

# 2017

## INVESTOR INITIATIVES COMPANY INFORMATION

NATIONAL CANCER INSTITUTE

**SBIR**  
DEVELOPMENT  
CENTER

Funding, mentoring, and  
networking assistance for  
next-generation cancer  
technologies

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## 7 Hills Pharma

Immuno-oncology drugs are ineffective in most patients because immune surveillance fails due to lack of T cell infiltration. 7 Hills has developed a novel immunomodulatory platform to improve cellular and tumor responses against solid tumors. The platform is based on the Integrin activators that stabilize cell-cell interactions required for effective priming, trafficking and infiltration of leukocytes. The lead compound, 7HP349 is an oral small molecule VLA-4 and LFA-1 allosteric activator that could be used to improve the effectiveness of immuno-oncology (IO) drugs such as checkpoint inhibitors and enable the promise of CAR-T therapy for solid tumors.

**Location:**  
Houston, TX

**Technology:**  
Immuno-modulatory Drugs

**Stage:**  
Pre-clinical development

## Abilita Bio

Abilita Bio's mission is to develop transformative therapeutics through membrane protein (MP) stabilization. The Company is developing and commercializing technologies aimed at the production of enhanced proteins that will enable discovery of new drugs and unlock the potential of antibody therapeutics against challenging membrane protein targets. Around 300 more medically relevant G protein-coupled receptors (GPCRs) have not been targeted. Due to their complex nature, efforts to develop targeted therapeutics against MPs through structural biology or therapeutic antibody discovery approaches have been largely unsuccessful. The application of new technologies to aid in the development of MP-targeting therapies represents a significant market opportunity for the betterment of human health.

**Location:**  
San Diego, CA

**Technology:**  
Breast Cancer Drug Testing Device

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

## Adecto Pharmaceuticals

Adecto Pharmaceuticals is an early-stage cancer therapeutics company, developing an antibody-based targeted therapy for treatment of patients with ADAM8-positive triple-negative breast cancer (TNBC). The technology is based on the discovery that the cell surface protein ADAM8 is a critical new driver of TNBC tumor growth and metastasis. ADAM8 is expressed in 34% of TNBC patient samples and 48% of all breast cancer-derived metastases, and is a predictor of poor prognosis. In TNBC animal models, ADAM8 was accessible to targeting with a monoclonal antibody, resulting in inactivation of two distinct functional domains and reduced tumor growth and metastasis. The Company has generated preclinical proprietary anti-ADAM8 mouse monoclonal antibodies.

**Location:**  
Brookline, MA

**Technology:**  
Antibody-based Targeted Therapy

**Stage:**  
Non-clinical technology in prototype development/testing stage

## Apexian Pharmaceuticals

Apexian Pharmaceutical's focus is the development of inhibitors of the APE1/Ref-1 protein. The APE1/Ref-1 protein effects redox signaling of transcription factors involved in cell growth and survival, including HIF1-alpha, NF-kB, AP-1, and STAT3. Elevated APE1/Ref-1 protein expression occurs in a variety of cancers. APE1/Ref-1 expression increases as tumors become resistant to therapy. APX3330 was tested by Eisai in over 400 patients, and the drug was safe and effective in decreasing liver inflammation caused by hepatitis. It was not tested in cancer patients when Eisai stopped development due to commercial reasons. Apexian is ready to commence a phase I study of APX3330 in patients with advanced cancers.

**Location:**  
Indianapolis, IN

**Technology:**  
APE1/Ref-1 Protein Inhibitors

**Stage:**  
In clinical trial (Phase I)

## CanCure

CanCure is an anticancer drug development company with a mission to transform the proprietary innovative cancer therapeutic technology into a marketable product and improve the survival of cancer patients. CanCure specializes in easily deliverable biotherapy drugs (antibodies) that can restore patients' own natural immune function to fight cancer. CanCure has a pipeline of therapeutic antibodies but currently focuses on taking its leading product CuraB-10 (also called B10G5) into clinic. CuraB-10 is a first-in-class monoclonal antibody targeting an immune suppressive molecule soluble MIC (sMIC) that was released specifically by tumor cells. CuraB-10 also remarkably enhance tumor response to immune checkpoint therapy when used in combination.

**Location:**  
Mount Pleasant, SC

**Technology:**  
Targeted Monoclonal Antibody

**Stage:**  
Pre-clinical development

## Curon Biotech

Curon Biotech (previously Invenio) is a biopharmaceutical company passionately committed to applying its scientific leadership in the field of cellular metabolism to transform the lives of patients with cancer and rare genetic disorders. The Company's first product, INV603, is a First in Class, NCE, Novel Small Molecule to inhibit cell metabolism enzyme MDH1. Under this umbrella, Curon's work encompasses two distinct areas of research and development: (1) cancer metabolism to inhibit key enzyme in cancer cell specific metabolic pathways to disrupt tumor cell proliferation and survival; and (2) metabolic immuno-oncology to alter the metabolic state of immune cells to enhance the body's antitumor response.

**Location:**  
Cleveland, OH

**Technology:**  
Small molecule to inhibit cell metabolism enzyme

**Stage:**  
Pre-clinical development

## Cynvec

Cynvec is a preclinical stage biotechnology company founded in 2004 to develop and commercialize innovative safe and effective cancer treatments based on intellectual property exclusively licensed from New York University (NYU). Cynvec is pursuing an ovarian cancer indication for the Company's second-generation candidate, CYN102. CYN102 is an immunotherapeutic that targets cancers that overexpress the high affinity laminin receptor (LAMR) and can activate an efficacious immune anti-tumor response. CYN102 utilizes the anti-cancer properties of a bio-engineered form of Sindbis virus vector (SVV) that expresses the tumor associated antigen (TAA) NY-ESO-1. Dr. Daniel Meruelo developed Cynvec's platform base (CYN101) and the CYN102 derivative.

**Location:**  
New York, NY

**Technology:**  
Immunotherapy for Ovarian Cancer

**Stage:**  
Pre-clinical development

## EvoRx Technologies

EvoRx Technologies develops next generation targeting agents for therapy and companion diagnostic imaging. The Company's lead products are for the staging and treatment of inflammatory Her2+ breast cancer (IBC). Many patients with IBC are Her2-positive and data suggests that patients could benefit from anti-Her2 therapies. However, up to 40% of IBC patients are mis-staged or lack of assessment for Her2 status which may prevent or delays access to Her2 therapies. The unique technology generates EvoTides - small, macrocyclic, protease resistant peptides – that combine the high binding affinities and binding specificities of antibodies with the deep tumor penetration of small molecules. EvoTides exhibit excellent in vivo distribution profiles and have lower COGS than antibody-, affibody-, or minibody-based technologies.

**Location:**  
Pasadena, CA

**Technology:**  
APE1/Ref-1 Protein Inhibitors

**Stage:**  
Pre-clinical development

## For-Robin

For-Robin is an antibody immunotherapy company whose primary mission is developing therapy for breast cancer patients. The Company's proprietary technology targets all breast cancer cell subtypes including triple negative breast cancer which currently has no targeted therapy. For-Robin plans to develop humanized JAA-F11(hJAA-F11) as an adjunct therapy for breast cancer as quickly, safely and efficaciously as possible. JAA-F11 patented antibody specifically targets the alpha-linked form of a disaccharide tumor marker, the Thomsen-Friedenreich glycoantigen (TF-Ag) a well-known antigen found on the surface of 80% of all carcinomas and not expressed on normal cells. JAA-F11 is expected to be safe as humans have small amounts of naturally-occurring antibody to the TF-Ag.

**Location:**

Williamsville, NY

**Technology:**

Breast Cancer Antibody Immunotherapy

**Stage:**

Pre-clinical development

## GlycoMantra

GlycoMantra is a startup biotechnology firm, registered in Virginia but operating in Maryland at the bwtech@UMBC Life Sciences Incubator. The Company's technology expertise is in glycobiology research leading to the development of a carbohydrate-based therapeutic (TFD100) for treatment of advanced prostate cancer. GlycoMantra has signed an exclusive license with the University of Maryland, Baltimore for U.S. Patent No. 9,180,175, titled "Methods of Use for a Natural Thomsen-Friedenreich Disaccharide Compound". GlycoMantra's President and CSO, Dr. Hafiz Ahmed is the lead inventor. rTFD100 is designed to suppress mCRPC by specifically targeting galectin-3 (Gal3).

**Location:**

Aldie, VA

**Technology:**

Carbohydrate-based Therapeutics

**Stage:**

Pre-clinical development

## Humanetics

Humanetics is a Phase II clinical development company, whose leading drug candidate is a proprietary radiomodulator called BIO 300. This product has been shown to sensitize cancerous solid tumors to the killing effects of radiation while at the same time protecting healthy tissues from radiation damage. Target indications include non-small cell lung cancer, head & neck cancer and prostate cancer. The Company completed a Phase I clinical safety trial for ARS and is currently in a Phase Ib/IIa clinical trial in non-small cell lung cancer patients. Plans for future commercial applications include testing in other solid tumor cancers, prevention of erectile dysfunction (ED) following prostate cancer radiotherapy, and as a radiation countermeasure for the DoD and U.S. Department of Health and Human Services.

**Location:**

Edina, MN

**Technology:**

Radiomodulator

**Stage:**

In clinical trial (Phase II)

## NĒRx Biosciences

NĒRx Biosciences specializes in the discovery and development of bio-pharmaceutical compounds targeting DNA repair pathways. Focusing on the Nucleotide Excision Repair pathway (NER), NĒRx's pipeline of targeted molecular therapeutics is unique and is supported by extensive clinical and pre-clinical target validation. Platinum (Pt)-based combination therapy is curative in testicular germ cell tumors with 10-year survival being ~95%. Pt drugs impart their chemotherapeutic effect by creating DNA damage, and it is well established that the repair of this DNA damage reduces the effect of Pt-therapy. NĒRx has developed a series of novel targeted therapeutics specifically designed to work with and enhance the clinical activity of Pt-based agents through targeted inhibition of DNA repair pathways.

**Location:**

Indianapolis, IN

**Technology:**

Targeted Molecular Therapeutics

**Stage:**

Pre-clinical development

## NuvOx Pharma

NuvOx Pharma is developing a nanotechnology platform of products for oxygen delivery to treat life-threatening diseases characterized by low oxygen (hypoxia). Upon intravenous administration, the oxygen therapeutics flow through the bloodstream arriving first at the lungs to pick up oxygen and finally to hypoxic tissue where they passively deliver the oxygen. The Company has positive results in a Phase Ib/II clinical trial in glioblastoma multiforme (GBM) showing safety and efficacy of NVX-108 (dodecafluoropentane emulsion, DDFPe) as a radiosensitizer. DDFPe is the first FC capable of multi-dose administration and clears via exhalation with a terminal half-life of 90 minutes. The preliminary data from the Phase Ib/II trial in GBM that shows DDFPe reverses hypoxia in cancer.

**Location:**  
Tucson, AZ

**Technology:**  
Oxygen Therapeutics Platform

**Stage:**  
In clinical trial (Phase I)

## Oncoceutics

Oncoceutics is a clinical-stage biopharmaceutical company engaged in the discovery and development of a class of small molecule compounds, called imipridones, which selectively target various G Protein-Coupled Receptors (GPCRs) for oncology. The first lead compound to result from this program is ONC201, an oral, small-molecule antagonist of Dopamine Receptor D2 (DRD2) that has shown effectiveness and that is well tolerated against both solid and hematological malignancies. The company has completed successful Phase I programs and is currently conducting multiple Phase II clinical programs in areas with significant unmet medical need. In addition, Oncoceutics' pipeline includes several other imipridones with differentiated GPCR targets and efficacy profiles.

**Location:**  
Philadelphia, PA

**Technology:**  
Small molecule compounds targeting GPCR

**Stage:**  
In clinical trial (Phase II)

## OncoTab

OncoTab was founded by a Mayo Clinic alumna, Dr. Pinku Mukherjee. The Company's technology is a patented monoclonal antibody, TAB004, which recognizes epitopes different from those recognized by other MUC1 antibodies. In vivo imaging studies in animal models for breast and pancreatic cancers have demonstrated localization of TAB004 on tumors but not on healthy tissue. demonstrated the feasibility of labeling TAB004 with radioiodine 131I and are in the process of fully humanizing TAB004. OncoTab also launched Agkura™ Personal Score – a simple, non-invasive blood test as a supplemental test for women with dense breast tissue whose cancers are missed by mammography.

**Location:**  
Charlotte, NC

**Technology:**  
Monoclonal Antibody

**Stage:**  
Pre-clinical development

## Privo Technologies

Privo Technologies is a development stage biotechnology with roots from MIT's Langer Laboratory in Cambridge, MA. The Company aims to provide treatment options which offer higher efficacy, lower toxicity, improved patient compliance, and lower costs. The Company has designed a nanotechnology-based topical drug delivery platform, the ChemoThin Wafer (CTW). CTW is a wafer-like device that delivers drugs, primarily chemotherapeutics, to mucosa or skin where they are locally retained. Privo first encapsulates drugs within nanoparticles, and embeds the nanoparticles within the CTW body. When CTW is topically placed onto tissue, the nanoparticles are released and locally retained. Privo has initially developed, optimized and tested CTW for the treatment of oral cancer.

**Location:**  
Peabody, MA

**Technology:**  
Nanotechnology-based drug delivery platform

**Stage:**  
Pre-clinical development

## Siamab Therapeutics

Siamab Therapeutics is developing therapies targeting cancers that express abnormal carbohydrates or glycans. These highly cancer-specific, tumor associated carbohydrate antigens (TACAs) are present in most solid tumors and are exploited by tumor cells to suppress innate immune function, enable tissue invasion and metastasis, resist chemotherapy, and promote a cancer stem cell (CSC) phenotype. Siamab has developed a technology platform that overcomes these challenges and enables the discovery of large numbers of highly specific, high affinity anti-TACA therapeutic antibodies. Siamab's lead program is in late preclinical development targeting a glycan target, STn, overexpressed in several solid tumors including ovarian, pancreatic, prostate, gastric and colon.

**Location:**  
Newton, MA

**Technology:**  
Anti-TACA Therapeutic  
Antibodies

**Stage:**  
Pre-clinical development

## StemMed

StemMed is a drug development and testing company, whose pipeline includes C188-9, a direct oral inhibitor of signal transducer and activator of transcription (STAT) 3. StemMed's objectives are three-fold: 1) to develop C188-9 to an NDA for treatment, either alone or combined with chemoradiation, of solid tumors in which STAT3 is activated and a validated target, including triple-negative breast cancer, hepatocellular carcinoma, and head and neck squamous cell carcinoma; 2) to develop C188-9 to a NDA for treatment of other diseases mediated by aberrant STAT3 activity including cachexia, idiopathic pulmonary fibrosis, scleroderma, steroid-resistant asthma, and anaphylaxis; and 3) to provide state-of-the-art, pre-clinical breast cancer drug-testing services to contracting pharmaceutical companies.

**Location:**  
Houston, TX

**Technology:**  
Small molecule therapeutics  
targeting STAT3

**Stage:**  
Pre-clinical development

## TargaGenix

TargaGenix is developing a novel therapeutic for the treatment of cancer. The product is a combination of a nanoparticle formulation encapsulating the novel therapeutic DHA-SBT-1214. DHA-SBT-1214 has been shown in preclinical models that it can treat and cure animals with tumor types that are resistant to current standard of care. DHA-SBT-1214 has also been shown to effectively kill cancer stem cells and this property may represent the mechanism of the long-term efficacy seen with DHA-SBT-1214 treatment. TargaGenix had a successful pre-IND meeting in December 2016 that confirmed a clear pathway to IND and through Phase 2 studies. In addition, the company has developed a large-scale production process that can reliably produce commercial scale amounts of product.

**Location:**  
Stony Brook, NY

**Technology:**  
Therapeutic targeting bulk  
tumor and cancer stem

**Stage:**  
Pre-clinical development

## TeamedOn International

TeamedOn has exclusive, world-wide IP rights to a class of novel small molecule therapeutics targeting Acute Myeloid Leukemia (AML), and have promising pre-clinical proof-of-concept (POC) data in human primary samples and an AML patient-derived xenograft (PDX) mice model. In addition, TeamedOn's molecule may be effective in treating lung cancers and lymphoma. Results from preliminary repeat-dose toxicity study in rodents suggest a good margin of safety. The Company plans to raise \$3.5M to complete the candidate confirmation and IND-enabling studies, and apply for permission to begin human Phase I trial within 24 months. TeamedOn has an experienced technical and leadership team with expertise in this field, and nationally-recognized key opinion leaders on the Scientific Advisory Board.

**Location:**  
Rockville, MD

**Technology:**  
Small Molecule Therapeutics

**Stage:**  
Pre-clinical development

## TheraTarget

TheraTarget is a preclinical stage pharmaceutical company that has created a patented, proprietary polymer-drug conjugate platform that effectively delivers anti-cancer drugs via the blood stream to solid tumors. This technology promises unparalleled ability to improve survival of cancer patients where current chemotherapy is sub-optimal. There are 7 long-circulating highly effective therapeutic oncology candidates in preparation for clinical trials. Among them the most advanced candidate is KT-1 (backbone degradable water-soluble N-(2-hydroxypropyl) methacrylamide (HPMA) copolymer - epirubicin conjugate for intravenous injection); an Investigational New Drug Application will be filed in 2020. TheraTarget validated the technology by challenging ovarian and pancreatic cancer preclinical animal models.

**Location:**

Salt Lake City, UT

**Technology:**

Polymer-drug conjugate platform

**Stage:**

Pre-clinical development



## Abreos Biosciences

Biologic drugs are the largest pharmaceutical growth segment and are among the most expensive pharmaceuticals. However, dosing regimens for biologic drugs are one-dose-fits-all and, as a result, most patients are being improperly dosed. Abreos Biosciences is poised to disrupt the current dosing paradigm and have a major impact on the delivery of life-saving medications for cancer, autoimmune diseases, and other serious illnesses. The cost is becoming unsustainable and these medicines are inaccessible to many patients in need. Precision dosing will maximize the value of the drugs and, by lowering overall costs, expands the access of these powerful medications to patients.

**Location:**

San Diego, CA

**Technology:**

Precision Dosing Platform

**Stage:**

Non-clinical technology in prototype development/testing stage

## EpiCypher

EpiCypher has developed the first quantitative ChIP approach, which uses post-translationally modified-recombinant nucleosomes (designer nucleosomes or 'dNucs') as internally calibrated "spike in" standards (ICeChIP). This will enable a marked expansion of ChIP applications into new markets including drug discovery and diagnostics. EpiCypher is developing a novel protein engineering tool for accelerated dNuc manufacturing. Sortase A (SrtA) is a transpeptidase that can be engineered by directed evolution to alter its recognition sequence and seamlessly ligate 'unnatural' protein substrates. Once complete, EpiCypher will test the utility of this tool to accelerated dNuc manufacturing by optimizing a single-step ligation reaction to rapidly synthesize diverse dNucs for ICeChIP assay development.

**Location:**

Durham, NC

**Technology:**

Quantitative chromatin Immunoprecipitation platform

**Stage:**

Non-clinical technology in full development/testing stage

## InnoGenomics Technologies

InnoGenomics has used proprietary methods to create an extremely accurate and sensitive multiplex qPCR assay that measures high copy number retro-transposable elements (REs) of varying sizes to assess circulating cfDNA concentration and integrity (fragmentation pattern). The assay amplifies robustly without requiring DNA extraction (direct qPCR) from as little as 2  $\mu$ L of plasma, with a validated detection capability of less than one picogram of DNA. The assay has demonstrated high predictive capacity in discriminating metastatic colorectal cancer (CRC) patients from healthy controls. Statistical comparisons showed significantly increased sensitivity and specificity compared to the reported performance of CEA, the serum biomarker currently used for CRC patient monitoring.

**Location:**

New Orleans, LA

**Technology:**

cfDNA Testing System

**Stage:**

Non-clinical technology in full development/testing stage

## PreCyte

PreCyte is a development stage company developing Indicator Cell Assay Platform (iCAP), a broadly applicable and inexpensive blood-based assay that can be used for early detection of disease, disease stage stratification, prognosis and response to therapeutic intervention for a variety of diseases. iCAP uses cultured cells as biosensors, capitalizing on the ability of cells to respond differently to signals present in the serum (or other biofluid) from normal or diseased subjects with exquisite sensitivity—as opposed to traditional assays that rely on direct detection of molecules in blood. The iCAP can overcome barriers to blood-based diagnostics like broad dynamic range of blood components, low abundance of specific markers, and high levels of noise. PreCyte is developing the iCAP for the blood-based diagnosis of lung cancer.

