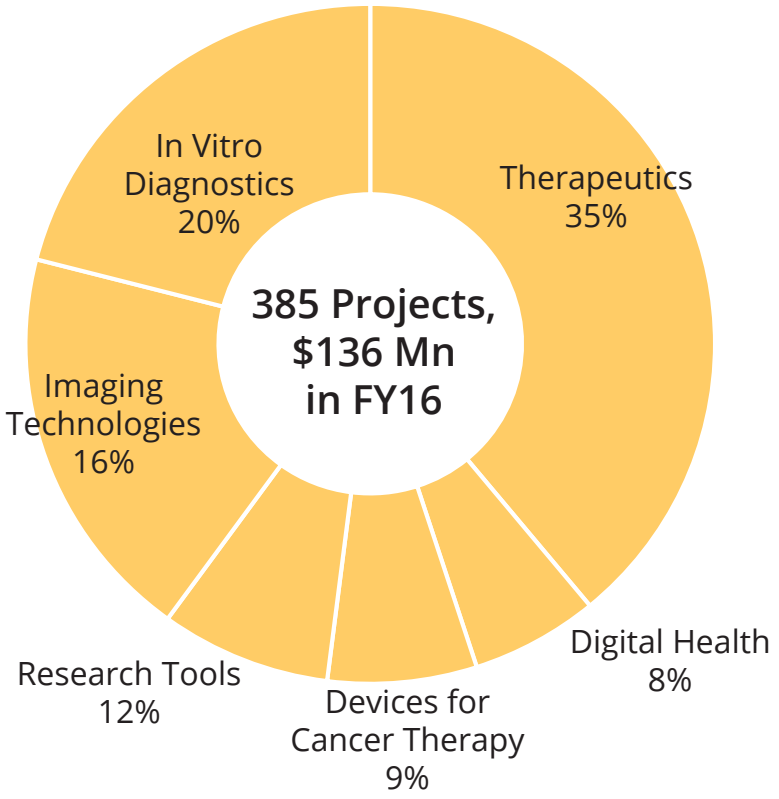
Company Profiles for 2016 Investor Initiative

NATIONAL CANCER INSTITUTE
SBIR
DEVELOPMENT
CENTER

OVERVIEW

The National Cancer Institute Small Business Innovation Research (NCI SBIR) Development Center is one of the nation's largest sources of financing for cancer-related technology innovation. Along with a range of funding opportunities designed to help small businesses in cancer research, NCI SBIR also provides resources for awardee companies to help drive their commercialization efforts in the right direction. The 2016 Investor Initiative is one of such resources. This year, more than 100 NCI SBIR/STTR awardee companies have applied to participate in the investor initative. The applications were vetted through a rigorous investor-based revew process in which more than 50 life science investors and pharmaceutical/strategic business development experts assessed the investment-readiness of applicant companies. We are happy to present the 35 selected SBIR-funded companies this year, and we hope to present many more SBIR-funded innovative cancer technology developers in the future.

MAJOR PORTOLIO AREAS FY 2016



Each year, NCI SBIR funds innovators in the field of cancer, with technolovies ranging from therapeutics to IT-based digital health solutions. The chart on the left shows major portfolio areas of all companies that received funding from NCI SBIR Development Center in FY2016. In FY16, we have provided a total of $136 million in SBIR and STTR funding for 385 projects.

CONNECT WITH US

ONLINE

https://sbir.cancer.gov
http://twitter.com/NCIsbir
http://bit.ly/Link_NCISBIR
ncisbir@mail.nih.gov

ON-SITE

9609 Medical Center Drive, 1W 550
Rockville, MD 20850
(240) 276-5300

TABLE OF CONTENT

AADi

Location:
Pacific Palisades, CA

Technology:
mTor Inhibitor

Stage:
Phase II clinical trial

AADi was founded in 2011 by Neil Desai, who played a major role in the invention/early development of Abraxane, to develop a `best-in-class' mTOR inhibitor. Their lead, ABI-009, is a clinical phase, targeted nanoparticle albumin-bound sirolimus (rapamycin), a highly active form of sirolimus complexed with albumin of size 100nm, which gives it a superior clinical and pharmacological profile.

Actinobac Biomed

Location:
Kendall Park, NJ

Technology:
WBC-targeting bacterial protein

Stage:
Pre-clinical development

Conducting IND-enabling studies of their lead therapeutic candidate Leukothera®, which is a bacterial protein that binds to and depletes a subset of white blood cells (WBCs) involved in the mechanism of a variety of diseases including hematological malignancies. Leukothera (leukotoxin, LtxA) rapidly and specifically targets and kills WBCs expressing activated leukocyte function antigen-1 (LFA-1) only present on WBCs, and its activated form is usually upregulated on cancerous WBCs. Leukothera has demonstrated efficacy in rodents, cats, dogs, and monkeys and maintains very desirable pharmacokinetic and safety profiles.

ADT Pharmaceuticals

Location:
Orange Beach, AL

Technology:
Ras-targeting therapeutics

Stage:
Pre-clinical development

Developing novel compounds that target constitutively active Ras and/or tumors overexpressing PDE10. Initial compound evaluation and optimization have demonstrated direct disruption of the Ras-Raf interactions, strong potency and selectivity, drug-like properties, and durable in vivo efficacy with no apparent toxicities.

CerRx

Location:
Lubbock, TX

Technology:
Ceramide-targeting cancer drug

Stage:
Phase II clinical trial

CerRx is a clinical-stage oncology drug development company that uses a novel pharmaceutical platform to target toxic intracellular waxes called 'ceramides,' specifically the dihydroceramide pathway. Their lead agent, IV fenretinide, has completed Phase I trials with some early signs of clinical efficacy for multiple cancers including relapsed T cell lymphomas, adenocarcimonas, and soft tissue sarcomas. Currently under the FDA's accelerated review, IV Fenretinide will be clinically tested in the U.S. starting in 2016 for peripheral T cell lymphoma at 26 sites.

Dekk-Tec

Location:
New Orleans, LA

Technology:
Blood brain barrier-crossing anti-cancer agent

Stage:
Phase II clinical trial

Clinically developing 4-Demethyl-4-cholesteryloxycarbonylpenclomedine (DM-CHOC-PEN), a polychlorinated pyridine cholesteryloxycarbonate. DM-CHOC-PEN's MOA works via bis-alkylation of DNA @ N7- guanine and N4-cytosine interrupting DNA coding, enabling it to be used in combination with O6-guanine alkylators - BCNU, temozolamide (TMZ), etc. and/or radiation therapy. DM-CHOC-PEN has demonstrated impressive objective responses and long term survival (60+ mos.) in adults with primary and metastatic cancers including GBM, astrocytoma, sarcomas, lung and breast cancers involving the CNS.

DNATrix

Location:
Houston, TX & San Diego, CA

Technology:
Viral-based immunotherapies

Stage:
Pre-clinical development

Developing viral-based immunotherapies that elicit aggressive and specific antitumor responses. The lead product, DNX-2401, is currently being tested in a Phase 2 GBM clinical trial in combination with anti-PD1 Ab Keytruda (in collaboration with Merck). With SBIR funding, DNATrix is preclinically developing a novel ex vivo virotherapy method using myxoma virus (MYXV), an oncolytic poxvirus, to improve the clinical outcomes in patients receiving stem cell transplants for cancers like multiple myeloma (MM) or other related blood cancers.

Humanetics

Location:
Edina, MN

Technology:
Healthy tissue protection during radiotherapy

Stage:
Phase II clinical trial

Developing BIO 300, a drug that protects healthy tissues during radiation therapy for cancer. BIO 300 was originally developed by Humanetics with funding from the DOD and BARDA as a radiation countermeasure to prevent acute radiation syndrome. In recent years, Humanetics has received multiple awards from the NCI for repurposing BIO 300 to reduce radiotherapy-related toxicities.

Iso Therapeutics Group

Location:
Angleton, TX

Technology:
Radiopharmaceutical for bone metastases

Stage:
Pre-clinical development

Developing CycloSam® (Sm-153-DOTMP), a new therapeutic radiopharmaceutical for the treatment of bone metastases. CycloSam combines a short half-lived radioisotope, samarium-153, with a phosphonic acid chelating agent, DOTMP. It can deliver prescribed radiation doses to bone tumors while avoiding radiation damage to normal, non-target tissues. CycloSam has demonstrated strong efficacy at doses well below the MTD and the initiation of first-in-human trials is expected shortly.

JSK Therapeutics

Location:
Sandy, UT

Technology:
Blood brain barrier-crossing anti-cancer agent

Stage:
Pre-clinical development

Developing JS-K, a first-in-class nitric oxide (NO)-generating compound with single-agent activity in animal models of many cancers. JS-K impairs tumor metabolism, inhibits tumor angiogenesis, and sensitizes malignant cells to immune effector cells by delivering a toxic payload of NO. JS-K completed preliminary non-GLP canine toxicity studies and was well tolerated without induction of hypotension. JS-K is currently conducting IND-enabling studies and has been granted orphan drug designation by FDA for AML and MM.

Keystone Nano

Location:
State College, PA

Technology:
Nano therapies for cancer

Stage:
Pre-clinical development

Developing Ceramide NanoLiposome (CNL) for liver cancer, Photo Immuno Nano Therapy (PINT) program for leukemia, and siRNA technology for treatment of breast cancer. Keystone Nano's lead candidate, Ceramide NanoLiposome (CNL), is expected to enter human clinical testing for liver cancer in mid-2016 with an SBIR grant. CNL has shown strong anti-tumor activity against multiple cancers in animal models with a clean, well-tolerated profile in pre-clinical testing.

NĒRx Biosciences

Location:
Indianapolis, IN

Technology:
Targeted therapeutics for cancer treatment

Stage:
Pre-clinical development

Developing novel therapeutics that target DNA repair pathways with a focus on the Nucleotide Excision Repair (NER) pathway. NERx's lead candidate, NERx-551, inhibits the human single-strand DNA binding protein replication protein A (RPA), which is an essential protein in the NER and homologous recombination repair (HRR) pathways. NERx has demonstrated in vivo single-agent efficacy in NSCLC xenograft models, low toxicity at efficacious doses, and synergy with cisplatin.

Novomedix

Location:
San Diego, CA

Technology:
Aberrant Protein Synthesis Inhibitor

Stage:
Pre-clinical development

Developing a novel class of translation inhibitors with demonstrated preclinical safety and efficacy in animal models of TNBC and in drug-resistant cell lines. NM922 inhibits translation initiation (mTORC1/eIF4E/4E-BP1 pathway) and protein synthesis to prevent cancer cell growth directly, potentially reversing the formation of cancer associated fibroblasts and preventing invasion/metastasis.

Oncoceutics

Location:
Philadelphia, PA

Technology:
Targeted small molecule andicancer compounds

Stage:
Phase I, II clinical trial

Developing a first-in-class oral small molecule, ONC 201, which targets known tumor suppressor pathways, for tumors that are resistant to treatment. The novelty of ONC 201 is that it targets a stress response pathway that is fatal to malignant cells. ONC 201 is currently in five over-subscribed Phase I/II clinical trials for multiple cancers.

Shuttle Pharmaceuticals

Location:
Rockville, MD

Technology:
Radiation sensitizers for treating cancers

Stage:
Phase I clinical trial

Developing radiation sensitizing drugs for the treatment of cancers, and radiation protectors of normal tissue for use in clinical radiation oncology. The initial focus is to begin clinical evaluation of their orally available prodrug ropidoxuridine as a radiation sensitizer for the combined modality treatment of Stages II and III rectal cancers.

SignalRx

Location:
San Diego, CA

Technology:
Dual inhibitors for combination cancer therapy

Stage:
Phase I clinical trial

Developing a molecular scaffold to create dual inhibitor molecules of signaling pathways. The key differentiating factor of Signal Rx technology is that it is not a conjugation of two separate drugs, but its scaffold approach inserts two inhibitor molecules that block two distinct catalytic protein sites simultaneously. Using the scaffold approach, SignalRx has several dual inhibition prototype molecules in development, focusing on the PI3K pathway.

Synactix

Location:
Tucson, AZ

Technology:
RET/VEGFR2 dual inhibitor

Stage:
Pre-clinical development

Developing novel therapeutics based on their proprietary “polypharmacology” development platform. Their lead candidate, Pz-1, is a RET/VEGFR2 dual inhibitor that can simultaneously block tumor growth and eliminate tumor vascularization at a single, low dose form with no apparent toxicities. Synactix is currently conducting IND-enabling studies and is first pursuing orphan drug status in medullary thyroid cancer. Additional indications for early clinical evaluation include papillary thyroid cancer, non-small cell lung cancer, and ER+ hormonal resistant breast cancer.

CatAssays

Location:
Rochester, NY

Technology:
New ELISA chemical signal amplification

Stage:
Phase I clinical trial

Developing a proprietary modification of ELISA with an 80-fold sensitivity increase from the standard ELISA format. The implementation of CatAssays' amplification chemistry, based on a unique palladium-catalyzed dye signal reaction, provides a significant cost/performance advantage since there is no need for any new capital expenditures or staff training. The first commercial CatAssays product, Ultra Palladium ELISA kit for the early detection of ovarian cancer, will address a pressing need for early detection of ovarian cancer, which is associated with mortality of 75% but can be cured in up to 90% of cases when diagnosed while still limited to the ovaries.

Inanovate

Location:
Research Triangle Park, NC

Technology:
Blood test for breast cancer recurrence detenction

Stage:
Pre-clinical development

Inanovate is developing a low-cost blood test that can detect breast cancer recurrence in advance of physican symptoms using its Bio-ID technology and panel breast cancer specific auto-antibody biomarkers. Bio-ID detects and quantifies the presence of disease related biomarkers from patient samples in one low-cost accurate test. To date, in a 400 patient trial with partners at Sanford Health, the test demonstrated the capability to identify breast cancer over healthy controls to a Sensitivity of 83% at a Specificity of 70%.

Glycosensors & Diagnostics

Location:
Athens, GA

Technology:
Glycan identification/analysis platform

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

Developing the Lectenz® and GlycoSense™ platforms for high-throughput and cost-effective glycan identification and analysis. These enabling technologies address unmet needs in disease biomarker detection, as well as process development and biomanufacturing of biologics and biosimilars. The Lectenz platform (focus of the company's SBIR award) engineers reagents with unique specificity and affinity for glycan targets and is capable of real-time glycoprofiling based on combining multiplex suspension array technology with glycan-specific reagents such as Lectenz, lectins, and antibodies.

JBS

Location:
Doylestown, PA

Technology:
cfDNA test for cancer screening

Stage:
Pre-clinical development

JBS Science focuses on the delivery of urine-based DNA tests for cancer screening and liquid biopsy for cancer precision medicine to improve disease management. JBS Science has demonstrated that urine contains cfDNA from the circulation and developed urine-based assays that detect DNA biomarkers for cancer. JBS Science discovered urine based DNA markers for AFP-negative HCC, which accounts for 50 % of liver cancer. This discovery enables JBS Urine DNA test to detect 90% of liver cancer. By using noninvasive urine test, patients can be monitored more frequently with good compliance which means more HCC can be detected early to improve prognosis.

KIYATEC

Location:
Greenville, SC

Technology:
3D Cell Based Cancer Diagnostic

Stage:
In feasibility/pilot trial

Developing live phenotypic 3D cell-based models for drug response profiling, generating information relevant to preclinical testing, clinical trials and clinical diagnostics applications. Kiyatec is prioritizing accurate ex vivo prediction of cancer patients' response to drug treatment with a focus on correlating data from their models to human clinical outcomes in order to minimize clinical trial failures and maximize patient outcomes in the clinic. Kiyatec's heterotypic, 3D perfused co-cultures established the use of a systemic strategy of adopting optimized scaffolds, cell types, and media conditions to KIYATEC's novel 3D perfusion bioreactor, the 3DKUBE™.

