCI, and clinical trial centers.	Q1 2022

Capitalization History

03/2014	Series A	BioVeda China	$8M
02/2018	Series B	Fortune Fountain Capital, Good Health Capital, Vision Max	$45M

Use of Proceeds

In addition to partnerships with instrumentation providers and healthcare diagnostic companies, DiaCarta's financial plan includes acquiring funds from several different sources that will be contacted during the Phase II SBIR. DiaCarta will use funds for phase III product development, regulatory approval, and launch of the RadTox assay upon successful completion of phase II milestones.

Key Team Members

Aiguo Zhang, Ph.D. - CEO

Dr. Zhang has industry experience as an expert in bDNA-based assays. Under his direction, DiaCarta will be responsible for all aspects of the project, its milestones, reporting, and financial management.

Michael Powell, Ph.D. - CSO

Dr. Powell has more than 25 years of experience in the management of molecular diagnostic assay research. He will assure that scientific progress and milestones are met and reported. He will deliver the CLIA-ready Alu assay for Phase II.

Paul Okunieff, M.D. - Subcontract PI

Dr. Okunieff is a radiation oncologist/biologist and chair of the UF Dept. of Radiation Oncology. He will oversee overall clinical direction and implementation of the clinical trial, result evaluation, timelines and milestones, and regulatory discussions.

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Company Overview (Clinical Impact and Value Proposition)

ImCare Biotech, LLC is a biotechnology company developing innovative diagnostic biomarkers and developmental drugs for the treatment of liver diseases such as hepatocellular carcinoma (HCC) and intrahepatic cholangiocarcinoma (ICC). Our leading product, HepatoDetect®, is a serum-based diagnostic immunoassay that is significantly more sensitive and specific in detecting liver cancer than existing generations of immunoassays and is effective for detecting HCC including in its early stages.

Market and Commercialization Strategy

Liver cancer is the 2nd most deadly cancer in the world. There are four patient groups that are at very high risk of developing liver cancer (HCC in particular), which include patients with chronic Hepatitis B, chronic Hepatitis C with cirrhosis, non-viral cirrhotic, and prior HCC. In total, there are 2.6 million patients in the U.S. and an effective risk assessment exam is necessary for these patients. The current standard practice screens these high-risk patients using an AFP biomarker and imaging (Ultrasound and/or MRI) every 3/6 months. Assuming screening is done every 3 months, total market value for our product is $2.1B. This assumes a test price of $200 (in line with similar cancer diagnostic immunoassays). The market is even larger internationally, with chronic hepatitis being significantly more prevalent in Asia than U.S. The most proven commercialization strategy for this type of cancer immunoassay is to partner with a large diagnostic company such as Roche or Abbott through a license agreement or full partnership. The biomarker and key antibodies would be integrated onto the partner's automated platforms and sold directly to lab customers like LabCorp. Running an innovative new proprietary biomarker like ours as a service is also an option. This could be done in a CLIA certified lab setting. Our pipeline includes several other antibodies and compounds that have immune-oncology and therapeutic applications.

Technical & Competitive Advantage

Currently, the most widely used biomarker for assessing risk of developing liver cancer (specifically HCC) is AFP. Our technology has a significantly higher sensitivity and specificity compared to AFP. The specificity of 95% for HepatoDetect compared to 71% for AFP means that our test can distinguish HCC cases much more clearly from those of pancreatitis, hepatitis, and liver cirrhosis. Moreover, our test can detect HCC in those patients where the AFP test gives a false-negative result (40% of the time). With a higher sensitivity, our test is also able to detect HCC in its early stages (BCLC Stage 0) where the tumor size <2cm. This allows for better treatment and is an area where imaging (MRI/CT) has traditionally not been able to function well. As the test is based on the proven blood sera based immunoassay technology (ELISA), it is relatively affordable (<1/5th the price of imaging) and easy to use (biopsies are invasive and imaging requires traveling to specialized centers). We believe that HepatoDetect will be ideally suited to be a standalone product or used in conjunction with other diagnostics modes such as imaging to accurately assess risk of HCC in various situations.

Regulatory Strategy & Intellectual Property

We have a broad patent strategy as well as a detailed strategy for company know-how. ImCare owns more than 35 Claims including both Method and Composition of Matter patents pending across N. America, EU, and Asia. All patents are fully owned by ImCare Biotech, LLC. We work closely advisors and consultants on the regulatory matters involving the FDA in the US and CE in Europe.

Key Milestones

Standardize Technology and Finalize HepatoDetect® for Clinical Use.	2018
Produce HepatoDetect® and begin Pivotal Clinical Study Required for FDA Clearance.	2019
Validate HepatoDetect® and Apply for FDA 510K Market Clearance.	2020
Commercialize HepatoDetect® and Begin to Distribute in the USA and Europe.	2021

Capitalization History

Various	Seed Capital	Friends and Family	$100K
03/2012	Grant	NIH/NCI	$292K
03/2015	Grant	NIH/NCI	$1.95M

Use of Proceeds

ImCare is in the process of securing Series A of $5-8M. The capital raised will be used to support the clinical study required for FDA 510K clearance, speed up commercialization, and develop of key technologies with potential for immuno-therapeutic utility.

Key Team Members

Xuanyong Lu, Ph.D. - CSO

Dr. Lu is a former professor at Drexel University, his research focused on long-term Hepatitis and the development of liver cancer. He has more than 50 publications in prestigious academic journals and is the inventor of 5 patented technologies.

Aaron Yefei Lu, M.B.A. - CEO

Dr. Lu has worked as a consultant at McKinsey & Company and brings a strong background in general business management and operational efficiency from working with Fortune 500 companies. He has also worked as an investment manager.

Mina Soryal, M.S. - Director of Commercialization

Mr. Soryal brings bioengineering and entrepreneurship background from Drexel University where he completed clinical practicums in interventional cardiology, bariatric surgery, and emergency medicine as well as working directly with entrepreneur in Residence.

KIYATEC / Patient-derived 3D Co-cultured Micro-Tumors

Matt Gevaert | matt.gevaert@kiyatec.com | 864-502-2013 | www.kiyatec.com

Company Overview (Clinical Impact and Value Proposition)

KIYATEC aims to change the future of cancer care by accurately predicting patient-specific response and non-response prior to treatment. We use the patient's own living tumor cells to create functional 3D models. Our goal is to enable physicians to isolate only the effective treatments as quickly as possible—making true personalized medicine a reality. Our approach has been validated through engagements with leading cancer hospitals and top 10 pharmaceutical companies. We have two ex vivo testing platforms, one with higher throughput/quicker results and one for more complex and/or longer duration biology. The former is a seven-day turnaround test, suitable for the chemotherapies and targeted agents which constitute the current first and second line therapy options for most solid tumors. The latter is our proprietary primary human derived 3D microtumors, which are heterotypic perfused co-cultures in which we have optimized a systemic strategy of adapting scaffolds, cell types, and media conditions to KIYATEC's novel and patented 3D perfusion bioreactor, the 3DKUBE™. We are publishing our first clinical data, a prospective multi-center study in ovarian cancer which demonstrates that we can make patient specific, future response and non-response predictions.

Market and Commercialization Strategy

For KIYATEC's higher throughput/quicker results platform, the total addressable U.S. market for patient specific drug response prediction is $850M annually, across the 4 solid tumor classes in our pipeline (ovarian cancer, gliomas, a subset of rare tumors and triple negative breast cancer). For our more complex and/or longer duration biology platform, the favorable health economics of our first platform testing mostly chemotherapies and targeted agents will be significantly more meaningful for testing of very expensive I/O therapies with our second platform. We anticipate that by the time this platform is commercialized for patient specific drug response prediction of immune oncology therapies, the total U.S. market for this testing will also be in the billions.

Technical & Competitive Advantage

KIYATEC's drug response profiling platform uses a 3D microenvironment to culture cells, enabling better prediction of clinical outcomes than 2D microenvironments. KIYATEC has shown accurate prediction of patient/clinical drug response using our 3D cell cultures, whereas 2D cultures have much less accurate predictions. KIYATEC has shown that cells cultured in an actively perfused microenvironment had increased cell viability, richer paracrine interactions, and increased cell functionality compared to static. Versus genomics, which provide a statistical possibility (with mutation A there is a B% chance the patient will respond to targeted agent C), KIYATEC provides pre-verification of outcomes (the patient will be a responder). KIYATEC's exceptional clinical connectivity results in more effective clinical testing procedures and more successful translation of laboratory results back into the clinic.