**Location:**

Palo Alto, CA

**Technology:**

Indicator Cell Assay Platform

**Stage:**

Pre-clinical development

## Antaya Science & Technology

Antaya Science & Technology (AS&T) was founded by Dr Timothy Antaya, a world-renowned accelerator physicist. Its core competencies include superconducting cyclotron design, superconducting magnet design, cyclotron radio-frequency (RF) design & analysis, and product commercialization. The aim is to design a state of the art compact cancer treatment system that will be more effective, non-invasive as well as cost equivalent to the current x-ray therapy systems (IMRT) and replace them with proton therapy systems. The Technically Advance Affordable Cyclotron (TAAC) will be the most compact PT cyclotron ever developed to reduce the cost and foot print of current cyclotrons used to generate proton beams. TAAC paired with PT Pedestal (PTP) will enable one and two room PT centers anywhere.

**Location:**  
Hampton, NH

**Technology:**  
Proton Therapy System

**Stage:**  
Pre-clinical development

## Celestial Medical

RadiaBeam Technologies and UCLA have created a new spinoff company, Celestial Medical, to develop a novel radiotherapy technology called  $4\pi$  radiotherapy. The principle behind this technology is that when radiation can be delivered from almost any angle and position, the dose distribution can be built up more precisely, with steep fall-off to better avoid healthy tissue (which normally limits the dose that can be delivered to the tumor). To reach all angles around the patient, a robotic delivery device is being designed, which will hold an extremely compact X-ray source. The more compact dose distribution spares normal tissue from excessive radiation doses, while precisely delivering greater doses to the tumor, resulting in comprehensive double-digit percentile improvements in organ-at-risk (OAR) dose and dose compactness.

**Location:**  
Santa Monica, CA

**Technology:**  
Radiotherapy Technology

**Stage:**  
Non-clinical technology in prototype development/testing stage

## CivaTech Oncology

CivaTech Oncology has two commercially available radiation devices to provide therapeutic doses to cancerous tissues in a localized, targeted delivery method. Both products use a patented platform technology that was developed, engineered, and now manufactured by CivaTech Oncology, which is an ISO 13485 certified facility. CivaString® and CivaSheet® are bio-compatible and bio-absorbable, and are designed to be easily implemented in the work flow of the current cancer care pathways. CivaTech's products have unique reimbursement (payment) codes issued by Medicare/Medicaid. The products are being used in 13 clinics nationwide including two of the exempt cancer specialty hospitals and 75% of clinics have re-ordered product within 6 months or less from the initial order.

**Location:**  
Durham, NC

**Technology:**  
Targeted radiation therapy devices

**Stage:**  
In clinical trial (feasibility/pilot);  
Commercially available

## Curadel Surgical Innovations

Curadel Surgical Innovations develops advanced surgical imaging solutions to enable surgeons to see that which is invisible to the eye in natural light. Curadel's technology, imaging system and dye, is called FLARE®: (FLuorescence-Assisted Resection and Exploration for surgery). It exploits near-infrared light to see millimeters deep into tissue and well beyond that possible in natural light. By injecting a contrast agent into the bloodstream, a surgeon can use FLARE imaging systems to pinpoint the exact location of the target, such as malignant tumors, and/or the exact location of targets that need to be avoided, such as blood vessels, nerves, and ureters. CSI currently sells FLARE devices to the non-FDA regulated research market. The devices will soon obtain regulatory clearance by CSI, 510(K) and CE-mark in Europe.

**Location:**  
Marlborough, MA

**Technology:**  
Surgical Imaging Solutions

**Stage:**  
In clinical trial (Phase I)

## LX Medical

LX Medical is a Massachusetts corporation commercializing a suite of endobronchial imaging probes and image-guided transbronchial biopsy tools for interventional pulmonologists and thoracic surgeons. The primary focus for the company is addressing unmet needs in lung cancer screening, diagnosis, and treatment. LX Medical's image-guided bronchoscopic biopsy tools address the need for safe and accurate diagnosis of lung nodules, by providing high-accuracy biopsies of sub-centimeter nodules with safe bronchoscopic procedures that minimize risks of complications, enabling timely identification and then treatment of early stage lung cancer without unnecessary surgeries in patients with benign disease.

**Location:**  
Westwood, MA

**Technology:**  
Image-guided bronchoscopic devices

**Stage:**  
Pre-clinical development

## RadioMedix

RadioMedix is a clinical stage biotechnology company with a primary focus on the commercializing of radiotherapeutic agents and the generator-produced radiotracers based on Ga-68 chemistry. 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. Research contracts and clinical activities provide revenue that support commercialization of radiotherapeutic agent, GlucoMedix™ (Pb212-RMX-GC) targeting glucose-avid aggressive cancers. RadioMedix develops and commercializes the platform of Pb212-labeled therapeutic agents. The Company has validated the development plan for another Pb212-radiotherapeutics targeting neuroendocrine tumors.

**Location:**  
Houston, TX

**Technology:**  
Radiotherapeutic agents

**Stage:**  
Pre-clinical development

## HuMurine Technologies

HuMurine Technologies was founded by Gerold Feuer, whose unique scientific expertise and 24 years' experience in academic research created an industry leader and innovator in "Humanized" immune system mice and implementing these mice into preclinical studies to more accurately predict human clinical trial outcomes. HuMurine has recently signed contracts with large biopharmaceutical clients (including Pfizer, J&J and Abbvie) that utilize HuMurine's CRO services. HuMurine's "Human-Immune-System" (Hu-MTM and Hu-3GMTM) mice are superior and outperform competitors' humanized mice by using proprietary stem cell isolation and detection matrixes, rigorous scientific standards, and decades of combined experienced scientific team.

**Location:**  
LaVerne, CA

**Technology:**  
Humanized mouse model

**Stage:**  
Commercially available

## SynVivo

SynVivo is a biologically realistic platform that enables real-time study of cell and drug interactions, offering a true breakthrough in drug development. SynVivo recreates the complex in vivo microvasculature including scale, morphology, fluidics and cellular interactions in an in vitro format for basic and applied life sciences research. Starting with medical images, SynVivo creates a replica of the microvascular environment onto a microchip, where animal or human cells can be cultured and studied under physiological conditions. The permeability between vascular and tissue regions is precisely engineered to mimic organ-specific architecture. The technology has been validated for applications in oncology, neuroscience, inflammation and toxicology.

**Location:**  
Huntsville, AL

**Technology:**  
Physiological tumor model

**Stage:**  
Non-clinical technology in full development/testing stage;  
Commercially available



### Company Overview (Clinical Impact and Value Proposition)

Immuno-oncology drugs are ineffective in most patients because immune surveillance fails due to lack of T cell infiltration. 7 Hills has developed a novel immunomodulatory platform to improve cellular and tumor responses against solid tumors. The platform is based on the Integrin activators that stabilize cell-cell interactions required for effective priming, trafficking and infiltration of leukocytes. The lead compound, 7HP349 is an oral small molecule VLA-4 and LFA-1 allosteric activator that could be used to improve the effectiveness of immuno-oncology (IO) drugs such as checkpoint inhibitors and enable the promise of CAR-T therapy for solid tumors. The Company is currently seeking \$15 million Series B2 capital and a developmental partner to complete a Phase I/IIa study of 7HP349 in patients that have failed anti programmed death-1 (aPD-1) based therapy.

### Market and Commercialization Strategy

Although Opdivo and Ketruda have had a remarkable impact on the treatment of melanoma and other cancers in subset of patients, >50 to 90% of patients may be refractory. In the US, 7,800 to 10,200 patients with melanoma may be resistant to aPD-1, and present an attractive orphan indication to validate the efficacy of 7HP349 as a potentially simple, cost-effective and universal means to reverse IO drug resistance against solid tumors. The refractory melanoma indication alone could represent \$427M in annual sales. In the short-term, the Company plans to partner with a larger pharmaceutical company to help transition 7HP349 into early clinical studies for advanced melanoma and other cancers.

### Technical & Competitive Advantage

7HP349 provides for a first-in-concept, as well as first-in-class strategy to increase the effectiveness of checkpoint inhibitors (e.g. aCTLA-4, aCD137), CAR-T therapies, and vaccines. Although there are >900 combination trials targeting this clinical program, there are very few approaches being developed to treat patients that have relapsed or are refractory to aPD-1 based therapies. Although intratumor approaches with oncolytic viruses or cytokines hold promise, they are limited to <10% of cancers. 7HP349 may be simple, cost-effective oral drug that could be used in the community practice setting in refractory patients to aPD-1.

### Regulatory Strategy & Intellectual Property

4 patent applications (PCT/US2011/060996, PCT/US15/15679, 62154554, PCT/US15/38447).

The immuno-modulatory platform and 3 pharmacophores are protected by above mentioned 4 patent applications. The Company anticipates to submit an IND within 12 to 18 months. PD-1 refractory melanoma may represent an orphan indication and the planned Phase I/IIa study could enable breakthrough status.

### Key Milestones

Use of 7HP349 to improve effectiveness of checkpoint inhibitors in aPDL-1 negative tumors	Q1 2016
Large Pharma validation of technology and close of ~\$4 million in Series B	Q4 2017
7HP349 IND Submission and close \$15 million series B2	Q2 2018
Phase I/IIa study start – Recommended Phase II established	Q2 2019
Phase I/IIa study start – Phase IIa melanoma proof of concept	2019

### Capitalization History

6/2014	Common	Founders	\$1,300
6/2014	Series A1	Founders	\$95K
2/2015	Series A2	Angels/Founders	\$156K
6/2016	Federal Grants	NCI/NHLBI	\$589,633
1/2017	Series B-1	Angels	\$3.8M

### Use of Proceeds

The use of proceeds will be to build upon potential Phase II grant funding and complete IND-enabling studies in the melanoma indication within 18 months, whereupon the Company expects to file an IND application. At the same time, within 12-18 months, 7 Hills anticipates a licensing deal with a large pharmaceutical company. In parallel, the Company plan to raise \$15M in venture funding to complete a Phase I/IIa clinical trial to assess safety and pilot efficacy of 7HP349 in combination with CTLA-4 using a 3x3 design.

### Key Team Members

#### Upendra Marathi, PhD, MBA - CEO

Dr. Marathi has led clinical and manufacturing programs for 5 INDs and 1 approved drug product from pre-clinical to FDA. He has raised over \$60 million in equity funding for various ventures.

#### Peter Vanderslice, PhD - Advisor

Dr. Vanderslice developed four clinical stage compounds. He helped raise \$100M in equity financing at Encysive

#### Darren Woodside, PhD - Advisor

Dr. Woodside is the Associate Director of Drug Discovery, Biological Sciences at Encysive Pharmaceuticals. Notable advisors include 2 former Presidents of ASCO.

**Company Overview (Clinical Impact and Value Proposition)**

Abilita Bio's mission is to develop transformative therapeutics through membrane protein (MP) stabilization. The Company is developing and commercializing technologies aimed at the production of enhanced proteins that will enable discovery of new drugs and unlock the potential of antibody therapeutics against challenging membrane protein targets. Around 300 more medically relevant G protein-coupled receptors (GPCRs) have not been targeted. Due to their complex nature, efforts to develop targeted therapeutics against MPs through structural biology or therapeutic antibody discovery approaches have been largely unsuccessful. The application of new technologies to aid in the development of MP-targeting therapies represents a significant market opportunity for the betterment of human health.

**Market and Commercialization Strategy**

Therapeutics targeting GPCRs represent about 30% of global drug revenue, or \$120B annually. They continue to be attractive targets: out of the 800 GPCR family members, 370 appear to be medically relevant targets; however, only 110 receptors are targeted by 437 approved drugs. Therefore, most medically relevant targets have yet to be exploited, and justifies major investments by large pharmaceutical companies to discover new entities targeting GPCRs. As such, Abilita's technology represents an opportunity for market creation and expansion, especially as a mechanism for moving programs forward, where technical hurdles may otherwise prevent organizations from advancing their drug discovery programs.

**Technical & Competitive Advantage**

The number of companies providing stabilized GPCRs to partners is small. The most established, Heptares Therapeutics, employs iterative mutagenesis (alanine-scanning) in specified regions and screening assays to achieve thermally stabilized receptors. Since their foundation in 2007, their approach has been validated by deals with larger partners, typically commanding \$5-10M upfront, worth ~\$200M each, and more than \$2.5B collectively. Japanese pharmaceutical company Sosei recognized the value of the platform and acquired Heptares for \$400M in 2015. Compared to Heptares, Abilita Bio intends to position its technologies for producing cost effective enhanced receptors, with a significantly faster turnaround time and ability to deliver diverse and cooperative receptor stabilizing mutational sets.

**Regulatory Strategy & Intellectual Property**

2 provisional patents (62/073,554; 62/331,628).

All existing and pending IP rights to Abilita Bio platform technology, as well as all IP rights to the portfolio of candidate therapeutics developed internally, are or will be fully owned by the company and will have long-term expiration dates. This ensures long-lasting IP protection and market opportunity, making their development for the indicated clinical applications highly attractive.

**Key Milestones**

Discover therapeutic antibody leads against breast cancer targets	Q4 2017
Improve stability of voltage-gated sodium channels and patent technology around it	Q2 2017
Discover therapeutics against ion channels either through collaborations or CROs	Q1 2018
Complete non-GMP IND-enabling studies around breast cancer therapeutic antibodies	Q1 2019

**Capitalization History**

2014-15	Angel	Angel investors	\$600K
2015	Partnership	Pharmaceutical company	<\$1M
2016	Grant	NIH/NCI	\$300K
2016	Partnership	Pharmaceutical company	<\$1M
2017	Venture/Seed	Pending	\$1-2M

**Use of Proceeds**

Abilita Bio believes that venture capital funds will be an additional source of capital that can be fundamental for the next stage of development of the company. The Company is interested in partnering with pharmaceuticals to expand and strengthen business development capabilities, as well as in engaging VC groups to explore financing opportunities.

**Key Team Members**
**Mauro Mileni, PhD - Founder & CEO**

Dr. Mileni is the inventor of the EMP™ technology, with 14+ years of experience in protein chemistry, protein engineering, crystallography and structure based drug design of GPCRs. Dr. Mileni was a Scientist at Receptos and has consulted for Eli Lilly.

**Rosario Billetta, DSc - CTO**

Dr. Billetta has held the position of CSO at Kai BioEnergy and CTO at Androclus Therapeutics. His experience includes immunology, protein engineering, vaccine development and immunotherapy of cancer and autoimmune diseases.

**Chris Roth, PhD - Vice President of Innovation**

He has 10+ years of innovation in MP engineering, structural biology and drug discovery. He was a Scientist at Receptos, Inc. and the lead inventor of GPCR protein engineering technologies patented and licensed to domestic and international industry partners.

## Company Overview (Clinical Impact and Value Proposition)

Adecto Pharmaceuticals is an early-stage cancer therapeutics company developing an antibody-based targeted therapy for treatment of patients with ADAM8-positive triple-negative breast cancer (TNBC). The technology is based on the discovery that the cell surface protein ADAM8 is a critical new driver of TNBC tumor growth and metastasis. ADAM8 is expressed in 34% of TNBC patient samples and 48% of all breast cancer-derived metastases, and is a predictor of poor prognosis. In TNBC animal models, ADAM8 was accessible to targeting with a monoclonal antibody, resulting in inactivation of two distinct functional domains and reduced tumor growth and metastasis. The Company has generated preclinical proprietary anti-ADAM8 mouse monoclonal antibodies. The plan is to bring forward a humanized monoclonal antibody with a strong data package to attract investors/strategic pharma partners for full development. Adecto envisions expansion to other ADAM8-driven oncology indications, such as gastric, lung and pancreatic cancers.

## Market and Commercialization Strategy

The Company's initial focus is the TNBC indication in the US market. The Company estimates that 62,284 recurrent TNBC patients and 93,440 early TNBC patients, with no brain metastasis, have ADAM8-positive disease and could benefit from Adecto's therapy. For the initial recurrent TNBC indication, this translates into a target market of 9,776 patients and revenue of \$615.9M. Once efficacy and safety in recurrent TNBC are established, Adecto plans to expand to patients with early TNBC. This would add 14,666 patients to the target market size and an extra \$924.0M in revenue, making the TNBC indication alone a \$1.5B opportunity.

## Technical & Competitive Advantage

Currently, there are no approved targeted therapies for TNBC. The standard of care for early disease is often ineffective and one third of patients recur within 1 to 3 years of initial treatment. An ADAM8 targeted therapy would address the need of a large section of the TNBC population that is currently poorly served by the standard of care. Targeted therapies are being tested in TNBC clinical trials, and three of these (IMMU-132, Atezolizumab and Pembrolizumab) are in late stages of testing. Strikingly, all have demonstrated low efficacy rates in TNBC. Thus, while any of these may become the first targeted therapeutic for TNBC, this would not preclude an anti-ADAM8 antibody from being adopted for treatment of a patient population with ADAM8-positive tumors or from being used in combinations with other agents to increase efficacy and overcome resistance.

## Regulatory Strategy & Intellectual Property

A methods patent has been filed (US 14/940,344; EP 14798014.8) and a composition patent is in preparation. Adecto has been offered a standstill agreement by Tufts University for development of this technology and have initiated negotiations on terms of an exclusive option to license these patents. Adecto's regulatory strategy focuses on recurrent ADAM8-positive TNBC with no brain metastasis as the clearest path to market. The goal is to demonstrate safety and efficacy in combination with chemotherapy.

## Key Milestones

Composition patent filing	January 2018
Demonstration of additive efficacy with chemotherapy and/or immunotherapy	June 2018
Antibody humanization and optimization	March 2019
Early toxicology	March 2019

## Capitalization History

2015	Award	Tufts 100K New Venture Competition	\$15K
2016	Grant	NIH/NCI (Phase I STTR)	\$300K
2016	Supplement	NIH/NCI (STTR)	\$63,490
2017	Supplement	NIH/NCI (STTR)	\$50K

## Use of Proceeds

Adecto aims to raise funds for the above-mentioned tasks (~\$2.5M) through non-dilutive government grants, but would welcome early investments in the interest of speeding development. The next stages will require substantially larger amounts of funding. The first formal round of financing will be in late 2018 or early 2019, when Adecto will be looking to raise ~\$12M for IND studies.

## Key Team Members

### Gail E. Sonenshein, PhD - President

Dr. Sonenshein is an internationally recognized expert on oncogenes and cancer. She co-founded and directed the Women's Health Interdisciplinary Research Center at Boston University (BU) and has served as PI on multi-investigator grants at BU and Tufts.

### Nora D. Mineva, PhD - Chief Scientific Officer

Dr. Mineva is an expert in cancer biology including animal testing. She had a leadership role in the research that led to the discovery and validation of Adecto's antibody-based approach to inhibit ADAM8-driven growth and spread of TNBC.

### Susan Long, PhD - Vice President of Business Development

Dr. Long was Vice President of Business Development at Genzyme Corporation, and a member of the senior management team for over 10 years, leading new business strategic planning, technology assessment, and business development activities

**Company Overview (Clinical Impact and Value Proposition)**

Apexian Pharmaceutical’s focus is the development of inhibitors of the APE1/Ref-1 protein. The APE1/Ref-1 protein effects redox signaling of transcription factors involved in cell growth and survival, including HIF1-alpha, NF-kB, AP-1, and STAT3. Elevated APE1/Ref-1 protein expression occurs in a variety of cancers. APE1/Ref-1 expression increases as tumors become resistant to therapy. APX3330 was tested by Eisai in over 400 patients, and the drug was safe and effective in decreasing liver inflammation caused by hepatitis. It was not tested in cancer patients when Eisai stopped development due to commercial reasons. Apexian is ready to commence a phase I study of APX3330 in patients with advanced cancers.

**Market and Commercialization Strategy**

Preclinical data from over 60 laboratories have confirmed the mechanism of action of APX3330 as an APE1 protein inhibitor and confirmed the role that APE1 plays in the development and maintenance of a variety of cancers. Preclinical data confirm additive or synergistic effect when APX3330 is added to compounds including chemotherapeutics such as cisplatin, 5FU, gemcitabine, as well as other targeted drugs. Given this data set and the fact that APX3330 is an orally-administered drug with an exemplary adverse event profile and low manufacturing cost, Apexian believes that APX3330 has the potential to be a "blockbuster" drug.

**Technical & Competitive Advantage**

Dr. Mark Kelley, Apexian's founder, is the world's leading authority on the APE1 protein target. APX3330 is the only oncology Phase I ready inhibitor of the APE1 protein and the Company is not aware of any other drug company developing an APE1 inhibitor. Eisai has already confirmed the safety of APX3330 in their hepatitis studies. Efforts by others to successfully develop an APE1 inhibitor have failed due to the complex 3-dimensional structure of the protein and the specificity with which APX3330 interferes with the unfolding of APE1 and redox signaling inhibition. An IND has already been issued by the FDA, and Apexian expects to reconfirm the safety profile and potentially identify anti-cancer efficacy. Additionally, recent data identifies APE3330 as having anti-CIPN (chemotherapy induced peripheral neuropathy) efficacy that does not negatively impact tumor efficacy. This is a novel and unique characteristic of the drug and target. There are no FDA approved drugs to treat CIPN.