Nortis

Location:
Woodinville, WA

Technology:
Organ-on-chip

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

Developing small disposable microfluidic tumor or organ 3D culture chips that can be subjected to the same substances that are usually put through lengthy and expensive lab animal testing. Nortis is working with its microfluidic chip technology to reproduce blood vessels, kidney, heart, brain, liver, immune system, breast cancer and other tissues and organs. Nortis' unique microfluidic chip technology enables scientists to create micro tubular lumens and vascularized tissue-specific microenvironments in a system that is free of artificial substrates. Researchers can create more complex 3D human tissue microenvironments, in which nutrients, growth factors, and test compounds may be perfused through the micro-tissue lumens and/or the surrounding matrix recapitulating key features of human tissue physiology.

Vitatex

Location:
Stony Brook, NY

Technology:
Proprietary invasive circulating tumor cells (iCTC) enrichment technology

Stage:
In feasibility/pilot trial

Vitatex Inc. developed a pipeline of research products, including Vita-Cap™ tubes and Vita-Assay™ culture plates, to enrich iCTCs in patients' blood. These disposable devices are compatible with standard Vacutainer® blood collection devices and can recover a higher percentage of cancer cells as compared to competing CTC enrichment methods. The products facilitate not only automated flow cytometry counting of iCTCs with the superior sensitivity and specificity in patients with breast, ovarian, prostate, colon, lung, pancreatic, and GI cancers, but also molecular analyses of cancer using gene expression profiling, qRT-PCR and NGS.

Accelerated Medical Devices

Location:
Berkeley, CA

Technology:
Predictive cancer diagnostics

Stage:
In feasibility/pilot trial

AMD's technology centers around giving 1% of the therapeutic dose (a microdose) of a platinum-based drug, followed by quantitation of drug-DNA adducts in biopsy tissue using accelerator mass spectrometry (AMS). The technology enables detection of drug-DNA damage as a predictive marker prior to initiation of full-dose chemotherapy in order to avoid unneeded treatment. AMS can measure individual tumor susceptibility to specific drugs without toxic side effects but does not require tumor genotype information or culturing of tumor cells.

Corvida Medical

Location:
Coralville, IA

Technology:
Closed system drug transfer device

Stage:
Commercially available

Developing an innovative, "best-in-class" closed system drug transfer device (CSTD) that optimizes safe handling of hazardous drugs. The Corvida Halo® CSTD boasts an innovative product design that is the culmination of an iterative development process driven by end-user feedback to address all market requirements. The Corvida CSTD solves issues from safety to usability/ergonomics and cost-effectiveness that is lacking in current offerings. Corvida Medical has filed formal patents, validated performance and usability with functional prototypes, secured related testing data, submitted the 510(k) to FDA and recently received FDA 510(k) clearance in Q3 2015. Management has already commenced customer pilots, and the Company has purchase commitments from first customers.

Privo Technologies

Location:
Boston, MA

Technology:
Nanotechnology drug delivery platform

Stage:
Pre-clinical development

Developing a drug delivery platform spun-out of Bob Langer's lab at MIT called the Chemo Thin Wafer – thin wafers that deliver chemotherapeutics, in this case cisplatin containing nanoparticles, when placed directly on mucosal surfaces. They are initially targeting oral cancers, and have demonstrated in rodent models 25-fold increased drug accumulation at tumor sites compared to systemic delivery, without general toxicities associated with systemic chemotherapy.

Tevido Biodevices

Location:
Austin, TX

Technology:
3D Bioprinting for custom grafts

Stage:
Pre-clinical development

TeVido BioDevices's platform technology uses proprietary 3D bio-printing processes and a patient's own living cells to build custom grafts that address significant unmet needs in the broad field of reconstructive surgery where current results are unpredictable. The first product is targeted to improve nipple reconstruction after mastectomy due to breast cancer, where current procedures often flatten and fade over time.

C4 Imaging

Location:
Doylestown, PA

Technology:
Positive-signal MRI markers

Stage:
Pre-clinical trial

Developing innovative and enabling medical devices that allow physicians to utilize optimal imaging to address key clinical needs in significant patient populations. The core technology is based on a proprietary positive-signal MRI contrast agent (C4) and associated encapsulation technologies developed at the MD Anderson Cancer Center. This technology is exclusively licensed to C4 Imaging. C4 Imaging recently launched its first product, the Sirius™ MRI Marker, as a permanently implantable medical device for use in the management of prostate cancer. It is the only FDA approved (510k) positive-signal MRI Marker. C4 Imaging is now developing a second generation multi-modality fiducial marker that will further enhance the management of prostate cancer, as well as provide better guidance to physicians treating a range of other patients.

CellSight

Location:
San Francisco, CA

Technology:
PET imaging agent

Stage:
In Phase I clinical trial

Developing clinical stage PET imaging tools that can increase the probability of clinical success of immunotherapies by determining early in the therapeutic regimen if the cancer patient is responding to their immunotherapy. Their lead imaging tracer,[18F]-FAraG (product name VisAcT), leverages existing health and PET imaging infrastructure but is specific to visualizing immune response to provide clinicians information to help make treatment decisions. VisAcT was first discovered in the Gambhir lab (Chair of Radiology at Stanford), is exclusively licensed to CellSight, and is being validated through pharma partnerships.

Cernostics

Location:
Pittsburg, PA

Technology:
Image analysis platform

Stage:
Clinical technolofy in full development/ testing stage

Developing a proprietary systems-biology based TissueCypher™ Image Analysis Platform to quantify biomarkers in the context of morphology and integrate with clinical variables to produce diagnostic, prognostic and predictive scores. Their platform is transformative as it enables early detection of malignant progression by quantifying molecular changes that are missed by standard pathology. While Cernostics has secured prior equity financing, they are currently raising equity capital to support commercial launch of TissueCypher™ for a Barrett's Esophagus assay.

On Target Labs

Location:
West Lafayette, IN

Technology:
Intraoperative optical imaging agents

Stage:
In Phase I, II, III clinical trials

Developing novel optical imaging agents that target and illuminate pathological cells. The technology provides surgeons a precise "lighted road map" to more effectively and efficiently diagnose and surgically treat diseased tissue ranging from cancer to autoimmune and inflammatory diseases. On Target's lead development candidate is OTL38, a modular compound or probe comprised of a near infra-red (NIR) dye joined by a linker system to the targeting ligand folate. OTL38 has been proven safe and effective in a completed Phase 2 clinical trial for the treatment of ovarian cancer, and another Phase 2 trial will begin shortly focusing on lung cancer.

SonoVol

Location:
Research Triangle Park, NC

Technology:
Robotically operated ultrasound device

Stage:
Pre-clinical trial

SonoVol is the first company to combine low cost robotics with ultrasound to improve drug research. Specifically, SonoVol has developed and patented a system that robotically manipulates an ultrasound device around the entire body of a small animal, and then constructs a whole-body image of the animal. The SonoVol system is capable of achieving whole body 3D imaging, and it is able to do this for ~$7x less than the next available entry-level 2D imaging system. Furthermore, by robotically positioning the ultrasound probe, the device reduces one of the major sources of inter-user variability and error, which can be ~20%. Increasing the durability and fidelity of this data has significant value to companies performing drug screening tests.

Spectral Molecular Imaging

Location:
Beverly Hills, CA

Technology:
Molecular imaging technology

Stage:
In early feasibility trial

SMI's core technologies are based on advanced optical imaging, encompassing methods with very high discrimination ability. Proof-of-concept and testing of the methods' usefulness in clinical applications has been carried out in the CEO's academic labs, under two decades of significant (~$75 million) peer-reviewed funding, thus providing validation and shortening times to market. The company's core competency is the molecular imaging technology combination that non-invasively quantifies the fundamental biological state of diseased tissue to couple early diagnosis and treatment, and guide them.

Adherence Health

Location:
San Francisco, CA

Technology:
Adherence & outcomes management solutions

Stage:
Commercially available

Developing eMedonline, a software tool that incorporates behavior change expertise of the company's founder and guides patients through their therapy plans, coupled with a smartphone/tablet app and RFID or barcode-tagged medication containers. This technology provides valuable insight into adherence and outcomes for healthcare providers. Their studies demonstrate increases in compliance by up to 95%.

Lumme

Location:
Amherst, MA

Technology:
Wearable technology for smoking cessation

Stage:
Pre-clinical development

Developing a personalized smoking cessation program by combining wearable sensors, data analysis, and behavioral psychology. Lumme's RisQ analyzes concurrent streams of sensor data from a wristband and mobile phone to infer behavioral patterns, and their proprietary algorithm automatically identifies triggers, mood, probability of lapse, and high-risk situations for each user. This information is used to deliver timely and contextually appropriate interventions in the form of text messages or therapist phone calls.

AADi / mTor Inhibitor

Neil Desai, CEO | ndesai@aadibio.com | 310-309-9036| www.aadibio.com

Company Overview (Clinical Impact and Value Proposition)
AADi, LLC is developing its 'best-in-class' mTOR inhibitor, ABI-009, in highly selected populations in diseases driven by mTOR activations. mTOR is a proven biological target across several cancer types and the marketed mTOR inhibitors have combined sales in excess of $2B despite their poor pharmacological profile. ABI-009 is based on the same albumin-bound technology platform as Abraxane® and in addition to select cancer indications, is being developed in cardiovascular and metabolic diseases

Market and Commercialization Strategy
ABI-009 is being targeted to rare/orphan diseases where mTOR is known to be activated. The lead indication in PEComa, a rare sarcoma, provides a rapid path to approval in a rare disease and AADi has initiated its phase 2 registration trial. In cardiovascular indications, AADi will initiate a clinical study in pulmonary hypertension, where no existing therapy addresses disease modification. ABI-009 will be tested in several pediatric indications in combination with standard therapies in a study to be run and sponsored by the Children's Oncology Group (COG). In early stage bladder cancer, ABI-009 is being studied in combination with existing therapies. These indications alone represent markets of several $100M and pediatric indications have the possibility of obtaining a pediatric voucher.

Technical & Competitive Advantage
ABI-009 is being developed as the 'best-in-class' mTOR inhibitor. This is based on its ability to target tumors more effectively as a result of the albumin-bound nanoparticle technology. In animals models ABI-009 shows significantly improved tumor regression and survival compared to current mTOR inhibitors. Its pharmacological profile is greatly improved with significantly higher exposures at similar doses as currently available mTOR inhibitors and improved safety profile demonstrated in the phase 1 trial. Unlike other mTOR inhibitors, ABI-009 is being developed in highly select populations in diseases driven by mTOR activations.

Regulatory Strategy & Intellectual Property
In the lead oncology indication of advanced PEComa, AADi has initiated its pivotal registration phase 2 study for approval of ABI-009 after agreement with the FDA. We currently expect an NDA filing in 2018. ABI-009 is covered by several issued and pending patents with term beyond 2028. In addition, the orphan and pediatric strategies will provide protection well into the forseeable future.

Key Milestones (Achieved and Planned)

PEComa Phase II registration trial (single agent)	Initiated Q2, 2016
Pulmonary Hypertension Phase 1 trial (combination with standard therapies)	2H, 2016
Early stage bladder cancer, phase II trial (combination with standard therapy)	2H, 2016

Capitalization History:

9/2012-8/2017	Grant R42CA171552	NIH / NCI STTR	$1.565M
8/2014	seed round	Private parties	$1.1M
8/2015	Convertible Notes	Corporate and private	$1.25M

Use of Proceeds:
AADi plans to raise about $15M in the second half of 2016 to fund its clinical studies through phase 2 completion over the next 3 years. Majority of these funds are for clinical operations. The AADi team will be lean with about 6-8 individuals to manage the different aspects of ABI-009 clinical and regulatory development.

Key Team Members
Neil Desai, Ph.D.: CEO
More than 20 years of experience in drug delivery and drug development; Inventor of 'nab' technology, Abraxane, Successful exit for Abraxis (sold to Celgene for ~$3B)
Mitchall Clark, BPharm: Head of Regulatory and Quality
Domain expertise in seed round; Global regulatory head, former staff at Abraxis
Berta Grigorian: Head of Clinical Operations
More than 20 years of experience in clinical operation; Former staff at Amgen, led global clinical trials

Actinobac Biomed / Therapies from human oral microbiome

Scott C. Kachlany, CSO | scottkachlany@actinobac.com | 973-972-3057| www.actinobac.com

Company Overview (Clinical Impact and Value Proposition)

Actinobac Biomed is examining the microbiome to identify breakthrough biological agents that can be used to treat diseases. Our primary drug candidate, Leukothera, a natural protein secreted by the bacterium, *A. actinomycetemcomitans*, found in the human mouth, rapidly and specifically targets and depletes cancerous and/or pro-inflammatory white blood cells without affecting other tissues. It provides a therapeutic option for many diseases whose etiology involves those cell types and thus plays a major role in medical conditions afflicting one-third of the world's population. In preclinical studies, Leukothera has already been found to be effective in treating leukemia, lymphoma, psoriasis, allergic asthma, HIV, and dry eye syndrome.

Market and Commercialization Strategy

Actinobac intends to carry out the preclinical development of Leukothera, while continuing to search for additional therapeutics from the oral microbiome. Following the filing and approval of an IND application for Leukothera as a treatment for hematological malignancies, we intend to commence clinical trials to confirm Leukothera's safety and pharmaceutical efficacy. Based upon the results of these studies, Actinobac will either license-out the agent to a pharmaceutical partner or undertake these tasks in-house.

Technical & Competitive Advantage

Leukothera acts by rapidly targeting and depleting cells that exhibit the activated form of the receptor, lymphocyte function associated antigen-1 (LFA-1) on their surface. Since only white blood cells, especially those associated with disease, possess this receptor, other bodily tissues are not affected. Given the fact that no other marketed therapeutic agents act in this manner, Leukothera can be expected to be effective in treating blood cancers, autoimmune/inflammatory diseases and latent infections even in patients with recurrent or drug-resistant disease.

Regulatory Strategy & Intellectual Property

Following a successful pre-IND meeting with the FDA, Actinoabc is undertaking activities to collect the data required for the filing of an IND application. Following its submission and approval, the company intends to conduct a Phase I and IIa clinical trial in patients suffering from hematological malignancies. The development and testing of Leukothera for the treatment of additional disease indications or for new drug candidates will follow a similar regulatory pathway. Actinobac has exclusively licensed four patents in the US and Europe covering the use of Leukothera for the treatment of hematological malignancies, autoimmune/inflammatory diseases and latent infections. Three additional applications are pending.

Key Milestones (Achieved and Planned)

Pre-IND meeting with FDA successfully-completed	Q2 2014
GMP manufacturing process R&D along with other IND enabling studies	Underway
Filing of an IND application	Planned
Perform clinical trials to determine drug safety and provide preliminary efficacy data	Planned

Capitalization History:

03/09	Seed	NJ Health Foundation, LLC	$500k

Use of Proceeds:

Actinobac intends to raise $6,000,000 to complete its preclinical studies, file an IND application, and conduct preliminary human clinical trials for, Leukothera. When adequate funding becomes available, these activities can be accomplished in 18-24months.

Key Team Members

Scott Kachlany, Ph.D.: CSO

Associate Professor in the Department of Oral Biology at Rutgers School of Dental Medicine; Expertise in bacterium, *A. actinomycetemcomitans*, its biosynthesis of Leukothera®, and the therapeutic uses of Leukothera® for 15 years.

Benjamin Belinka, Ph.D.: CEO

Extensive expertise in pharmaceutical R&D and product commercialization; Served as a scientist and manager at several companies including VectraMed, Inc., Virium Pharmaceuticals, Cytogen Corporation, and Sandoz Pharmaceuticals (now Novartis).