Regulatory Strategy & Intellectual Property

KIYATEC has four issued and two pending patents. Our filed patent applications contain product and method claims that mostly center around our 3D micro-tumor platform and our commercialized 3DKUBE(R) perfusion bioreactor system. Our business utilizes a central lab model which makes the technology difficult to reverse engineer.

Key Milestones

Publication of ovarian cancer pilot clinical study data demonstrating high test predictive accuracy	Q3/4 2018
Close initial tranche of Series C funding	Q3/4 2018
Interim analysis of clinical data from currently accruing study	2019
Launch and first clinical revenue commercial clinical products	2020

Capitalization History

2012-14	Series A	Angels, VC	$2.8M
2013-	Contracts	NIH/NCI	$4.2M
2015-17	Series B	Angels, VC	$4M
2015-	Grants	NIH/NIBIB	$1.7M
2017	Bridge Round	Angels	$2.2M

Use of Proceeds

We are raising a $20M Series C round with use of funds to include, by 2022, completion of patient testing for three initial clinical products, commercial launch of two clinical products, and a strong foundation for sales and marketing as well as payer engagement.

Key Team Members

Matthew Gevaert, Ph.D. - CEO

Dr. Gevaert has led the company through start-up and into revenue (millions), ~20 employees and has raised >$9M investment. Prior roles including IP commercialization and technology start-up experience as well as R&D experience at Merck, 3M and Dow.

Tessa DesRochers, Ph.D. - CSO

Dr. DesRochers has more than 14 years' experience in complex 3D cell culture and analysis, through graduate work and post-doc in Boston (Tufts and Children's Hospital). She serves as PI on KIYATEC's SBIR awards.

Lillia Holmes, M.S. - COO

Ms. Holmes has more than 20 years' operations / regulatory experience, including manufacture & delivery of cellular therapies.

Steven Bogen | sbogen@mdpsci.com | 617-636-5422 | mdpcontrols.com

Company Overview (Clinical Impact and Value Proposition)

Medical Discovery Partners (MDP) solves the problem of high error rates (up to 25%) in protein biomarker testing of tumor specimens. Our products address an important unmet need for accuracy and reproducibility. More than 100 such protein biomarker (immunohistochemical) tests are used daily for cancer diagnosis and determination of appropriate therapy. The problem with immunohistochemical tests is that they do not have the quantitative accuracy that patient care requires. The field struggles to standardize measurements that employ different antibodies, detection systems, instruments, and protocols. The problem affects routine histopathologic diagnosis as well as companion diagnostics, as there are hundreds of drugs in development linked to a protein biomarker measurement. This makes it difficult to identify suitable patient groups, a problem that our technology solves. Like Diagnostic Immunohistochemistry (IHC), other *in vitro* diagnostic disciplines also often have numerous commercial methods for performing the same test. Yet this diversity does not create the same magnitude of difficulty in standardization and accuracy as it does in Diagnostic IHC. The challenges associated with protein biomarker measurements in tumors are unique because conventional methods of standardization could never be applied. Unlike other *in vitro* diagnostic disciplines, reference standards, calibrators, and traceable units of measure do not exist. The technology has never been developed. MDP solved this technical hurdle. We created the first system of standardized immunohistochemistry calibrators and controls incorporating traceable units of measure, clinically tested them in customer laboratories, published the data, and established cGMP manufacturing. The value proposition for adoption by the Diagnostic IHC laboratory is the same that drove adoption in other laboratory testing disciplines.

Market and Commercialization Strategy

MDP is bringing to market the first Diagnostic Immunohistochemistry calibrators and controls characterized in traceable units of measure. We estimate the annual worldwide market size as approx. $100M. Outside research pegs annual IHC market growth at 11%/year. Also, solving accuracy and standardization challenges may have an outsized impact on the $1-1.5B Diagnostic IHC market.
Calibrators: There are no calibrators in the field of Diagnostic IHC. Calibrators enable precise, quantitative test results that are otherwise impossible to achieve. The commercialization strategy is to demonstrate to pharmaceutical firms how calibrators improve patient treatment stratification by fostering reproducible, accurate companion diagnostic testing. We further plan to demonstrate to clinical laboratories how calibrators improve the accuracy of immunohistochemical tests already on the market. To this end, we are establishing clinical trial collaborations with international laboratory accreditation agencies.
Controls: Diagnostic IHC laboratories use controls every day to verify that the test is working properly before reporting patient test results. MDP's controls replace a homebrew market in which each lab creates controls from archived patient test samples. There is currently no standardization of controls. The commercialization strategy is to demonstrate to clinical laboratories that standardized controls are more sensitive, reproducible, simple to use, better characterized, and a fraction of the cost.

Technical & Competitive Advantage

MDP's controls and calibrators are a platform technology with which many individual products will be created. The most important competitive advantage is the ability to define the products with traceable, quantitative units of measure. This is a sine qua non for calibrators. There are no competing commercial products on the market with this essential attribute.

Regulatory Strategy & Intellectual Property

Most of the products are Class I in vitro diagnostics. The remainder require a 510(k), the first of which we are submitting. MDP has two pending patents that capture the innovations associated with its composition and method of use.

Key Milestones

Recruit VP Sales & Marketing	Q4 2018
Complete protein biomarker controls product launch menu	Q2 2019
Pharmaceutical partner for calibrators	Q2 2019

Capitalization History

2014-19	Grants	NIH/NCI	$2.87M

Use of Proceeds

MDP is raising a seed round to launch the calibrators and controls product lines, attaining MDP's first commercial sales.

Key Team Members

Steven Bogen, M.D., Ph.D. - President

Dr. Bogen is a board-certified clinical pathologist. He founded CytoLogix, a diagnostics company that developed the Artisan instrument line and was acquired by Dako/Agilent. He is co-inventor of the technology and has expertise in IP/project management.

Seshi Sompuram, Ph.D. - VP R&D

Dr. Sompuram is a co-inventor of MDP's technology and leads the product expansion effort.

Kodela Vani, M.S. - Manufacturing Manager

Ms. Vani has more than 20 years' experience in product development and is Manufacturing Manager for the Company.

Harry Ostrer | harry.ostrer@gmail.com | 917-881-4204 | www.morganandmendel.com

Company Overview (Clinical Impact and Value Proposition)

Morgan and Mendel Genomics (MMG) is a start-up genomics technology company that creates and commercializes simple and accurate genetic tests for patient diagnosis and risk assessment using low-cost, novel technologies. MMG's novel flow variant assay (FVA) method measures the response of human blood cells to radiomimetic chemicals that damage DNA in the key double strand break repair, cyclin-checkpoint and mismatch repair pathways. The company seeks to develop and commercialize an innovative, simple, rapid and inexpensive clinical test that will identify with high accuracy those at high risk for breast cancers and other cancers as well as those with cancer who may be responsive to certain classes of drugs. This test will be implemented initially as a laboratory-developed test (LDT) and subsequently as an FDA-approved in vitro diagnostic (IVD). Current strategic partnerships include the two largest health care systems in New York State whose catchment areas provide care to 8 million people, NCI Breast Cancer Family Registry, a state-of-the art equipment manufacturer, and a major provider of reagents for this technology. The strengths of the company include platform technology development, ability to scale this technology to large numbers of patients/samples, sophisticated knowledge of the genetic testing market, including criteria for utilization and reimbursement and name recognition.

Market and Commercialization Strategy

Germline assessment of breast cancer risk is one of the most common genetic tests in the U.S. This market is expected to increase to over a million per year as accuracy improves and testing is expanded to more people who seek genetic screening in the absence of diagnosis or strong family history. Currently, there is no comparable test for the type of analysis conducted by FVAs. Today, these needs are met with DNA sequence-based tests that have limited accuracy, speed and cost. The FVA test is faster and more accurate for identifying genetic risks than gene panel sequencing. The clear delineation of risk groups with minimal overlap and highly significant p-values (10^{-8} to 10^{-4} range) in statistical testing over 2 independent studies demonstrated that this work is extremely robust and unlikely to be revised as new cohorts of subjects are tested. Our clinical test represents a major conceptual alteration, because it detects functional alterations that are caused by genetic mutations. Initially the test will be deployed as a laboratory-developed follow-up test (LDT) for those with variants of uncertain significance, who can be assigned to high-risk or population-risk (low-risk) groups, removing them from the limbo of uncertainty and creating a new market for follow-up testing. With FDA approval, the test will be marketed to commercial and academic medical center labs to identify those at high-risk whose mutations are missed by DNA sequencing, thus removing them from the false-negative group and *creating a new market for population screening*.