**Regulatory Strategy & Intellectual Property**

4 issued patents (9,040,505; 9,089,605; 9,193,700; 9,315,481) and 2 filed (PCT US2012/040515; PCT US2016/030904). Apexian's use patents offer protection for a significant period. Since the Company can utilize the safety program Eisai completed, demonstration of clinical efficacy and registration of the compound for use in cancer therapy offer an attractive path forward with this molecule. Apexian plans to demonstrate APX3330 as a single agent and then utilize this observation to select key approved chemotherapy agents to evaluate the clinical relevance of this observation for patients on approved therapies.

**Key Milestones**

Initiate Phase I clinical study	September 2017
Complete 1a/b portion (dose escalation phase; cohort expansion in 1 or more cancers)	March/December 2018
Gain approval of Phase II protocol for lead indication & Manufacture clinical supplies to support Phase II study	June 2019
Initiate Phase II study	September 2019
Complete Phase II study to demonstrate efficacy of APE3330	September 2021

**Capitalization History**

2009	Grant	HHS (STTR) R41EY019784	\$225,064
2013	Grant	HHS (SBIR) R43CA171344	\$240,322
2012	Series A	Multiple	\$1.99M
2015	Series A	Multiple	\$600K
2017	Series A	Multiple	\$300K

**Use of Proceeds**

Apexian is seeking \$10M as part of a Series B round that the Company would like to close by 2017. The capital would be used to complete the Phase I study, manufacture clinical-grade APX3330, conduct stability testing, and advance the pipeline agents.

**Key Team Members**

**Steve Carchedi, BS, MBA - CEO**

Dr. Carchedi was the vice president at Eli Lilly and commercialized Gemzar and Alimta. He has more than 30 years of commercial industry experience focused in Oncology, Neurology, Urology, Endocrinology and Cardiology.

**Mark Kelley, PhD - CSO**

Dr. Kelley is the Betty and Earl Herr Chair in Pediatric Oncology Research and Professor Indiana University School of Medicine. Dr. Kelley holds numerous patents related to the use of DNA repair target for cancer and has published over 177 articles in journals.

**Richard Messmann, MD, MHS, MSc - CMO**

Dr. Messmann is an NCI fellowship-trained medical oncologist with extensive experience in clinical trials in oncology and radiologic imaging. He was an academic oncologist at Michigan State University, heading the breast cancer team as Principal Investigator.



## Company Overview (Clinical Impact and Value Proposition)

CanCure is an anticancer drug development company with a mission to transform the proprietary innovative cancer therapeutic technology into a marketable product and improve the survival of cancer patients. CanCure specializes in easily deliverable biotherapy drugs (antibodies) that can restore patients' own natural immune function to fight cancer. CanCure has a pipeline of therapeutic antibodies but currently focuses on taking its leading product CuraB-10 (also called B10G5) into clinic. CuraB-10 is a first-in-class monoclonal antibody targeting an immune suppressive molecule soluble MIC (sMIC) that was released specifically by tumor cells. Releasing sMIC is a method by which tumors evade immune attack. CuraB-10 has been tested in pre-clinical small animal models and shown to be very effective and safe in inducing regression of advanced cancers, such as metastatic cancers. CuraB-10 also remarkably enhance tumor response to immune checkpoint therapy when used in combination, including tumors that failed to respond to immune check point therapy, such as Opdivo (BMS) and Keytruda (Merck).

## Market and Commercialization Strategy

Current immunotherapy only presented survival advantage for a small percentage (less than 15%) of the overall cancer patients, with curative rate less than 3%. CuraB-10 is projected to penetrate the unmet market not only as a stand-alone therapy, but also in combination with current FDA approved immunotherapies. The pre-clinical response rate is 85%. Given the indication, even CanCure captures 1% of the cancer immunotherapy market; the anticipated revenue would be \$2 billion in 2021.

## Technical & Competitive Advantage

CuraB-10 is the first-in-class cancer immunotherapeutic antibody. There is no similar product on the market or in clinical trial. A few biopharma such as Innate Pharma and BMS have programs or interests in developing anti-sMIC antibody. However, by far CuraB-10 is the leading product from its proof-of-concept unique mechanism of action and implications either as a stand-alone therapy or in combination with other cancer immunotherapies. Except innate Pharma, none of products from other pharma has achieved pre-clinical proof-of-concept studies. The crucial limitation of these Pharma to develop their products is lack of pre-clinical animal model, because MIC/sMIC is a human-specific molecule that does not exist in rodents. CanCure is the only company that owns the genetically engineered (GEM) animal models that enables the pre-clinical proof-of-concept study.

## Regulatory Strategy & Intellectual Property

2 converted (61/843,182, 61/893,734), 1 nationalized (PCT/US2014/045366), 3 pending (14/900,510, 14819961.5, 62/367,673). Dr. Wu, the founder and the Interim CEO of CanCure, is the inventor of all filed patents. With specific emphasis in all the files patent claims licensed to CanCure—different from other granted or pending patents may be in the same line of target—the utility, composition, and specific indications of Cura-B10 have validated by preclinical proof-of-concept studies. CanCure is in process of filing new patents to strength the claims related to CuraB10. These new patents include: 1) the epitopes in the antigen specifically recognized by Cura B-10; 2) new combination therapy with CuraB-10.

## Key Milestones

Completed stable cell line generation	June 2017
GLP and IND-enabling pre-clinical toxicity study	September 2018
GMP production and IND filing	December 2018
Phase I clinical trial and commercialization	2019

## Capitalization History

9/2016	Grant	NIH/NCI STTR	\$299,994
1/2017	Grant	SC Launch STTR	\$50,000

## Use of Proceeds

CanCure is currently seeking \$3-10M to move the technology toward Phase I clinical trial and thus commercialization. The fund will be used for IND-enabling studies, IND application, cGMP production, and possibly Phase I/II clinical trials. The immediate \$3-5M will be sought in the next 6-12 months to cover the expenditure of IND-enabling studies, IND application, and cGMP production.

## Key Team Members

### Jennifer Wu, PhD - CSO, Interim President and CEO

Dr. Wu brings her expertise and vision in Onco-Immunology and her prior experience with Biotechnology Development. Dr. Wu is a Professor in Cancer Immunology.

### Craig W. Philips, MBA - COO and CFO

Mr. Philips has over 25 years of Biopharma leadership experience including Executive VP of Commercial operation and President of Kineta Inc, President of Cell therapeutics Inc, VP and General Manager of Bayer Oncology, Berlex Biosciences etc.

### Eddie Xing, MD - Medical Director

Dr. Xing brings his more than 20 years of medical experience into Drug Development. Dr. Xing has a wealth of experience in conducting clinical research and trial management in oncology and internal medicine.

**Company Overview (Clinical Impact and Value Proposition)**

Curon Biotech (previously Invenio) is a biopharmaceutical company passionately committed to applying its scientific leadership in the field of cellular metabolism to transform the lives of patients with cancer and rare genetic disorders. Curon believes that dysregulation of normal cellular metabolism plays a crucial role in many genetic diseases, and it is among the first in using cellular metabolism as a platform for developing potentially transformative medicines. The Company’s first product, INV603, is a First in Class, NCE, Novel Small Molecule to inhibit cell metabolism enzyme MDH1. Under this umbrella, Curon’s work encompasses two distinct areas of research and development: (1) cancer metabolism to inhibit key enzyme in cancer cell specific metabolic pathways to disrupt tumor cell proliferation and survival; and (2) metabolic immuno-oncology to alter the metabolic state of immune cells to enhance the body’s antitumor response. Curon’s management team plan to raise \$3 million from institutional investors or partner with pharmaceutical companies to continue clinical development of INV601 within 4 years.

**Market and Commercialization Strategy**

Curon’s clinical consultants indicate that a safe, cell differentiation therapy like INV601 can be valued \$50K+/patient/year for AML treatment. Curon expects INV601 to have sales \$9MM in the first year with 3% penetration in the AML market. The only FDA approved cell differentiation product is tretinoin (ATRA). Par Pharmaceutical is one of the companies selling FDA approved generic tretinoin capsules with annual U.S. sales of \$29M. Agios’s cell differentiation therapy Enasidenib has been accepted for the FDA’s priority review, and Syros Pharmaceuticals plans to initiate clinical trials with tamibarotene. Recently, Agios and Syros completed initial public offerings to raise \$106 million and \$57.5 million, validating a market need for differentiation therapies.

**Technical & Competitive Advantage**

The only drug to receive FDA approval in the past 30 years (PFE’s Mylotarg) was withdrawn following its failure in conformational 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, differentiation agents do not need to directly induce cell death for efficacy and thus have the potential to have significantly lower toxicities. Curon’s 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 United States for Vidaza and Dacogen protected by its orphan product designation has also expired.

**Regulatory Strategy & Intellectual Property**

3 provisional (61/886,448; 61/942,880; 62/051,595), 2 filed (PCT/US14/59104; PCT/US14/59112), multiple approved. INV601 regulatory path will follow Vidaza and Dacogen’s regulatory path, with comparison to best available therapy. Foregoing IP strategy will be orchestrated by Curon and Case Western Reserve University with efforts from experienced IP law firms. Curon is planning to file 2 Orphan Drug Designations in the US and EU in 2016.

**Key Milestones**

Completion of late preclinical studies	June 2017
Completion of IND-enabling Studies	June 2018
Initiation of Phase 1 Clinical Trial	June 2019

**Capitalization History**

2011	Grant	NIH/NCI (Phase II SBIR)	\$844K
2011	Grant	State of Kentucky (SBIR Matching)	\$500K
2014	Grant	Harrington Foundation	\$230K
2015	Grant	NIH/NCI (Phase II SBIR)	\$1.5M

**Use of Proceeds**

Curon is seeking Series A financing of \$3 million (2 tranches) to complete pre-IND studies with INV603 and enable us to partner with strategic pharma partners.

**Key Team Members**

**Santhosh Vadivelu, PhD - CEO**

Dr. Vadivelu has been a healthcare venture capitalist at Canaan Partners and has raised more than \$150 million private investments and helped several startup biotech companies both in clinical development operations and pharma M&A partnering.

**David Wald, MD, PhD - President**

Dr. Wald is the co-founder and Chief Medical Officer of Curon and has extensive experience as a serial physician entrepreneur in the hematology markets. Dr. Wald is an employee of Curon. He has lead several pharmaceutical company scientific partnerships.

**Ulrich Muehlner, PhD - CBO**

Dr. Ulrich Muehlner was recently with Novartis as the Global Head for Corporate Strategy and has led and managed corporate strategic planning and conducted major initiatives.

**Company Overview (Clinical Impact and Value Proposition)**

Cynvec is a preclinical stage biotechnology company founded in 2004 to develop and commercialize innovative safe and effective cancer treatments based on intellectual property exclusively licensed from New York University (NYU). Cynvec is pursuing an ovarian cancer indication for the Company’s second-generation candidate, CYN102. CYN102 is an immunotherapeutic that targets cancers that overexpress the high affinity laminin receptor (LAMR) and can activate an efficacious immune anti-tumor response. CYN102 utilizes the anti-cancer properties of a bio-engineered form of Sindbis virus vector (SVV) that expresses the tumor associated antigen (TAA) NY-ESO-1. Dr. Daniel Meruelo developed Cynvec’s platform base (CYN101) and the CYN102 derivative.

**Market and Commercialization Strategy**

Ovarian cancer is the 5th leading cause of cancer death among women and yearly estimates for treatment of ovarian cancer just in the US are \$2.2 billion. A therapeutic prescribed to 25% of patients that do not respond to platinum based therapeutics would have a market of >3,500 patients a year. Current market prices for new cancer treatments are averaging over \$120,000; Cynvec conservatively estimates a market price range of \$60,000 to \$80,000 per CYN102 treatment course. It is not unreasonable to estimate an initial >\$210 M U.S. market. Cynvec’s goal is for SVV to serve as a technology platform to treat multiple cancer types. For example, SVV candidates in the Cynvec pipeline have shown significant efficacy in ovarian, kidney, pancreatic, colon, lung and other cancers in mouse models. Demonstrating clinical success in ovarian cancer with CYN102 will significantly de-risk the approach for other cancers.

**Technical & Competitive Advantage**

SVV binds to LAMR, which is over-expressed in many cancer cell types. Large inserts/multiple genes can be incorporated and expressed in SVV. SVV disseminates systemically and is expressed on mouse lymph nodes within 3 hours. The SVVs carrying TAAs induce NK and T-cell activation. These activated cells migrate to the tumor site where they are efficacious against tumor cells. In preliminary mouse biodistribution and toxicology studies, the base vector, SVV, appears to be cleared rapidly and has not demonstrated any deleterious effects at high doses. CYN102 has demonstrated a significant reduction in tumor cell growth and prolongation of survival in mice.

**Regulatory Strategy & Intellectual Property**

Six approved patents (US 7,306,792; 7,807,147; 7,303,898; 8,093,021; 8,282,916; 8,530,232), 1 pending (PCT/US2014/054356). The intellectual property for the Sindbis virus (SV) platform has been carefully protected to preserve the commercial promise the technology demonstrated since its discovery in 2002. As the company evolves and additional therapies are developed, Cynvec intends to file for additional patent protection. Cynvec will prioritize intellectual property protection as critical to its business strategy. The company’s intellectual property counsel is Clark & Elbing, LLP, which specializes in Biotech and Pharma patent law.

**Key Milestones**

Manufacture of clinical CYN102 drug product	January 2018
IND submission to CBER	April 2018
Execution of a Phase I dose-escalation study of CYN102 in women with ovarian cancer	May 2018
Execution of a Phase II efficacy study of CYN102 in women with ovarian cancer	May 2019

**Capitalization History**

2004-14	Philanthropists	Angel	\$14.6M
2015	Individuals	Class C Preferred Stock	\$4.3M
2016	NIH/NCI	SBIR Grant	\$2.0M

**Use of Proceeds**

Cynvec is now preparing an offering memorandum to seek a \$15 M cash infusion. Funds are planned for additional manufacturing of CYN102 and a goal of initiating a multi-center Phase 2 clinical study within 2019. In addition, the SVV platform will have a robust and consistent manufacturing process, now being optimized with CYN102; therefore, other pipeline candidates can be pursued in a parallel effort for additional cancer indications. The strategy also includes the hiring of a Chief Medical Officer.

**Key Team Members**

**Steven Blumenthal, BS - Chairman**

Mr. Steve Blumenthal is responsible for operations, finance, business development.

**Dan Meruelo, PhD - Chairman, Scientific Advisory Board**

Dr. Meruelo is a Professor of Pathology at NYU and the Head of Gene Therapy with the medical school. He is responsible for Sindbis viral vector development, pipeline generation, initial proof of principle studies, and exploring mechanistic properties of SVVs.

**Scott Winram, PhD, PMP - Vice President**

Dr. Winram is responsible for moving candidate SVVs forward into the clinical pathway and brings almost 2 decades of product development experience from GSK, the NIH, and SAIC/Leidos.



**Company Overview (Clinical Impact and Value Proposition)**

EvoRx Technologies develops next generation targeting agents for therapy and companion PET imaging agents. Our lead program is for the staging and treatment of inflammatory Her2+ breast cancer. IBC is a highly aggressive disease with a five-year survival rate below 30%. IBC is difficult to detect on mammograms and challenging to biopsy since it does not form a discrete lump. This often leads to an imprecise diagnosis or staging of the disease. Many patients with IBC are Her2-positive and data suggests that patients could benefit from anti-Her2 therapies. However, up to 40% of IBC patients are mis-staged or lack of assessment for Her2 status which may prevent or delays access to Her2 therapies. The unique technology generates EvoTides - small, macrocyclic, protease resistant peptides – that combine the high binding affinities and binding specificities of antibodies with the deep tumor penetration of small molecules. EvoTides exhibit excellent in vivo distribution profiles and have lower COGS than antibody-, affibody-, or minibody-based technologies. We have additional programs for 1) a companion Her2 therapeutic agent and 2) agents targeting beta catenin in colorectal cancer.

**Market and Commercialization Strategy**

Of the ~232,000 cases of breast cancer annually, ~20-40% are Her2+. The first market for staging and assessment of Her2+status in inflammatory breast cancer (IBC), where ~52% of patients with IBC are Her2+. A second market are patients with Her2+ lymph nodes treated with neoadjuvant trastuzumab (>17,200/year). A PET scan able to prevent unnecessary dissection can potentially save over \$300M/year. A third market is as a Her2-companion diagnostic imaging agent that will predict which patients will best respond to anti-Her2 therapy, especially those patients with metastases that are difficult, painful, and impractical to biopsy. For our Her2-imaging agent, future markets will focus on imaging of other Her2+ cancers and the development of a companion therapeutic for metastatic and brain-Her2+ cancer.

**Technical & Competitive Advantage**

EvoRx’s main competition for our lead product is from antibody-based PET imaging. Despite commercial use of antibodies, antibodies are uncommon clinical PET imaging agents. Supporting this notion are the development of Affibodies and antibody fragments (Imaginab) for PET imaging. EvoRx has several advantages over these technologies: Ease of Synthesis; Automated Synthesis; Low Molecular Weight PET Tracers; PET Imaging Modality; PET/CT is more widespread, enabling easier adoption.

**Regulatory Strategy & Intellectual Property**

4 patents filed (064189-5150; 064189-5100; 502899923; 502899901).

The technology for generating SUPR peptide imaging agents and the composition of matter of the Her2 binding peptides have been exclusively licensed to EvoRx Technologies by the University of Southern California. EvoRx will continue its R&D efforts to produce “next-generation” enhanced imaging agents to remain competitive and seek or maintain IP protection for such improvements.

**Key Milestones**

Finalize med chem for the imaging agent 12/31/2017	December 2017
Apply for SBIR for the companion therapeutic agent 1/5/2018	January 2018
Finalize med chem for the therapeutic agent fall 2018	Fall 2018
Apply for IND for imaging agent Dec 2018	December 2018

**Capitalization History:**

2012, 13	Angel	Local investors	\$750K
2014	Collaboration	Big pharma	\$500K
2014, 15	Grant	NIH/NCI (2 Phase I SBIRs)	\$550K
2016	Collaboration	Pharma (2 Collaborations)	\$1.4M
2016	Grant	NIH/NCI (Phase II SBIR)	\$2.0M

**Use of Proceeds:**

We will be seeking funding to finalize preclinical studies, submit IND package to the FDA, and pay for a phase I clinical trial on the imaging agent. We expect the funding raise to be 1.5 to 2 years from now, but would like to introduce EvoRx to the proper investment groups early.

**Key Team Members:**

**Steven V. Fiacco, PhD - CEO/Co-founder**

Dr. Fiacco has advanced the business through multiple collaborations and license agreements with pharmaceutical companies such as AstraZeneca. He earned his PhD in Chemistry from USC.

**Paul Burke, PhD - Advisory board**

Dr. Burke was the head of Pfizer's global Center of Excellence for targeted drug delivery and imaging, and CTO of the Oligonucleotide Therapeutics Unit. He was Executive Director at Merck, and Executive Director of Pharmaceuticals at Amgen

**Richard Roberts, PhD - Advisory board**

Dr. Roberts currently serves as Professor and Chair of Chemical Engineering.



# For-Robin, Inc./ Breast Cancer Antibody Immunotherapy

Kate Rittenhouse-Olson | krolson@for-robin.com | 716-866-6941 | www.for-robin.com

## Company Overview (Clinical Impact and Value Proposition)

For-Robin, Inc. founded in 2012 and named in honor of the founder's sister who died at age 31 of breast cancer, is an antibody immunotherapy company whose primary mission is developing therapy for breast cancer patients. The Company's proprietary technology targets all breast cancer cell subtypes including triple negative breast cancer which currently has no targeted therapy. For-Robin plans to develop humanized JAA-F11(hJAA-F11) as an adjunct therapy for breast cancer as quickly, safely and efficaciously as possible. JAA-F11 patented antibody specifically targets the alpha-linked form of a disaccharide tumor marker, the Thomsen-Friedenreich glycoantigen (TF-Ag) a well-known antigen found on the surface of 80% of all carcinomas and not expressed on normal cells. JAA-F11 is expected to be safe as humans have small amounts of naturally-occurring antibody to the TF-Ag, indicating likelihood of safety at higher quantities.

## Market and Commercialization Strategy

Of the more than 1.5 million new cases of cancer in the US each year about 50% are expected to be potential targets for hJAA-F11. In 2017, 44 mAb products are in the oncology market segment. Some of the most successful products like Avastin, Opdivo and Keytruda form the basis of a multibillion-dollar market for cancer immunotherapy. Importantly, mAb therapy generally has less negative side effects than standard chemotherapy, radiation and surgical treatments. For-Robin's main competitor in breast cancer immunotherapy, Herceptin, treating only 25% of BrCa, generated \$6.78 billion in revenue in 2016 with an ~4% growth in market per year. This makes the effective market for hJAA-F11 potentially > \$22 billion. Antibody Drug Conjugate (ADC) therapies use a highly selective antibody to target (deliver) a toxic payload to cancer cells.