Roger K. Strair, M.D., Ph.D.: CMO

Director of Hematologic Malignancies at Cancer Institute of New Jersey; Performs both basic and clinical research and has carried out numerous investigator-and industry-initiated phase I through phase III clinical trials.

ADT Pharmaceuticals / Ras-targeted Therapeutics

Michael R. Boyd, CEO | mboyd@ADTPharma.com | 251-786-4527

Company Overview (Clinical Impact and Value Proposition)

ADT Pharmaceuticals, Inc. is a Delaware C-corporation formed in September, 2014, focused on a mission of anticancer developmental therapeutics. Company technology includes a novel proprietary compound class that interacts directly with the Ras oncoprotein to inhibit with extraordinary potency and selectivity the growth of cancer cells harboring constitutively activated Ras. Many human cancers, prominently lung, colorectal and pancreatic cancers, are driven by Ras that is constitutively activated through mutations in the encoding ras gene, or through mutational activation of upstream component(s) (e.g. EGFR, Her2) in Ras-mediated signaling pathways. Ras-driven cancers also emerge during the development of resistance to conventional chemotherapy and/or radiation. Our cell-based, phenotypic screening of a focused chemical library of compounds having an indene core structure similar to that of the NSAID, sulindac, followed by extensive chemical optimization and confirmatory testing in isogenic cell lines with and without activated Ras, led to our elucidation of a drug development candidate, DC070-547 and several backup compounds and prodrug formulations. The compounds have attractive drug-like properties and in vivo antitumor efficacy with no discernable toxicity in preclinical models investigated to date. This technology will address a vast unmet medical need, potentially capturing a commercial market niche exceeding $1B/yr.

Market and Commercialization Strategy

The company is initiating a search for prospective investors and/or partners for planning, financially supporting and/or participating in an accelerated development program for our initial Ras-inhibitory drug, DC070-547. ADT aims to complete clinical phase I/IIa studies of this compound by 2018-19 as an intravenous infusion, and subsequently as prodrug(s) suitable for multiple routes of administration. With achievement of clinical proof-of-concept (POC), the company preferably will exit through M&A, or alternatively will license to an established major pharmaceutical company capable of full clinical development and commercialization of the technology.

Technical & Competitive Advantage

Compared to other known potential drugs in development that may target Ras, ADT's compounds have a distinctive constellation of attributes including: 1) non-peptidic, stable, small-molecules of modest MW, 2) favorable physicochemical properties meeting "Lipinski" criteria, 3) readily synthesized and modified, 4) inexpensive and safe dosage forms for large-scale manufacture, 5) highly potent, selective, non-covalent targeting of constitutively activated Ras and Ras-mediated biological processes, independent of Ras isoform or specific mutation, 6) highly active *in vivo* in animal-modeled, Ras-driven cancer, 7) availability of highly active backup compounds and prodrug formulations, substantially mitigating risks for successful drug development, and 8) strong intellectual property positioning.

Regulatory Strategy & Intellectual Property

U.S. Patent App. Nos. (Pub. Nos.): 14/571,647 (US 2016/0168113 A1), 14/571,690 (US 2016/1068108 A1), 15/056,202 (US 2016/0175275 A1), 62/268,266 (Prov.); International Patent App. Nos. (Pub. Nos.): PCT/US2015/066146 (WO 2016/100542 A1), PCT/US2015/066154 (WO 2916/100546 A1), PCT/US2014/070511 (WO 2016/099452 A1).

Key Milestones (Achieved and Planned)

More than 20 major global pharmaceutical companies have expressed interest, and two SBIR grants have been awarded to date.

Apply for 3rd SBIR Ph1 grant and 1st SBIR Ph2 grant; identify prospective investor(s)/partner(s)	2016
Win additional SBIR awards; secure additional funding for patenting costs	2016-2017
Secure external funding of $20M; complete IND-enabling R&D of DC070-547 and backup cpd and/or prodrug	2017-2018
Complete POC clinical trial; license out, merge with or be acquired by established company	2018-2019

Capitalization History

2014	convertible notes	co-founders	$150,000
2015	personal loans	co-founders	$62,500
2015	business line of credit	BB&T	$200,000
2015 - 2016	1st & 2nd SBIR Ph1 grant	NCI/NIH	$525,000

Use of Proceeds

External funding is sought for: 1) an accelerated IND-enabling preclinical development program for DC070-547, 2) a focused POC phase I/IIa clinical evaluation of DC070-547 and/or a backup or prodrug thereof as an IV formulation within 2-3 years, and 3) general corporate expenses, particularly patent-related. A total requirement of $20M is estimated.

Key Team Members

Michael R. Boyd, MD, PhD: Co-Founder, CEO & President

Expert in oncology and drug development; led more than 30 successful INDAs at NCI

Gary A. Piazza, PhD: Co-Founder, Chief Scientist

Expert in cancer pharmacology; wide experience in drug R&D in industry and academia

Mark D. Hankins, M.S. J.D., Chief Business Officer

Expert in biopharma business development, intellectual property and technology transfer

CerRx, Inc. / Ceramide Targeting Platform

Bill Simpson, CEO | Bill.Simpson@cerrx.com | 480-488-3138 | www.CerRx.com

Company Overview (Clinical Impact and Value Proposition)
CerRx is a clinical-stage, oncology drug development company using a novel pharmaceutical platform to target toxic intracellular waxes, called `ceramides' and specifically the dihydroceramide pathway. This ceramides-based technology induces high rates of cancer cell death by increasing and manipulating ceramides exclusively in cancer cells, not normal cells. Phase I trials of lead agent IV fenretinide have produced multiple, sustained (+5 years) complete remissions, partial remissions and other signals of activity in difficult-to-treat cancers, including relapsed T-cell lymphoma, adenocarcinoma of the esophagus and colon, soft tissue sarcoma, neuroblastoma and others.

Market and Commercialization Strategy
CerRx is currently conducting a Phase 2 trial of IV fenretinide to be reviewed for accelerated-approval as 3rd line therapy in Peripheral T-cell Lymphoma (PTCL) under FDA Subpart H. US sites are currently enrolling. Additional sites are under negotiations in Europe, Australia and Korea. PTCL will be our first product indication in an area of high unmet need where current therapies provide marginal benefit and significant toxicity.

Technical & Competitive Advantage
In relapsed peripheral and cutaneous T-cell lymphomas, Phase I results included multiple, complete responses durable for greater than 5 years. The overall response rate of IV fenretinide in relapsed T-cell lymphomas has been impressive with a 40% overall response rate and 20% of patients experiencing durable complete response. The response rate is much higher than seen with the most recently approved products for PTCL.

Regulatory Strategy & Intellectual Property
First registration NDA/EMA under Orphan Drug Designation in PTCL will be filed by end of 2018 in the US, EU and other major markets. Additional monotherapy or combination programs are planned in CTCL, SCLC, and adenocarcinoma of the upper esophagus – additional areas of high unmet need and under orphan drug designations.

Key Milestones (Achieved and Planned)

Phase I solid tumors and leukemia/lymphoma (IV fenretinide); Phase I/II neuroblastoma (IV/oral fenretinide)	Complete
Phase I monotherapy and combination therapy – IV safingol	Complete
Phase II monotherapy for accelerated approval in refractory/resistant peripheral T-cell lymphoma	Enrolling
Phase I combination therapy – IV fenretinide + IV safingol	Enrolling

Capitalization History:

03/2014	Grant	Cancer Prevention and Research Institute of Texas (CPRIT)	$6.0M
06/2014	Grant	SBIR	$1.1M
	Investment	Angel Investors	$9.0M

Use of Proceeds:
$30M to complete first registration trial in PTCL, complete commercial manufacturing, and file NDA/EMA.

Key Team Members:
Richard Love, BS/MS: Chairman
Richard was founder of Triton Biosciences and ILEX Oncology. Served as CEO and led the teams responsible for the clinical development of multiple products, four of which remain in use: Betaseron® for treatment of multiple sclerosis; Fludara® and CAMPATH®, both for chronic lymphocytic leukemia; and Clolar™ for treatment of acute lymphocytic leukemia. Served in senior executive positions at three non-profit research institutions, the Cancer Therapy and Research Center, The San Antonio Technology Accelerator Initiative and the Translational Genomics Research Institute (TGen). Currently serve as a director of Parexel International; Cell Therapeutics Inc., Applied MicroArrays Inc., Cancer Prevention Pharmaceuticals Inc. and SalutarisMD Inc.
William J Simpson, BA: Chief Executive Officer
Bill has lead multiple US and Global oncology drug development and commercial teams responsible for the development and commercialization of Arimidex® for breast cancer, Casodex® and Zoladex® for prostate cancer, and other leading oncology and non-oncology brands in the US. Bill has held senior leadership roles with leading oncology companies including AstraZeneca, Adria Laboratories (now Pfizer), and Ascalon International.
C. Patrick Reynolds, MD, PhD: Chief Scientific Officer
Pat is the Cancer Center Director, Professor of Cell Biology & Biochemistry, Pediatrics, Internal Medicine, School of Medicine, Texas Tech University Health Sciences Center; a member of the FDA Pediatric Subcommittee of the Oncologic Drugs Advisory Committee; Director of the South Plains Oncology Consortium, and many other local and national positions in oncology research. Pat's major interest is in cancer developmental therapeutics with a particular focus on retinoids as differentiation inducers and as cytotoxic agents.

DEKK-TEC, Inc. / Cancer R&D

Lee Roy Morgan, CEO | lrm1579@aol.com| 504-583-6135| www.dekk-tec.com

Company Overview (Clinical Impact and Value Proposition)

DEKK-TEC, Inc. is a New Orleans based R & D group that has been involved in the research and development of new drugs and devices to advance the management of cancer since 1983. The current principle interest is 4-demethyl-4-carbonyloxycholesterylpenclomedine (DM-CHOC-PEN). DM-CHOC-PEN has completed Phase I/II trials in subjects with brain cancers – primary and metastatic and is being readied for Orphan Drug Designation review. The drug has demonstrate complete remissions, excellent responses, improved quality of life and long term survival (>2.5 + yrs.) in subjects lung cancer metastatic to the brain. DM-CHOC-PEN has a unique mechanism of action with minimal toxicities; plus it potentiates radiation (a radiosensitizer). It has a $200-600 MM market in the US alone.

Market and Commercialization Strategy

There are no drugs that are not target agents effective in lung cancer involving the brain and CNS. Once the ODD is obtained we will pursue the commercialization route for non-small cell lung cancer (NSCLC) with investors and then expand to other tumor types once revenue is initiated from sales. The goal is to form a partnership with another company or investors to accomplish the above.

Technical & Competitive Advantage

DM-CHOC-PEN is sensitive against all types of (NSCLC), especially adenocarcinomas. Tumor markers are not required (not a target agent), making it unique. The drug readily crosses into the brain and active against tumors for which there are no known therapies. The drug also is a radiosensitizer and potentiates radiation effects. There are no competitive agents.

Regulatory Strategy & Intellectual Property

The regulatory support is strong. Rare Disease Therapies will distribute the drug when approved by the FDA. Their regulatory staff has been of utmost assistance and has allowed us to reach this position. Us and world-wide patents are in place.

Key Milestones (Achieved and Planned)

Phase I/II clinical trials (adults) completed in brain tumors – primary and metastatic cancers	Completed Q2 2016
Phase I trial in pediatric/adolescent subjects – in progress	Complete Q3 2018
Phase I trial in adults with CNS cancer plus radiation – in progress	Complete Q1 2019

Capitalization History:

2000 -16	SBIR	NCI	$4.8 M
2005-15	Licensing of products	Ziopharm & Tigris	$2.2 M
2014-15	LA State Tax Credits	State of LA	$680K
2002-16	Investors	Topaz Equity Fund	$1.8 M

Use of Proceeds:

It is proposed that $1.5 – 2.0 M will be required to treat ~35 subjects with NSCLC involving the brain that will allow NDA submission and commercialization may begin. This will primarily be used to fund the necessary trials to obtain subject enrollment.

Key Team Members:

Lee Roy Morgan, M.D., Ph.D.: CEO

Dr. Morgan has been involved with DEKK-TEC since its conception in 1983. He is a retired Professor/Chairman of Pharmacology, LA State Medical School and certified oncologist. Dr. Morgan has a PhD in organic chemistry and designed/synthesized DM-CHOC-PEN. He has dozens of patents and has licensed several other products. He would like to remain active in the drug's development.

Andrew H. Rodgers, Ph.D.: Director of Clinical Research

Dr. Rodgers has been with DEKK-TEC since 1989. He is an analytical chemist and toxicologist with training in regulatory affairs. He has been involved in the DM-CHOC-PEN project since its conception.

Edmund Benes, B.S.: Regulatory Affairs

Mr. Benes is a cytologist who has been with DEKK-TEC since 2000. He manages the FDA data and communication with the clinical trial sites. He is also trained in regulatory affairs.

DNAtrix / Virus-driven Cancer Immunotherapy

Frank Tufaro, CEO | ftufaro@dnatrix.com | www.dnatrix.com

Company Overview (Clinical Impact and Value Proposition)

DNAtrix is a privately held, clinical stage, biotechnology company developing virus-driven immunotherapy platforms for oncology. DNAtrix's vision is to leverage the significant advantages of oncolytic viruses to develop safe and effective therapies for difficult cancers, including glioblastoma (GBM) and other high grade tumors. Based on the natural ability of the engineered products to trigger an antitumor immune response, DNAtrix is building a pipeline of virus-based drugs for use as monotherapy or in combination with checkpoint inhibitors and other immuno-oncology drugs. The recent US and EU approval of the first oncolytic virus therapy, Imlygic (a human herpesvirus) to treat melanoma paves the way for oncolytic virus-based immunotherapy, such as those in the DNAtrix Platform, to join or complement small molecules, antibodies and cell-based therapies in the fight against cancer.

Market and Commercialization Strategy

Based on promising clinical data with the lead product candidate, DNX-2401, DNAtrix is conducting a Phase 2 study in a drug collaboration with Merck to test the efficacy of DNX-2401 in combination with the Merck checkpoint inhibitor, Keytruda (pembrolizumab). A randomized Phase 3 registrational study of DNX-2401 for recurrent GBM is in preparation under a Special Protocol Assessment (SPA). DNAtrix's next generation platform of "armed" viruses combine the clinically effective and safe virus backbone of DNX-2401 with potent T-cell immune modulators. The first candidate from this platform, DNX-2440, which expresses OX40L (a co-stimulatory ligand for T-cell activation), will enter clinical trials for metastatic disease in 2017. DNAtrix holds worldwide rights to all its programs.

Technical & Competitive Advantage

Over 140 patients have been treated with DNX-2401 across multiple clinical studies demonstrating that DNX-2401 can (1) replicate in human tumors for a period of weeks to months, (2) trigger immune cell infiltration into the tumor, (3) cause ongoing tumor destruction and (4) induce durable responses to therapy following a single intratumoral injection. In these studies, patient survival has been prolonged in a subset of patients, including in those achieving a complete response. In addition, DNX-2401 has an excellent safety profile, making it a suitable candidate for combination therapy with many classes of drugs. "Armed" oncolytic viruses in the next generation platform can be engineered to target a wide variety of cancers. Notably, adenovirus platform products are manufactured efficiently and at low cost using industry-standard reagents and fermenters.

Regulatory Strategy & Intellectual Property

DNAtrix has licensed >50 patents world-wide covering product classes with composition and utility of its platforms.