Technical & Competitive Advantage

With a single, unified workflow, the test produces a result within 2 days compared to 2 weeks or longer for gene panel sequencing. In the published studies, the sensitivity (FVAs 0.98, panel sequencing 0.25-0.3) and specificity (FVAs 1, panel sequencing 0.6-0.8) were superior. Also, the cost was lower (FVAs <$200, gene panel sequencing $250-$1400). Thus, FVAs are well-positioned to become a follow-on and subsequent replacement method for panel sequencing.

Regulatory Strategy & Intellectual Property

MMG has two pending patents filed by Albert Einstein College of Medicine and the technology was licensed by MMG. The first is a blanket technology patent and the second applies specifically for the breast cancer risk assessment test.

Key Milestones

Develop reagents for FVA kits, including proprietary antibodies and software	2018
Develop hazard ratios for breast cancer risk by decade	2018
Establish LDT laboratory partnerships	2018
Expand use of FVAs for other breast cancer indications and for other cancers	2019-20

Capitalization History

2014-17	Angel	Family and friends	$204.5k

Use of Proceeds

MMG is currently seeking $2.5M for 3 years—40% in year 1, 35% in year 2, and 25% in year 3. MMG plans to use the proceeds toward lab space, equipment, patenting, legal, regulatory, and hiring a senior scientist and a business developer.

Key Team Members

Andrew Paul, M.S. - President/CEO

Mr. Paul is a serial entrepreneur who established and carries out the business practices of the company, including incorporation and internal business structures. He manages contracting, compliance, IP, collection and payment of funds and bookkeeping.

Harry Ostrer, M.D. - Founder/Chairman of Scientific Advisory Board

Dr. Oster is a board-certified medical and molecular geneticist. He oversees clinical genetic test, including test design and analysis, clinical partnerships, proposal and manuscript drafting and submission, public presentations, and regulatory compliance.

Johnny Loke, M.S. - Founder/Scientific Advisor

Mr. Loke is a genomic scientist. He oversees technology development, including methods for perturbing and assessing genetic pathways, selection of reagents and evaluation of machines. He subsequently locks down protocols for clinical implementation.

Jerry Williamson | jwilliamson@nanoviewbio.com | 781-365-VIEW | www.nanoviewbio.com

Company Overview (Clinical Impact and Value Proposition)

NanoView's mission is to facilitate the use of Extracellular Vesicles (EVs) to life science research, clinical diagnostics, and therapeutics by providing proprietary, high-throughput, cost-effective analysis solutions. The EV field is rapidly growing and the past 5 years have shown that EVs have huge potential in oncology. EV-based liquid biopsies are being investigated for early detection, predict sites of metastasis, and used to guide treatment monitoring. NanoView's ExoView Platform collapses characterization of EVs from 3 steps into a single high-throughput process by removing the need for purification and combining single EV analysis with specific analyte capture. The platform also allows combined proteomic and nucleic acid co-localization on single EVs. The ExoView platform will expedite EV biomarker research, reveal new data around EV heterogeneity and make-up, and facilitate translation of EV-based diagnostics. The initial go-to-market strategy is a Research-Use Only platform that consists of an analytical instrument (EV1 Reader) and single-use consumables for multiplexed EV characterization.

Market and Commercialization Strategy

1) Early Access Program (EAP) to define offering (Year 1): Stratify high value customers based on their research impact on important diseases and access to clinical samples. Collaborate closely with key opinion leaders to define disease specific panels of biomarkers.
2) Leverage existing research product to facilitate research (Years 1-2): Phased to follow and run concurrently with long-term EAP collaborations. Publish seminal papers that demonstrate the value of the ExoView platform versus other approaches. Leverage existing market knowledge through employees known to the community. Drive instrument sales and robust consumable revenues.
3) Enhance existing product to facilitate manufacturing of therapeutic vectors (Years 1-3): Leverage the growth in EV therapeutics by enabling efficiency gains in downstream processing of EV vectors. Embed 21 CFR Part 11 requirements into existing portfolio to facilitate biopharma utility. Broaden customer base by providing analytical services to manufacturers of therapeutic vectors.
4) Deliver high-value precision diagnostic products (Years 2-5): Use academic collaborations to select diagnostic assays aimed at unmet needs. Establish co-ownership of content development. Address precision medicine oriented (oncology- pancreatic cancer).

Technical & Competitive Advantage

There are two levels of competition: (1) Workflow, scalability and sample analysis cost, and (2) Analytical performance versus other techniques. Currently, there are many workflows for processing EV samples that are taken from clinical sources or from cell-culture. Irrespective of source, the sample will be processed using a combination of purification techniques such as precipitation kits, ultra-centrifugation, and size-exclusion chromatography in attempts to produce a pure EV sample. We've found out through 100+ interviews that the purification requirement before EV analysis was a pain-point in both labor and variability, and removing the need to perform this step was a major value proposition to our customers. Our assay condenses the purification and analytical processes (size, concentration, and multiplexed phenotyping) into a single step and reduces operator hands on-time by 94%. A more direct competition is in analytical instrumentation. Existing analytical tools, requiring purification, are our direct competition. Here we focus on tools designed for characterizing nanoparticles (without specificity) and applied to EV research and phenotypical tools.

Regulatory Strategy & Intellectual Property

Much of this project was originally developed at Boston University (BU) and NanoView has a license with the BU for exclusive field-of-use for the patent applications that protect the platform for all exosome and extracellular vesicle applications.

Key Milestones

Selection, payment, and delivery to 6 Early Access Program Partners	Q3 2018
High-Impact Journal Publication	Q4 2018
Demonstration of Commercial Pipeline in-line with financial model	Q1 2019
Proof-of-principle clinical demonstration of Liquid Biopsy for PDAC (NCI)	Q2 2019

Capitalization History

02/2017	Series A	Sands Capital, PBM Capital, Esco Ventures (Amount undisclosed)	-
05/2017	Grant	NIH/NCI	$225k
2017-18	Grants	NSF	$975k

Use of Proceeds

For Series B, we are raising $10M to support commercial launch of the RUO platform.

Key Team Members

Jerry Williamson, M.B.A. - CEO

Mr. Williamson brings more than 30 years of commercial operating, business development and corporate management experience (Biacore, Pyrosequencing, Genetix), in the diagnostic and life science analytical tool marketplace where he has held leadership roles. Most recently, he was CEO of Kew, a precision diagnostics company.

David Freedman, Ph.D. & George Daaboul, Ph.D. - Co-founders

Drs. Freedman and Daaboul developed the technology during graduate and post-graduate work at Boston University. They have developed the platform to the point where it is ready for commercial launch.

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Company Overview (Clinical Impact and Value Proposition)

OncoTAb aims to develop and commercialize a continuum of products to address unmet needs in breast and pancreatic cancer diagnosis and treatment. Our platform is a patented monoclonal antibody (TAB004) that specifically recognizes the tumor form of MUC1 (tMUC1). OncoTAb's first product is Agkura® Personal Score (APS)–a simple blood test to screen for breast cancer as an adjunct to mammography in women with dense breast tissue. In a blinded study, the APS test demonstrated the ability to detect, up to 2 years earlier, ~70% of cancers that would progress to be late stage when screened with mammography alone. This test is currently offered in OncoTAb's CLIA certified laboratory. We are in negotiation to launch APS via a Joint Venture in India and are in early discussions with a multinational firm. Fully humanized TAB004 (hTAB004) has been used to demonstrate imaging breast and pancreatic cancer in-vivo, with localization of hTAB004 on tumors but not on healthy tissue. We have demonstrated exquisite targeting of triple negative breast cancer (TNBC) xenograft tumors with Actinium-225 labeled hTAB004. Treated animals showed ~90% regression of tumors and 100% survival.

Market and Commercialization Strategy

More than 266,000 women will be diagnosed with breast cancer in 2018, and ~40,000 of the diagnosis will be TNBC. The U.S. market size for a 225Ac-DOTA-hTAB004 targeted therapy for TNBC is at ~$3B. This is based on sales of Xofigo ($69k per patient for 6-month treatment). The FDA approved Xofigo three months ahead of schedule. Assuming a similar adoption rate, radiolabeled hTAB004 is projected to have year 1 sales of $52M and an annual growth rate of 38%. Radiolabeled TAB004 will address an unmet need for TNBC patients with metastasis since there are no targeted therapies for TNBC. The localized radiation is an advantage given the known benefit of radiation reducing loco-regional recurrence. Preclinical studies using TAB004 to target tMUC1+ tumors with other immunotherapy approaches have also been conducted—nanoparticle-TAB004 conjugates were able to eliminate xenograft pancreatic tumors. OncoTAb is seeking to partner/out-license CAR-T therapy and ADC development.