## Technical & Competitive Advantage

hJAA-F11 has potential to become the next blockbuster biologic for use as an adjunct in therapy for BrCa treatment. hJAA-F11 also addresses the unmet need for treating the most aggressive breast cancers that are triple negative for other biomarkers (estrogen, progesterone and Her2). Herceptin is currently the most successful antibody immunotherapy for BrCa and is off patent in US in 2019. While Herceptin is effective therapy for only 20-25% of all BrCa (Her2+), it generated \$6.78 billion in worldwide sales in 2016. Kadcyla, Herceptin's Ab-drug conjugate generated \$831 million in 2016 while Perjeta which along with Herceptin targets Her2-driven signaling pathways generated \$1.84 billion in 2016.

## Regulatory Strategy & Intellectual Property

4 approved (US7374755, Canada 2,582,252, UK/FR/GR 1789027, JP2904266), 2 provisional (US61/981,240, Intl PCT/US 15/26595). JAA-F11 is owned and patented by the University at Buffalo and exclusively licensed to For-Robin for commercialization. IP position is based on the novel design of the humanized antibodies composition and the resulting unique characteristics for ADCC and for internalization for tumor targeting and drug delivery. Coverage has been extended to multiple countries.

## Key Milestones

Develop and validate tests for candidates for direct Ab and ADC therapy supporting pre-IND animal testing	August 2016
Pre-IND meeting with FDA	November 2017
Develop GMP cell lines for lead candidates	December 2017
Submit regulatory IND documentation	June 2018

## Capitalization History

6/2013	Grant	NYSTAR UB Cat (total from 3 grants)	\$78,591
7/2013	Grant	UB Catalyst (total from 2 grants)	\$90,000
5/2013	Grant	STTR Phase I	\$282,224
6/2014	Grant	STTR I Supplement	\$128,000
5/2015	Grant	STTR II	\$1,986,991

## Use of Proceeds

For-Robin is currently seeking \$3 million (\$1 million/year) in matching funds starting 5/1/2017 to be able to apply for SBIR/STTR IIb Bridge funding of up to \$3 million over a three-year period from the NIH/NCI. The \$6-10 million total will take product development through Phase I trial, a milestone where interest in acquisition or strategic partnerships is expected.

## Key Team Members

### Kate Rittenhouse Olson, PhD, SI, ASCP - President

Dr. Rittenhouse Olsen is a University of Buffalo Professor & Research Professor in Biotechnical and Clinical Laboratory Sciences as well as Epidemiology and Environmental Health. She was involved in studying carbohydrate tumor associated antigens and TF-Ag.

### James Olson, PhD - Chairman

Dr. Olson is University at Buffalo Distinguished Professor, specializing in toxicology and the environmental health sciences.

### Sally Quataert, PhD - Chief Executive Officer

Dr. Quataert specializes in RQAP-GLP operational and strategic management. She has previous experience in start-up vaccine business, large pharmaceutical R&D, clinical translational research and compliance/QA.



## Company Overview (Clinical Impact and Value Proposition)

GlycoMantra is a startup biotechnology firm, registered in Virginia but operating in Maryland at the bwtech@UMBC Life Sciences Incubator. The Company’s technology expertise is in glycobiology research leading to the development of a carbohydrate-based therapeutic (TFD100) for treatment of advanced prostate cancer. GlycoMantra has signed an exclusive license with the University of Maryland, Baltimore for U.S. Patent No. 9,180,175, titled “Methods of Use for a Natural Thomsen-Friedenreich Disaccharide Compound”. GlycoMantra’s President and CSO, Dr. Hafiz Ahmed is the lead inventor. rTFD100 is designed to suppress mCRPC by specifically targeting galectin-3 (Gal3).

## Market and Commercialization Strategy

The global market for prostate cancer treatment will expand rapidly from \$7.6 billion in 2014 to \$13.6 billion by 2021, representing a CAGR of 9.5%. The increase will occur across the eight major markets of the US, Canada, France, Germany, Italy, Spain, the UK and Japan and will be driven primarily by growth in disease prevalence due to an aging global population. GM101 (future lead compound derived from TFD100) will target mCRPC. As a benchmark, Zytiga and Xtandi are both blockbuster drugs, indicated for mCRPC, with global sales in 2014 of \$2.2 billion and \$2.1 billion, respectively. If GM101 shows superiority in overall survival of >4.8 months, the Company expects to win at least half the market share of each of these drugs for \$2B annual revenue. The end user for this therapeutic drug will be mCRPC patients. These will be men on average from 50-75 years of age whose disease has progressed from hormone sensitive status. Given world prevalence rates and pharmaceutical consumption, the Company intends to achieve regulatory approval in USA, Canada, Europe, Australia and Japan and serve patient populations in these countries.

## Technical & Competitive Advantage

TFD100 binds galectin-3 with very high affinity (97 picomolar) – the affinity is so high (10-100-fold more) it outcompetes the interactions of galectin-3 with endogenous tumor-associated TFD-containing O-glycosylated ligands. Moreover, this high affinity should overcome immunogenicity issues common with biologics -- antibody-antigen KD are typically 100X lower. TFD100 or GM101 provides a competitive advantage over other known galectin antagonists such as TD139 (14 nanoM), MCP or GCS-100 (2.6 microM), GM-CT-01 or GR-MD-2 (10 microM). These galectin antagonists not only have low affinity to galectin-3 and but also bind other galectins non-specifically. GM101 is multi-pronged, attacking tumors by at least three putative mechanisms: blocking tumor angiogenesis, blocking tumor-endothelial cell interactions, and enhancing anti-tumor T-cell response. Thus, GM101 is expected to have longer efficacy than single-target drugs to which the cancer invariably develops resistance. The Company predicts that GM101 will increase overall survival of mCRPC patients significantly over placebo and also be superior to Zytiga and Xtandi which only offer 4.6 and 4.8 months’ improvement in overall survival.

## Regulatory Strategy & Intellectual Property

1 patent approved (9,180,175).

GlycoMantra has signed an exclusive license with the University of Maryland for the above patent. GlycoMantra’s strategy is to file the US provisional application on the composition of matter soon after the lead drug candidate GM101 is identified. The Company will file a PCT and plan to nationalize into all major pharmaceutical markets. GlycoMantra will work closely with its patent attorney to ensure that confidentiality agreements and trade secret practices are tight enough to avoid inadvertent public disclosures.

## Key Milestones

IND enabling experiments such as development of master cell bank, cGMP run	2017-2018
PK/PD, Toxicology	2018-2019

## Capitalization History

2015	MII	TEDCO	\$150K
2015	Grant	NIH/NCI (SBIR Phase I)	\$224,871
2016	Grant	NIH (I-Corps at NIH)	\$40K

## Use of Proceeds

GlycoMantra aims to source the following funds: \$0.75M from Angel Foundation; \$1.0M from Series A-1 funding, \$2.8M from Series A2 funding, \$3M from Series A3. From 2017 to 2021, the company seeks a total of \$15.05M from federal and private funding.

## Key Team Members

### Hafiz Ahmed, PhD - President

Dr. Ahmed has 30 years of experience in glycobiology, protein chemistry, oncology, and secured over \$4 Million grant as PI/Co-PI.

### Khairul Anam, PhD - Research Associate

Dr. Anam has over 18 years of research experience in immunology and stem cell therapy including wound healing.

### Elizabeth Smith, PhD, MBA - Consultant

Dr. Smith has over 15 years of experience in biotechnology corporate business development activities.



**Company Overview (Clinical Impact and Value Proposition)**

Humanetics is a Phase II clinical development company, whose leading drug candidate is a proprietary radiomodulator called BIO 300. This product has been shown to sensitize cancerous solid tumors to the killing effects of radiation while at the same time protecting healthy tissues from radiation damage. Target indications include non-small cell lung cancer, head & neck cancer and prostate cancer. Humanetics licensed BIO 300 from the U.S. Department of Defense (DoD), where it emerged as the leading drug candidate for prevention of Acute Radiation Syndrome (ARS) and was further supported by BARDA funding. The Company completed a Phase I clinical safety trial for ARS and is currently in a Phase Ib/IIa clinical trial in non-small cell lung cancer patients. Plans for future commercial applications include testing in other solid tumor cancers, prevention of erectile dysfunction (ED) following prostate cancer radiotherapy, and as a radiation countermeasure for the DoD and U.S. Department of Health and Human Services.

**Market and Commercialization Strategy**

The clinical market for BIO 300 comprises more than 250,000 cancer patients annually. Radiotherapy (RT) is expected to increase 22% from 2010-2020, with lung cancer and prostate cancer RT use rising 26% and 35% respectively. Treatment with BIO 300 will require daily dosing starting one week before RT and continuing through the entire course of treatment, which is typically about 6 weeks. At an average treatment regimen of seven weeks, the target market for BIO 300 in RT is approximately \$700M. Humanetics believes it can capture a significant portion of this market through the competitive advantages of BIO 300. Prevention of ED caused by prostate cancer RT is another possible market. Of the 80,000 patients that undergo RT as part of their primary treatment, more than half will develop ED within 3-5 years. Current treatment options are limited with minimal efficacy.

**Technical & Competitive Advantage**

Amifostine is the only FDA-approved drug for protection of normal tissues during RT and is indicated for reduction of xerostomia resulting from head and neck RT. Its clinical adoption is low due to severe side-effects and logistical issues associated with IV administration prior to each RT dose. BIO 300 overcomes these limitations. It is a self-administered oral drug that has a strong safety profile, with little to no side effects observed in clinical trials. Other drugs under development as radiomodulators are at Phase I or II stage and all require parenteral administration. The Company is unaware of other drugs which have the ability to sensitize cancerous solid tumors to RT while at the same time protecting healthy tissues.

**Regulatory Strategy & Intellectual Property**

Technologies are being developed under appropriate regulatory pathways for the given indication. Humanetics currently has 4 open INDs. In addition, the Company is pursuing Orphan Drug Designations where appropriate and already has one designation for its lead candidate. Composition, methods of use and methods of making patents have issued (6,841,578; 8,551,530; 8,900,635; 9,084,726; 9,308,167; 9,387,171; 9,623,003; 9,623,004; 9,636,322), with many others pending worldwide. Humanetics’ intellectual property portfolio provides robust protection for commercialization of its cancer therapies.

**Key Milestones**

Commence Phase IIB RDBPC clinical trial in non-small cell lung cancer	2018
Commence Phase IIB RDBPC clinical trial in head and neck cancer	2018
Conduct pivotal studies under animal rule for radioprotectant countermeasure for warfighters	2019
Obtain licensure for radiation countermeasure indication resulting in commercial sales & priority review voucher	2020
Out-license or sell assets related to oncology indications	2021

**Capitalization History**

1990-2000	Individual Investors	Private placement equity offerings	\$12.0M
2000-15	Dietary ingredient business	Net income from operations and sale of business	\$40.0M
2006-10	Appropriations	Department of Defense	\$10.0M
2012-16	Contract/Grant	BARDA / NIH/ NCI / NIAID / NSBRI / NASA / CDMRP	\$11.3M

**Use of Proceeds**

In addition to several substantial non-dilutive government funded grants and contracts (\$21M to date), proceeds from investor participation will be used to fund Phase IIB clinical trials in anticipation of an IPO or licensing or sale to big pharma.

**Key Team Members**

**Ronald J. Zenk, MBA - CEO**

Mr. Zenk is the founder and director of the Humanetics. He is responsible for financial strategy and overall business management.

**John C. Dykstra - COO**

Mr. Dykstra is the director of the Company. He is responsible for management of pre-clinical, clinical and ongoing operations.

**Michael Kurman, MD - CMO**

Dr. Kurman is responsible for clinical trials for all drug candidates. He has strong experience in oncology drug development and clinical trials.

**Company Overview (Clinical Impact and Value Proposition)**

NERx Biosciences specializes in the discovery and development of biopharmaceutical compounds targeting DNA repair pathways. Focusing on the Nucleotide Excision Repair pathway (NER), NERx’s pipeline of targeted molecular therapeutics is unique and is supported by extensive clinical and pre-clinical target validation. Platinum (Pt)-based combination therapy is curative in testicular germ cell tumors with 10-year survival being ~95%. Pt drugs impart their chemotherapeutic effect by creating DNA damage, and it is well established that the repair of this DNA damage reduces the effect of Pt-therapy. With the goal of achieving responses that rival those in testicular cancer, NERx has developed a series of novel targeted therapeutics specifically designed to work with and enhance the clinical activity of Pt-based agents through targeted inhibition of DNA repair pathways.

**Market and Commercialization Strategy**

The focus of the initial clinical efforts on ovarian cancer for early clinical trials, with a secondary focus on lung cancer, but recognize the market potential for the Company’s compound with other solid tumors that receive Pt-based drugs. The ovarian cancer market is expected to increase 300% in the next 10 years from \$460 million to \$1.2 billion. Cisplatin remains the standard of care for EOC but unfortunately greater than 85% of those women who initially respond to Pt-based chemotherapy will also experience a recurrence within 5 years. Chemotherapy has been used successfully in a curative manner in the treatment of metastatic testicular cancer, setting a strong precedence for chemotherapy as part of the effective treatment. Therefore, the market would appear to drive efforts to enhance chemotherapeutic agents like Pt-based drugs. Furthermore, interest in targeting DNA repair pathways has increased and therefore, a gap in combination therapy that targets a DNA repair pathway still exists for exploration.

**Technical & Competitive Advantage**

The development of selective inhibitors of the NER proteins, RPA and XPA, would be a significant advance and fill an unmet need in clinical medicine as a combination adjuvant with cisplatin. These molecules have commercial applicability as both biochemical reagents to study DNA repair and clinically as an adjuvant treatment for solid-tumor cancers receiving Pt-based therapy. There are no current therapies designed to enhance the activity of Pt-based agents. NERx’s molecules have an edge in combination therapy with Pt drugs because they target the specific pathway that is responsible for the repair of the DNA damage that is induced by Pt drugs. The Company also has a strong advantage over other druggable molecules with the Company’s innovative approach of targeting a non-enzymatic protein-DNA interaction. These competitive advantages uniquely position us to make a clinical impact on large group of patients for which there are no targeted therapies and who will otherwise have grim clinical outcomes.

**Regulatory Strategy & Intellectual Property**

2 patents approved (8,980,955; 8,859,532), 1 provisional (62/340,639). RPA Inhibitors are covered under two issued composition of matter patents with use as in anticancer strategies. XPA inhibitors composition of matter is covered under a provisional patent application. Use patents in anticancer and other uses are expected in 2017.

**Key Milestones**

Lead compound optimization, scale up synthesis, formulation	August 2017
In vivo assessment in PDX	December 2017
GMP synthesis, animal pharm/tox, CMC	June 2018
FDA filing of IND application	December 2018

**Capitalization History**

2014	Angel investment	Private investor	\$250K
2012	Grant	NIH/NCI (STTR Phase I)	\$229,690
2012	Grant	NIH/NCI (SBIR Phase I)	\$299,922
2015	Grant	NIH/NCI (SBIR Phase I)	\$249,431
2016	Grant	NIH/NIGMS (SBIR Phase I)	\$293,005

**Use of Proceeds**

NERx is seeking a \$3.6M Series A round of equity capital from institutional and private investors. These funds will allow the completion of preclinical studies and the enabling studies necessary for filing an IND application with the FDA.

**Key Team Members**

**John Turchi, PhD - CSO/CEO**

Dr. Turchi is Professor and Associate Director of Research at Indiana University-Heme/Onc, NERx technology is based on the 25 years of NIH funded discovery based research from his lab.

**Katherine Pawelczak, PhD - Vice President**

Dr. Pawelczak has 15 years’ experience in DNA repair mechanisms in industry and Academia, including 3 years in Discovery at Dow.

**Nicholas Ball – CFO**

Mr. Bell has 30 years of experience in finance, including start-up founder and various CFO positions.



**Company Overview (Clinical Impact and Value Proposition)**

NuvOx Pharma is developing a nanotechnology platform of products for oxygen delivery to treat life-threatening diseases characterized by low oxygen (hypoxia). Upon intravenous administration, the oxygen therapeutics flow through the bloodstream arriving first at the lungs to pick up oxygen and finally to hypoxic tissue where they passively deliver the oxygen. The Company has positive results in a Phase Ib/II clinical trial in glioblastoma multiforme (GBM) showing safety and efficacy of NVX-108 (dodecafluoropentane emulsion, DDFPe) as a radiosensitizer, and will now test NVX-108 in a randomized Phase II clinical trial in association with chemo-radiation and chemotherapy of primary GBM (IND allowed by FDA). In animal studies, a dose of DDFPe less than 1/200<sup>th</sup> the gram weight of fluorocarbon (FC) of previously tested FC's is effective while breathing air. Other FC's failed due to high doses, resultant adverse events, requirement for high FiO<sub>2</sub>, and prolonged retention of FC. DDFPe is the first FC capable of multi-dose administration and clears via exhalation with a terminal half-life of 90 minutes. The preliminary data from the Phase Ib/II trial in GBM that shows DDFPe reverses hypoxia in cancer, which should improve patient response to radiation and chemotherapy.

**Market and Commercialization Strategy**

NuvOx's lead drug candidate is NVX-108. Potential customers include radiation oncologists, medical oncologists and ultimately, the patients. There are currently no FDA approved competitive agents. NuvOx has created a risk-adjusted net present value model of financial projections for sales of NVX-108 for GBM, and has validated this model with a potential corporate partner. Under the assumptions that there are 13,000 GBM patients in the US, a price of \$100K per patient, 35% market penetration, and the rest of world ≈ US, global peak sales are estimated to be \$900M annually.

**Technical & Competitive Advantage**

DDFPe has an excellent safety profile and has shown efficacy in pre-clinical studies for at least 7 different potential indications. There are drugs in clinical trials for newly diagnosed GBM, but the drugs would not remove the need for radiation therapy, and NuvOx's drug would likely be complimentary. NuvOx's most direct competitor is Diffusion Pharmaceuticals, which is developing trans sodium crocetinate (TSC) as a radiosensitizer. Per published animal studies, the effect on tumor oxygenation of TSC is less than NVX-108's. TSC's Phase Ib/II trial did not validate reversal of tumor hypoxia nor use genetic profiling. NuvOx has done both for better validation and better comparison to historical control. There are no other FC's in clinical trials for GBM, stroke or SCD besides DDFPe.

**Regulatory Strategy & Intellectual Property**

Originally, DDFPe was developed as a contrast agent, EchoGen®, by Sonus. EchoGen was approved in Europe and approvable in the US but never launched. NuvOx obtained ownership of these regulatory documents, which the FDA has agreed that NuvOx can reference. NuvOx improved the DDFPe formulation and obtained US Patent No. 8822549 (valid till at least 2032), two notices of allowances and 12 patent applications pending. DDFPe is regulated by the US FDA as a Biologic (potential for 12-years exclusivity). NVX-108 has Orphan Drug designation for GBM and NVX-508 for SCD; NuvOx has applied for Orphan Drug designation in Europe.

**Key Milestones**

Allowed IND for the randomized clinical trial in primary GBM patients	Q1 2017
Initiate a randomized, prospective, placebo controlled trial of NVX-108 in treatment of GBM	Q1 2018
Complete enrollment of the trial	Q1 2019
Analyze progression free survival to determine if Phase II trial can be expanded to pivotal trial	Q1 2020
To partner with an established pharma company to help defray expenses in order to market NVX-108	Q2 2020
To perform pilot studies in non-small cell lung cancer, pancreatic cancer, and brain metastases	Q4 2020

**Capitalization History**

2010	Series A-1	Founders	\$765K
Still open	Series A-2	Angel Investors (\$6M authorized, \$400K remains as of 7-3-17)	\$5.6M
2010-now	In Kind Investment	Founders/employees (deferred compensation and rent)	>\$3M
2010-now	Non-dilutive financing	NIH, ACA(majority from NIH)	≈\$5M

**Use of Proceeds**

NuvOx will use the proceeds to conduct clinical studies of NVX-108 in GBM and to advance other programs.

**Key Team Members**

**Evan Unger, MD - CEO/cofounder**

Founded two other biotechnology companies. He sold his first company to DuPont with a greater than twenty-fold ROI, second company went public and is an inventor on 115 issued US patents.

**Rajan Ramaswami, PhD - Chief Operating Officer**

20 years of experience in product and process development with emphasis on emulsion and microbubble based products.

**Gordon Brandt, MD - Vice President of Regulatory Affairs**

Former Vice President of Clinical and Regulatory Affairs at the company that originally developed DDFPe as the ultrasound contrast agent EchoGen and was President of a publicly held biotech company.