Key Milestones (Achieved and Planned)

Phase 2 DNX-2401 + Pembrolizumab in recurrent glioblastoma (currently enrolling)	2016 - 2017
Phase 1 DNX-2440 (OX40L expressing virus)	2017 - 2018
SPA for DNX-2401	2017
Phase 3 DNX-2401	2017 - 2019

Capitalization History

2008	Series A Equity	Venture Capital	$0.5M
2012	Series A-1 Equity	Venture Capital	$4.0M
2014	Grant	State of Texas, CPRIT Grant	$10.8M
2014	Series B Equity	Venture Capital	$18.5M
2016	Federal Grant	FDA Orphan Products Development Grant	$2.0M

Use of Proceeds

DNAtrix will raise financing of $40-$50 million for its platform technologies. These proceeds will be used to support the product approval process for adenovirus platform products in glioblastoma and the development of pipeline candidates for additional cancer indications.

Key Team Members

Frank Tufaro, PhD: CEO

Experienced biotech executive and former professor of Microbiology and Immunology; previous successes with NeuroVir (founder, CSO, CEO), MediGene (Managing Director), Nurel (founder and CEO)

Imre Kovesdi, PhD: Sr. VP of R&D

Professor of Tumor Biology and Cancer Research (University of California San Francisco); founder and previous CSO of Onyx Pharmaceuticals

Drew Pardoll, MD, PhD: Board Member

Co-Director, Cancer Immunology and Hematopoiesis Program and Professor of Oncology (Johns Hopkins University of Medicine)

Humanetics / Virus-driven Cancer Immunotherapy

Ronald Zenk, CEO | RZenk@Humanetx.com | 952-400-0400 | www.humaneticscorp.com

Company Overview (Clinical Impact and Value Proposition)

Humanetics' product portfolio features multiple drug candidates at various stages of clinical development. Areas of focus include a therapy aimed at improving treatment outcomes for solid tumor cancers; and a therapy to prevent and treat age-related cognitive decline associated with normal aging or neurodegenerative disease (e.g. Alzheimer's disease). Both therapies have the potential to become widely adopted new treatment paradigms that could significantly improve upon the current standard of care.

Market and Commercialization Strategy

Humanetics intends to advance its proprietary drug candidates through Phase 2 clinical trials, and then partner with Big Pharma to complete clinical testing leading to an exclusive license or acquisition for commercialization. Certain indications with easily accessed commercial distribution, such as drugs intended for the Department of Defense or the National Strategic Stockpile, may be fully developed through internal resources supported by government contracts.

Technical & Competitive Advantage

Humanetics is developing new standards of care to treat solid tumor cancers, cognitive decline and Alzheimer's disease that are unparalleled in the market. Advantages lie in multiple attributes such as unique mechanism of action, lower toxicities and ease of administration. All technologies are protected by an expansive intellectual property portfolio.

Regulatory Strategy & Intellectual Property

Technologies are being developed under the most attractive regulatory pathways for the given indication, which may include drug or medical food. Humanetics currently holds 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 issued and pending for all drug candidates.

Key Milestones (Achieved and Planned)

Launched Phase II clinical trial in non-small cell lung cancer	Q1 2015
Completed Phase I / II clinical trial in Alzheimer's disease	Q4 2015
Planned Phase II clinical trial to replace chemotherapy in combined chemoradiotherapy cancer treatments	Q3 2017
Planned Phase II clinical trial to prevent DNA damage caused by low dose radiation exposure (CT Scans)	Q3 2017

Capitalization History

1990's	Common stock	Private offering to individual accredited investors	$12M
2005/2010	Development grants	U.S. Department of Defense / U.S. Congress	$10M
2012	Development grants	BARDA	$3.5M
2014	Sale of business unit	Ingredient business sold to competitor	$9M

Use of Proceeds

Approximately $10MM in additional funds are needed to further advance the Company's proprietary drug candidates to obtain sufficient Phase II efficacy data to license or sell to Big Pharma. Humanetics currently holds four open IND's to conduct such studies. Additional proceeds will be used to formulate and manufacture GMP drug required for Phase II trials.

Key Team Members

Ronald Zenk, M.B.A.: CEO

Mr. Zenk founded the company in 1988. He has a long history of collaborating with national government agencies, including multiple agencies under the National Institutes of Health (e.g. NCI and NIAID).

John Dykstra, B.S.: COO

Mr. Dykstra has spent 18 years as Chief Operating Officer of Humanetics Corporation. He is a highly experienced senior executive with 35 years of experience in starting, operating and growing successful businesses across a variety of industries including pharmaceuticals, nutritional products, computer technology and manufacturing.

Michael Kaytor, Ph.D.: Director of Research and Development

Dr. Kaytor has over 20 years of research and development experience in projects aimed at developing therapies for chronic medical conditions. He directs all scientific affairs for the Company.

IsoTherapeutics Group, LLC
Radiopharmaceutical R&D and Consulting

IsoTherapeutics Group / Radiopharmaceutical for metastases

R. Keith Frank, CEO | keithfrank@isotherapeutics.com | 979-415-4094 | www.isotherapeutics.com

Company Overview (Clinical Impact and Value Proposition)
IsoTherapeutics Group LLC (ITG) is a radiopharmaceutical R&D company specializing in therapeutic radiopharmaceuticals. ITG is developing CycloSam (Sm-153-DOTMP), a new therapeutic radiopharmaceutical for the treatment of bone metastases. CycloSam delivers prescribed radiation doses to bone tumors while minimizing radiation damage to normal, non-target tissues. CycloSam promises to provide pain palliation, improved quality and extension of life to the large number of patients suffering from metastatic bone cancer.

Market and Commercialization Strategy
Bone metastases arise in about 5% of all types of cancer (nearly 600,000 worldwide). GlobalData estimated the value of the global bone metastasis therapeutics market in 2017 as $6.4 billion. CycloSam would be provided to clinics via a network of local radiopharmacies. ITG plans include out-licensing of CycloSam to the appropriate pharma partner.

Technical & Competitive Advantage
CycloSam promises to be more efficacious, more readily available and lower in cost than both of the primary competing radiopharmaceuticals, Quadramet and Xofigo. In addition, CycloSam has lower radionuclidic impurities than Quadramet, which will allow for repeated dose administration, which has been shown to contribute to extension of life.

Regulatory Strategy & Intellectual Property
ITG has developed trade secrets and know-how, and filed two patent applications to protect CycloSam technology: PCT/US2014/059385 "High Purity Bone Agents" protects the use of low specific activity Sm-153 with DOTMP and PCT/US2016/033900 "DOTMP Kit Formulation for Radioisotopes" protects the use of the kit to prepare CycloSam. CycloSam is a registered trademark of ITG. ITG has had a pre-IND meeting with the FDA and all the requirements for filing an IND are nearly complete. The regulatory strategy is to first obtain approval for treatment of metastatic bone cancer, then to pursue other indications.

Key Milestones (Achieved and Planned)
Completed pre-clinical work including toxicology, demonstration of efficacy in dogs and CMC. Pre-IND meeting w/ FDA.

Phase 0 Trial (Dosimetry) – MD Anderson Cancer Center (MDACC)	Q2 2017
Phase 1/2 Trial in combination w/XRT (high risk osteosarcoma) – Johns Hopkins University (JHU)	2018
Phase 1/2 Trial (Sclerotic bone metastases) – IsoTherapeutics Group sponsored (at MDACC)	2020

Capitalization History

Mth/yr	Funding	Provider	Amt
Ongoing	Company Resources	IsoTherapeutics Group LLC	$1.3M
10/2010	Qualifying Therapeutic Discovery Project Program	IRS Code Section 48D	$242K
9/2010	SBIR Phase 1	NIH/NCI	$144K
7/2013	SBIR Phase 2/Supplemental	NIH/NCI	$1.49M

Use of Proceeds:
Immediate need - $300,000 for supporting Phase 0 and 1/2 institutional (MDACC & JHU) INDs.
2017 – 2020 - $5M for supporting ITG Phase 1/2 trial

Key Team Members:
R. Keith Frank, Ph.D.: President and CEO
Co-founder of ITG. Organic chemist with 23 yrs at The Dow Chemical Company - development of radiopharmaceuticals, including two approved products (Quadramet® and Iotrex™). 22 US patents, over 30 publications. Initiated and led ChelaMed℠ radiopharmaceutical services at Dow.
Jaime Simon, Ph.D.: VP and Chief Scientific Officer
Co-founder of ITG. Radiochemist with 25 yrs at Dow - development of new pharmaceutical technologies. Over 50 US patents, including the key patents covering Quadramet® for the treatment of bone cancer and STR (Ho-166-DOTMP) for safely ablating bone marrow prior to bone marrow transplants. Over 70 publications.
Shannon Phillips, Ph.D.: Quality Systems Manager and Scientist
Analytical chemist with 5 yrs at Bristol-Myers Squibb and 3 yrs at Dow. Made significant contributions to the CMC filing for an NDA and helped design and implement two GMP laboratories. 5 publications.

JSK THERAPEUTICS
CHEMISTRY AGAINST CANCER

JSK Therapeutics / Nitric Oxide Generating Compound

Sudhir Sahasrabudhe, CEO | rinesco@gmail.com | 801-891-7880 | www.jskthera.com

Company Overview (Clinical Impact and Value Proposition):
JSK Therapeutics (JSKT) was founded in 2008. The lead compound that JSKT will bring to market is JS-K, a first-in-class nitric oxide (NO)-generating compound of the arylated diazeniumdiolate class. Dr. Larry Keefer at the NCI and Dr. Paul Shami at the University of Utah developed JS-K. JS-K has activity in animal models of acute myeloid leukemia (AML), multiple myeloma (MM), non-small cell lung cancer, hepatocellular carcinoma, prostate cancer, glioma and Ewing's sarcoma. JS-K also inhibits metastasis development in an orthotopic renal cell carcinoma model. JSKT has executed exclusive licenses for the composition of matter, cancer use, and formulation patents for JS-K with the NCI and the University of Utah. The FDA has granted orphan drug designation for JS-K for the indications of AML and MM, which are the initial target diseases for the development of JS-K.

Market and Commercialization Strategy:
JS-K is at an advanced stage of pre-clinical development. First-on-human clinical trials will follow after completion of IND-enabling studies, advancing the clinical investigation leading to approval and marketing of JS-K. Our initial target diseases for JS-K are AML and MM, both areas of unmet need. The FDA has granted orphan drug designation for JS-K for both diseases. We are seeking collaboration with strategic industry partners and are planning to bring JS-K to market through such a strategic partnership.

Technical & Competitive Advantage:
JS-K is active in animal models of 8 different cancers. Besides its direct cytotoxic effects, JS-K is a potent inhibitor of tumor angiogenesis (vessel growth). It also inhibits the interaction between MM cells and the bone marrow microenvironment. Mechanistically, JS-K impairs the redox state of malignant cells by depleting intracellular glutathione, a critical tripeptide cellular antioxidant. JS-K could sensitize MM cells to the cytotoxic effects of immune effector cells. JS-K was well tolerated without induction of hypotension in a preliminary non-GLP dog toxicology study. There are currently no anti-cancer agents that impair tumor metabolism, inhibit tumor angiogenesis, inhibit tumor-microenvironment interaction, and sensitize malignant cells to immune effector cells by delivering a toxic payload of NO into malignant cells. Consequently, JS-K could constitute a paradigm shift in cancer therapy.

Regulatory Strategy & Intellectual Property:
Composition of matter (#6,610,660), cancer use (#8,404,665), and formulation (#9,005,656) patents were licensed by the NCI and the University of Utah to JSKT. The FDA has granted orphan drug designation for JS-K for the indications of AML and MM. A provisional patent for the combination of JS-K with immune-modulating agents was filed on 2/11/16.

Key Milestones:
Milestones achieved so far: 1) Demonstrated activity in 8 animal models of cancer; 2) Clinically usable formulation developed; 3) Multiple mechanisms of action demonstrated; 4) GMP scale up of drug substance with stability studies conducted; 5) Exclusive licenses and orphan drug designations obtained; 6) Assay to measure JS-K developed; 7) pre-IND meetings with the FDA conducted; 8) JS-K was well tolerated in a non-GLP dog toxicology study.

Completion of GLP animal toxicology	Q3 2017
IND Submission	Q4 2017
Initiate Phase I clinical trial	Q2 2018

Capitalization History:

2008-2009	Convertible note	Kickstart (Utah-based angel fund)	$325,000
2009	Grant	State of Utah	$100,000
2010-2012	Convertible notes	Private investors	$100,000
2010	Grant	Cephalon	$50,000
2010-2014	SBIR Phase I/II Grant	National Cancer Institute	$1,070,380

Use of Proceeds:
Funds needed are $5,500,000 in order to complete IND-enabling studies, write and file the IND, initiate and complete first-in-human clinical trial.

Key Team Members:
Dinesh Patel, Ph.D.: Chairman of the Board of Directors
Inventor, venture capitalist, and serial entrepreneur in the biotech arena who has created value by innovative development strategies.
Sudhir Sahasrabudhe, Ph.D.: CEO
23 years of experience in drug discovery/development in oncology and neurodegeneration; has developed PRLX 93936 for multiple myeloma, currently in Phase 2 clinical trials.
Paul Shami, M.D.: Scientific founder and Chief Medical Officer
Duke-trained hematologist at the Huntsman Cancer Institute with expertise in hematologic malignancies; 25 years of experience in lab-based and clinical cancer drug development.

Keystone Nano / Nano Therapies for Cancer

Jeff Davidson, CEO | jdavidson@keystonenano.com | 814-466-5080 | www.keystonenano.com

Company Overview (Clinical Impact and Value Proposition)

Keystone Nano (KN) is an emerging biopharmaceutical company seeking financing and partners for two distinct nano-platforms for improved cancer treatment. Our lead product, Ceramide NanoLiposome (CNL), is entering Phase I/II clinical testing (partially funded by the NIH) in 3Q-2016 for liver cancer. The company is also seeking partners to accelerate a second platform - the development of our Photo Immuno Nano Therapy (PINT) program for leukemia, and to advance our NanoJacketed RNA delivery technology for treatment of cancer and infectious disease. Investors have an opportunity to help us develop new cancer therapies that originated with Universities, have been carefully built and refined within KN, and are leveraged by grants and corporate partners to generate high value therapies. KN, which has the opportunity to bring 3 product programs into the clinic over the next 3 years, believes it is on the edge of a substantial increase in value as it transitions to a clinical stage biopharma company.

Market and Commercialization Strategy

The target market for KN's two products exceed $100bn worldwide and is growing 7% a year. KN's lead product, CNL, is entering clinical testing for liver cancer in 2016. Data indicates it has substantial potential for expansion to other cancers. KN received the FDA's orphan drug status for Ceramides for liver cancer treatment. KN intends to partner CNL after the Phase I/II trial. KN also has active co-development programs with major pharmas for mRNA and miRNA delivery using our "NanoJackets (NJ)".

Technical & Competitive Advantage

KN's CNL is a PEGylated liposome formulation that has shown efficacy in 12 animal models of cancer including liver cancer (hepatocellular carcinoma or HCC), and has no toxicity as demonstrated in 13 cGLP safety studies. CNL triggers several mechanisms for anti-cancer efficacy in tumor tissue, including regulation of multiple signaling cascades, inhibition of the glycolytic pathway, and disruption of tumor-induced host immunotolerance. Nanojackets are a versatile platform for the delivery of siRNA, mRNA and miRNA beyond the liver. KN's siRNA-NJs have achieved 97% target protein knock-down in mouse models of human breast cancer. KN has developed both passively and actively targeted NJs. KN has active corporate partner programs for RNA-NJs, has successfully encapsulated siRNA, mRNA, and miRNA in NJs, and has demonstrated cell targeting and *in vivo* expression with RNA-NJs.