Technical & Competitive Advantage

The advantages of radiolabeling a tumor-specific antibody such as hTAB004 for targeted radionuclide therapy include: (1) potential theranostic application of hTAB004 to image as well as treat; (2) lower locoregional recurrence without the risks of Whole Breast Radiation Therapy (WBRT); and (3) potentially lower cardiac toxicity compared to WBRT. Competing products include antibody-drug conjugates (IMMU-132 by Immunomedics), targeting frizzle receptors (Vantictumab by OncoMed), and combination therapies (Atezolizumab + nab-paclitaxel by Roche). Results to date have shown combination therapy to have a higher objective response rate of 43% (vs 33%). ~60% of patients receive radiotherapy as part of their treatment, and ~40% of cancer cures include radiotherapy. Therefore, hTAB004 targeted radionuclide therapy is expected to be received well in combination with other novel therapies.

Regulatory Strategy & Intellectual Property

A portfolio of 10 patents protect the antibody and its fragments, and use of antibody for diagnostics, imaging and therapeutics. University of North Carolina (UNC) at Charlotte holds the patents and OncoTAb has a worldwide exclusive license to the technology.

Key Milestones

Secure Funding for Targeted Radionuclide Therapy development	Q1 2019
Initiate pharmacology and pharmacokinetic studies with bioreactor produced antibody from stable cell line	Q1 2020
Produce GLP grade antibody, complete toxicity studies and submit IND for First in Human (FIH) Clinical Trial	Q1 2021
Produce GMP grade antibody and initiate FIH Clinical Trial	Q4 2021

Capitalization History

2012-14	Angel & Research Loan	LLC, Individuals, IMAF Charlotte & NC Biotech Center	$1.93M
2016-18	Convertible Debt & etc.	Founders & Angels	$185k
2016-18	Grants & Contract	NIH/NCI & NC Matching Awards	$825k

Use of Proceeds

We are seeking $10M to take the hTAB004 based radionuclide therapy through FIH studies: Antibody manufacturing scale-up and IND enabling studies: $2M; GMP grade antibody production and FIH Imaging Trial: $2M; FIH Therapy Trial: $6M.

Key Team Members

Rahul Puri, Ph.D. - Co-founder/CEO

Dr. Puri has more than 25 years of professional and executive leadership experience across multiple sectors. He is a creative and enthusiastic problem solver credited with multiple inventions and holder of eleven patents.

Pinku Mukherjee, Ph.D. - Co-founder/CSO

Dr. Mukherjee has been a cancer researcher for 27 years. She is the Irwin Belk Endowed Professor for Cancer Research and Chair of biological sciences at the UNC. She was an associate professor at the Mayo Clinic and has 100+ peer reviewed publications.

Taffy Williams, Ph.D. - Chairman of the Board

Dr. Williams has extensive pharmaceutical experience and his previous roles include: President and CEO of Photogen Technologies Inc., President and Founder of InKine Pharmaceutical Company; and, CEO, Chairman and President of Panax.

Tymora Analytical Operations / Phosphoprotein Liquid Biopsy

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Company Overview (Clinical Impact and Value Proposition)

Tymora Analytical Operations offers innovative research products and services to R&D organizations within the life sciences market. Tymora has developed a set of effective technologies for analysis of protein phosphorylation that relates to the onset of diseases, most notably cancer. Our flagship products, including PolyMAC and pIMAGO, enable the discovery of novel disease biomarkers and support our efforts to develop non-invasive cancer diagnostics methods using protein phosphorylation in urine and plasma. We have developed a highly efficient method for isolation of extracellular vesicles (EVs) to enable the discovery of cancer-specific proteins, phosphoproteins, and other molecules in plasma, urine, and saliva. EVs are shed by cells into virtually every biological fluid and provide a good representation of the parent cells. EV-based disease markers can also be identified well before the onset of symptoms or physiological detection of a tumor. Using our method, we can identify hundreds of phosphoproteins from EVs from only 1mL of plasma or 10mL of urine. We have generated a list of most promising phosphoprotein markers present in bladder cancer EVs, which will enable differentiation of low-grade and high-grade bladder cancer patients from healthy individuals. We plan to develop a reliable platform for biofluid-based phosphoprotein analysis with an initial focus on bladder cancer.

Market and Commercialization Strategy

It would be appealing to develop biomarkers from urine for urologic cancers such as bladder or prostate cancer. Urine has multiple advantages, including truly non-invasive sampling compared to blood draw, opportunity for more frequent collection and larger obtainable volumes. The market for a new detection/monitoring test is >$1B in the U.S. (based on annual cystoscopy/cytology.) referrals. However, this does not include the extra 6 million annual hematuria cases that are never followed through for cancer testing. Considering this, the market potential for a new non-invasive alternative to cystoscopy for early detection is >$4B in the U.S. Combined with $700M post-treatment monitoring market, the overall market for bladder cancer testing is close to $5B. We estimate the accessible market size for our assay at $600M. Our efforts will result in three unique market opportunities: 1) business partnerships for development and validation of a functional workflow for routine protein/phosphoprotein biomarker discovery; 2) a device for automated simultaneous EV enrichment and protein cargo extraction; and 3) licensing of a novel diagnostic assay.

Technical & Competitive Advantage

Our EV trapping technology enables 10-40-fold increase in recovery compared to other products. It is also highly reproducible, fast, and simple to use. These features are critical for effective biomarker discovery and validation for disease diagnosis. For bladder cancer detection, the new EV phosphoprotein detection test is expected to provide significant improvements over current procedures. Improved performance along with non-invasive nature of the assay will benefit patients, clinicians, and payers. The current standard is the cystoscopy, which is invasive, painful, expensive and often has poor sensitivity for low-grade tumors.

Regulatory Strategy & Intellectual Property

EV diagnostics is an immature field, so the IP space is wide open. We have filed the patent for our method to capture and extract proteins and phosphoproteins from EVs in biofluids. Tymora has three patents pending in total and has exclusive licenses to the two technologies developed by Tymora's co-founders, for PolyMAC and pIMAGO, through Purdue University-owned granted patents.

Key Milestones

Finish and commercialize EV capture from biofluids technology	Q4 2018
Validate bladder cancer biomarkers	2020/2021
Register ASR with FDA	2022

Capitalization History

2011-17	Grants	NIH, NSF, & State of IN	$2.3M

Use of Proceeds

Tymora is looking to partner with other organizations to bring our new technology and biomarker panel to clinical relevance and fully realize its commercialization potential. We also plan to secure new collaborative projects and customers with organizations interested in using our non-invasive biomarkers approach to develop their own diagnostics assays and companion diagnostic tests.

Key Team Members

Anton Iliuk, Ph.D. - President/CTO

Dr. Iliuk is the co-inventor of PolyMAC, pIMAGO, EVCISE, EVtrap and all other Tymora's technologies. He is responsible for daily operations, R&D management, and bringing product and service ideas to the market.

Andy Tao, Ph.D. - CSO

Dr. Tao is a professor of biochemistry at Purdue University, where he runs an active research group. He was mentored by two great scientific minds and inventors—professors Leroy Hood (postdoctoral advisor) and R. Graham Cooks (Ph.D. advisor).

Peter Kissinger, Ph.D. - Board Member

Dr. Kissinger is a successful entrepreneur and a product commercialization expert. His previous positions include the founder of Bioanalytical Systems, Inc., which is now a multi-million-dollar analytical instrumentation and clinical services company).

American BioOptics / Point-of-Care Cancer Risk Screening System

Eric Benson | ebenson@abo.health | 312-933-7427 | www.abo.health

Company Overview (Clinical Impact and Value Proposition)

American BioOptics (ABO) is revolutionizing cancer screening with the introduction of its InPoint™ System—the first point-of-care, personalized cancer risk assessment tool to provide fast and accurate identification of high-risk patients needing further evaluation. ABO's InPoint System consists of a bedside cart–classified as durable medical equipment–containing a spectrometer, filters, calibrator, computer and reusable fiber optic trunk. A disposable probe tip is integrated with the reusable trunk and introduced into the distal part of the rectum. The screening test lasts ~5-10 minutes and is highly accurate for identification of advanced adenomas; a precursor to cancerous polyps. The system then provides a cancer risk assessment–average risk vs high-risk–whereby high-risk patients should be further evaluated by colonoscopy. For clinicians, the InPoint System will identify high-risk patients. For patients, the InPoint System will be the preferred screening process since it is minimally invasive, provides immediate results, and does not require a demanding pre-procedure preparation. For providers and payers, the InPoint System delivers a cost-effective use of resources by early identification of high-risk patients that need invasive evaluation by colonoscopy.