## Company Overview (Clinical Impact and Value Proposition)

Oncoceutics is a clinical-stage biopharmaceutical company engaged in the discovery and development of a class of small molecule compounds, called imipridones, which selectively target various G Protein-Coupled Receptors (GPCRs) for oncology. GPCRs are one of the most exploited targets in drug development, engaged by more than 30% of all approved drugs, but have never been effectively targeted for clinical oncology. The first lead compound to result from this program is ONC201, an oral, small-molecule antagonist of Dopamine Receptor D2 (DRD2) that has shown effectiveness and that is well tolerated against both solid and hematological malignancies. The company has completed successful Phase I programs and is currently conducting multiple Phase II clinical programs in areas with significant unmet medical need. In addition, Oncoceutics' pipeline includes several other imipridones with differentiated GPCR targets and efficacy profiles.

## Market and Commercialization Strategy

The clinical development program for ONC201 is focused on tumor types that have significant unmet medical need, where ONC201 has shown compelling clinical data, sensitivity to ONC201 in pre-clinical models and DRD2 target expression. These tumor types include gliomas, including glioblastoma, endometrial cancer and B-Cell malignancies such as non-Hodgkin's Lymphoma and multiple myeloma and are focused on patients with relapsed and refractory disease. The unique binding target of ONC201 and downstream signaling results in highly selective anti-tumor activity and safety. ONC201 is currently in seven clinical trials, and the current trials will treat more than 200 patients through 2018.

## Technical & Competitive Advantage

Surprisingly few GPCR-targeted therapies have been developed for oncology, despite frequent dysregulation of the receptors and their signaling mediators that control pro-survival and stress signaling pathways that are important in cancer. Furthermore, the clinically validated ability to target GPCRs safely without cytotoxic effects to normal cells represents a significant opportunity for novel therapeutics that contrast with currently available chemotherapies and targeted agents.

## Regulatory Strategy & Intellectual Property

7 US patents issued (8,673,923, 9,061,032, 9,072,744, 9,265,765, 9,376,437, 9,452,165, 9,688,679)

The company has six issued patents covering specific tumor types for method of use in cancer and one issued patent for a series of imipridones, including the IND candidate ONC206, as well as multiple pending patents for ONC201 and other imipridones. Additionally, the company is utilizing a variety of regulatory methods for generating additional market exclusivity, and has received Orphan Drug Designation for multiple indications.

## Key Milestones

Phase I completed with safety, PK, PD	2016
Initial read-out from Phase II glioblastoma trial; manuscript published	2017
Significant clinical efficacy data in other ongoing trials, including endometrial cancer	Late 2017
Initial read-out from expanded Phase II glioblastoma trial	Mid 2018
Initial read-out from Phase II multiple myeloma trial	Late 2018

## Capitalization History

2012	Grant	PA Department of Health	\$1.3M
2014	Series seed	Spring Mountain Capital + Individuals	n/a
2015	Grant	NCI SBIR (Extended with \$225K; drawn through 2017)	\$1.8M
2015	Series A	Spring Mountain Capital + Individuals	n/a
2016	Grant	FDA Orphan (Drawn through 2020)	\$1.7M
2017	Series A-2	Spring Mountain Capital + Individuals	n/a

## Use of Proceeds

Oncoceutics has funding through 2019. Additional proceeds would be used to develop clinical trials in additional tumor types with compelling rationales, including combination trials, and to introduce a second imipridone into the clinic.

## Key Team Members

### Wolfgang Oster, MD, PhD - CEO/co-founder

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

### Lee Schalop, MD - Chief Operating Officer/co-founder

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

### Martin Stogniew, PhD - CDO

Dr. Stogniew is an experienced drug developer with 26 US patents and 8 NDAs.

## Company Overview (Clinical Impact and Value Proposition)

OncoTAB was founded by a Mayo Clinic alumna, Dr. Pinku Mukherjee. The Company's technology is a patented monoclonal antibody, TAB004, which recognizes epitopes different from those recognized by other MUC1 antibodies. In vivo imaging studies in animal models for breast and pancreatic cancers have demonstrated localization of TAB004 on tumors but not on healthy tissue. demonstrated the feasibility of labeling TAB004 with radioiodine 131I and are in the process of fully humanizing TAB004. The Company plans to determine bio-distribution in mice and assess long-term localization and radiation dosimetry in tumor bearing mice. In this program, the Company also plans to establish the efficacy of 131I-labeled TAB004 in retarding growth and reducing TNBC tumor burden in mice and conduct preliminary toxicity studies. OncoTAB also launched Agkura™ Personal Score – a simple, non-invasive blood test as a supplemental test for women with dense breast tissue whose cancers are missed by mammography.

## Market and Commercialization Strategy

The US market size for a radiolabeled TAB004 targeted therapy for TNBC is \$3B, based on sales of Xofigo, a radiotherapy for prostate cancer with bone metastasis. Assuming a similar adoption rate, the Company can expect year 1 sales of \$52M and an annual growth rate of 38%. TAB004 will address an unmet need for TNBC patients with metastasis since there are no targeted therapies for TNBC. Further, the localized radiation will be an advantage given that radiation reduces loco-regional recurrence. OncoTAB has commercialized a Laboratory Developed Test (LDT) using TAB004 to aid the diagnosis of breast cancer in women with dense breast tissue. The US market for this indication is \$8B. The test was able to distinguish between cancer patients responding to treatment versus those whose disease progressed, opening up additional monitoring applications with a market of > + \$ 10 Billion.

## Technical & Competitive Advantage

Advantages of <sup>131</sup>I-TAB004 Targeted Radionuclide Therapy include considerable clinical experience with <sup>131</sup>I, ability to image with <sup>124</sup>I to tailor dose of <sup>131</sup>I to individuals, lower locoregional recurrence without the risks of Whole Breast Radiation Therapy (WBRT), and potentially lower cardiac toxicity compared to WBRT. Roughly 60% of patients receive radiotherapy as part of their treatment, which is one of the most cost-effective cancer treatments. Around 40% of cancer cures include the use of radiotherapy, either as a single modality or combined with other treatments.

## Regulatory Strategy & Intellectual Property

7 patents issued (2 US, 2 Japan, Australia, China, Russia), 17 applications filed.

Given that the method of labeling OncoTAB plans to use is not covered by any IP, the Company does not anticipate any barriers to commercialization. OncoTAB has a worldwide exclusive license to the technology for all applications.

## Key Milestones

Fully humanized TAB004	Q2 2017
Complete pre-clinical evaluation of radiolabeled TAB004 and TAB004 + Lip-MSA-IL2	Q4 2017
Initiate prospective multimodal clinical trial for breast cancer screening with Agkura Personal Score	Q1 2018
Initiate next phase of development for targeted radionuclide therapy for TNBC	Q2 2018

## Capitalization History

2012	Angel	LLC & Individuals	\$571K
2013	Angel	Inception Micro Angel Fund	\$461K
2014	Angel + Res. Loan	All of the above; NC Biotech Center	\$900K
2016	Convertible Debt	Founders	\$100K
2016	Grant + Contract	NCI SBIR & North Carolina	\$600K
2017	Grant	NCI SBIR (collaboration)	\$225K

## Use of Proceeds

OncoTAB is seeking \$12.5 Million to take the targeted radionuclide therapy for triple negative breast cancer through Phase I clinical studies. The funding will be used for (a) manufacturing humanized antibody and conduct preclinical studies including tissue cross reactivity, pharmacokinetics, animal toxicity; and (b) manufacturing GMP quality humanized antibody and conduct Phase I studies.

## Key Team Members

### Rahul Puri, PhD - Co-founder/CEO

Dr. Puri has over 24 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 seven patents.

### Pinku Mukherjee, PhD - Co-founder/CSO

Dr. Mukherjee has been a cancer researcher for the past 28 years. She is the Irwin Belk Endowed Professor for Cancer Research and Chair of Biological Sciences at the University of North Carolina at Charlotte.

### Taffy Williams, PhD - Chairman of the Board of Directors

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.

**Company Overview (Clinical Impact and Value Proposition)**

Privo Technologies is a development stage biotechnology with roots from MIT’s Langer Laboratory in Cambridge, MA. The Company aims to provide treatment options which offer higher efficacy, lower toxicity, improved patient compliance, and lower costs. The Company has designed a nanotechnology-based topical drug delivery platform, the ChemoThin Wafer (CTW). CTW is a wafer-like device that delivers drugs, primarily chemotherapeutics, to mucosa or skin where they are locally retained. Privo first encapsulates drugs within nanoparticles, and embeds the nanoparticles within the CTW body. When CTW is topically placed onto tissue, the nanoparticles are released and locally retained. Privo has initially developed, optimized and tested CTW for the treatment of oral cancer.

**Market and Commercialization Strategy**

Privo’s market and commercialization strategies have been based on the following: (1): Reformulating already FDA approved drugs with well-known toxicity profiles. For oral cancer, Privo uses the drug cisplatin. (2): Ensuring that all other excipients are FDA Generally Recognized as Safe (GRAS) to minimize regulatory and testing costs. (3): Using a nanoparticle synthesis method which eliminates any chemical changes to FDA approved ingredients which would increase regulatory scrutiny. (4): Targeting a disease which qualifies for FDA’s Orphan Designation. Privo has been approved for this designation for oral cancer as well as anal cancer. Privo has focused on primarily raising non-dilutive grant funding for the majority of the company’s history, and has to date secured over \$5 million in grant funding. Privo plans to leverage its orphan designation to perform clinical trials at minimal cost and commercialize CTW

**Technical & Competitive Advantage**

Privo’s topical treatment is placed directly onto a cancerous lesion to provide a highly concentrated and localized chemotherapy. Studies done by other competitors failed to retain their drug in the tumor mainly because drugs with low molecular weight can rapidly permeate through the tumor and pass right through into the blood and result in a short retention time in the tumor. Privo’s encapsulation of the drug addresses this issue by allowing higher retention in the tumor using nanoparticles, and this has been confirmed in numerous animal studies. With this patch design, Privo has been able to provide a unidirectional localized treatment that can then be customized to the patient’s needs. Effectively treating the oral cancer with a concentrated dose of chemotherapy, while significantly reducing toxicity and creating a more comforting procedure is where Privo will have the advantage over any other competitor. Privo’s system is also customizable.

**Regulatory Strategy & Intellectual Property**

Privo has 4 pending patent applications which have been filed as utility patents by Bruce Sunstein of Sunstein Law. Bruce Sunstein is considered one of the top 5 patent attorneys in Boston, and these patents cover CTW and variants of CTW. In addition, two provisional patents have also been filed and are in the process of being finalized and filed as utility applications.

**Key Milestones**

File 5 provisional or pending patent applications	2016
Complete preclinical animal studies	2016
Finalize Privo’s Clinical Study Design	2017
Submit IND Application	2017
Begin Phase II clinical trials	2017

**Capitalization History**

2013-15	Grant	NSF, MIT Deshpande Innovation Center, NIDCR	>\$500K
2015	Grant	NIH/NCI	\$2.3M
2015	Grant	NIH/NIDCR	\$2M
2016	Equity Investment	Private	\$1M

**Use of Proceeds**

The proceeds from this program will provide support for completing the necessary steps to begin clinical trials.

**Key Team Members**

**Manijeh Goldberg, PhD, MBA, MS - Chief Executive Officer**

Dr. Goldberg is the Founder and CEO of Privo. She has over 20 years of experience in the biomedical industry, in large companies and five startups, one of which was acquired for \$275 million.

**Michael Silverman, MD, FACP, - Chief Medical Officer**

Dr. Silverman is a board-certified internist with 3 decades of experience in biopharmaceutical industry research, product development, and strategic planning. He has managed pharmaceutical and biotechnology projects across a broad scope of therapeutic areas.

**Ellen Milano, MS - VP of Regulatory**

Ellen Milano brings more than 40 years of extensive experience in Regulatory Affairs and pharmaceutical technical issues. Her broad knowledge of the FDA-regulated industry includes both pre-and post-approval stages of development.



## Company Overview (Clinical Impact and Value Proposition)

Siamab Therapeutics is a biopharmaceutical company developing therapies targeting cancers that express abnormal carbohydrates or glycans. These highly cancer-specific, tumor associated carbohydrate antigens (TACAs) are present in most solid tumors and are exploited by tumor cells to suppress innate immune function, enable tissue invasion and metastasis, resist chemotherapy, and promote a cancer stem cell (CSC) phenotype. Siamab has developed a technology platform that overcomes these challenges and enables the discovery of large numbers of highly specific, high affinity anti-TACA therapeutic antibodies. Siamab's core technologies were licensed from the laboratory of Dr. Ajit Varki (UCSD), a world expert in glycobiology and sialic-acid biochemistry. Siamab's lead program is in late preclinical development targeting a glycan target, STn, overexpressed in several solid tumors including ovarian, pancreatic, prostate, gastric and colon.

## Market and Commercialization Strategy

Based on target expression, Siamab's product can be used to treat patients with multiple tumor types; the Company is focusing on ovarian cancer as a first indication due to high target expression and successful PDX data generated with the lead ADC. 85% of ovarian tumors express Siamab's target and more than 70% of cases are diagnosed after metastasis. Based on these statistics, the potential market in the United States and Europe is 24-30k patients per year. Current treatment options result in a 5-year survival rate of only 30%. Follow-on indications are likely to include pancreatic and gastric cancer.

## Technical & Competitive Advantage

With its lead program, Siamab has developed a panel of highly cancer-specific antibodies to the STn glycan. With support from both several SBIR awards as well as private investors, these mAbs have been successfully humanized and then engineered into antibody drug conjugates (ADCs) using the vc-MMAE technology. This technology has been FDA approved in the product Adcetris and has extensive clinical experience with other products in development. The core idea is to use the specific STn mAb to target tumors, bind to the cell surface, internalize into the lysosome, at which point the conjugated toxin (a tubulin inhibitor, auristatin) is released from the ADC and can then kill the cell. Currently there are no active therapeutic programs in direct competition with Siamab's ST1 program. While several reagent-quality murine STn mAbs have been developed for research purposes, unlike Siamab antibodies, these older attempts demonstrate poor specificity, are cross-reactive with other glycan structures, and are not humanized; and therefore unsuitable for therapeutic use.

## Regulatory Strategy & Intellectual Property

Multiple patents filed. Most critical to this program include: WO2016077526, US20160130356, and WO2016201240. Siamab's IP falls into three main categories - legacy/licensed IP from UCSD, Siamab platform technology that enables anti-glycan antibody discovery, and the antibody portfolio IP that focuses on the composition of matter for specific antibody molecules. Siamab works closely with a specialized biotechnology IP law firm, DT Ward PLC, to protect the Company's core IP and execute IP strategies.

## Key Milestones

Siamab has generated a strong preclinical data set and generated important and exciting data about the cancer stem-cell phenotype of STn+ cancer cells and their role in chemoresistance in collaboration with Dr. Bo Rueda at Mass General Hospital.

Cell Line Development	Now
GMP Manufacturing	2017-18
Phase I Clinical Trial	2019

## Capitalization History

2007-16	Grants & Contracts	Angels & Family Office (& Momenta Pharma)	\$7M
2008	Grants	Angels & Family Offices (& Novartis)	\$4.2M
2009	Grants	NCI Phase I & Phase II	\$2.9M
2010-14	Series A – A-6	NIAMS Phase I	\$153K
2015-16	Series B – B-2	NIGMS Phase I + Supplement	\$202K

## Use of Proceeds

Siamab is currently seeking \$20-25m in order to accomplish the next stages of development for the STn-ADC program: GMP manufacturing, IND enabling studies, and Phase I/Ib proof of concept clinical trials. With this funding, the Company would initiate manufacturing in 2017 and clinical studies would be initiated in late 2018.

## Key Team Members

### Jeff Behrens, MBA - President & CEO

Mr. Behrens worked at Edimer Pharmaceuticals, Alnylam and Biogen Idec, prior to joining Siamab in May of 2012.

### Daniel Dransfield, PhD - Senior Vice President of R&D

Dr. Dransfield received his PhD from Tufts University with post-doctoral training at Yale and the Medical College of Georgia and has more than 20 years of drug development and research experience in both industry and academia.



## Company Overview (Clinical Impact and Value Proposition)

StemMed, Ltd. is a drug development and testing company, whose pipeline includes C188-9, a direct oral inhibitor of signal transducer and activator of transcription (STAT) 3. StemMed's objectives are three-fold: 1) to develop C188-9 to an NDA for treatment, either alone or combined with chemoradiation, of solid tumors in which STAT3 is activated and a validated target, including triple-negative breast cancer (TNBC), hepatocellular carcinoma (HCC), head and neck squamous cell carcinoma (HNSCC), non-small cell lung cancer (NSCLC), gastric adenocarcinoma, colorectal cancer, and metastatic melanoma; 2) to develop C188-9 to a NDA for treatment of other diseases mediated by aberrant STAT3 activity including cachexia (muscle wasting), idiopathic pulmonary fibrosis, scleroderma, steroid-resistant asthma, and anaphylaxis; and 3) to provide state-of-the-art, pre-clinical breast cancer drug-testing services to contracting pharmaceutical companies.

## Market and Commercialization Strategy

StemMed's business development team is still evaluating marketing and commercialization scenarios for C188-9. The most likely path is to sell or license the Company's technology to an established player in the oncology field after clinical proof of principle. Another option is to work with a contract sales force such as Quintiles. Also, because there are fewer than 8,000 oncologists in the US, there also is an option to develop StemMed's own sales force for the US. Of note, geographic partnerships are an option in all scenarios. StemMed expects pricing of C188-9 to be in line with other small-molecule targeted therapies for cancer, such as Gleevec.

## Technical & Competitive Advantage

Despite being well validated as a target for treatment of breast and other cancers, no agent that inhibits STAT3 has become salvage or standard treatment for any cancer. There are three orally bioavailable, small-molecule competitors of C188-9 in development, napabucasin (BBI-608; Boston Biomedical) and OPB-31121/51602 (Otsuka Pharmaceutical Company). Evidence that BBI-608 targets STAT3 is limited; also, it failed to improve responses in a Phase III clinical trial that compared paclitaxel plus BBI-608 vs. paclitaxel alone in gastric and GE junction cancers. In Phase I studies, OPB-31121 caused profound gastrointestinal adverse events and underwent extensive first-pass metabolism in humans resulting in low and highly variable compound exposures. Similarly, in Phase I studies, OPB-51602 showed low tolerance, high incidence of side effects, and low efficacy. Thus, future development of these 3 competitors of C188-9 is uncertain.

## Regulatory Strategy & Intellectual Property

A total of 19 patents have been filed covering composition of matter and uses of C188-9. Four patents have issued (US, Canada, Europe, and Australia) that concern composition of matter and uses of C188-9 in cancer. Three additional sets of patents were filed in the US, Canada, Australia, Europe, and Hong Kong that concern composition of matter and use of C188-9 in muscle wasting (cachexia), fibrosis, and allergic reactions.

## Key Milestones

Approval of StemMed-sponsored Phase I dose-escalation protocol at MD Anderson Cancer Center (MDACC)	December 2016
Approval of IND	July 2017
Start Phase IA C188-9 dose escalation in 7 solid tumors	October 2017
Start Phase IIA in 7 solid tumors (14 patients each; Stage 1)	November 2018
Start Phase IB to determine RP2D of C188-9 when combined with docetaxel in TNBC	November 2018
Start Phase IIA (Stage 2; 16 patients each) in each solid tumor showing response in $\geq 1$ of Stage 1	October 2020
Start Phase IIB combination of C188-9 + docetaxel in TNBC	October 2020

## Capitalization History

2014	Grant	NIH/NCI R21	\$430K
2014	Grant	V Foundation	\$600K
2014	Grant	Cancer Prevention & Research Institute of Texas	\$2.0M
2016	Grant	NIH/NIDDK	\$1.72M
2016	Line of Credit	Chase Bank (Unrestricted)	\$500K

## Use of Proceeds

StemMed is poised to obtain additional funding from a CPRIT Investigator Initiated Research Award for Clinical Translation (IIRACT; \$2M) and an NIH/NCI Small Business Innovation Research (SBIR) Phase 2 award (\$2M) for continued development of C188-9 into a treatment for solid tumors. It is requesting \$18M to support development of C188-9 through Phase II studies that will lead to a NDA for one or more solid tumors.

## Key Team Members

### Atul Varadhachary MD, PhD - CEO (StemMed) and Managing Partner (Fannin Innovation Studio)

Former President of U.S. Operations at Reliance Life Sciences and former President & COO of Agennix, Inc..

### Apostolia Tsimberidou MD, PhD - Clinical Director

Professor, Investigational Cancer Therapeutics (MDACC), and Phase I PI.