Regulatory Strategy & Intellectual Property

KN has an extensive patent portfolio comprised of 11 patent families resulting in 14 issued patents and 10 pending applications to date. KN's regulatory strategy for CNL is to proceed through standard Phase I – III clinical testing and partner the drug when efficacy (and commercial value) has been demonstrated, i.e., after the Phase I/II trial ends in late 2017/early 2018.

Key Milestones (Achieved and Planned)

KN has produced cGMP clinical supplies for CNL and established a multi-site clinical collaboration for the CNL clinical trial at the University of Maryland, the University of Virginia and the Medical University of South Carolina. Objectives for the next 2 years are:

Start the CNL Phase I/II clinical trial	6 months
Complete the CNL Phase I/II clinical trial	24 months
Secure a corporate partner for CNL (for Phase III and marketing)	18 – 30 months
Start Phase I/II clinical trial for PINT - Leukemia	18 – 24 months

Capitalization History

No Date	Seed	Angels	$2.1M
No Date	Corporate Partnerships	Sponsored Research	$4.1M
No Date	Grants	Federal & State	$5.1M

Use of Proceeds

KN is seeking $18 million over 2 years, $6 million in Year 1 and $12 million in Year 2. The funds will be used to drive clinical development of its product platforms. The company is also seeking partners to accelerate the development of CNL, PINT program for leukemia, and to advance our siRNA technology for treatment of breast cancer and infectious disease.

Key Team Members

Jeff Davidson, MBA, BS Ch.E.: CEO

Experienced biotech executive; Responsible for start-up & all $12+ million raised for KN, cGMP manufacturing, & initiation of the CNL Phase I/II study.

Mark Kester, PhD: CMO

World renowned ceramide expert; nano technology expert; Director of UVA NanoSTAR program, pharmacologist; Inventor of KN's NanoLiposome. Responsible for invention and development of CNL, PINT, RNA-NJs co-developer.

James Adair, PhD: CSO

World expert on nanoparticles and materials science; Director of PSU Center for NanoMedicine and Materials, Professor of Materials Science, Inventor of KN's NanoJackets. Responsible for invention and development of PINT, RNA-NJs.

NĒRx BioSciences / Targeted Cancer Therapeutics

Katherine Pawelczak, VP of Research | kspawelczak@nerxbiosciences.com | 937-554-4954 | www.nerxbiosciences.com

Company Overview (Clinical Impact and Value Proposition)

Targeted therapies represent the future of cancer treatment and combination therapy remains necessary for treating the most aggressive cancers including lung, pancreatic, and ovarian cancer. Together, these cancers will account for nearly 300,000 new cases and over 200,000 deaths in 2016. The opportunity exists to employ recent scientific advances in our knowledge of the underlying biology behind these cancers to create novel targeted therapeutics to dramatically enhance patient response to therapy and ultimately increase patient survival. NĒRx Biosciences specializes in the discovery and development of biopharmaceutical compounds targeting DNA repair pathways. Focusing on the Nucleotide Excision Repair pathway (NER), our pipeline of targeted molecular therapeutics is unique and is supported by extensive clinical and pre-clinical target validation. It has been estimated that nearly half of all patients receiving treatment for solid tumor cancers will receive a platinum-based therapeutic during the course of their treatment. Platinum-based combination therapy is curative in testicular germ cell tumors with 10 year survival being ~95%. The clinical response to platinum-based therapy is woefully inadequate in ovarian, lung, and pancreatic cancer with 5 year survival rates of 46%, 17% and 7%, respectively. Platinum 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 platinum-based agents through targeted inhibition of DNA repair pathways

Market and Commercialization Strategy

The market for our therapeutic drug is expansive, as our compound is uniquely targeted to impact patients who receive platinum-based therapy. We are focusing our initial clinical efforts on lung, ovarian and pancreatic cancer but recognize the market potential for our compound with other solid tumors that receive platinum-based drugs during the course of their cancer therapy. Marketing targeted specifically at the clinic will occur through interactions with physicians who will be responsible for distributing the drug to patients.

Technical & Competitive Advantage

There are no current therapies that are designed to enhance the activity of platinum-based agents. Current combination therapy is based on differing toxicity profiles and while effective in some cases, is considerably less effective in the majority of lung, ovarian and pancreatic cancers. NĒRx developed agents are novel and directed against previously untargeted proteins and pathways.

Regulatory Strategy & Intellectual Property

Two patents have been issued covering our novel inhibitors and licensed to NĒRx Biosciences and an additional provisional patent has been filed concerning our newest molecular entity for both composition of matter and use as a cancer therapeutic. Two additional invention disclosures have been filed regarding DNA repair targeted agents and will fall under the existing license. To develop a regulatory strategy for advancement of our drugs through the clinic, we have consulted with top medical oncologists specializing in lung and ovarian cancer. Under their counsel we are prepared to begin clinical trials for our DNA repair inhibitors following IND approval.

Key Milestones (Achieved and Planned)

Milestones achieve so far.

Lead compound optimization, scale up synthesis, formulation	Q3/Q4 2016
In-vivo assessment in PDX, companion diagnostic assay	Q2 2017
GMP synthesis, animal pharm/tox, CMC	Q2/3 2017
FDA filing of IND application	Q4 2017

Capitalization History:

07/2016	SBIR Phase I grant	NIH/GM	$293k
06/2015	SBIR Phase I grant	NIH/NCI	$249k
01/2014	Angel Investment	Private	$250k
09/2013	STTR Phase I	NIH/NCI	$229k

Use of Proceeds:

We are seeking a $3.6M Series A round of equity capital from both 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, Ph.D.: Co-founder and CSO

25 years' experience in cancer research and the study of DNA repair and drug development.

Katherine Pawelczak, Ph.D.: VP of Research

10+ years' experience in scientific research and development in academia and industry.

Nick Ball: VP of Finance

30+ years' experience in business development and finance.

NovoMedix / Inhibition of Aberrant Protein Synthesis

Cathy A. Swindlehurst, CEO | cswindlehurst@novomedix.com | www.novomedix.com

Company Overview (Clinical Impact and Value Proposition)

NovoMedix has invented a platform technology for the discovery and development of novel drugs that block aberrant protein synthesis for the treatment of cancer and fibrotic disorders, with an initial focus on Triple Negative Breast Cancer (TNBC). TNBC is a particularly aggressive, high grade malignancy that has higher rates of drug resistance, recurrence, and death than other subtypes. Although these tumors often respond initially to chemotherapy, most recur and are resistant to standard chemotherapy. Our lead drug candidate has demonstrated efficacy in animal models of TNBC and is 18 months away from the clinic. It is part of a series of novel, patented compounds that inhibit eIF4E-dependent synthesis of oncogenic proteins with minimal effect on the synthesis of normal/housekeeping proteins. It is orally available, is well tolerated at 1000 mg/kg in a non-GLP rodent study, is stable for at least one year at room temperature, and has been scaled up to 2.5 kg cGMP. We are raising $1M in seed financing to leverage $5M in non-dilutive funding raised to date and to achieve a significant milestone: completion of the studies needed to conduct a pre-IND meeting with the FDA. This will mitigate any risks associated with the filing of the IND and will move our drug closer to the clinic. NovoMedix will need an additional $3M to complete IND enabling studies and file an IND in 2017 and an additional $5M to complete a Phase I clinical trial. We anticipate raising $3M of this through SBIR funding. Once clinical proof of mechanism is established in the Phase I trial, the anticipated valuation could be in excess of $100M.

Market and Commercialization Strategy

The initial target is relapsed, refractory TNBC with high eIF4E (estimated market=$450M). There is potential for use in first-line therapy for TNBC and other solid tumors with elevated eIF4E and a significant stromal component and in metastasis; as well as fibrosis. NovoMedix intends to fund development through Phase I clinical trials and then partner for Phase II/III clinical trials and commercialization.

Technical & Competitive Advantage

Our platform technology treats of TNBC by a novel mechanism: inhibition of tumor cell growth (including chemotherapy resistant tumor cells) and prevention of the recruitment and activation of stromal cells in the tumor microenvironment. eIF4E is overexpressed 3-30 fold in TNBC regardless of genetic make-up and overexpression correlates with recurrence and death. NovoMedix lead drugs block the eIF4E dependent synthesis of oncogenic proteins needed by the tumor, with little effect on normal proteins; resulting in a large therapeutic window. eIF4E levels will also serve as an important biomarker for patient selection for clinical trials.

Regulatory Strategy & Intellectual Property

Our lead drug candidate and its analogs represent a potential new class of drugs and is covered by an issued composition-of-matter patent (US 20140155477). NovoMedix will design, review with the FDA, and execute an IND-enabling nonclinical safety program to support a Phase 1 clinical trial to be conducted in patients with advanced metastatic disease.

Key Milestones (Achieved and Planned)

Achieved: Clinical candidate selection: efficacy in animal models, PK properties, rodent non-GLP safety (1000 mg/kg), scale-up to 2.5 kg cGMP, GMP stability studies initiated (>one year at room temp), issued patent.

Pre-IND meeting: proof of mechanism, dose range finding studies, cGMP material	Q1 2017
IND	Q42017
Phase I clinical trial	Q12018

Capitalization History

2001 – 2010	Founders investment, contract research revenue		$169k
2007	Phase I SBIR (1 R43 DK077285-01)	NIDDK	$999k
2010-15	Phase I, I & II SBIR (1R43CA144156-01A1, 1R43CA165739, 2R43CA144156)	NCI	$2.6M
2010 - 2011	Qualifying Therapeutic Discovery Project (IRS/HHS)	IRS/HHS	$182k
2015 – 2016	Series A Preferred (open)		$340k
2016	Phase I SBIR (1R43HL131356)	NHL	$300k

Use of Proceeds:

2016: $1M – Pre-IND meeting: proof of mechanism, dose range finding studies in non-rodent, cGMP API. 2017: $3M – IND: GLP studies, human oral formulation, IND submission, corporate partner discussions. 2018-2019: $5M – Phase I clinical trial, corporate partnership.

Key Team Members:

Cathy A. Swindlehurst, Ph.D.: CEO

26 years of experience in biotechnology; Former VP at PanCel, MagneSensors, and NovaDx.

Leah Fung, Ph.D.: VP Drug Discovery

23 years of experience in drug discovery; Management positions at Structural Genomics, Structural Bioinformatics, and Celgene.

Robert Sullivan. Ph.D.: ED Drug Development

23 years of experience in drug development and manufacturing; Management positions at Amylin Pharmaceuticals and Boehringer Ingelheim/BenVenue Laboratories.

Oncoceutics / Targeted Small Molecule Anticancer Compounds

Lee Schalop, CBO | lee.schalop@oncoceutics.com | 917-327-6423 | www.oncoceutics.com

Company Overview

Oncoceutics, Inc. is a clinical-stage drug discovery and development company with a novel class of selective G protein-coupled receptor (GPCR)-targeting compounds for oncology called imipridones. The first lead compound from this program is ONC201, an orally active and blood brain barrier-penetrating small molecule that has anticancer activity in many challenging preclinical models. The company recently completed a successful Phase I study in solid tumors and has begun additional Phase I/II and Phase II clinical programs in solid and hematological malignancies at world-renowned cancer centers including Massachusetts General Hospital, Rutgers Cancer Institute of New Jersey, Fox Chase Cancer Center, and with the University of Texas MD Anderson Cancer Center via a landmark alliance that provides for a sharing of risk and potential commercialization of ONC201. The company is also developing other imipridones that maintain the desirable features of ONC201 but that exhibit distinct spectrums of activity with high potency.

Market and Commercialization Strategy

Based on a variety of factors, including compelling preclinical data and unmet medical need, Oncoceutics is targeting five tumor types in the relapsed/refractory setting as ONC201 lead indications: non-Hodgkin's lymphoma, multiple myeloma, prostate cancer, glioblastoma and acute leukemias, with a focus on patients with relapsed and refractory disease. ONC201 could also be developed for a variety of follow-on indications, based on preclinical efficacy. ONC206 and ONC212 are other imipridones that are being developed towards an IND based on potent activity in preclinical models.

Technical & Competitive Advantage

ONC201 directly and specifically targets a GPCR, called DRD2, that is overexpressed in many cancers and controls pro-survival and stress signaling pathways that are critical in cancer. Target engagement by ONC201 activates the integrated stress response (ISR) and inactivates pro-survival Ras signaling to triggers a strong antiproliferative and pro-apoptotic response in tumor cells without harming normal cells. ONC201's unique method of activating the ISR avoids the proteasome or ER stress altogether and thus has a significant safety advantage over approved proteasome inhibitors. The ability of imipridones to target oncogenic GPCRs with a high degree of selectivity represents a novel therapeutic approach for oncology that results in well-tolerated and effective therapeutics.

Regulatory Strategy & Intellectual Property

The company has four issued patents covering specific tumor types for method of use in cancer, combination with other drugs, and the formulation of the novel salt as well as multiple pending patents for ONC201 and an issued patent as well as multiple pending patents for composition of matter for the analog family. The company's ideal regulatory/approval path is to obtain breakthrough designation for one of the indications in Phase II and enter into pivotal study with a single agent and single arm design in this indication.

Key Milestones

The company has completed the Phase I trial, demonstrating exceptional safety with a therapeutic pharmacokinetic (PK) profile, induction of pharmacodynamic (PD) markers, and early efficacy signals in a number of different types of cancer.

Completion of Phase I trial at CINJ	Mid-2015
Initiation of additional trials and ~100 patients enrolled in five clinical trials	Mid-2016
Significant clinical efficacy data in lymphoma, leukemia and glioblastoma from ongoing trials	End of 2016

Capitalization History

6/2012	Grant	PA Dept. of Health	$1.3M
9/2014	Series Seed	Spring Mountain Capital + Individual Investors	undisclosed
2/2015	Grant	SBIR	$1.6M
10/2015	Series A	Spring Mountain Capital + Individual Investors	undisclosed
08/2016	Grant	FDA Orphan Products Grant	$1.7M

Use of Proceeds

The company is interested in a strategic partnership for co-development of ONC201 toward a registration trial and opening an IND for two additional imipridones.

Key Team Members

Wolfgang Oster, MD, PhD: CEO and Co-Founder

Hematologist/oncologist, an accomplished entrepreneur and industry executive with deep expertise in drug development;

Lee Schalop, MD: CBO and Co-Founder

Successful Wall Street executive and life science venture capitalist with substantial experience in fund raising and trade sales.

Martin Stogniew, PhD: CDO

More than 30 years of executive experience in pharmaceutical industry; 8 NDAs

Shuttle Pharmaceuticals / Radiation Sensitizers for Treating Cancers

Anatoly Dritschilo, CEO | anatoly.dritschilo@shuttlepharma.org | (240)403-4212

Company Overview (Clinical Impact and Value Proposition)

Shuttle Pharmaceuticals is an early clinical stage biotech, incorporated in the State of Maryland in 2012. The Company's primary purpose is to develop and commercialize unique drugs that sensitize cancers to radiation to improve the outcomes of patients receiving radiation therapy. With support from a Small Business Innovation Research (SBIR) contract from the National Cancer Institute (NCI), the company is testing a clinical product (ropidoxuridine) as a sensitizer of actively growing cancer cells in combination with radiation therapy in a phase I clinical trial. The company also has obtained an option to rights to a second product (doranidazole), a sensitizer of hypoxic cancer cells, developed by a Japanese pharmaceutical company for use with intra-operative radiation therapy.

Market and Commercialization Strategy

The company intends to raise capital to perform efficacy trials of ropidoxuridine and doranidazole as radiation sensitizers in combination with conventional radiation therapy and stereotactic body radiation therapy, respectively. Currently, clinicians use chemotherapeutic agents "off-label" in combination with radiation therapy to sensitize cancers to treatment, obtaining improved cancer control that by the use of chemotherapy or radiation therapy alone. There is a clinical need for a non-cytotoxic radiation sensitizer. Shuttle proposes to perform proof-of-principle efficacy clinical trials to advance its products to commercialization.