Market and Commercialization Strategy

ABO is entering the $13.8B global colorectal (CRC) diagnostic and testing market with its InPoint System to provide a cancer risk assessment during annual physicals. Current cancer screening programs assess patients based on age and known risk factors, whereby the US Preventive Services Task Force recently lowered the CRC screening age to 45 for average risk patients. However, current CRC screening methods are demanding on the patient, resulting in only 60% of the designated population remain compliant. Whereas, ABO's InPoint System will improve patient compliance by making cancer screening fast, easy, and accessible; done in 5-10 minutes, no bowel preparation or sedation, and at PCP's office or outpatient clinic. Upon 510(k) de novo approval, ABO will launch the InPoint System and its $170 disposable tips with a three-stage commercialization strategy—targeting U.S. clinical sites in year one, U.S. regional GIs and PCPs years two and three, national U.S. coverage and EU admission thereafter; peak US sales estimated at $2B. During which, ABO will continue to expand the platform's value by seeking marketing approval in the $17.5B lung cancer screening market, uses in the $17.3B endoscopic market, and post-market CRC label expansion to include 35 to 44 year-olds.

Technical & Competitive Advantage

ABO's competitors are current CRC monitoring technologies, such as FOBT and Cologuard. However, these non-invasive screening methods have a low detection rate for advanced adenomas and/or CRC and require the patients to self-perform the test by following complex instructions and handling body secretions; all of which limits their compliance. Invasive screening methods (colonoscopy and sigmoidoscopy) are more accurate, but they require a demanding two-day process of bowel preparation and then performed by specialists under sedation. None of these tests have reduced the 40% CRC screening non-compliance rate. Liquid biopsy is an emerging modality for identifying high-risk patients, but the impact on cancer screening has not yet been reported. The InPoint System will improve testing compliance by making cancer screening accessible through its minimally invasive, point-of-care test.

Regulatory Strategy & Intellectual Property

ABO's IP portfolio focuses on protecting core low-coherence enhanced backscattering technology and optical probe. We are also incorporating proprietary features to prevent generic disposables from being used on our system, along with non-compete agreements with specialty component suppliers. ABO has four approved patent families exclusively licensed by Northwestern.

Key Milestones

InPoint™ Beta design	Q4 2018
InPoint™ Beta build (10-12 systems, and 2,500 disp tips)	Q2 2019
Pivotal FDA trial (1,100 avg risk CRC patients, prospective targeting Advanced Adenomas)	Q4 2019
510(k) de novo approval for CRC risk stratification, prep for commercialization	Q3 2021

Capitalization History

09/2016	Direct to Phase II Grant	NIH/NCI	$1.8M

Use of Proceeds

ABO is seeking $2M in angel funding to finish human factors research/Beta design and to build 10-12 systems & 2,500 disposable probe tips. For 2019-20, we will seek $5M to conduct Pivotal trial and obtain 510(k) de novo approval on a 1,100 patient study.

Key Team Members

Eric Benson, M.B.A., B.M.E. - CEO

Dr. Benson is a successful medical product and technology entrepreneur with 20+ years' experience in leading business operations, financial analysis and planning, commercial strategy and M&A investment banking. He is founder of Lucic Partners.

Dr The-Quyen Nguyen, Ph.D., M.S. - CTO

Dr. Nguyen has 20+ years' experience in micro-fabrication of optical devices and diagnostic fiber-optics, and provides unique understanding for commercialization. He was the 2014 recipient of the SPIE Translational Research Award.

Dr Hemant Roy, M.D. - CMO

Dr. Roy is a clinical gastroenterologist, professor of medicine, and chief of gastroenterology at Boston University Medical Center.

David L. Danielsen | danielsen@cairnsurgical.com | 508-736-0283 | www.cairnsurgical.com

Company Overview (Clinical Impact and Value Proposition)

CairnSurgical, Inc. is a clinical stage company developing the Breast Cancer Locator (BCL) system for use in Breast Conserving Surgery (BCS) procedures, also known as lumpectomy procedures. The BCL system enables the surgeon with information and a device that provides guidance cues on and within the breast at the start of the procedure to precisely localize and resect non-palpable and palpable tumors. Importantly, the device matches the surface and shape of the patient's breast in the supine/surgical position. The BCL is intended to improve both procedure outcomes and procedure economics. It is comprised of a patient-specific, 3D-printed device that is made using proprietary software that analyzes patient MRI images and provides device manufacturing instructions for industry standard additive manufacturing materials and techniques. Our business model will be a service provider and a device manufacturer-seller.

Market and Commercialization Strategy

Nearly 300,000 women are diagnosed with breast cancer annually in the US (invasive cancers plus DCIS). About 70% of these women choose breast conserving surgery (BCS). The goal of BCS is to resect the tumor with a surrounding margin of tissue that is free of cancer while simultaneously preserving the overall shape and appearance of the breast. Positive margin rates associated with BCS are high (~22%-42%) and cause significant strains on patients and the cost of breast healthcare. Meta-analyses of the impact of surgical margins on local recurrence also confirm that negative margins have a positive prognostic effect. The BCL is intended to improve the accuracy and cost-effectiveness of BCS by reducing positive margin rates, and consequently eliminating the need for re-excision surgeries. Our solution is clinically validated in an IRB-approved and published study to have reduced the re-excision rate to zero.

Technical & Competitive Advantage

Competing technologies exist in the form of traditional wire localization, newer localization technologies, and intra-operative tissue inspection devices. These other solutions do not offer the comprehensive image guidance and clinical transfer of cues provided by the BCL technology. Newer solutions either only localize the cancer at a point near its center using replacements for wire localization or provide intra-operative diagnostic information by surveying the excised specimen or the surgical cavity with a probe or scanning device. BCL provides the most comprehensive set of planning and surgical guidance cues to help the surgeon not only localize the position of the tumor but also its spatial extents via surface and interstitial markings of the tumor edges, based on accurate 3-dimensional models of the breast surface and the tumor.

Regulatory Strategy & Intellectual Property

CairnSurgical will seek 510k approval for the BCL. Multiple patents have been filed in the US, Europe, and selected countries utilizing a broad multi-modality approach.

Key Milestones

Complete multi-site feasibility trial in palpable cancers	2018
Submit 510k	Early 2019
Complete randomized, prospective study in non-palpable cancers	2019

Capitalization History

2014	Grant	Synergy Program – Dartmouth	$50k
2015	Grant	New Hampshire Small Business	$100k
2016	Grant	NIH/NCI	$209k
2017	Grant	NIH/NCI	$2M
2018	Grant	NIH/NCI	$2.2M

Use of Proceeds

We are seeking to raise $8M in additional funding through a combination of grants and private equity financing, which will be used to fund a post market pivotal study, BCL production scale-up, and limited launch commercial operations during the pivotal study.

Key Team Members

David L. Danielsen, M.B.A. - CEO

Mr. Danielsen has more than 25 years managing devices, genetic testing, imaging, and health care IT at US Surgical, Boston Scientific, Genzyme Genetics, Hologic, CRA Health. Highly experienced in product and market development, commercialization, and strategy.

Richard L. Barth, M.D. - Co-founder & CMO

Dr. Barth is the Professor of Surgery at Geisel School of Medicine, and chief of General Surgery at Dartmouth-Hitchcock Medical Center. He is a widely-published thought leader in breast cancer and opioid management.

Venkat Krishnaswamy, Ph.D. - Co-founder & CTO

Dr. Krishnaswamy is an entrepreneur experienced in translating ideas into clinically successful products and in managing grant funded programs. Previously he worked as an Assistant Professor at Thayer School of Engineering.