## Company Overview (Clinical Impact and Value Proposition)

TargaGenix is developing a novel therapeutic for the treatment of cancer. The product is a combination of a nanoparticle formulation encapsulating the novel therapeutic DHA-SBT-1214. DHA-SBT-1214 has been shown in preclinical models that it can treat and cure animals with tumor types that are resistant to current standard of care. DHA-SBT-1214 has also been shown to effectively kill cancer stem cells and this property may represent the mechanism of the long-term efficacy seen with DHA-SBT-1214 treatment. TargaGenix had a successful pre-IND meeting in December 2016 that confirmed a clear pathway to IND and through Phase 2 studies. In addition, the company has developed a large-scale production process that can reliably produce commercial scale amounts of product. TargaGenix plans on receiving an IND in Q4 2017 and be in the clinic in Q1 2018.

## Market and Commercialization Strategy

The Company's lead product has been shown to completely cure mice in aggressive models of pancreatic, prostate, colon and breast cancer. The company plans to first develop the product in colon and pancreatic cancer. Taxotere® reached peak sales of \$3.1 billion in 2010. Abraxane did almost \$1 billion in sales. Preclinical evaluation of DHA-SBT-1214 has shown that it's active in tumor types resistant to paclitaxel and docetaxel. Use of these targeted therapies is not without limitations due to the development of resistance or the low response rate, and therefore an agent that can broadly de-bulk the tumor and eradicate the cancer stem cell population would be an important agent as a stand-alone therapy or in combination.

## Technical & Competitive Advantage

The most innovative aspect of DHA-SBT-1214 is that it exerts remarkable efficacy against highly drug resistant tumor xenografts in mice and is effective against cancer stem cells. DHA-SBT-1214 is far more potent than paclitaxel, especially against multi-drug - resistant cancer cell lines and tumors. The observed efficacy of SBT-1214 against several tumor xenografts, including DLD-1 (colon), PANC-1 and CFPAC-1 (pancreatic), clearly demonstrates that this is a critical jump. DHA-SBT-1214 has been shown to be active in several colon cancer models and this could represent a powerful new drug option for colon cancer.

## Regulatory Strategy & Intellectual Property

1 patent approved (7,820,839), 2 filed (2007/0148194), PCT/US17/36330.

TargaGenix's lead product DHA-SBT-1214 is covered by issued and pending United States and foreign patents and patent applications. The company plans to file for Breakthrough status and Orphan Drug designation upon completion of the Phase 1/2 clinical trial. These patents will be used by the company to block market entry of competing products infringing the patents, approval of generic products while the patents are in force, and importation of infringing products produced outside the U.S.

## Key Milestones

IND Submission	December 2017
Receive IND number	February 2018
First patient enrolled in Phase I/II clinical trial	March 2018
Complete Phase I study	June 2019

## Capitalization History

2015	Contract	NIH/NCI	\$2.3M
2016	Grant	NY Biotechnology Center	\$40K
2016	Grant	NY Sensor CAT	\$78K
2016	Grant	NY Biotechnology Center	\$40K
2017	Grant	NY Sensor CAT	\$60K

## Use of Proceeds

Upon completion of the proposed IND-enabling project, the company seeks to raise \$12 million in a preferred stock offering to advance NE-DHA-SBT-1214 through Phase 1/2 clinical studies. The company will seek to find a strategic partner to further develop the product or alternatively seek money in the public markets. The Company will leverage the clinical program to obtain a development deal with a pharmaceutical partner.

## Key Team Members

### James E. Egan, PhD, MBA - President/CEO

Dr. Egan was vice president of business development at IRX Therapeutics, where he raised over \$90M and negotiated the option to sell the company to Celgene Corporation in 2014.

### Iwao Ojima, MS, PhD, - Scientific Advisor

Dr. Ojima has served as a consultant to companies including Eli Lilly, Rhone-Poulenc Rorer, ImmunoGen, Taiho, and Aventis.

### Mansoor Amiji, RPh - Scientific Advisor

Dr. Amiji is distinguished professor & chair of Department of Pharmaceutical Sciences at Northeastern University School of Pharmacy.

**Company Overview (Clinical Impact and Value Proposition)**

TeamedOn has exclusive, world-wide IP rights to a class of novel small molecule therapeutics targeting Acute Myeloid Leukemia (AML), and have promising pre-clinical proof-of-concept (POC) data in human primary samples and an AML patient-derived xenograft (PDX) mice model. In addition, TeamedOn's molecule may be effective in treating lung cancers and lymphoma. Results from preliminary repeat-dose toxicity study in rodents suggest a good margin of safety. The Company plans to raise \$3.5M to complete the candidate confirmation and IND-enabling studies, and apply for permission to begin human Phase I trial within 24 months. TeamedOn has an experienced technical and leadership team with expertise in this field, and nationally-recognized key opinion leaders on the Scientific Advisory Board.

**Market and Commercialization Strategy**

The market size of TeamdOn's therapeutic TN1161 in AML is estimated by using the price of a comparator drug, Gleevec (Novartis) which is used to treat chronic myeloid leukemia (CML), and generates approximately \$4.7B annually (CNNMoney, April 26, 2013). The annual cost of Gleevec to a patient is \$100,000. Total estimated number of new AML cases in the US was 19,000 for 2014. TN1161 initially targets the newly diagnosed patients with acute myeloid leukemia  $\geq$  60 years of age. Therefore, TeamedOn estimates ~16,000 AML cases suitable for TN1161 in the US, and the new AML cases outside-US (EU, Japan, Australia, and Canada) is approximately the same as the US. TN1161 is expected to be efficacious in all subtypes of AML. TeamedOn estimated a 10% initial market penetration rate, and an estimated annual cost to the patient of \$25,000 per patient which is 25% of the annual price of Gleevec. The predicted revenue for the first year is \$80 million and by year 3 revenues increase to \$184 million.

**Technical & Competitive Advantage**

TeamedOn identified several companies (Tolero, Dynamix, Pfizer, and Agios) each working on the same target (PKM2), but for solid tumors, not liquid tumors. The Company also performed head-to-head comparison of TN1161 with competitor PKM2 activators in colony formation assay using human primary AML CD34+ leukemia stem cells (LSCs). Results show that TN1161 outperforms other compounds on targeting LSCs. The unique target and mechanism of action (targeting LSCs) will allow the proprietary compounds to work in combination with other AML current or future drugs. For examples, chemo drugs (inhibitors of DNA synthesis, DNA methyltransferase etc.) cannot target LSCs, therefore, TN1161 could complement with current and future chemotherapies. FLT3 mutations result in phosphorylation of PKM2 and subsequent nucleus translation, which suggests TN1161 could synergize with FLT3 inhibitor treatments in AML. In addition, TeamedOn's platform technology presents a reduced risk of investment. Since many cancers express the target, the PKM2 enzyme, the Company believes that the candidate therapeutic, TN1161, has therapeutic potential against several other cancers. For example, TeamedOn have demonstrated that TN1161 potently inhibits tumor growth in both lung cancer and lymphoma xenograft mouse models.

**Regulatory Strategy & Intellectual Property**

1 patent filed (PCT/ US2009/60237), 5 approved (Japan 531221-2011; US 13/123297; 13/433656; 14/576,333; 15/076259). The patents for this technology are licensed from NIH under a worldwide exclusive license agreement.

**Key Milestones**

Development candidate confirmation	End of 12 months
Complete IND-enabling studies and IND submission	End of 24 months

**Capitalization History**

2016	Grant	NIH/NCI (SBIR)	\$278K
2017	Convertible Note	TEDCO	\$100K

**Use of Proceeds**

TeamedOn significant licensing/collaboration income at the end of Year 4 after the successful completion of Phase 1 clinical trials in AML. The Company plans to raise \$0.5M in next 3-6 months to complete the candidate confirmation and raise \$3M within 6-12 months to complete IND-enabling studies and IND submission to FDA.

**Key Team Members****Peter Mu, PhD, MBA - President and CEO**

Dr. Mu has previously worked at Covance, Lexicon, and WuXi AppTec. He has extensive experience in new drug development.

**Gary G. Altman, PhD - Vice President**

Dr. Altman is an experienced business leader in therapeutics and diagnostics, raised angel and venture capital.

**Joseph Chen, PhD - Vice President**

Dr. Chen worked at Boehringer Ingelheim, Tanox, J&J, and Lexicon. He is an expert in pharmaceutical development.



## Company Overview (Clinical Impact and Value Proposition)

TheraTarget is a preclinical stage pharmaceutical company with a goal to become a leader in the field of innovative macromolecular therapeutics. TheraTarget has created a patented, proprietary polymer-drug conjugate platform that effectively delivers anti-cancer drugs via the blood stream to solid tumors. This technology promises unparalleled ability to improve survival of cancer patients where current chemotherapy is sub-optimal. There are 7 long-circulating highly effective therapeutic oncology candidates in preparation for clinical trials. Among them the most advanced candidate is KT-1 (backbone degradable water-soluble N-(2-hydroxypropyl) methacrylamide (HPMA) copolymer - epirubicin conjugate for intravenous injection); an Investigational New Drug Application will be filed in 2020. TheraTarget validated the technology by challenging ovarian and pancreatic cancer preclinical animal models. Compelling therapeutic efficacy has been observed, in particular in the biodegradable HPMA copolymer-EPI conjugate group.

## Market and Commercialization Strategy

TheraTarget will attach epirubicin (off-patent) to the polymer backbone. This polymer drug conjugate will target the solid tumor cancer market. Epirubicin is used alone or in combination with other antineoplastics to treat breast cancer, lung cancer, ovarian cancer, stomach cancer, and lymphoma. The market for solid tumors was \$11B/yr in 2015 and will continue to grow at a CAGR of 4.4%. An IND for epirubicin will provide a simultaneous increase in efficacy, a reduction in adverse effects and significantly reduce the dosage of anti-cancer drugs needed. Traditional and targeted drug delivery account for nearly 20% of all pharmaceutical sales in the United States, totaling \$76.6B in 2014. Problems with traditional therapy include adverse side effects and decreased efficacy. TheraTarget's conjugates will significantly reduce the toxicity, increase delivery efficacy and reduce the dosage of drug needed.

## Technical & Competitive Advantage

TheraTarget's polymer-drug conjugates possess advantages over current marketed chemotherapeutic agents in that they have extended intravascular half-life and enhanced concentration of antineoplastic agents in tumors resulting in significantly improved effectiveness. Some of the unique advantages of this technology compared to other long-circulating conjugates, micelles and liposomes on the market or in development include a well-controlled polymerization process providing highly reproducible polymer-drug conjugates and a biodegradable backbone allowing the use of high molecular weight HPMA polymer carriers. There is very low risk in development as toxicity for all components is already well known. The technology is versatile, so a large variety of conjugates can be prepared.

## Regulatory Strategy & Intellectual Property

1 provisional patent (US61/311,459), 1 non-provisional (US13/583,270), 1 international (PCT/US2011/027337), 1 issued (below). "Polymeric Drug Delivery Conjugates and Methods of Making and Using Thereof", issued March 22, 2016; US 9,289,510 B2. Patents in Japan and EU will be issued soon.

## Key Milestones

Venture capital to complete milestones	December 2017
GLP-GMP production scale-up	April 2018
ADME Tox studies & IND preparation	September 2018
Initiate Phase I clinical studies of first polymer-drug conjugate	January 2020

## Capitalization History

2008	Private Equity	Founders/private	\$43K
2009-13	Partners	Rexahn Pharmaceuticals	\$115K
2010-11	Grant	NIH/NCI	\$348K
2011-12	Grant	Utah State TCIP	\$80K
2014-16	Grant	NIH/NCI	\$2,489,613

## Use of Proceeds

TheraTarget is seeking approximately \$4.6M Series A financing to meet preclinical IND milestones. Funds of will be needed for required scale-up of manufacturing processes, ADME Tox studies and preparation of an IND application.

## Key Team Members

### Darwin Cheney, PhD - CEO

Dr. Cheney has 40+ years of experience in drug R&D and management. Dr. Cheney worked as a pharmaceutical executive at FIDIA Research Foundation, Cyprotex, and CIBA-Geigy.

### Hamid Ghandehari, PhD - CSO

Dr. Ghandehari has 30+ years of experience in drug delivery technology and is a polymer expert in targeted delivery.

### Chang-Ho Ahn, PhD - Advisor

Dr. Ahn is a drug development expert and founder of Rexahn. He has 40+ years of pharmaceutical and regulatory experience.

### Company Overview (Clinical Impact and Value Proposition)

Biologic drugs are the largest pharmaceutical growth segment and are among the most expensive pharmaceuticals. However, dosing regimens for biologic drugs are one-dose-fits-all and, as a result, most patients are being improperly dosed. Abreos Biosciences is poised to disrupt the current dosing paradigm and have a major impact on the delivery of life-saving medications for cancer, autoimmune diseases, and other serious illnesses. The cost is becoming unsustainable and these medicines are inaccessible to many patients in need. Precision dosing will maximize the value of the drugs and, by lowering overall costs, expands the access of these powerful medications to patients.

### Market and Commercialization Strategy

Abreos Biosciences is enabling precision dosing of biologic drugs. The market for therapeutic dose monitoring of biologics sits at the intersection of several billion-dollar markets: biologic drugs (\$287 billion by 2020), companion/complementary diagnostics market (\$8.7 billion by 2020), and small molecule therapeutic dose monitoring (\$3 billion by 2020). Abreos' major source of revenue will be commercializing point of care complementary diagnostics. Abreos has a quick path to revenue by partnering with pharmaceutical companies to develop custom Veritope assays for marketed drugs, as well as drugs in development. These partnerships will help foster future complementary diagnostic development projects. And finally, the Company is in discussion with several large pharmaceutical companies and will develop custom point of care devices for clinical trial patient stratification; these devices can be subsequently commercialized as complementary diagnostics.

### Technical & Competitive Advantage

Existing technologies include anti-idiotypic antibodies and recombinant proteins, used to capture monoclonal antibodies-based therapies. Both methods are extremely laborious, time consuming, and expensive to develop. Moreover, anti-idiotypic antibodies and recombinant proteins are neutralizing antibodies and captures both active and inactive drug. Veritopes are surrogate ligands of biologic drug, only selecting for free, active drug, and can be rapidly developed against a novel target in 4-6 weeks.

### Regulatory Strategy & Intellectual Property

2 approved (9,250,233; 8,895,242), 2 provisional (PCT/US2015/025796; PCT/US2016/014924), 2 filed (15/185,549; 62/374,217).

The original patent covering the mimotope peptide technology platform was awarded to UC San Diego in February 2016 and Abreos Biosciences has secured an exclusive license for this patent.

Regulatory: The Company confirmed with the FDA during a pre-submission discussion that a point of care dose monitoring test follows a de novo 510(k) pathway.

### Key Milestones

Partnership with large pharma to develop POC dose monitoring device for their biosimilar drug	June 2017
Partnership deals with 5 large pharma to develop custom reagents and assays for novel & marketed	June 2018
FDA submission of first POC dose monitoring system	February 2019

### Capitalization History

2013	Seed	Private individual	\$150K
2014	Grant	NIH/NCI	\$370K
2015	Grant	NIH/NCI, NIAID, NIAMS	\$889K
2016	Angel	UCSD Triton Fund + Private Individuals	\$725K
2017	Angel	TLP Investments + Private Individuals	\$1.2M

### Use of Proceeds

Abreos Biosciences is seeking an \$8 million Series A to fund the development of its complementary diagnostics. The Company will develop a pipeline of recurrent revenue with preclinical custom services for pharmaceutical companies. With pharmaceutical partners, the Company will develop and manufacture the point of care complementary diagnostics under design control, analytically validate the devices, and initiate clinical studies within the next 24 months.

### Key Team Members

#### Bradley Messmer, PhD - Founder & CEO

Dr. Messmer is a biotechnology expert with extensive experience in assay design and molecular immunology. He invented the Veritope technology while a faculty researcher at UC San Diego.

#### Michael C. Little, PhD - Chief Operating Officer

Dr. Little has over 27 years' experience in biotech and diagnostics research and commercialization. As the Global Head of Novartis' Diagnostics Development, he managed the diagnostic development of all molecular diagnostic programs.

#### Bryan Walser, MD, JD

Dr. Walser has extensive experience as a biotechnology executive, formerly serving as the CEO of the Allergan Research Corporation, CEO at Perlegen Sciences, and VP of the Chiron Corporation. He is trained in Emergency Medicine at UCLA and holds his law degree, magna cum laude, from Harvard Law School.



**Company Overview (Clinical Impact and Value Proposition)**

EpiCypher is advancing the science of epigenetic regulation to deliver new epigenetic tools to improve human health. The Company has developed the first quantitative ChIP approach, which uses post-translationally modified (PTM)-recombinant nucleosomes (aka designer nucleosomes or ‘dNucs’) as internally calibrated “spike in” standards (ICeChIP). This will enable a marked expansion of ChIP applications into new markets including drug discovery and diagnostics. EpiCypher is developing a novel protein engineering tool for accelerated dNuc manufacturing. Sortase A (SrtA) is a transpeptidase that can be engineered by directed evolution to alter its recognition sequence (LPXTG; where X = any amino acid) and seamlessly ligate ‘unnatural’ protein substrates. Once complete, EpiCypher will test the utility of this tool to accelerated dNuc manufacturing by optimizing a single-step ligation reaction to rapidly synthesize diverse dNucs for ICeChIP assay development.

**Market and Commercialization Strategy**

Until now, there has been no approach to quantitate ChIP, thereby severely limiting the applicability of the tool for reliable results. ICeChIP platform provides the first quantitative ChIP technology, which is expected to have a profound and favorable impact on ChIP-Seq market expansion. In 2016, the ChIP-seq market was approximately \$40 million with an annual growth rate of 9.4%. Major players in global epigenetics market include Abcam (UK), Active Motif (US), Diagenode (Belgium), EMD Millipore (US), Illumina (US), New England Biolabs (US), Qiagen (Netherlands), Sigma-Aldrich (US), Thermo Fisher Scientific (US), and Zymo Research (US). Segment analysis shows that, currently, the research segment dominates the ChIP-seq markets, reflecting the challenges arising from highly variable results. However, as ICeChIP is introduced into the marketplace, clinical applications will grow.

**Technical & Competitive Advantage**

Currently, there are no quantitative ChIP technologies available. Thus, ICeChIP is highly differentiated and fills a great unmet need in the epigenetic space. It is important to note that a related ChIP product was recently released by Active Motif that uses drosophila-derived chromatin for sample normalization, not quantification. EpiCypher has recently compared this technology head-to-head with ICeChIP, revealing that the Company’s approach provides superior sample normalization, as well as the ability to quantify PTM

**Regulatory Strategy & Intellectual Property**

1 filed (US 20130196867 A1) 1 Non-exclusive license (US6875594), 2 Exclusive license (US20160341743 A1; US7723069). The ICeChIP platform was initially developed by collaborator, Dr. Alexander Ruthenburg at University of Chicago. EpiCypher has recently negotiated an exclusive license from University of Chicago to transfer this technology for rapid commercialization. The Company anticipates that additional applications and improvements shall be patented, thereby extending the protection for EpiCypher.

**Key Milestones**

Complete External Testing for ICeChIP product line	Fall 2017
Develop SrtA-H3 variant for increased dNuc manufacturing	Fall 2017
Launch ICeChIP	Winter 2017
Use SrtA-H3 Engineering to rapidly expand ICeChIP product line (50 unique commercial kits)	Spring 2018

**Capitalization History**

2012	Angel	Friends and Family	\$250K
2016	Bank Loan	NCBC	\$250K
2014-15	Grant	NIH	\$675K
2016	Grant	NIH	\$2.025M
2017-Now	Grant	NIH	\$825K

**Use of Proceeds**

EpiCypher is seeking an additional \$2M in funds from outside investors. These funds will be used to expand manufacturing laboratory as well as establish an ICeChIP services laboratory at EpiCypher headquarters in Research Triangle Park, North Carolina.

**Key Team Members**

**James Bone, PhD - President and Chief Executive Officer**

Dr. Bone worked for Upstate Biotechnology (now part of EMD-Millipore) for six years, directing their efforts producing and selling products for chromatin biology and epigenetics research. After leaving Upstate, Dr. Bone founded Lake Placid Biologicals.

**Zu-Wen Sun, PhD - Vice President, Product Development**

Dr. Sun served as an Assistant Professor in the Department of Biochemistry at Vanderbilt University School of Medicine. He is widely recognized for his work on understanding how histone ubiquitination affects chromatin structure and gene expression.

**Michael Keogh, PhD - Chief Scientific Officer**

Dr. Keogh was a Principal Investigator in the Department of Cell Biology at Albert Einstein College of Medicine. His work has focused on many key oncology research areas including epigenetics and DNA repair.

## Company Overview (Clinical Impact and Value Proposition)

InnoGenomics Technologies has used proprietary methods to create an extremely accurate and sensitive multiplex qPCR assay that measures high copy number retrotransposable elements (REs) of varying sizes to assess circulating cfDNA concentration and integrity (fragmentation pattern). The assay amplifies robustly without requiring DNA extraction (direct qPCR) from as little as 2  $\mu$ L of plasma, with a validated detection capability of less than one picogram of DNA. The assay has demonstrated high predictive capacity (AUC values > 0.98) in discriminating metastatic colorectal cancer (CRC) patients from healthy controls. Statistical comparisons showed significantly increased sensitivity and specificity compared to the reported performance of CEA, the serum biomarker currently used for CRC patient monitoring. The NCI Phase I project results suggest strong potential clinical utility in (1) treatment monitoring for CRC stage IV patients, (2) recurrence surveillance for CRC stage I-III patients, (3) prognosis to help to guide cancer therapeutic management, and (4) surveillance for multiple cancers (in addition to CRC).