Technical & Competitive Advantage

Radiation sensitization has been demonstrated to improve clinical outcomes of cancer patients undergoing radiation therapy leading to improved disease control and survival. Since there is no FDA approved drug for the indication of radiation sensitization, shuttle proposes to fill the need for non-cytotoxic radiation sensitizers for use with radiation therapy in cancer care.

Regulatory Strategy & Intellectual Property

Shuttle filed a patent application for method of use of ropidoxuridine in combination with radiation therapy for personalized medicine in 2013. In addition, initial clinical trials of ropidoxuridine and radiation therapy will be performed in disease sites that qualify for "orphan" designation by the FDA to provide Company benefits of a period of exclusive marketing protection and favorable tax treatment of clinical trial expenses. Shuttle has obtained an option to license patents for doranidazole and will also initially target orphan cancer diseases for efficacy evaluation.

Key Milestones (Achieved and Planned)

Phase I clinical trial of ropidoxuridine and RT in GI cancers, currently in progress	Q4 2015 - 2017
Planned Phase Ib/II clinical trial initiation of ropidoxuridine in brain tumors (glioblastoma)	Q4 2017 - 2019
Planned Phase II clinical trial initiation of ropidoxuridine in rectal cancer	Q2 2017 - 2020
Planned Phase I/II clinical trial of doranidazole and SBRT in pancreatic cancers	Q4 2017 - 2020

Capitalization History

01/2013	Angel	Private investor	$1M
09/2014	SBIR contract	NIH/NCI	$1.4M

Use of Proceeds

Shuttle plans to raise $ 32M to support clinical trials of ropidoxuridine with fractionated RT (phase Ib/ for brain tumors, rectal cancers and sarcomas) and a clinical of doranidazole with large fraction SBRT (phase I/II in pancreatic cancer).

Key Team Members

Anatoly Dritschilo, M.D.: CEO

Physician/administrator with experience in radiation oncology, academic medicine and the biotech industry. He has served as Department Chairman, Hospital Medical Director and Cancer Center Director. He was a founding director of Neopharm, Inc. (acquired by Insys, Inc.), and participated in the biotech company development leading to the initial public offering.

Milton Brown, MD, Ph.D.: Chief Scientist for Drug Discovery and Development.

He is Director of the Drug Discovery Center at Georgetown University and is the principal investigator of an NIH/NCI funded Chemical Diversity Center. He brings to Shuttle 15 years of experience in drug discovery and service on government committees, including scientific counselor to the U.S. Secretary of Health.

Mira Jung, Ph.D.: Chief Radiation Biologist

She has more than 20 years in molecular radiation biology research and is an expert in mechanisms of radiation resistance and the roles of HDAC inhibitors in modifying the radiation responses.

SignalRx Pharmaceuticals

SignalRx / Dual Inhibitors for Combination Cancer Therapy

Joseph Garlich, CEO | garlich@signalrx.com | 808-365-4124 | http://www.signalrx.com

Company Overview (Clinical Impact and Value Proposition)
SignalRx focuses on designing and developing new anticancer drugs that inhibit multiple key cancer targets for maximum efficacy with good safety profiles. Its current platform is based on a patented thienopyranone molecular scaffold that potently inhibits PI3 kinase (PI3K) and through the use of in silico molecular design/modeling can be constructed to also inhibit other select targets. The company has proof of concept for several dual inhibition prototype molecules such as PI3K/PARP, PI3K/CDK4-6, and PI3K/BRD4. Of these, the dual PI3K/BRD4 inhibitor, SF2523 is the lead first-in-class candidate for preclinical development as it provides for the first time a dual mechanism to inhibit the activity of MYC by enhancing its degradation (PI3K inhibition) and blocking MYC production via the inhibition of MYC transcription (BRD4 inhibition). The transcription factor, MYC (c-MYC and MYCN) plays a key role in cancer growth, proliferation, and survival; it is overexpressed in a subgroup of most human cancers, leading to resistance to PI-3K and other signaling pathway inhibitors. The technology allows for sophisticated combinations with better safety profile to treat PI-3K/MYC dependent malignancies.

Market and Commercialization Strategy
SignalRx's commercial application focus is driven by the unique ability of SF2523 to maximally disrupt the cancer-driving effects of MYC; its expression is estimated to be elevated or deregulated in up to 70% of human cancers. Company will incorporate three-tiered approach to the commercial application of SF2523 in cancers for which they have experience, including Hepatocellular carcinoma, HPV+ Squamous cell carcinoma of head & neck cancer, and pediatric medulloblastoma/neuroblastoma. Out-licensing planned at phase I.

Technical & Competitive Advantage
SF2523 can maximally disrupt the cancer-driving effects of MYC by inhibiting both PI3K (resulting in MYC degradation) AND BRD4 (blocking transcription of MYC), positioning the candidate to be superior for treating MYC-driven cancers. Data from its Phase I indicates that this single molecule that inhibits both PI3K and BRD4 has less toxicity compared to a traditional PI3K inhibitor+BRD4 inhibitor combination. SF2523 will allow for well tolerated combinations, such as with Sorafenib for HCC, that would likely not be possible using a combination of a separate PI-3K inhibitor with a BRD4 inhibitor.

Regulatory Strategy & Intellectual Property
SignalRx has teamed up with Ventana Medical Systems Inc. to work with SF2523 to develop a companion diagnostic to determine MYC status and PI3K pathway status in patients to find those who might be most responsive to the dual PI3K/BRD4 inhibitor SF2523. The short term strategy is to finish preclinical studies and to file an IND for a phase I ascending dose trial to find the MTD in patients.

Key Milestones (Achieved and Planned)
Over 40 compounds based on the company's patented thienopyranone have been synthesized and tested to produce a lead candidate SF2523. SF2523 inhibits BRD4 with an IC50 of 318 nM and inhibits PI3K isoforms alpha, beta, delta, and gamma with an IC50 of 17 nM, 214 nM, 27 nM, and 232 nM, respectively. SignalRx has demonstrated animal anticancer efficacy and PD target knockdown with SF2523 in multiple mouse models with no toxicity which bodes well for clinical efficacy. SignalRx is now prepared to move SF2523 through further preclinical studies including formal tox studies and then file an IND.

Capitalization History

pre-2012*	Angel/private venture	Indiana angels and boutique VC groups	$25M
pre-2012*	State & Foundation	Indiana State Govt ($2M) & Multiple Myeloma Research Foundation ($1M)	$3M
3/1/2012	Angels/individual	Founders	$200K
7/1/2014	Clinical trial grant	NANT (New Agents in Neuroblastoma Treatments)	$130K
4/8/2015	STTR 1 Yr grant	NCI	$209K

*precursor company Semafore Pharmaceuticals Inc.: SignalRx was formed and acquired all assets of Semafore in 2012

Use of Proceeds
SignalRx is preferably seeking partnerships with pharmaceutical companies to help accelerate clinical entry of its dual inhibitors. Alternatively, looking to immediately raise $3-5M to fund their IND-enabling studies and enter Phase I human clinical trials.

Key Team Members
Donald Durden, MD, PhD: **Founder and Sr. Science Advisor.**
Expert in PTEN/PI3K signaling, tumor/immune compartment cancer biology and small molecule inhibitor discovery, over 17 years of NIH funded pioneering work. Board certified practicing and attending pediatric hematologist-oncologist at UCSD.
Joseph Garlich, PhD: CEO/CSO.
Inventor on 25 US patents; medicinal chemistry expert with 31 years of R&D experience taking 4 new small molecules into first-in-man studies. Previously at Semafore as CSO, CEO and President raising about $30 million.
Guillermo Morales, PhD, MBA: VP & Director of R&D and BD.
21yrs in drug development; inventor on 10 patents; expert in medicinal chemistry, chemoinformatics, and computer-aided drug design; experienced in optimizing & formulating anticancer drug candidates to IND-ready status. Previously at Semafore as Dir. of chemistry

Synactix Pharmaceuticals / RET/VEGFR2 Dual Inhibitor

Dr. Brendan Frett, CEO | bfrett@synactixpharma.com | 800-366-1752 | www.synactixpharma.com

Company Overview (Clinical Impact and Value Proposition)

Synactix Pharmaceuticals, Inc. was established to help decrease the catastrophic burden that cancer has placed on global health. Instead of looking at cancer as a whole, Synactix identifies unique, malignant pathways in cancers that are amenable to therapeutic intervention. Using bioinformatics, interdependent pathways are identified and a single-agent is designed and synthesized to block both pathways at a single therapeutic dose. Resistance is the major limitation for successful treatment of cancers. Synactix has developed an effective strategy to block multiple, malignant pathways thus decreasing the frequency of resistant disease and enhancing treatment response. Synactix is revolutionizing precision medicine through the strategic targeting of multiple-disease pathways with single agents.

Market and Commercialization Strategy

The current technology of Synactix aims at capturing oncology markets for medullary thyroid cancer (MTC) (2,000 patients/year), papillary thyroid cancer (2,000 patients/year), a subset of non-small cell lung cancer (3,000 patients per year), and ER+ hormonal resistant breast cancer (>48,000 patients/year). Together this represents a cumulative potential market of >$7B. To capture these markets, a chemical and testing strategy was initiated to discover Pz-1, a dual inhibitor of the RET and VEGFR2 kinases. The Pz-1 technology represents a new model for targeted therapy demonstrating that the strategic inhibition of multiple disease pathways is well tolerated and highly efficacious compared to mono-targeted or broadly-targeted treatments. Synactix is first pursuing orphan drug status in MTC.

Technical & Competitive Advantage

Pz-1, the Synactix lead candidate, is a readily synthesized small molecule with dual inhibition capacity against both RET and VEGFR2 targets. The current market for RET-targeted therapeutics consists of MTC. Due to high involvement of known RET-driver mutations and therapeutic limitations of current therapies (vandetanib/cabozantinib), the first market targeted by Pz-1 is MTC. Pz-1 has been designed for RET and is the first inhibitor to display activity against all mutant RET variants. Pz-1 will first address the unmet medical need for mutation-resistant therapy and become a preferred treatment for MTC because of improved safety and effectiveness. Since Pz-1 is the first true RET inhibitor, with no significant off target inhibition, additional RET indications will be pursued with an est. $7B market potential.

Regulatory Strategy & Intellectual Property

Synactix Pharmaceuticals has an exclusive license to the Pz-1 technology from the University of Arizona, including an extensive portfolio of international patent applications. The patent application was published in the PTC as WO 2015/187818 A1. Synactix expects to obtain orphan designation for Pz-1 in the US to help accelerate clinical development. Synactix has an agreement with Chongqing University of Arts and Sciences to complete an investigate new drug (IND) package in the United States.

Key Milestones (Achieved and Planned)

Preclinical Identification of Pz-1	2015
Clinical Candidate Selection of Pz-1 & Orphan Designation	2016
Completion of Investigative New Drug Package	Q2 2017
Initiation of Phase I Clinical Trials	Q4 2017
Initiation of Phase II Clinical Trials w/ Breakthrough Designation	2019
Pz-1 Market Approval	2020

Capitalization History

08/2015	STTR Small Business Grant	National Institutes of Health / National Cancer Center	$299,995
03/2016	NIH I-Corps® Program	National Institutes of Health / National Cancer Center	$40,000
2017	SBIR Small Business Grant	National Institutes of Health / National Cancer Center	~$2.0 M

Use of Proceeds

Synactix will need funds to complete Phase I clinical development, and it is expected that Synactix will receive these funds through a Phase II SBIR (small business grant) from the NIH. The next major milestone that requires funding is Phase II clinical development. Synactix is looking to partner with a larger pharmaceutical company or enlist the aid of VC firms to fund Phase II development.

Key Team Members

Brendan Frett, Ph.D.: Founder and CEO

Identified several clinical candidates, which possess novel mechanisms to treat human disease; expertise in business management, accounting, and legal affairs, in combination with his robust medicinal chemistry background

Hong-yu Li, Ph.D.: Founder and President.

10+ years of experience at Eli Lilly & Co. as a senior organic chemist, research scientist, and senior research scientist; currently Professor of Medicinal Chemistry at the University of Arkansas for Medical Sciences.

Thomas Goodman, PhD, MBA, Head of Business Development.

Experience in biotechnology project management, business development and investing and is assisting with project planning, business development, and strategic partnerships.

CatAssays / New ELISA Chemical Signal Amplification

Henry Gysling, Managing Partner | hgysling@rochester.rr.com | (585) 507-8157 | www.catassays.com

Company Overview (Clinical Impact and Value Proposition)

CatAssays' current focus is the application of its patented generic technology to provide a significant sensitivity increase in the sandwich ELISA format widely used in medical diagnostic laboratories worldwide. The *UltraPalladium™* platform addresses the critical need of the medical community for increased test sensitivity for detection of disease biomarkers in blood serum and other body fluids, while retaining the high selectivity of the well-established sandwich ELISA protocol by using a unique new palladium catalyst and novel high-gain chemical amplification reaction. Our *UltraPalladium* technology is a cost-effective "drop-in" modification of the standard enzyme-based ELISA protocol that, by simple replacement of 3 chemicals of the catalyst/dye signal amplification part of the assay provides ca. a 100-fold sensitivity increase – all without any new equipment or staff training for easy laboratory implementation. This sensitivity breakthrough, which translates to earlier diagnosis and treatment of catastrophic diseases and increased patient survival rates, is achieved while maintaining the format of the standard sandwich ELISA protocol.

Market and Commercialization Strategy

Our marketing will focus on demonstrated ca.100-fold sensitivity increase vs standard ELISA using our proprietary dye signal amplification system while otherwise retaining the ELISA protocol. CatAssays' first *UltraPalladium* product will be an ELISA kit for the early detection of ovarian , and the kit will include a panel of 3 antibodies for quantification of 3 ovarian cancer biomarkers and provide tests for 96 patients. The inclusion of 2 new biomarkers, in addition to the currently used CA125, will provide a significant decrease in false test positives, as well as allow the diagnosis of the early stages of this disease. Current CA-125 ELISA kits can only diagnose advanced stages of ovarian cancer.

Technical & Competitive Advantage

CatAssays' *UltraPalladium* technology provides ca. a 100-fold sensitivity increase in ELISA format tests by simply replacing the standard enzyme catalyst and dye forming chemistry with our proprietary palladium catalyst and dye forming redox amplification system.

Regulatory Strategy & Intellectual Property

U.S. 7,820,394 (2010): Mark Lelental and Henry J. Gysling, Ultrasensitive Bioanalytical Assay Based on the Use of High-Gain Catalytic Chemical Amplification (PROCESS PATENT)

U.S. Patent Application 2015/0050672 A1 (Feb. 19, 2015): Mark Lelental and Henry J. Gysling, Catalytic Marking Nanoparticles for Ultrasensitive Bioassay Applications (COMPOSITION OF MATTER PATENT)

Key Milestones (Achieved and Planned)

1. Demonstrated 80-fold sensitivity increase in test for tPSA vs standard ELISA (GEN 1 – Pd catalyst incorporated in detection antibody)
2. Designed, synthesized and successfully tested GEN 2 material – a universal ELISA labeling reagent comprising polymeric nanoparticles loaded with palladium and surface functionalized with streptavidin for binding to any biotinylated detection antibody

Optimize our universal labeling reagent to provide 200-fold sensitivity increase vs standard ELISA for target biomarkers	Q1 2017
SBIR Phase 2 submission	Q3 2017
Develop testing protocol for FDA approval	Q4 2117

Capitalization History

9/2015	Phase 1 SBIR	NCI	$225K
2008-14	Funding for initial technology development & IP costs were provided by co-founders		

Use of Proceeds:

Funds ($2M) will be used for 4 areas: 1. material optimization of universal ELISA labeling regent ; 2. ELISA format testing focused on medically significant cancer biomarkers where need for increased sensitivity has been identified ; 3. testing for FDA approval ; 4. setting up manufacturing/packaging facility (2 materials will be made in-house: 1) universal labeling reagent and 2) tetrazolium salt used in dye amplification system ; all other materials will be sourced from external vendors for packaging in ELISA kits at CatAssays' plant)

Key Team Members:

Mark Lelental, M.S.: Co-founder & Managing Partner

30 years experience in material science, catalysis and chemical amplification processes for imaging and patterning application at Kodak Research Labs, from basic research through scale-up and product commercialization (resulting in 50 US patents and 55 journal publications)

Henry Gysling, Ph.D.: Co-founder & Managing Partner

33 years experience in materials design, synthesis and characterization, catalysis and chemical amplification processes for imaging and patterning application at Kodak Research Labs, from basic research through scale-up and product commercialization (resulting in 48 US patents and 60 journal publications). Technology Director at company developing emission control products for diesel engines (5 years - AirFlow Catalyst Systems ; expertise centered on heterogeneous catalysis and coating technologies).