Mitch Moeller | mitch.moeller@corvidamedical.com | 949-293-6500 | www.corvidamedical.com

Company Overview (Clinical Impact and Value Proposition)

Corvida Medical is a medical device manufacturer that optimizes the safe handling of hazardous drugs, such as chemotherapeutics used to treat cancer patients. According to Occupational Safety & Health Administration (OSHA) and National Institute of Occupational Safety & Health (NIOSH), millions of healthcare providers in the U.S. are at risk of exposure to hazardous drugs each year, resulting in serious illnesses such as cancers, reproductive toxicity, genetic mutations, etc. Corvida's Halo Closed System Drug Transfer Device (CSTD) is comprised of a patented disposable medical devices that attach to standard vials, syringes, and IV sets to prevent spills, vapor leaks, and needle-sticks. The device is used during the drug preparation phase in the pharmacy compounding area, as well as at the bedside during drug delivery. Corvida's Halo device is airtight and leak proof and is intuitive and easy to use. Corvida has engineered product for manufacturing; partnered with an industry leading medical device contract manufacturer; validated production molding and assembly processes; and is targeting commercialization in late Q3 2018. We have generated initial sales as part of a limited launch from March-December 2016, piloting in 20 hospitals. During the limited launch, 13,000 doses of hazardous drugs had been administered using Halo. Corvida has received 510(k) clearance, CE Mark, and ISO13485 certification.

Market and Commercialization Strategy

More than 8,000 U.S. cancer clinics/hospitals and another 10,000 cancer centers internationally comprise a total market for CSTD's of US$1.9B that is approximately 50% penetrated. This market is experiencing rapid growth driven by safety demands, peer-reviewed publications and published best practices as well as recent state regulations introducing the first legal requirements that hospitals provide adequate personal protective equipment for workers handling hazardous drugs. Numerous organizations such as OSHA, NIOSH, Joint Commission, ONS, American Society of Health-System Pharmacists, International Society of Oncology Pharmacy Practitioners, and European Association of Hospital Pharmacy focusing on improved safety are helping to drive growth in the market.

Technical & Competitive Advantage

Corvida Medical provides a disposable CTSD that provides greater safety and significantly improved usability compared to any other product on the market, enabling healthcare providers to safely deliver the highest quality care to patients. The device integrates with industry standard drug vials, syringes and IV sets and is available at market competitive prices. Competitive advantages of using Corvida's Halo over competing products include: superior fluid and vapor containment as compared to the market leading device, fewer pieces/parts and less steps, and less forceful manipulations resulting in less repetitive stress injuries. Safety, simplicity, ease of use and ergonomics drive end-user preference in pharmacy and nursing.

Regulatory Strategy & Intellectual Property

Corvida has a strong Intellectual Property Portfolio, consisting of the following: 45 patents awarded to date; 16 additional patents pending; freedom-to-operate (FTO); and 4 registered/allowed trademarks.

Key Milestones

Generate $1-2M of FY 2018 Sales	Q4 2018
Raise $10M+ Series D Growth Financing to grow from $500k/month to $1.5M/month in sales	Q4 2019
Generate $10-15M of FY 2019 Sales ($1.5M/month by Dec. 2019) and achieve positive cash flow	Q4 2019

Capitalization History

12/2009	Seed	Founders/Family/Friends	$250K
09/2011	Series A	CMA Ventures, RGPC Ventures and Angel Investors	$2.25M
06/2015	Series B	Brandmeyer Holdings, CMA ventures, RGPC Ventures and Angel Investors	$10.9M
12/2016	Convertible Note Financing	InfuseSafe and Others	$6.9M
01/2018	Series C	Longmeadow Capital Partners and Existing Investors	$12M

Use of Proceeds

Corvida is currently seeking $19M ($12M closed; $7M available). The funds are to support capital expenditures for product manufacturing, inventory purchases and a scaling of the sales organization to support 2018 / 2019 sales goals.

Key Team Members

Mitch Moeller - CEO/President

Mr. Moeller brings 30 years of medical device experience with McGaw, B. Braun, Kendall Healthcare and other large OEMs. Most recently, he led a medical device contract manufacturer through a high-growth phase (>$100M in sales) and undisclosed acquisition.

Paul Smith - CFO

In his 25 years of experience, Mr. Smith has been CFO for multiple early phase companies through acquisition including Terascape, DataSage, and 170 Systems. He has extensive M&A experience, preparing due diligence materials, developing multiyear finance plans, and post deal integration

Bonnie Bovee - VP of Sales and Business Development

Bonnie brings 17+ years of experience in marketing, sales, training and strategic alliances working with large pharma to startups. She has deep experience and relationships in the oncology market including a role as Regional Business Director at Equashield

IGI Technologies / Interventional Radiology Fusion System

William Plishker | will@igitechnologies.com | 202-713-9571 | www.igitechnologies.com

Company Overview (Clinical Impact and Value Proposition)

Founded in 2007, IGI Technologies is a University of Maryland-based startup focused on delivering high-speed image registration solutions to clinicians. We are embedded within Children's National Medical Center providing daily access to clinicians on ongoing collaborative efforts. IGI Technologies has created a multimodality fusion solution to accelerate interventional radiology (IR) procedures such as biopsies and ablations, reducing time and cost of procedures. Our product, IGTFusion, is an IR fusion system focused on revealing non-contrast CT-invisible tumors. We achieve this thorough accurate, autonomous real-time registration and fusion of existing diagnostic images (MRI or PET) that show the tumor with intra-procedural CT that does not. Diagnostic scans play an important role in interventional radiology, including the decision to perform a procedure. Our proposed technology will enable using them directly for instrument guidance.

Market and Commercialization Strategy

IR procedures have an important role in the management of patients with cancers. Percutaneous image-guided needle biopsy and ablations are increasingly common ways to diagnose and treat cancer. More than a million biopsies are performed in the U.S. every year and ~40,000 tumors worldwide (approx. half in the U.S.) were ablated in 2005. The number of ablations is growing at a 15-20% annual rate. The global ablation devices market has been growing at a rate of 10% CAGR, reaching approx. $12B by 2016. The forecasted growth of these procedures is driven by the coming era of personalized medicine and increased use of targeted therapies and biopsies. Accurate, rapid, and easily available fusion brings the important information obtained through previously acquired diagnostic MRI and PET scans, boosting confidence and saving time during procedures, value propositions which appeal to both clinicians and hospital administrators. We will sell directly to hospitals while pursuing strategic partnerships with existing channels.

Technical & Competitive Advantage

Even though there is no complete solution to the problem, in the space of interventional radiology, commercial efforts have progressed in providing some fusion capabilities for enhancing visualization for interventional radiology. Broadly speaking the efforts have come from 3 major fronts: imaging equipment companies, ablation companies, and navigational companies. Each of these think of fusion as an added value to some existing product, so is specifically meant to enhance other product offerings. Registration focused companies (e.g., Mirada and MIM) do exist as well, but do not focus on interventional radiology. Registration focused companies provide workstations intended for diagnostics or planning purposes, not real-time use during procedures. None of these solutions deliver on the promise of multimodality registration, namely the autonomous fusion of multimodal preprocedural images with navigational images accounting for soft tissue movement during the procedure for example from hydrodissection or breathing. The reason this has yet to appear in the market is because of its reliance on anatomy general and scanner general registration engine that is fast and multimodal. With our own customized engine which can do just that, target lesions that are either invisible or not well seen with CT, MRI- or PET-visible but CT-invisible liver tumors.

Regulatory Strategy & Intellectual Property

The core technology is patented, and the software is copyrighted and has never been open sourced. We have a pipeline of new technologies in house that we are currently treating as trade secrets which we plan to file patents on as they mature.

Key Milestones

FDA 510(k) Application Submitted	Q1 2018
FDA 510(k) Clearance	Q3 2018
Bridge Funding Application Submitted	Q3 2018
First Sale of 510(k)-cleared Product	Q3 2018

Capitalization History

2010-18	Grants	NIH/NCI	$4M

Use of Proceeds

IGI hopes to raise $2M to support evaluation sites and fill sales pipeline. Our three-year plan is a series of one-year tranches.

Key Team Members

William Plishker, Ph.D. - CEO

Dr. Plishker brings startup experience and application acceleration expertise to the effort. He has worked at 3 different startups in Silicon Valley as an engineer and a member of a marketing and sales team as a Mayfield Fellow in 2005.

Raj Shekhar, Ph.D. - CTO

Dr. Shekhar has 20+ years of academic and commercial image registration experience. Two of his inventions have led to successful commercial products: cardiac CT system marketed by Philips & intravascular ultrasound segmentation algorithms offered by Volcano Therapeutics, a Philips company.

Scott Peairs, M.B.A. - Advisor

Mr. Peairs is an industry veteran with experience at INTIO, Faxitron, and Covidien. His expertise includes marketing and sales management, strategic planning, new product development and launches, and strong surgeon and radiologist relationships.