## Market and Commercialization Strategy

CRC is the third most common cancer in both men and women; nearly 135,000 new cases are anticipated in the United States in 2016. InnoGenomics is initially targeting CRC recurrence/treatment monitoring. Approximately 1.2 million Americans are presently living with CRC and require some form of recurrence surveillance. As a reliable, minimally invasive early recurrence monitoring tool, InnoGenomics' cfDNA test has the potential to be used over a patient's lifetime. Initially, InnoGenomics will focus on incorporating its cfDNA test into the routine five-year, post-treatment surveillance. The Company's initial annual target is approximately 450,000 patients, and the Company estimates an initial selling price of \$1,000 per test. With at least 2 tests per year per patient, a \$900MM annual market potential is estimated for this product.

## Technical & Competitive Advantage

The InnoGenomics test is expected to provide significantly more reliable and accurate cancer monitoring than current IVD blood tests. The Company's Phase I SBIR data showed the test's ability to detect CRC with very high sensitivity and specificity (AUC values > 0.98). InnoGenomics is aware of several companies attempting to develop IVD cancer blood tests but the Company believes the test will provide more reliable detection capability, greater diagnostic utility, and greater ease of use and affordability due to its simplicity, low plasma volume requirements and compatibility with already widely used analytical instrumentation. The test measures cfDNA concentration and fragmentation pattern, which are more generalized biomarkers that have been strongly linked to common tumor cell-death pathways; therefore it is likely to be more informative as a long-term monitoring tool.

## Regulatory Strategy & Intellectual Property

2 approved (USP 7537889; USP 7405044), 2 non-provisional (PCT/US 13/964,970; PCT/US 62/118,666).

InnoGenomics has several awarded and pending patents that enable successful development and commercialization of its genomic testing solutions. The Company holds trade secrets related to key aspects of its technology that provide additional barriers to entry.

## Key Milestones

NCI SBIR Phase I Contract Completed Demonstrating High Predictive Capacity (AUC values > 0.98)	March 2017
Submit Results from SBIR Phase I for Publication	September 2017
Apply for NCI SBIR Phase II Contract	October 2017
Start NCI SBIR Phase II Contract (\$2MM)	August 2018

## Capitalization History

2010	Private equity	Founders	\$383K
2011-16	Grant	NSF	\$876K
2015-17	Grant	NIH/NCI	\$299K
2012-15	R&D Tax Credits	State of Louisiana	\$516K
2016-17	Grant	National Institute of Justice	\$349K
2016-17	Sales Revenue	Revenue from sales of forensic DNA products/services	\$305K

## Use of Proceeds

InnoGenomics is seeking ~\$4 million to complete its initial commercialization plan, which covers R&D and validation necessary to finalize its product for clinical applications. Most of the R&D costs will be covered by grants and revenue from InnoGenomics' forensics business. Additional costs associated with clinical studies as well as FDA submissions and SG&A expenses will be covered by outside investment, grants, and revenue from the company's forensics business.

## Key Team Members

### Sudhir K. Sinha, PhD - CEO/PI

A successful entrepreneur with over 36 years of experience in chemical and biochemical research who previously founded a pioneering genetic testing firm that was acquired by Orchid Cellmark in 2007.

### Jonathan S. Tabak - Vice President

An outstanding track record of success in the life sciences/applied genomics industry over the last 16 years.



**Company Overview (Clinical Impact and Value Proposition)**

PreCyte is a development stage company developing Indicator Cell Assay Platform (iCAP), a broadly applicable and inexpensive blood-based assay that can be used for early detection of disease, disease stage stratification, prognosis and response to therapeutic intervention for a variety of diseases. iCAP uses cultured cells as biosensors, capitalizing on the ability of cells to respond differently to signals present in the serum (or other biofluid) from normal or diseased subjects with exquisite sensitivity—as opposed to traditional assays that rely on direct detection of molecules in blood. Deploying the iCAP involves measuring only the expression of genes that are features of the disease classifier using cost-effective tools. The iCAP can overcome barriers to blood-based diagnostics like broad dynamic range of blood components, low abundance of specific markers, and high levels of noise. PreCyte is developing the iCAP for the blood-based diagnosis of lung cancer (LC). Blood biomarkers of LC are a significant unmet medical need for use in combination with existing imaging tools to improve diagnostic accuracy. The long-term goal is to develop a blood-based assay for clinical use on patients who have indeterminate pulmonary nodules (IPN) identified by imaging to distinguish those with LC from those with benign nodules. This assay will help patients with benign nodules avoid invasive biopsy.

**Market and Commercialization Strategy**

There is a need for a cost effective non-invasive blood test to distinguish benign from malignant pulmonary nodules. Assuming a 200,000-patient market, and a \$1500 test there is a \$300M opportunity limited to potential savings of over \$3B in healthcare costs. The iCAP LC will be indicated for patients who present with an indeterminate pulmonary nodule, typically identified by chest CT (between 150,000 and 1,000,000 / yr. in the U.S.) In parallel with this effort, PreCyte is developing a iCAP-AD to test older patients who present with memory problems to identify those who are likely to advance to Alzheimer's disease. With a \$750-1,500 test, this is a \$1B opportunity. This test is in the optimization and validation phase of development.

**Technical & Competitive Advantage**

The Company's competitive advantage will be an assay that is less invasive and has lower cost (\$800-\$1,500) and higher performance than existing assays. The existing competing on-market tests are from Integrated Diagnostics and VeraCyte. The Integrate Diagnostics test has a published specificity significantly below 50% and a comparable cost. The VeraCyte test has performance comparable to the Company's current pre-optimized performance. However, as it requires a bronchoscopy to access tissue, the overall test cost exceeds \$5000. PreCyte believes that the iCAP assay, exploiting the natural capabilities of cells, will enable PreCyte to develop a higher performance and lower cost test than other technologies. The Company has an exclusive license from the Institute for Systems Biology to the underlying intellectual property.

**Regulatory Strategy & Intellectual Property**

3 patents filed (US 13/429,143; PCT/US14/057,530; US 15/252,039). A fourth patent based upon the recently completed Lung Cancer POC work discussed above is in preparation. PreCyte's claims are broad as to the methods of using broad classes of cells as transducers to convert signals of disease in patient samples to detectable changes in cell response, including for example gene expression.

**Key Milestones**

Complete Lung Cancer Assay POC	March 2017
Validate Alzheimer's Disease Test	September 2017
Optimize Lung Cancer Assay	June 2018
Validate Lung Cancer Assay	December 2018

**Capitalization History**

2015	Grant	NIH/NIA (Phase II SBIR for Alzheimer's Disease)	\$2M
2016	Grant	NIH/NCI (Phase I SBIR for lung cancer)	\$300K

**Use of Proceeds**

PreCyte projects diagnostic service revenues of 200k, \$1M, and \$5M in 2018, 2019, and 2020, respectively. We are looking to raise \$3M at this time to complement the non-dilutive research funds to support patent prosecution, business development early market, regulatory, and reimbursement analysis and rehost the assay in a CLIA environment.

**Key Team Members**

**Robert Lipshutz, PhD - CEO/Founder**

Dr. Lipshutz has 23 years of experience in molecular diagnostics, life science business development, and bioinformatics at Affymetrix and ISB. Initiated Affymetrix Dx business and grew it to \$30M per year.

**Jennifer Smith, PhD - CSO/Founder/Inventor**

Dr. Smith has 22 years of experience in systems, cell and molecular biology at ISB, Center for Infectious Disease Research (CIDR), and University of Alberta. Together with John Aitchison, she conceived the iCAP and led the initial development of the assay for detecting presymptomatic ALS in a mouse model, and for detecting early-stage AD from human plasma.



## Company Overview (Clinical Impact and Value Proposition)

Antaya Science & Technology (AS&T) was founded by Dr Timothy Antaya, a world-renowned accelerator physicist. Its core competencies include superconducting cyclotron design, superconducting magnet design, cyclotron radio-frequency (RF) design & analysis, and product commercialization through licensing, joint ventures, and co-development. The aim is to design a state of the art compact cancer treatment system that will be more effective, non-invasive as well as cost equivalent to the current x-ray therapy systems (IMRT) and replace them with proton therapy systems. The Technically Advance Affordable Cyclotron (TAAC) will be the most compact PT cyclotron ever developed to reduce the cost and foot print of current cyclotrons used to generate proton beams. TAAC paired with PT Pedestal (PTP) due to the decrease in size and cost, will enable one and two room PT centers anywhere.

## Market and Commercialization Strategy

There are just over 3000 x-ray based radiation therapy centers in the U.S., and another 6800 centers worldwide. It is AS&T's aim to replace these centers with proton radiation based ones. Proton therapy is growing at a rapid pace and worldwide there are 57 proton therapy rooms centers. In 4 years that number will increase to 187. IBA and Mevion are leading the market in growth of these centers with Varian Medical systems behind them. At the price point of the system AS&T is designing, the market for the PTP could realistically replace up to 30% of the current radiation therapy centers equipment worldwide.

## Technical & Competitive Advantage

Current proton therapy systems require a minimum investment of \$20M per room. The major competitive advantage of AS&T's system is that will complete the first proton therapy system to cut cost by at least 50% of systems being installed by IBA and Mevion. The smaller size and cost will allow existing IMRT x-ray treatment rooms to be retrofitted into proton therapy treatment rooms. The first equipment provider will have economic advantage, and AS&T is the only group that has solved this problem technically and commercially. Dr. Antaya has been a contributor in the most successful compact systems in market. He has the inside knowledge and relationships to bring this next generation system to market.

## Regulatory Strategy & Intellectual Property

1 patent filed (US 2016/0353562 A1).

AS&T is primarily a small, flat, advanced science based Design and IP development company that licenses IP. It has developed and de-risked to co-development partners that have an urgent commercial strategic need- either more bang for the buck in an existing market, or the creation of new markets. Dr. Antaya has more than 25 awarded patents in the US and other countries.

## Key Milestones

TAAC Cyclotron New Technology fully vetted	December 2017
HII Regulatory Approval	2017
PTP Engineering Design Complete	2017
PTP Technology Demonstration Complete	2018

## Capitalization History

2013	Grant	NIH/NCI	\$228K
2015	Grant	NIH/NCI	\$1.65M
2013-17	Contract	Varian Medical Systems (plus licensing fees)	\$7M+
2017-18	Contract	Phase 1&2 KACST Contracts	\$3.5M
2018	Other	Commitment from Clatterbridge Cancer Trust & University of Manchester	\$500K

## Use of Proceeds

AS&T is currently seeking \$7.5M to design and build the prototype of the PTP over a 24-month project period. Approximately \$4M would be used to fund the equipment and materials needed for the prototype, \$2M for direct personal, \$800K for F&A (overhead), and \$700K set as maximum contingency. The company is open to a co-development agreement or a joint venture to include a spin off to the two-room proton therapy center concept.

## Key Team Members

### Timothy Antaya, PhD - Chief Physics Officer

Dr. Timothy Antaya is a world-renowned accelerator physicist, many of whose innovations are already used in radiation therapy and soon non-invasive cardiac imaging. 4 successful commercial companies are based on his intellectual property. Dr. Antaya was a Principal Investigator at the Plasma Science and Fusion Center at the Massachusetts Institute of Technology.

### Timothy Lefebvre - Technical Project Manager

Mr. Lefebvre received his BA in Biology and Chemistry from Plymouth State University and specializes in effective business plans in the life sciences markets. He has opened, staffed and managed multiple field offices in Europe, North America and Asia.

### Paul Ruggiero, MS - Lead Mechanical Engineer

Mr. Ruggiero received his M.S. in Mechanical Engineering and Applied Mechanics from the University of Rhode Island in 2006. Prior to joining Antaya Science and Technology, Paul worked as a mechanical engineer for Sensata Technologies and Raytheon.



## Company Overview (Clinical Impact and Value Proposition)

RadiaBeam Technologies and UCLA have created a new spinoff company, Celestial Medical, to develop a novel radiotherapy technology called  $4\pi$  radiotherapy. The principle behind this technology is that when radiation can be delivered from almost any angle and position, the dose distribution can be built up more precisely, with steep fall-off to better avoid healthy tissue (which normally limits the dose that can be delivered to the tumor). To reach all angles around the patient, a robotic delivery device is being designed, which will hold an extremely compact X-ray source. The more compact dose distribution spares normal tissue from excessive radiation doses, while precisely delivering greater doses to the tumor, resulting in comprehensive double-digit percentile improvements in organ-at-risk (OAR) dose and dose compactness. The patient simply lies on the couch and remains stationary during treatment.

## Market and Commercialization Strategy

In 2014, the total EBRT (External Beam Radiation Therapy) market was estimated at \$4.8 billion. The linac based EBRT segment accounted for the largest share of the global radiation therapy market at ~\$3.24 billion. The U.S. market is relatively mature and represents a significant portion of installed capacity worldwide. The market will be largely driven by replacements of older systems with newer, cutting edge ones. It is estimated that 38% of all units, or ~1,113 units, are planned to be replaced from 2015 to 2025. Celestial's first target market is leading university cancer centers in the U.S EBRT segment. Given the timing and need for a large number of replacement EBRT systems in the U.S, the U.S market presents a unique opportunity to offer Celestial as a newly developed, highly automated EBRT systems. Celestial will be marketed to provide a broad range of treatment plans, most importantly introducing a dedicated system for full  $4\pi$  radiotherapy.

## Technical & Competitive Advantage

Current radiation therapy platforms are complex, expensive, and too inflexible to deliver highly compact dose distribution. The Company was able to design a compact linac that can be mounted on a commercial robot to access all the needed beam angles without moving the couch and the patient. To fully exploit the advantages of  $4\pi$  radiotherapy, Celestial will make the linac, mount it on a robot, complete physics testing and develop a planning system for the machine.

## Regulatory Strategy & Intellectual Property

3 provisional (62/245,840; 62/128,906; TBD).

The original concept of  $4\pi$  radiotherapy has been published in a series of scientific publications starting in 2012. Thus, the central idea of optimizing a treatment with a large number of noncoplanar angles is in the public domain. In late 2016, RadiaBeam hired the IP Capital Group to perform an IP scan. A list of 95 inventions was generated, many of them covering the RF design, mechanical engineering, and manufacturing processes of the linac head and key components. Most of this IP will be protected as trade secrets, however the Company has identified a few key inventions in this area for which patent protection.

## Key Milestones

Treatment robot prototype installed and functional at UCLA with linac delivering 800 MU/min	November 2017
Prototype planning system with novel functionality available for select outside users	December 2017
System integration of planning and hardware delivering full 4 Pi trajectory treatment	June 2018
Product fully specified, market roll-out plan and regulatory readiness	February 2019

## Capitalization History

2017	Grant	NIH/NCI	\$2M
2017	Seed	Raising seed round	\$1M

## Use of Proceeds

Celestial is currently raising \$1 million in seed funding to further the business development and pay for IP protection. A \$5 million Series A round is planned to be closed by early 2018 to take us through to FDA clearance.

## Key Team Members

### Michelle Svatos, PhD - CEO

Over the 20 years of her career in Radiation Oncology, Dr. Svatos has worked in a National Lab (LLNL), a University Hospital (UCSF), 2 large multinational companies (Siemens, Varian), and has been deeply involved in 2 start-ups.

### Salime Boucher, BS, - COO

Mr. Boucher has been the CEO of RadiaBeam since founding it in 2004, and under his guidance RadiaBeam has grown to \$11 million in revenue and has 50 employees, including 10 PhD scientists, 20 engineers, 10 machinists and 6 technicians. RadiaBeam has dedicated incubation space and resources for Celestial, giving it direct access to the full RadiaBeam Technologies team.

### Ke Sheng, PhD - CTO

Dr. Sheng has been an extremely prolific inventor for the past 16 years, including originating the 4 pi concept. His dozens of publications include planning and clinical studies of administering radiation from many noncoplanar angles.



## Company Overview (Clinical Impact and Value Proposition)

CivaTech Oncology has two commercially available radiation devices to provide therapeutic doses to cancerous tissues in a localized, targeted delivery method. Both products use a patented platform technology that was developed, engineered, and now manufactured by CivaTech Oncology, which is an ISO 13485 certified facility. CivaString® and CivaSheet® are bio-compatible and bio-absorbable, and are designed to be easily implemented in the work flow of the current cancer care pathways. CivaTech’s products have unique reimbursement (payment) codes issued by Medicare/Medicaid. The products are being used in 13 clinics nationwide including two of the exempt cancer specialty hospitals and 75% of clinics have re-ordered product within 6 months or less from the initial order.

## Market and Commercialization Strategy

CivaSheet provides an opportunity to deliver radiation therapy in patient populations where (1) external beam radiation is difficult to use and/or (2) patients have already met the external beam radiation limit. CivaSheet adds revenue stream for hospitals to give the patients an option to receive a clinically beneficial radiation therapy. CivaSheet has a market potential of treating 250,000 cases of cancer in the U.S., and will also be used immediately to treat ~50,000 cases of cancer recurrence. The total U.S. market is estimated to be over \$2Bn. The company is focused on expanding the use of products in many clinical applications. The company intends to sell additional equipment to support the expanded use. Primary indications for use of CivaSheet include colorectal and pelvic, head and neck, brain, and pancreatic cancers. CivaSheet is priced to be competitive with external beam therapy costs.

## Technical & Competitive Advantage

CivaSheet is the only unidirectional, permanently implantable radiation device cleared for sale in the US. The shielded radiation source allows for delivery of radiation therapy targeted tissue in a localized and directed approach. The device minimizes radiation damage to neighboring tissues. In the current radiation therapy paradigm, the radiation dose to healthy tissues limits the total amount of radiation to the cancerous tissue. CivaSheet delivers very high doses of radiation locally to the cancerous tissue and almost no dose to surrounding tissues, sparing side effects. CivaSheet could be used to provide a very high dose of radiation locally to early stage disease. CivaSheet would be placed in a single ~30 minute procedure during the patient's initial surgical resection, and the patient would not have to return for 6+ weeks of external beam radiation.

## Regulatory Strategy & Intellectual Property

5 patents issued (7,686,756; 8,323,172; 9,180,310; 9,358,377), 1 pending (13/594,214).

CivaTech has developed and fully owns all patents and trademarks. CivaTech has protected the methods of polymer encapsulation and proprietary manufacturing techniques, as well as directionality of the radiation distribution and the method for encapsulating the radiation in polymers to form sealed sources.

## Key Milestones

Scale up manufacturing to meet growth projections currently underway	2017-2018
Two FDA cleared products and reimbursement codes	2017-2018
Expanding sales of CivaSheet through technical publications beginning with ABS	2017-2019
Excellent Outcome data for pancreatic and other cancers	2018-2020

## Capitalization History

2007-12	Series A-D	Private (R&D Phase)	\$6M
2013-14	Series C	Private (Commercializing 1 <sup>st</sup> Product)	\$1M
2014-15	Series D	Private (Commercializing 2 <sup>nd</sup> Product)	\$2.3M
2015-17	Convertible Notes, Series E	Private (Scale/Commercial)	\$4M

## Use of Proceeds

CivaTech is seeking \$10-15M in equity to provide working capital for purchase orders, fund post market clinical studies, and resources to expand sales and corporate infrastructure and is seeking this funding as soon as possible. Revenues for 2014-2016 were in the range of \$500K per year. Sales are projected to be \$1.2M-\$2.5M or higher in 2017.

## Key Team Members

### Suzanne Babcock - CEO

Mrs. Babcock is a Founder and Executive Chairman who has diverse business development and technical capabilities to foster creative talent to develop novel radiation devices, build infrastructure, and guide the company to commercialization.

### Kristy Perez, PhD - Vice President, Clinical Programs

Dr. Perez has a PhD in Medical Physics. She has lead the team in translating the products from R&D to the clinic, including managing product testing and development, writing applications for regulatory clearances, and educating clinics.

### Randy Harrison, MA - National Sales Manager

Mr. Harrison has 30 years of experience in sales of medical products including Mammosite and Hologics brachytherapy products. Previously he held sales roles for Johnson and Johnson Ethicon and Rita Medical.