Inanovate / Breast Cancer Recurrence Detection

David Ure, CEO | dure@inanovate.com | 617-610-1712 | www.inanovate.com

Company Overview (Clinical Impact and Value Proposition)

Inanovate has developed a patented blood analysis system (called the Bio-ID) that improves the cost, accessibility and accuracy of diagnostic tests. The first application of the Bio-ID is a new blood test to detect breast cancer recurrence when it can still be cured. Studies have shown that early detection of recurrence can improve survival rates by up to 50%. We are addressing this need. A 400 patient trial has already been completed with our clinical partners Sanford Health, and has shown our test can correctly identify over 8 in 10 cases of breast cancer, with only 3 in 10 false positives.

Market and Commercialization Strategy

The total market available to a test for breast cancer recurrence includes all women who have received treatment for primary breast cancer. Taking an average figure of 240,000 breast cancer cases per year in the US, alongside a test price (charged by the testing laboratories) of $150, and a test frequency of twice per year in the first 5 years, followed by once per year from years 5 to 10, this delivers an aggregate monetary market size for the recurrence test in the US alone of $540million. Extrapolating worldwide provides a market potential in excess of $1.2Billion annually. Even an adoption rate of just one third of this, e.g. an average of 1 test per breast cancer patient through the first 5years following treatment, would generate $175million in annual revenues in the US and over $435million worldwide. Inanovate's commercialization strategy is to focus on the production and sale of the Bio-ID's disposable test cartridges (the 'razor blades' of the biomarker testing industry). Accordingly, once the breast cancer monitoring test has been advanced through prospective trials and launch as a LDT (Laboratory Developed Test) within the Sanford Health Network, Inanovate will partner with a large diagnostic company to advance full commercial launch (national and international) of the test in 'kit' form.

Technical & Competitive Advantage

There are two areas of competitive advantage:

1. The breast cancer biomarkers: These are a patent protected set of markers that differentiate breast cancer from healthy samples to a Sensitivity of 83% at a Specificity of 70%, and hold significant potential to revolutionize breast cancer recurrence monitoring by enabling a cost effective blood test that can screen for and identify recurrence at a stage when it may still be cured.
2. The Bio-ID platform: The Bio-ID is a patent protected biomarker analysis platform that uniquely enables users to accurately measure the concentration of a near unlimited range of biomarkers in one low-cost test. It's advantages in accuracy, range, sample use and cost are essential to ensuring the proposed breast cancer test can be successfully implemented in clinical practice.

Regulatory Strategy & Intellectual Property

Inanovate has built a comprehensive IP portfolio covering the Bio-ID platform. The portfolio includes 8 issued and pending patents covering the novel biomarker analysis methodology that lies at the heart of the Bio-ID platform, called Longitudinal Assay Screening (or LAS); as well as design and method patents covering the detector/analyzer, the disposable cartridge, analysis techniques and the breast cancer biomarkers. The breast cancer biomarker patent is owned by Sanford Health. Sanford are licensing this patent to Inanovate as part of our ongoing partnership. All other patents are owned directly and exclusively by Inanovate.

Key Milestones (Achieved and Planned)

To date: 1) Completed development and demonstration of Bio-ID multiplexing platform. 2) Completed 400 patient trial on initial application (breast cancer recurrence monitoring). 3) Secured key clinical & commercial partnerships. 4) Secured key patent protection.

Complete extended trial across 1,000 patients	Q2 2017
Establish Standard Operating Procedures (SOP's) for use in prospective phase of trials	Q2 2017
Optimize biomarker set and single sample predictive model for prospective trials	Q2 2017
Transition Bio-ID production to GMP compliant contract manufacturer	Q2 2017

Capitalization History:

2011-15	Series A	Various private investors	$2M
2015-16	Series B	Various private investors	$2.5M

Use of Proceeds:

$4million being raised to complete the above listed milestones and move forward with prospective trials through to launch of the test in LDT format in second half of 2018.

Key Team Members:

David Ure: CEO

15 years of experience in executive management within the Life Science industry.

Dr. M. Kostura: CSO

25 years of experience in developing technologies for biotech & pharmaceutical markets.

Dr. J. Nelson, CTO

Over 16 years of experience in developing biomolecule screening technologies.

Glycosensors & Diagnostics / Glycan ID/Analysis Platform

Kausar N. Samli, CEO | ksamli@glycosensors.com | 512-751-6371 | www.glycosensors.com

Company Overview (Clinical Impact and Value Proposition)

Glycosensors & Diagnostics, LLC (G&D) is commercializing the Lectenz® and GlycoSense™ platforms for high-throughput and cost-effective glycan identification and analysis. G&D's platform technologies will reduce the time and costs associated with FDA and EMA requirements for glycoprofile characterization of biologics and biosimilars. The Lectenz® platform engineers reagents with unique specificity and affinity for glycan targets. G&D is translating its Lectenz® technology into an easy-to-use platform called GlycoSense™. This innovative approach is capable of near real-time glycoprofiling by combining multiplex suspension array technology with glycan-specific reagents. The entire analysis can be obtained in less than a minute on a basic flow cytometer. The technologies address unmet needs in biomarker detection, and bioprocess development and biomanufacturing of biologics and biosimilars.

Market and Commercialization Strategy

G&D has grown through funded R&D and is pursuing commercialization through a blend of product sales, contracted services, licensing, and strategic partnerships. Lectenz® kits for glycomics analysis will be made available to customers. Service for engineered Lectenz® reagents and customized GlycoSense™ kits is available for custom applications. Joint ventures through strategic partnerships that employ G&D's technologies in the development of custom products are being pursued. G&D is currently working with two biopharma companies (MTAs compelted). Sales/licensing/royalty revenue is anticipated from strategic partnerships.

Technical & Competitive Advantage

The Lectenz® platform technology enables the development of glycan-recognizing reagents engineered from glycan-processing enzymes by employing computationally-guided directed evolution. These enzyme-derived Lectenz® reagents are engineered to be catalytically inactive, and have high affinity and specificity for the originating enzyme's natural glycan substrate. Engineered Lectenz® reagents offer a competitive alternative to lectins and antibodies, which are known to display cross-reactivity towards similar carbohydrate structures. The GlycoSense™ platform offers a robust, cost-effective, and easy-to-use platform for the rapid analysis of glycan structures.

Regulatory Strategy & Intellectual Property

International (US, Canada, Europe, Japan, & Israel) patent applications on Lectenz® and GlycoSense™ platforms are pending.

Key Milestones (Achieved and Planned)

1. GlycoSense™ bioprocess monitoring (Beta) kits: near real-time qualitative glycan analysis of biologics during biomanufacturing.
2. N-glycan Lectenz® (Beta): detection & enrichment of N-glycoproteins relevant for the manufacturing of biologics such as mAbs.
3. O-GlcNAc Lectenz® (Beta): detection & downstream analysis of the O-GlcNAc marker for diseases states including cancer.
4. Sialic Acid Lectenz® (Alpha): detection of terminal sialic acid for manufacturing of biologics & analysis of PSA and influenza markers.

University In-Licensing	2016 Q4
Beta Product Validation (MVP)	2017 Q1
Strategic Partnership	2017 Q3
Product Launch	2017 Q4

Capitalization History:

1/2015	STTR grant phase I	NIH/NIGMS	$700K
9/2011, 9/2013	SBIR contract phase I, II	NIH/NCI	$150K, $1M
8/2009, 9/2013	STTR grant phase I, II	NIH/NIGMS	$200K, $1.7M
9/2012	SBIR grant phase I	NIH/NIGMS	$100K
5/2012	Grant	IAVI/Glycomimetics, Inc.	$250K
10/2010	QTDP grant	IRS	$118K
3/08, 12/09, 8/10	Seed grant	GRA Ventures	$15K, $25K, $25K

Use of Proceeds:

Strategic investment will allow G&D to expand its patent portfolio and product offerings, secure licenses to additional technologies that would strengthen and expand G&D's freedom to operate, scale product production, build sales and marketing teams, customer supports teams, and recruit domain experts with complementary expertise to expand the company's management team.

Key Team Members:

Kausar N. Samli, Ph.D.: CEO & Associate Founder

Technology commercialization, strategy, partnerships, investor relations.

Lori Yang, Ph.D.: CSO & Co-Founder

Technological development, corporate partnerships, non-dilutive funding.

Robert J. Woods, Ph.D.: President & Co-Founder

Professor of Biochemistry at the University of Georgia – Productization, commercialization strategy, research direction.

JBS Science / cfDNA Test for Cancer Screening

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

Company Overview (Clinical Impact and Value Proposition)

JBS Science Inc. is a discovery and development phase cancer diagnostic company focused on the delivery of urine based DNA tests for cancer screening and liquid biopsy for cancer precision medicine to improve disease management. Our team includes experts in biomarker research, clinical oncology, and the diagnostics industry, to develop highly desired diagnostic/screening tools. Our innovative technologies set out to change the way medicine is practiced by detecting primary and recurrent cancers and providing cancer genetics for precision medicine. The company's mission is to improve early detection of cancer and cancer management by providing diagnostic tools with precision detection of the most promising cell-free DNA (cfDNA) modifications in urine and blood that are derived and associated with prospective cancers, to improve the prognosis of the disease.

Market and Commercialization Strategy

The market for JBS HCC DNA test is the in-vitro diagnostic market. The target population would be high-risk individuals including individuals that have HBV and HCV infections (500 million people worldwide and 2 million in the USA) to screen every 6 months and every 3 months for monitoring HCC recurrence. Within the next 18 months, JBS Science plans to obtain CLIA certification. Patient samples will be sent to the JBS Science laboratory (once CLIA certified) in Doylestown, PA. After analysis, a report will be sent to the ordering physician. JBS Science will market the test to hepatologists. Peer reviewed publications, presentations at medical meetings and reaching out to professional societies will be the highlights of our marketing strategy. Price for the test is expected to be approximately $500, which is the current reimbursement for a similar DNA cancer screening assay. JBS Science will ultimately file for FDA approval. For Asia, the major market of liver cancer screening, we plan to start a clinical trial in China for HCC screening for CFDA approval in 2017 and for other countries after.

Technical & Competitive Advantage

JBS urine DNA test is to replace the AFP and ultrasound (US) test as a screening test. Currently, AFP test and US are the standard screening methods, but miss ~50% HCC, whereas CT and MRI are primarily for diagnosis, not used for screening due to the expensive cost of the test. JBS HCC test is a DNA test that can detect almost 90% HCC at 90% specificity. The cost effective nature of the JBS HCC test as compared to MRI/CT incentivizes government or private healthcare insurance providers to utilize this HCC screening test to minimize potential costs in HCC treatment.

Regulatory Strategy & Intellectual Property

The HCC test, JBS first cancer screening test, will be commercialized in US as CLIA-certified LDT for HCC screening of at-risk population, with proper CPT codes for reimbursement. To commercialize JBS HCC test in Asia, we will apply for China CFDA approval and for other countries after. **IP:** 1. Detection of a panel of urine DNA markers for HCC screening and disease management (Non-provisional US#14079649, some claims allowed, still working on rest claims); 2. Detection of hepatitis B virus (HBV) DNA and methylated HBV DNA in urine of patients with HBV-associated hepatocellular carcinoma (US Non-provisional #62012618 (pending), PCT filed on 6/16/2016); 3. Detection of CRC-associated circulation-derived DNA markers for early detection of colon cancer (provisional #62309999); 4. Quantitative measurement of hepatitis B virus cccDNA assay (provisional #62295481); 5. Method for HCC screening using a panel of urine DNA markers (provisional #62325457); 6. Method and kit for detecting and characterizing HCC (provisional #62341734).

Key Milestones (Achieved and Planned)

Milestones for SBIR Phase II, achieved for obtaining a HCC screening test for 90% sensitivity at 90% specificity	May, 2016
Achieving at least 80% sensitivity at 80% specificity for HCC screening in a blinded validation study	December, 2016
To obtain/ identify a CPT code for a panel of a 5 cfDNA assays as JBS HCC screening test	March, 2017
To obtain CLIA certification for five JBS cfDNA assays	December, 2017

Capitalization History:

2012-2016	SBIR phase I and II	NIH	3.3 million

Use of Proceeds:

JBS needs funds to commercialize JBS HCC urine test. This include to complete the SOP and high throughput of the test in year 2016-2017 to prepare for CLIA certification and to launch to the market first for research purposes and to clinic by simultaneously initiating clinical trial in Asia (2017-2018) for CFDA, and data analysis for 600 blinded study for CLIA-certified test with CPT codes.

Key Team Members:

Wei Song, M.D., Ph.D.: CEO and the Director of The Board

Board-certified hematologist and medical oncologist, trained at The Temple/Fox Chase Cancer Center program focusing on liver cancer.

Ying-Hsiu Su, Ph.D.: COO

Pioneer in trans-renal DNA technology for cancer detection, recently joined the team to take the technology to clinic.

Kathleen Czupich, M.B.A.: Director of Business Development and Management (part-time)

Over 20 years experience with companies ranging from early startups to multinational corporations.

KIYATEC / 3D Cell-based Cancer Diagnostic

Matt Gevaert, CEO | matt.gevaert@kiyatec.com | (864) 502-2013 | www.kiyatec.com

Company Overview (Clinical Impact and Value Proposition)

Correctly predicting the effectiveness of cancer drugs before their use in people has enormous implications for each cancer patient, for clinicians and medical payers, for the pharmaceutical industry, and for our society as a whole. Yet despite the high importance of accurate drug response profiling before use in humans, current methods (2D cell culture and animal models) are poorly predictive and there is a tremendous opportunity to address this. **KIYATEC has created the technology platform and business strategy to make accurate drug response profiling a reality.** By engineering 3D microenvironments, the biologically relevant interaction of multiple cell types, perfusion and higher functioning cells as needed into its cell cultures, KIYATEC maximizes its prediction of patient drug response and has kept this as a priority while increasing the scalability and throughput of its systems. Bolstered by ~$4M of National Cancer Institute funding, revenue generating service contracts with top pharma and tech companies, and exciting early correlations between drug response predictions and patient data, the company is deploying its drug response profiling technology into preclinical cancer drug screening contract research services and clinical cancer diagnostics.

Market and Commercialization Strategy

KIYATEC's preclinical contract research services (a $275M segmented market) are already commercialized and generate revenue; clients include several top 15 pharma and biotech companies. KIYATEC's clinical cancer diagnostics pipeline is led by an ovarian cancer offering currently being demonstrated in a pilot clinical study; breast cancer, GBM, and lung cancer diagnostics are in various earlier stages of development. These offerings address a $6B segmented market for predictive cancer diagnostics.