Intelligent Optical Systems / Sensor Integrated Biopsy Device

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Company Overview (Clinical Impact and Value Proposition)

Founded in 1998, Intelligent Optical Systems, Inc. (IOS) is developing cutting-edge technologies, including fiber optic-based sensors for space, aeronautic, and medical applications. IOS has developed a sensor integrated biopsy (SIB) device for in-situ tissue analysis that enables biopsy teams to measure local tissue chemistry in real time during biopsy procedures, adding a valuable new set of parameters to augment and extend conventional image guidance. As the biopsy needle progresses into the patient's body, real-time chemical data informs the surgeon when the needle has encountered tumor tissue, because the chemical signature of tumor tissue differs from that of healthy tissue. This will guide the surgeon in placing the needle in the core of the tumor mass and in areas of high cell viability, rather than in the tumor periphery or in calcifications.

Market and Commercialization Strategy

Image-guided large-core breast biopsy is a growing alternative to open breast biopsy. Ultrasound-guided 14-gauge core-needle biopsy of breast lesions does not deform the breast, causes less patient discomfort, leaves minimal to no scarring on subsequent mammograms, and is quicker and less expensive than surgical biopsy. However, there is still a need for "smart" biopsy devices that ensure that the tissue is collected from the optimal area of the lesion. Every year, ~8 million suspicious breast lesions are discovered by initial screening. Of these, physicians select ~1.3 million for biopsy. Breast cancer biopsies costs on average $2,620 per patient. The global breast biopsy market was valued at $977M in 2016 and is projected to reach $1.4B by 2023, (CAGR of 5.3%). This represents only the initial market niche for the SIB device, which could be in used for other types of tumors. In assuming that smart needle technologies will comprise 5% of the total breast biopsy market, and that IOS technology will in turn capture 30% of the market, our revenue forecast for SIB technology is $21M/year.

Technical & Competitive Advantage

There are no commercially available biopsy devices that enable real-time tissue analysis during biopsy procedures, and no technologies complementary to imaging systems to guide the biopsy needle towards areas of greatest interest. Two U.S. patents describe the development of probes for tumor tissue analysis, but both focus on physical characteristics of the tissue and do not provide chemical information, which has significant relevance for assessing tumor status. Neither approach proposes integration with biopsy devices and established methods. Our SIB device is more compact and less expensive than the two approaches, and its system and protocols are compatible with current biopsy protocols. Also, the biochemical information provided by the SIB needle in the tumor area has significantly more potential for tumor diagnosis, prognosis, and even treatment determination than physical measurements alone. In the SIB device, only the trocar of the coaxial introducer needles is modified slightly to accommodate the sensors, making the device universally compatible with all 14-gauge core biopsy needles and modifiable to fit additional size needles.

Regulatory Strategy & Intellectual Property

IOS currently holds 60 granted and pending patents. We require all staff to sign non-disclosure agreements to set up temporal barriers to protect innovative ideas. IOS filed a U.S. patent application for the sensor integrated biopsy device entitled in 2017.

Key Milestones

Large animal model testing validates reliability, safety, and compatibility with a standard biopsy procedure.	Q3 2018
Clinical trial demonstrates clinical utility; IDE obtained from the FDA.	Q1 2019
Complete integrated sensor biopsy system tested by NCI.	Q2 2019
Needle production and commercialization agreement in place; Phase II funds and support secured.	Q2 2019

Capitalization History

09/2014	Grant	NIH/NCI	$225k
09/2016	Grant	NIH/NCI	$1.5M

Use of Proceeds

We anticipate the entire 510(k) approval process will take approximately two years beyond Phase II at a cost of $1M to $1.5M. The process will be supported in part by internal funding (already committed $200k) and by Optech Ventures, a company that has aided IOS in the past (already committed $200k). We will seek an additional $600k in private capital and Phase II continuation funds.

Key Team Members

Jesus Delgado Alonso, Ph.D. - Program Director

Dr. Alonso has more than 20 years of fiber optic sensor development experience and is responsible for all technical milestones and future technology transfer.

John Farina, M.A. - Chairman

Mr. Farina has 24+ years of experience in tech including digital imaging, software development, e-commerce, computer graphics, and electronic publishing. He was the President of Vidyah, Inc., which pioneered the use of interactive video over the Internet.

Reuben Sandler, Ph.D. - President & Chief Executive Officer

Reuben has been in top corporate management and on the board of several tech companies. As Executive Vice President at Makoff R&D Laboratories, Inc., he was instrumental in their acquisition by Watson Laboratories for $184M.

Otomagnetics / Drug Delivery Technology Using Magnetic Fields

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Company Overview (Clinical Impact and Value Proposition)

Otomagnetics' patented technology uses magnetic fields to non-invasively deliver therapy to hard-to-reach targets in the body. The technology works like a syringe, but instead of a needle we use magnetic forces acting on bio-compatible magnetic nano-particles that transports them through tissue barriers to targets that are not reached by current medical care or require an invasive surgery to reach. The particles can carry drug, protein, or gene therapy. In animal studies and human cadavers, we have shown delivery, safety, and efficacy. We are focused first on delivery to the cochlea and the retina. There are no drug delivery methods that deliver sufficient therapy to the cochlea, and the retina is reached by needle injections into the eye. Platin chemotherapy regimens cause severe to complete hearing loss in patients. There are drugs that can protect hearing, but they cannot be administered systemically because they cause unacceptable side effects and can degrade the anti-tumor action of the chemotherapy. Our method delivers to the ear only, without any risk of systemic side-effects or chemo degradation. In animals, we have also shown reversal of noise-induced hearing loss, suppression of tinnitus, and delivery into the eye. The particles are based on lessons learned from magnetic iron-oxide nano-particles FDA-approved for treatment of iron deficiency anemia.

Market and Commercialization Strategy

Action on Hearing Loss, a charity focused on hearing loss treatment, estimates the cisplatin hearing protection market to be worth >$500M/year. In the US and Europe, there are over 700,000 patients/year who receive cisplatin chemotherapy. Our nano-particle and steroid formulation can protect hearing from platin chemotherapy; we have shown in animal studies that the formulation can also reverse noise-induced hearing loss and can suppress tinnitus. These markets are estimated to be at $1.9B/year (12 million patients/year and growing) and $940M/year (12 million patients/year with 2 million/year with severe tinnitus). Other markets include macular degeneration ($5.3B/year). We already have a major pharma interested in our magnetic delivery to the eye.

Technical & Competitive Advantage

Our method uses safe magnetic fields (at a strength below clinical grade MRI machines) to deliver therapy through tissue barriers to the disease targets behind them. The nano-particles we use are composed of materials all previously approved by the FDA as safe to inject into the body, and our delivery has not caused any harm in live animal studies. We can non-invasively deliver into ear compartments, the eye, the skin, and the brain. For the cochlea, compared to the current standards of care that do not deliver enough drug to the cochlea to reach a therapeutic effect, our technology can deliver orders-of-magnitude more drug. We have seen efficacy in recognized animal models of cisplatin and noise-induced hearing loss, and tinnitus. For the eye, we can deliver therapy into the eye and all the way to the retina without having to insert a needle into the eye. Compared to intra-tympanic injections for the ear, needle injections into the eye, and surgery, our technology delivers a high dose simply, easily, safely, and effectively.

Regulatory Strategy & Intellectual Property

Otomagnetics has a strong patent portfolio that protects not only the device and the particles but includes backup claims and patents for each indication. Our foundational patents cover magnetic injection of any carrier to any target, with CIPs for back up.

Key Milestones

Sub-license additional indication to a first big pharma company	Q4 2018
cGMP production of this formulation (1-year program, start upon completion of our Series A raise)	Q3 2019
Pre-clinical safety testing of our formulation. Funded by the NCI SBIR contract (2-year program)	Q1 2020
Enter human clinical trials for cisplatin otoprotection	Q2 2020

Capitalization History

2013-18	Grants	NIH, DOD, AHL, & State of MD	$8.5M
2017	Seed	BHA & AngelMD	$350k
2018	Series A	Neela Chipalkatty, AngelMD, Catalyst, & TEDCO	$1.45M

Use of Proceeds

We are currently seeking the second half of our $3M raise. Funds will be used to complete IND-enabling pre-clinical testing so that we may enter human clinical trials which will be funded by a Series B raise to gain FDA approval.

Key Team Members

Abhita Batra, M.S., M.B.A. - CEO

Ms. Batra has strong connections to the pharmaceutical industry. In less than a year she has brought in almost $2M of investment from AngelMD, Catalyst (a VC fund), angel investors, and high net worth individuals.