**Company Overview (Clinical Impact and Value Proposition)**

Curadel Surgical Innovations (CSI) develops advanced surgical imaging solutions to enable surgeons to see that which is invisible to the eye in natural light. Curadel’s technology, imaging system and dye, is called FLARE®: (FLuorescence-Assisted Resection and Exploration for surgery). It exploits near-infrared light to see millimeters deep into tissue and well beyond that possible in natural light. By injecting a contrast agent into the bloodstream, a surgeon can use FLARE® imaging systems to pinpoint the exact location of the target, such as malignant tumors, and/or the exact location of targets that need to be avoided, such as blood vessels, nerves, and ureters. CSI currently sells FLARE® devices to the non-FDA regulated research market. These devices will soon obtain regulatory clearance by CSI, 510(K) and CE-mark in Europe for clinical use. CSI’s flagship dye is ZW800-1®, an entirely new class of "zwitterionic" NIR fluorophore that demonstrates ultralow non-specific uptake, 100% renal clearance, and bright fluorescence. ZW800-1 is on target to become the first contrast agent approved for ureter mapping, a procedure that enables surgeons to avoid damage to the ureters during abdominopelvic surgery. ZW800-1 is entering Phase 2 clinical study, and its derivative, ZW700-1 Forte®, is the subject of an ongoing SBIR project to work out kg scale cGMP manufacturing to support Phase 2 and 3 trials, as well as market approval.

**Market and Commercialization Strategy**

Proprietary dyes, such as ZW800-1, retail for \$300-1500 per dose. Using the conservative estimate of \$300 per dose, and assuming 15% of the 4 million surgeries performed each year around the world are abdominopelvic, a 5% market penetration would result in \$9M in revenue and a 25% penetration \$45M in revenue. As market share grows, and drug lot production runs increase, costs drop approximately 20%. The remaining cost of bringing ZW800-1 to market from this point forward is estimated to be \$4-8M, so profitability should begin in year 2 even with only a 5% market penetration. CSI will use channel partners for sales, those market leaders seeking to maintain competitive advantage by advancing the quality of care of their customers and with sales reps already in the field.

**Technical & Competitive Advantage**

There are four things that set CSI apart from all of its competitors: (1) Simultaneous acquisition and display of color video and two independent channels of NIR fluorescence; (2) Optical resolution, sensitivity, and accuracy; (3) Drug development expertise; and (4) Continual quality improvement. The Company believes it has a sustainable 5-year advantage over any other systems manufacturer, and an indefinite lead over any other dye manufacturer insofar CSI does not see anyone currently with more than 3-5 applications versus CSI’s 35 (and counting) large animal tested/large market/ high clinical impact portfolio of agents.

**Regulatory Strategy & Intellectual Property**

Multiple patents approved and filed.

CSI and its parent company Curadel has invested over \$350,000 to date on IP protection of its proprietary devices and drugs. CSI has also secured worldwide trademark of the names ZW800-1®, ZW-700-1®, FLARE®, and the phrase "Seeing is Curing®". CSI has 315 unique compositions of matter for which IP protection has been filed, and the Company is now securing individual claims on particular high value chemical structures.

**Key Milestones**

150 g cGMP synthesis of ZW800-1 to support full two-species toxicology	2014
Full toxicology package for ZW800-1 (two-species including dog telemetry)	2015
Phase 1 clinical trial for ZW800-1	2017

**Capitalization History**

2014-18	Grant	NIH/NCI (R01 & SBIR)	\$10M+
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**Use of Proceeds**

CSI is seeking a strategic investor to assist us in completing market approval activities in exchange for distribution rights for the drug. Revenue from sales of research-grade devices and drugs was \$0.5M in 2016 and is on track for \$1.5M in 2017.

**Key Team Members**

**John V. Frangioni, MD, PhD - CEO/Co-Founder**

Dr. Frangioni has been board-certified in both Internal Medicine and Medical Oncology and for the last 17 years has been an independent Principal Investigator funded by the NIH, DOE, and multiple non-profits. He is an experienced manager, overseeing 10-20 FTEs over the last 17 years.

**Stephen A. Cervieri, MBA - Business Development/Co-Founder**

Mr. Cervieri is a graduate of Harvard Business School with over 20 years of experience as an investment banker in the healthcare sector, having work previously for companies such as Goldman Sachs, and Montgomery Securities (currently Bank of America).

**Company Overview (Clinical Impact and Value Proposition)**

LX Medical is a Massachusetts corporation commercializing a suite of endobronchial imaging probes and image-guided transbronchial biopsy tools for interventional pulmonologists and thoracic surgeons. The primary focus for the company is addressing unmet needs in lung cancer screening, diagnosis, and treatment. LX Medical's image-guided bronchoscopic biopsy tools address the need for safe and accurate diagnosis of lung nodules, by providing high-accuracy biopsies of sub-centimeter nodules with safe bronchoscopic procedures that minimize risks of complications, enabling timely identification and then treatment of early stage lung cancer without unnecessary surgeries in patients with benign disease.

**Market and Commercialization Strategy**

LX Medical's precision guided interventions address a worldwide market opportunity exceeding \$800M. Its addressable global market opportunity for lung nodules exceeds \$300M, annually. The same imaging probes can also guide decision making and therapy for a range of additional lung treatments including monitoring lung transplant rejection and guiding bronchial thermoplasty in patients with severe asthma. These additional treatments address a worldwide annual market opportunity exceeding \$500M. LX Medical has validated the need and various market opportunities through over 100 interviews with clinicians and industry representatives as part of its participation in the I-Corps at NIH program. The Company is developing engineered systems and pursuing FDA Clearance, supported by investment funds and pilot sales. Building on its track record for obtaining grants, LX Medical plans to leverage NIH funding to support clinical validation of the technology, to highlight the efficacy and superiority of its technology. This will position the Company for strong sales, and potentially leading to an acquisition.

**Technical & Competitive Advantage**

LX Medical's products are based on intelligent biopsy technology and multi-modality OCT developed at MGH and BCCA. This cutting-edge technology provides superior tissue characterization, with an almost 100 times higher level of structural detail than possible with the current standard-of-care imaging used for guidance of bronchoscopic biopsies such as CT or ultrasound. This technology can be miniaturized into small probes that integrate with biopsy tools for real-time guidance of tissue collection. The real-time OCT guidance integrated in LX Medical's products provides inherent, physics based, advantages over competing approaches for high-precision guidance. It enables the high-accuracy biopsy of small lesions, not achievable with biopsy guided by the today's leading tools such as endobronchial ultrasound, fluoroscopy, electro-magnetic and virtual navigation.

**Regulatory Strategy & Intellectual Property**

2 approved (US 9,364,167; US 9,439,570 B2), 4 filed (PCT/US14/0273804; US 15/237,517; PCT/US13/78156; PCT/CA15/050085). LX Medical has secured access to enabling technologies from two the best academic centers in the field of pulmonary OCT imaging, MGH and BCCA. The Company is methodically building protective barriers around the product family with strong IP portfolio. This portfolio includes two issued and three pending LX Medical patents, as well as exclusive licenses from MGH and BCCA for two enabling patents.

**Key Milestones**

Completion of animal studies for Phase I SBIR Grant	January 2018
510(K) clearance of LX Medical imaging probe system	January 2019
Deployment of pilot systems in clinical sites	January 2019

**Capitalization History**

2013	Seed Round	Friends and family	\$700K
2015	Grant	Massachusetts Life Science Center	\$70K
2016	Grant	NIH/NCI (SBIR Phase I and I-Corps at NIH)	\$325K
2017	Grant	NIH/NHLBI (SBIR Phase I/Phase II Fast Track)	\$1.5M

**Use of Proceeds**

LX Medical is seeking to raise funds to supplement NIH funding for high-impact clinical trials and pilot sites, as well as funding to support ongoing operations of the company, including Intellectual Property and regulatory activities.

**Key Team Members**

**Raanan Miller, PhD, MBA - Chairman/Interim CEO.**

Dr. Miller brings expertise in business development as an innovative leader with expertise in commercialization of cutting edge technologies for life science and medical devices. He has previously co-founded Sionex Corporation and Amsel Medical Corporation.

**Andrei Vertikov, PhD - Chief Technology Officer.**

Dr. Vertikov has over 15 years of experience leading development teams in the medical device field and in semiconductor metrology and inspection, with successful products on the market.

**Scott Grant, BSc Health Management Services - Chief Commercial Officer.**

Mr. Grant has a broad experience in market development and sales of novel clinical products. He served previously as VP of Sales and Marketing in several medical device companies in the field of interventional pulmonology.



## Company Overview (Clinical Impact and Value Proposition)

RadioMedix, Inc. is a clinical stage biotechnology company with a primary focus on the commercializing of radiolabeled therapeutic agents and the generator-produced radiolabeled diagnostic agent. 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. Our company is an US-exclusive distributor of radiopharmaceutical products of ITG GmbH (Germany) and Trasis SA (Belgium). Research contracts and clinical activities provide revenue that support commercialization of radiotherapeutic agents, GlucoMedix™ (Pb<sup>212</sup>-RMX-GC) targeting glucose-avid aggressive cancers and AlphaMedix™, targeting neuroendocrine tumors. We have established strategic partnership with ArevaMed, a company specializing in the GMP production of Pb<sup>212</sup>.

## Market and Commercialization Strategy

There is a strong interest in commercialization of radiotherapeutic agents. It is expected that radiotherapeutic market will grow 26%, annually to 2030. The promise of use of extremely energetic alpha particles causing double strand DNA damage and therefore aiming for “cure” or increasing the progression free survival of patients is extremely enticing. There is no available radiotherapeutics agent that targets glycolytic pathway and glucose-transporter (GLUT) in cancer cells. GlucoMedix will target the same market segment as diagnostic F<sup>18</sup>-FDG, providing therapeutic treatment option for patients with aggressive glucose-avid cancers. Our agent will specially be effective in areas in oncology that have significant unmet needs, such as therapy of all highly aggressive glycolytic and GLUT-over-expressing cancers.

## Technical & Competitive Advantage

Majority of aggressive cancers in humans use glucose as their main source of energy (Warburg effect). The F<sup>18</sup>-FDG is the only FDA approved tracer that recognizes overexpression of glycolytic pathway in cancer cells and it is now the most commonly used PET agent in diagnosis, staging and monitoring response to therapy. GlucoMedix will be the first agent that can advance targeted alpha-emitter therapy (TAT) and deliver therapeutic radiation dose precisely to highly proliferative aggressive cancer cells. It can circumvent beta-radiation resistance or multi-drugs resistance of cancer cells. The commercial potential of TAT therapies is tremendous and it has been confirmed by recent introduction of Xofigo for therapy of bone metastasis in prostate cancer.

## Regulatory Strategy & Intellectual Property

2 patents granted (US200858476; PCT/US12/43255), 1 provisional patent application (PCT/US2014/042535), 1 non-provisional patent application (US62/445,541).

We have established strong network of partners with expertise with kit scaled-up production, and clinical data evaluation that will support production and clinical studies of GlucoMedix. RadioMedix has already served as co-sponsor and collaborator on the clinical studies of Lu<sup>177</sup>-labeled and Pb<sup>212</sup>-labeled radiotherapeutics used for therapy of cancer patients (neuroendocrine and prostate cancers).

## Key Milestones

eIND clinical study to determine safety, biodistribution of radiolabeled GlucoMedix™	November 2017
Pre-IND meeting with FDA to seek agency feedback on the regulatory pathway of Pb <sup>212</sup> -TAT	March 2018
eIND clinical study of Pb <sup>203</sup> -GlucoMedix™ to determine pharmacokinetic, dosimetry	June 2018

## Capitalization History

2010	Grant	Texas Emerging Technology Fund	\$2.4M
2014	Grant	NIH/NCI	\$160K
2015	Contract	NIH/NCI	\$74K
2016	Contract	NIH/NCI	\$299K

## Use of Proceeds

RadioMedix successfully secured funds from multiple agencies to support validation studies of GlucoMedix. We are seeking \$3M to complete clinical studies of Pb<sup>212</sup>-labeled radiotherapeutic and submission of NDA in next 3 years.

## Key Team Members

### Ebrahim S. Delpassand, MD - CEO and Chairman

Dr. Delpassand is Board Certified in Nuclear Medicine and Fellow of the ACNM. He founded 4 healthcare startups prior to RadioMedix. He has authored more than 50 peer reviewed manuscripts in nuclear medicine.

### Azar Delpassand, RN, BS - President

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

### Izabela Tworowska, PhD - CSO

Dr. Tworowska has a strategic role in development of radiotherapeutic Pb<sup>212</sup>-labeled agents including GlucoMedix™, and AlphaMedix™ and oversees all activities related to their pre-/clinical development and commercialization. She served as Principal Investigator of SBIR NCI/NIH grants, SBIR NIH/NCI Contracts and authored more than 30 peer reviewed manuscripts in chemistry.

## Company Overview (Clinical Impact and Value Proposition)

HuMurine Technologies was founded by Gerold Feuer, whose unique scientific expertise and 24 years' experience in academic research created an industry leader and innovator in "Humanized" immune system mice and implementing these mice into preclinical studies to more accurately predict human clinical trial outcomes. HuMurine's preclinical platforms are less expensive and more accurate in predicting clinical outcomes in comparison to existing animal models. HuMurine has recently signed contracts with large biopharmaceutical clients (including Pfizer, J&J and Abbvie) that utilize HuMurine's CRO services. HuMurine's technology enables the biopharmaceutical industry to rapidly transition new therapies from preclinical to clinical stage. HuMurine's "Human-Immune-System" (Hu-M™ and Hu-3GM™) mice are superior and outperform competitors' humanized mice (i.e., Jackson Labs, Crown Bio, Taconic) by using proprietary stem cell isolation and detection matrixes, rigorous scientific standards, and decades of combined experienced scientific team. Screening for efficacy and adverse effects of new immune checkpoint inhibitors in Hu-M and Hu-3GM mice will uniquely position this novel animal model in preclinical testing.

## Market and Commercialization Strategy

The global humanized mice model (including services) is estimated is expected to reach \$107.9 million by 2020. Personalized medicine includes tailored medicines to target individualized treatment and care based on personal genetic variations. The development of personalized medicine involves the use of animal models, particularly mice models. The growing demand for personalized medicine will spur the demand for humanized mice models. Validation of the Hu-3GM™ mouse for preclinical screening of efficacy and adverse effects of these biologics will create a huge demand for screening immunotherapeutics in this humanized mouse platform. HuMurine expects to capture a large share of this expanding market due to the Company's reputation for extremely high quality humanized mice and industry-leading flow cytometric analyses.

## Technical & Competitive Advantage

HuMurine has substantial name recognition as the leader in providing the best humanized mouse and high quality contracting services in the world. Decades of experience are the foundation of HuMurine's specialty process for the generating a scientifically challenging platform, which has no other competing model. HuMurine has extensive expertise, proprietary procedures on isolation of human CD34+ stem and essential 'know-how' in successfully implementing this challenging model into the commercial space. HuMurine's main differentiator is that the Company purifies CD34+ HPCs from human tissue, and these cells are QC-screened for pluripotency prior to injection. Better stem cells, better humanized mice, and superior flow cytometric analyses are HuMurine's competitive advantages.

## Regulatory Strategy & Intellectual Property

Although humanization of immune deficient mice is not "patentable", trademarks for Humurine's humanized NOG mouse (Hu-M) and humanized IL3/GM-CSF-NOG mouse (Hu-3GM) have been filed to differentiate and identify HuMurine's superior products and services. The HuMurine team has extensive "know-how" and proprietary processes that cover the individual stages.

## Key Milestones

Verify if Ipilimumab treated HLA-A2 matched PDX- Hu-3GM™ mice generates tumor specific T cell response	Winter 2017
Determine anti-tumor efficacy of combinatorial blockade of CTLA4 and PD1 on PDX-Hu-3GM™ mice	January 2018
AML 'Avatar' models by engrafting AML patient PBL into IL3/GM-CSF NOG mice for therapy studies	June 2017

## Capitalization History

2010-Now	Loan	Family (Cumulative Debt)	\$956,000
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## Use of Proceeds

HuMurine recorded total revenue of \$614,134 in 2016, \$288,822 in 2015, and \$187,504 in 2014. The company is seeking up to \$20M to Fund Expansion Opportunities; General Corporate and Working Capital Purposes.

## Key Team Members

### Gerold Feuer, PhD - Founder, Chief Scientific Officer

Dr. Feuer was formerly an associate professor at SUNY Upstate Medical Center and was the founder and director of "Center for Humanized SCID Mouse Models and Stem Cell Lab" (1996-2015). He specializes in lentiviral gene therapy vectors, human stem cells, humanized mouse models and human virology.

### Jenny Rowe, PhD - Director of Laboratory Operations

Dr. Rowe specializes in humanized mouse models and has 12 years of academia and industry experience in operational management and leadership roles for preclinical studies.

### Chris Bradley - CEO

Chris Bradley earned his Bachelor of Arts degree in Economics at the University of California at Berkeley and completed his MBA at Duke University. Bradley was previously CIO at Entertainment Partners, overseeing Software Development, IT infrastructure and Customer Support.



**Company Overview (Clinical Impact and Value Proposition)**

SynVivo is a biologically realistic platform that enables real-time study of cell and drug interactions, offering a true breakthrough in drug development. SynVivo recreates the complex in vivo microvasculature including scale, morphology, fluidics and cellular interactions in an in vitro format for basic and applied life sciences research. Starting with medical images, SynVivo creates a replica of the microvascular environment onto a microchip, where animal or human cells can be cultured and studied under physiological conditions. The permeability between vascular and tissue regions is precisely engineered to mimic organ-specific architecture. The technology has been validated for applications in oncology, neuroscience, inflammation and toxicology. SynVivo is expected to contribute to two major research thrusts in drug development and delivery: (1) “targeted therapeutics” where SynVivo is used for screening the dynamics of innovative nanoparticle and macromolecular delivery approaches; and (2) “personalized medicine” where SynVivo can be used to culture a patient's own cells for directly relevant drug efficacy studies.

**Market and Commercialization Strategy**

The SynVivo technology addresses two distinct markets: investment intensive drug development market (\$2B for secondary screening in the US alone) and cancer treatment market (\$100B spent on chemotherapy in the US alone). SynVivo has commercially launched its drug development/research tools and the company has enjoyed early traction (\$1M in booking and more than 40 customers in 2016). The company is now raising funds to create a formal sales and marketing organization to capitalize on its early success as a key drug development and research tool. The company will focus on substantiating the clinical application of its platform technology for determining the best treatment for cancer patients.

**Technical & Competitive Advantage**

The SynVivo-Tumor model is the only model that reproduces three main elements seen by any cancer therapeutic: (1) ability of the drug to be transported via bloodstream to the 3D tumor site aided by flow; (2) ability of the drug to cross vasculature walls to reach the tumor in tissue; (3) ability of the drug to traverse the interstitial space to deliver drugs effectively to all the tumor cells aided by diffusive flow. Other advantages of the SynVivo platform include: a) physiologically and morphologically realistic environment, b) quantitative real-time monitoring and evaluation of cell-drug interactions, c) significantly reduced consumable use, and d) compatibility with standard analytical instrumentation.

**Regulatory Strategy & Intellectual Property**

2 approved patent on tumor modeling (8,355,876; 9,453,252 B2), 12 other patents. SynVivo uniquely captures the dynamics and realism of the in vivo environment. SynVivo is the trademark registered in 2013. Most patents were filed with the original name: Synthetic Microvasculature Network (SMN).

**Key Milestones**

Strategic partnerships with multiple (4-5) major biopharma	2017
Clinical pilot study complete	2018

**Capitalization History**

2016	Angel	Individuals	\$550K
2012-2015	Grant	NIH/NCI - Tumor Drug Delivery	\$1.3M
2016-2018	Contract	NIH/NCI - Tumor Microenvironment Validation	\$1.5M

**Use of Proceeds**

SynVivo is seeking \$1.5M capital investment by 2017. The funds will be used to: (1) ramp up marketing and sales activities for the drug development tools application (2017 target: \$1M in revenue, \$2M in bookings), (2) carry out a pilot clinical study (~30 patients, single comprehensive cancer center) for personalized drug therapy application, and (3) pursue additional assays and IP. Overall, SynVivo is planning to raise \$9M to execute the business strategy including (1) Drug development tools revenue ramp-up to \$20-25M (in Year 5 post full funding), (2) Personalized drug therapy application: Full clinical study, regulatory/reimbursement strategy, customer development, and partnerships. Current projections show revenue ramp-up to >\$100M (in Year 5).

**Key Team Members**

**Kapil Pant, PhD - President & CEO**

Dr. Pant has 20+ years of experience in life sciences industry. He has led large cross-functional teams focused on technology development and commercialization, customer development, partnerships, strategic planning and corporate development.

**B. Prabhakar Pandian, PhD - CTO**

Dr. Pandian has 20+ years of experience in the life science arena with experience in concept development for commercial products in the field of biological systems, biomedical devices and systems biology.

**Gwen Fewell, PhD - Chief Commercial Officer**

Dr. Fewell has 15+ years of experience in biotechnology and life science research tools market and domain expert in gene-based technologies. She has led commercial strategy and implementation at both start-up and large life science research tools companies.

# INQUIRIES