Benjamin Shapiro, Ph.D. - Co-founder/CTO

Otomagnetics is a spin-out from Dr. Shapiro's laboratory in Bioengineering at the University of Maryland in College Park. His lab is a leader in the field of magnetic drug targeting. Magnetic injection was invented in his lab and exclusively licensed to Otomagnetics.

Irving Weinberg, M.D., Ph.D. - Co-founder/Board Member

Dr. Weinberg is the President of Weinberg Medical Physics. He has spent two decades launching startups in the medical device field. He has had a part in launching four FDA-approved products and he served as Chief Technology Officer and President of Naviscan.

Veriskin / Non-Invasive Hand-Held Device for Skin Cancer Detection

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Company Overview (Clinical Impact and Value Proposition)

The lack of accurate, objective skin cancer assessment tool for frontline caregivers leads to preventable loss of lives and costs the healthcare system more than $3B each year. The VeriSkin device is a proprietary, non-invasive, low-cost, hand-held unit (COG<$250) that aids a non-expert user to rapidly (~2 min) and objectively determine whether a suspect skin lesion is cancerous. The patent pending technology works by detecting and analyzing force-induced hemodynamic differences between the normal and malignant skin lesions. VeriSkin has developed an AI algorithm and protocols to achieve unparalleled screening accuracy in differentiating skin cancer from a variety of benign conditions. The device provides a score of 0 to 100% indicating the probability that a lesion is cancerous. Pilot clinical studies performed in dermatology clinics have shown sensitivity of ~100% and specificity of 96.7% in skin cancer screening. The device is intended to be used as a decision support tool during routine physical exams by non-specialists

Market and Commercialization Strategy

There are three main markets in the U.S.: (1) PCPs (260,000+ offices) and nurse practitioners (55,000+); (2) walk-in clinics (11,000+); and (3) dermatologists (~18,000). They will utilize the device to aid in their screening of possible abnormal skin lesions that may be due to cancer. All three specialties also have a common need both for accuracy over their current procedures and streamlined workflow that causes minimal disruption to current practice. The rapidity, simplicity, and accuracy of the test are anticipated to be key factors governing its acceptance. For PCPs, the product is anticipated to be a part of a routine physical exam, and included as needed, based upon the PCP's ability to spot a suspicious mole or skin blemish. Currently, PCPs employ the visual ABCD exam (area, border, color and diameter). The Veriskin test would add another factor in the review process and serve to improve the quality of assessment and reduce the number of unnecessary referrals, biopsies, and pathology reports. Based on the $1,000 per device cost and $50 test fee (combination of a hygienic consumable and a per-use fee), the total U.S. market is estimated at $2.4B ($7.7B worldwide TAM). Other uses include in pre-emergent and post-emergent wound healing, diabetes and endothelial dysfunction.

Technical & Competitive Advantage

The major competition in skin cancer screening is that of dermatoscopes, but they require highly specialized training. Other devices (multispectral imaging, light scattering, Raman, electric impedance-based) are costlier ($10k-$100k) and have only shown nominal benefits in clinical effectiveness because they are restricted to melanoma (2 % of all skin cancers) or of too low specificity. Multiple telemedicine apps that use a dermatologist to "read" the image suffer from a high false negative rate (<70%). In contrast, VeriSkin 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 the cancer-induced angiogenesis which is a known hallmark of cancer. Higher information content within such measurements (as compared to competitors) coupled with AI-assisted machine learning analysis of the force-induced hemodynamic response provides for rapid, quantitative answers with outstanding sensitivity and specificity.

Regulatory Strategy & Intellectual Property

All IPs are owned by Veriskin. We have filed two original provisional applications, followed by two PCT applications and multiple national phase conversion fillings. These patents claim the methods and devices of the core technology, as well as potential uses.

Key Milestones

Presubmission Meeting with the NIH	Q1 2019
Perform clinical studies with preproduction prototype to increase the size of training data set	Q3-Q4 2018
Finalized data analysis algorithm	Q4 2018
Pivotal FDA Clinical Trial	Q3 2019

Capitalization History

2016	Grant	NIH/NCI	$1.87M

Use of Proceeds

The Company is seeking $7M in late 2018 to (1) conduct pivotal clinical trial; (2) obtain FDA clearance; (3) obtain CE Mark; and (4) prepare for the transition to manufacturing and obtain all required quality certifications. We expect to receive FDA approval in 2021.

Key Team Members

Mirianas Chachisvilis, Ph.D. - CEO/CTO

Dr. Chachivilis is a consultant to early stage tech companies. He has served both as a faculty member in academia and in R&D roles in private enterprises. Most recently, he has served as CSO to Dynamic Connections, a San Diego healthcare technology incubator.

Carl Edman, Ph.D. - COO

Dr. Edman is an experienced early stage medical device executive, co-founder of PhiloMetron (wireless medical devices) and Corventis (acquired by Medtronics $150M), and strategy/business advisor to entities including Topera (acquired by Abbott $250M).

Eugene Tu, M.S. - CBO

Mr. Tu was a founding team member of multiple biotech startups (Nanogen, Genoptix, Nanomix, Omniome) and consultant to early stage biotechs. He has 30 years' experience converting research ideas to CLIA and FDA approved products in genomics/diagnostics.

CareProgress

Care Progress / Nurse Triage/Patient Engagement Software

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Company Overview (Clinical Impact and Value Proposition)

Located in Bethesda, Maryland, Care Progress, LLC creates compelling software and machine learning solutions to improve clinical outcomes and reduce health resource consumption. With a primary clinical focus on oncology, it is the recipient of multiple National Cancer Institute and National Science Foundation funding awards. Its clinical partners include Georgetown University Lombardi Comprehensive Cancer Center, and Rush University Medical Center. The company's key product/service is CarePrompter, a cloud-based, nurse triage/patient engagement software platform to improve symptom management of ambulatory patients regardless of their disease state(s). Patients download the CarePrompter app onto their Smartphones or tablets and "check in" on a range of symptoms. If patient responses are suboptimal, protocols can be triggered, and alerts can be sent to the pagers, smartphones, or cell phones of nurses or medical assistants. Nurses may choose to receive alerts via the secure messaging area of the EHR and/or open a dashboard to better understand what is going on with individual patients and how the practice's patients are faring at a population level. CarePrompter can also be leveraged by biopharmaceutical companies, including to generate RWE and/or to improve the safety profiles of their drugs in clinical trials.

Market and Commercialization Strategy

Our overall market is hospital oncology departments and community oncology practices. Our initial target market is large academic medical centers with high medical oncology volumes. We estimate the total market size at $750 million. After gaining traction in oncology, we seek to create an enterprise version that works across departments and disease states. At present, management of cancer symptoms is poor. Typically, patients or caregivers use the phone to discuss complaints and resolve issues with their care. This typically leads to telephone tag, disjointed telephone encounters and excess time understanding what's going on with the patient. Our solution makes this process far more efficient and effective, cutting down on the need for a telephone encounter and providing the care plan and other critical information immediately. We are currently developing predictive risk algorithms as well as a clinical decision support module for clinicians.

Technical & Competitive Advantage

Our competitive advantages are: experience in hospitals/healthcare; understanding complicated provider workflows; psychological states of patients and caregivers; optimal ways of integrating with EHRs; strong programming capability. We also maintain strong expertise in UI/UX from both a patient and clinician perspective.

Regulatory Strategy & Intellectual Property

Our main IP is trade secrets in the form of software development and UI/UX.

Key Milestones

Commercial Sales of CarePrompter	Q2 2018
Clinical Decision Support module for clinicians	Q1 2019
Predictive algorithm (risk scores)	Q3 2019
RCT for CarePrompter	Q3 2108

Capitalization History

07/2014	Grant	NSF	$150k
09/2015	Grant	NSF	$1.02M
09/2017	Contract	NIH/NCI	$225k
05/2018	Contract	NIH/NCI	$1.5M

Use of Proceeds

For Caregiver Buddy, we expect to receive $1.7 million from NCI as we have applied for and received Fasttrack approval. We are seeking to raise $3-4 million to accelerate product development and add marketing/business development staff to market CarePrompter. We plan to raise these funds in Q4 2018.

Key Team Members

Howard Isenstein, Ph.D. - President

With over 15 years of experience in healthcare, Dr. Isenstein has played key roles in health information technology, quality improvement and management at the Federation of American Hospitals, Walgreen's and Booz Allen Hamilton.

Amine Raounak, Ph.D. - CTO

Mr. Raounak has spent over 15 years in software development, architecture and security at AOL, Bethesda Softworks, the U.S. Digital Service, and Capitol One.