Technical & Competitive Advantage

- Combined use of a 3D cell culture microenvironment, multiple types of primary cells (i.e. co-culture) and when advantageous perfusion drive superior predictive accuracy of KIYATEC's clinical data and correlations to patient response outcomes
- KIYATEC's exceptional clinical integration translates materially to a competitive advantage. No other competitors are co-located with a cancer institute in a very large hospital, enabling direct access to patient tissue and superior knowledge of the complex environment products are developed for. This is further bolstered by a 60% employment commitment practicing oncologist Chief Medical Officer and a Scientific Advisory Board including the past president of the AACR and an oncology KOL from MD Anderson.

Regulatory Strategy & Intellectual Property

Aspects of our offerings are protected by issued and pending patents, including US Patent No. 8,865,460 featuring both product and method claims. Our clinical diagnostics will be ultimately offered through tests regulated by a traditional FDA pathway (PMA) complemented by opportunistic early deployment through an LDT backed by strong demonstration of clinical utility.

Key Milestones (Achieved and Planned)

Became revenue stage with private sector preclinical pharma contracts and key patent issued	2014
Awarded first $1M+ contract (NCI SBIR Phase II)	2014
Awarded second $1M+ contract (NCI SBIR Phase II that is independent from first)	2015
Clinical collaboration with Mayo Clinic using KIYATEC's ovarian cancer offering	2016
First regulatory approval / regulated offering (ovarian cancer)	Q1 2017

Capitalization History:

2012–14	Series A round	Institutional VC, Syndicated and Individual Angels, State Econ. Dev.	$2.4M
2014–16	Non-dilutive major contracts	National Cancer Institute (NCI) of the NIH	$3.7M
2015–16	Series B round (if full subscr.)	Institutional VC, Syndicated and Individual Angels, State Econ. Dev.	$4.9M

Use of Proceeds:

Currently open B round: finish pilot clinical study, LDT approval, IDE regulatory submissions for pivotal, pivotal study planning and prep
Future C round (2017): execute 300-500 patient pivotal clinical study, scaled capacity, regulatory / reimbursement submissions

Key Team Members

Matt Gevaert, Ph.D.: CEO

As CEO, has grown company to $1M+ revenue. Former IP commercialization / technology start-up experience and R&D experience with Merck, 3M and Dow Chemical.

Hal Crosswell, M.D.: Chief Medical Officer

Practicing hematologist/oncologist following 3-year fellowship in hematology/oncology and molecular oncology. Lead investigator for 40+ industry and NCI-sponsored clinical research studies.

Robert Silverman, M.B.A.: Chairman of the Board

Diagnostics industry veteran whose last company was acquired by Roche for $270M. Board leadership and connectivity spanning the medical industry and venture capital.

Nortis / Organ-on-Chip

Thomas Neumann, CEO| neumann@nortisbio.com | 206-245-4193 | www.nortisbio.com

Company Overview (Clinical Impact and Value Proposition)

Nortis is a leading company in the rapidly emerging organ-on-chip field. Segments of human organs, grown inside small microfluidic chips, are becoming powerful alternatives to the use of laboratory animals in the pharmaceutical industry, academic research, and many other areas. Animal testing is expensive and often produces results that fail to predict outcomes in humans. Ultimately, more than 90% of all drugs that pass animal testing eventually fail in human subjects and never make it to the clinic. Nortis' revolutionary technology serves as a novel platform for modeling of drug efficacy and drug-induced toxicity prior to clinical trials, making drug development more efficient.

Market and Commercialization Strategy

Nortis' business model focuses on two main market segments: (1) hardware sales and (2) providing drug-testing services for the pharmaceutical industry. Hardware sales comprise the disposable microfluidic chips as well as perfusion systems that provide the chips with controlled flow of nutrient solutions and test compounds. The commercial launch of Nortis' hardware was in August 2015. Customers are from the pharmaceutical industry and academic institutions. Fee-based testing of drug candidates for several global pharmaceutical companies is scheduled to begin in the fourth quarter of 2016.

Technical & Competitive Advantage

Recent third party market analyses have identified Nortis as one of the leading vendors in the organ-on-chip market. In addition to our early market presence (Nortis has been selling prototype microfluidic chips since 2012), Nortis has advantages such as a robust intellectual property barrier, proven entrepreneurial expertise, a carefully selected team of top-notch engineers and scientists, and strong partnerships with world-class researchers in academia and industry.

Regulatory Strategy & Intellectual Property

From its inception, Nortis has developed a strong national and international patent portfolio. The company has four issued U.S. patents and 14 international patents. Six national and 32 international patents are currently pending. Nortis is the sole owner of its Intellectual Property. Besides patents and trademarks, trade secrets play a significant role in protecting Nortis' products from copying and reverse engineering. Importantly, the terms of sales for Nortis' products provide options to commercialize organ models or assays developed by the customer using our technology. This allows Nortis to tap into the creativity and scientific expertise of the research community.

Key Milestones (Achieved and Planned)

Establish footprint in the organ-on-chip field: start of operations; sales of prototypes to key opinion leaders	Q1 2012
First partnership with a leading pharmaceutical company	Q1 2015
Establish footprint in the commercial market: launch of first commercial product line	Q3 2016
Start in-house drug testing services for pharmaceutical industry	Q4 2016
Introduction of next generation of commercial product	Q3 2017

Capitalization History

Before 2012	Common stock	Angel Investors	$198,000
2012	Common stock	Angel Investors	$320,000
2013	Common stock	Angel Investors	$777,250
2014	Common stock	Angel Investors	$2,175,000
2015	Common stock	Angel Investors	$3,400,000

Use of Proceeds

Nortis is seeking $10 million in Series A funding. The investment will be used to fund operational growth ($6.4 million), to purchase capital equipment ($2,7 million), and for working capital ($900,000).

Key Team Members

Thomas Neumann, M.D.: Founder, President and CEO

Dr. Neumann's expertise in the tissue-engineering field spans over two decades. He has laid the foundation for Nortis' patented microfluidic technology.

Alan Nelson, Ph.D.: Chairman

Successful serial entrepreneur in the biomedical field; former CEO of Neopath, current CEO of VisionGate

Ken Fisher: VP of Operations

Significant experience in high tech engineering/manufacturing industry; 13 years in medical device startups.

Vitatex / Proprietary iCTC Enrichment Technology

Wen-Tien Chen, President & CSO | wentien@vitatex.com | 631-706-4689 | www.vitatex.com

Company Overview (Clinical Impact and Value Proposition)

Vitatex Inc., a biotech company, is the global provider of proprietary invasive circulating tumor cells (iCTCs) enrichment technology and products to develop revolutionary cancer genetic and cellular blood tests, also called liquid biopsies. Liquid biopsies with a focus on next generation sequencing (NGS) detection and flow cytometry have recently been adopted by the clinical lab community to characterize cancer cells and/or their DNA in blood samples non-invasively and serially, and to acquire genetic mutations and drug resistance information, which have the potential to replace tests run on surgical biopsies. Liquid biopsies have become the main driver of personalized medicine diagnostics – by far the fastest growing segment of cancer diagnostics with a $20 billion market ready to explode. Vitatex Inc. developed a pipeline of research products, including Vita-Cap™ tubes and Vita-Assay™ culture plates, to enrich iCTCs in patients' blood. These disposable devices are compatible with standard Vacutainer® blood collection devices and can recover a higher percentage of cancer cells as compared to competing CTC enrichment methods. Our products facilitate not only automated flow cytometry counting of iCTCs with the superior sensitivity and specificity in patients with breast, ovarian, prostate, colon, lung, pancreatic, and GI cancers, but also molecular analyses of cancer using gene expression profiling, qRT-PCR and NGS.

Market and Commercialization Strategy

Vitatex Inc. produces proprietary Vita-Cap™ and Vita-Assay™ cell preparation products to enrich *i*CTCs, and anti-metastasis monoclonal antibodies to identify *i*CTCs. Our products fill a unique market niche in developing various liquid biopsy assays. Vitatex plans to commercialize its products by: (1) partnering with companies with molecular diagnostic capability to develop liquid biopsy assays, (2) selling directly research and diagnostics-manufacture products, and (3) develop our own liquid biopsy flow cytometric assay.

Technical & Competitive Advantage

Vita-Cap™ and Vita-Assay™ products for CTC enrichment are not biased to particular capture antibody biomarkers or physical properties of the tumor cell and can isolates more tumor cells by capturing CTCs of different sizes and phenotypes. Vitatex's CTC enrichment products can also isolate viable and invasive tumor cells from blood with a manufacture workflow enabling development of automated flow cytometry CTC detection and liquid biopsy genomic assays using NGS and qRT-PCR. Additionally, our products facilitate culture of metastasis-initiating tumor cells in blood for development of *ex vivo* drug sensitivity testing and animal *in vivo* drug selection models.

Regulatory Strategy & Intellectual Property

The majority of the IP (7 patents and 25 applications) associated with (1) Vitatex's CTC enrichment platform and (2) biomarkers for detection of CTCs are exclusively licensed from the State University of New York at Stony Brook, which allow us to bring to bear the IP enforcement resources of the SUNY network. In addition, Vitatex has expedited entry of our *i*CTC assays into clinical trials and will obtain subsequent FDA clearance of our *i*CTC products that will ultimately protect our IP to full commercialization.

Key Milestones (Achieved and Planned)

Initial meeting with FDA for clearance process for Vita-Cap™ and Vita-Assay™ products	Q4 2016
Develop cGMP capability of 300 units of Vita-Cap™ and Vita-Assay™ products each per lot	Q2 2017
Engage 2 partners with NGS or qRT-PCR CTC detection expertise / 1 partner to enter Asian market	Q4 2017
Increase cGMP production from 300 units to 1,200 units per lot	Q4 2018

Capitalization History:

3/2008	NCI STTR Grant	NCI R42CA108247	$2.3M
8/2013	Angel	VAngels Partnership	$850k
4/2014	Investment	Stony Brook University	$963,502
7/2014	NCI SBIR Grant	NCI R44CA140047	$2.3M
12/2015	Angel	ZhengHe International Inc.	$388,888
6/2018	NCI SBIR Contract	HHSN261201500011C	$2.2M

Use of Proceeds:

Vitatex is seeking an investor funding to bring Vita-Cap™ and Vita-Assay™ products to cGMP standard in order to promote product sale, initiate FDA process, and strengthen the PCR and NGS collaboration with strategic partners.

Key Team Members:

Qiang Zhao, M.D.: Director of Medical Research
Huan Dong, Ph.D.: Director of Product Research
Shaun Tulley, Ph.D.: Director of Quality Management

Accelerated Medical Diagnostics / Predictive Cancer Diagnostics

Paul Henderson, CEO | paul@acceleratedmeddiagnostics.com| 925-570-1615 | www.acceleratedmeddiagnostics.com

Company Overview (Clinical Impact and Value Proposition)

AMD will enable personalized chemotherapy for cancer patients using PlatinDx, a test for predicting the efficacy of commonly used platinum drugs. 300,000 patients per year in the US are treated with platinum-based chemotherapy, but less than half respond, resulting in over $2.5B wasted on needless toxic treatments. There are no clinically accepted tests for predicting response to these drugs. With PlatinDx, cancer patients are given 1% of the therapeutic dose (a microdose) of a platinum-based drug, followed by quantitation of drug-DNA adducts in biopsy tissue using accelerator mass spectrometry (AMS). This platform technology enables detection of drug-DNA damage as a predictive marker prior to initiation of full-dose chemotherapy.

Market and Commercialization Strategy

Our first test is for bladder cancer, and has a US addressable market of $110M (~$400M globally). As the platform expands to other cancer and other chemotherapy drugs, the total addressable market rises to $3-5B. Key opinion leaders participating in our clinical trials will publish the clinical validation results and are expected to be early adopters upon launch. Health economic studies will be performed to justify reimbursement. We will sell drug microdoses and assay kits to hospitals/clinics, and establish a reference laboratory for sample analysis. As regulated approved tests, we plan to license individual tests to large diagnostics companies.

Technical & Competitive Advantage

PlatinDx measures individual tumor susceptibility to specific drugs without toxic side effects. Tumor genotype information or culturing of tumor cells is not required. Other tests rely on quantitation of a single of a few gene mutations or expression levels, which are inadequate for prediction of platinum-based drug efficacy. Regulatory approval of our tests will lower barriers to reimbursement.

Regulatory Strategy & Intellectual Property

PlatinDx is a drug/device combination product requiring regulatory approval. We are pursuing a device approval pathway (PMA). There will be an additional need for CLIA certification of our analytical facility to permit laboratory testing of human specimens. AMD filed a PCT application on July 7, 2016, covering several tests under development. Drug formulations, the specific methods used in the analysis, and the databases generated through clinical trials for specific cancers that are used to calculate the response probability are being claimed.

Key Milestones (Achieved and Planned)

- Obtained FDA and IRB approvals for two pilot/feasibility clinical trials (one with carboplatin and the other with oxaliplatin)
- Manufactured and released for human use, sterile, pyrogen free microdose formulations of ^{14}C-carboplatin and ^{14}C-oxaliplatin
- Microdosed and obtained preliminary safety and feasibility data from >20 patients

Planned milestones (only listed for the Phase II SBIR funded bladder cancer test program):

Generate report of feasibility study results, which will support Series A fund raising	Q4 2016
Design pivotal trial and submit plan to the FDA, initiate trial	Q2 2017
Finalize manufacturing supply chain and generate CMC section data for FDA submission	Q1 2019
Finalize clinical study, submit regulatory package to the FDA	Q1 2019

Capitalization History

2011	Contract	Phase I NIH/NCI SBIR (Bladder test with carboplatin)	200,000
2012	Award	NSF Partnership for Innovation Commercialization Plan Award	30,000
2012	Contract	Phase II NIH/NCI SBIR (Bladder test with carboplatin)	1,500,000
2012	Contract	Phase I NIH/NCI SBIR (Colorectal cancer with oxaliplatin)	200,000
2014	Contract	Private research contract with Truckee Applied Genomics LLC	60,000
2014	Private Equity Investment	Individual Investor	60,000
2015	Grant	EU Horizon 2020 Phase I Grant	50,000 Euros

Use of Proceeds

We project a need of $5M Series A, $6M Series B and $4.5M in NIH funds to establish a manufacturing supply chain, complete a pivotal trial and apply for regulatory approval while maintaining an R&D program to develop a pipeline of products based on our platform technology.

Key Team Members

Paul T. Henderson, Ph.D.: CEO & Co-Founder

Assistant Professor at UC Davis Medical Center, has >15 years of experience in research focused accelerator mass spectrometry.

Chong-Xian Pan, M.D., Ph.D.: Co-Founder

Assistant Professor at UC Davis Medical Center, is a clinical oncologist and the principle investigator of the first PlatinDx clinical trials.

George D. Cimino, Ph.D.: VP of Development

30 years of experience in the area of regulated drug/medical device combination product development.

Corvida Medical / Safer Closed System Drug Transfer Device

John Slump, CFO | john.slump@corvidamedical.com | 319-335-2547 | www.corvidamedical.com

Company Overview: (include unmet needs and value proposition)
Corvida Medical is an emerging device company optimizing the safe handling of hazardous drugs, such as chemotherapeutics used to treat cancer patients. Millions of healthcare providers are at risk of exposure to hazardous drugs each year, resulting in adverse events such as cancers, reproductive toxicity, genetic mutations, etc. The company has developed an Innovative Device to Improve Safety of Preparing and Administering Chemotherapy supported by the National Cancer Institute as well as private investors. Corvida's device enables safer, more efficient and cost-effective preparation, administration, and disposal of hazardous pharmaceuticals. The company has leveraged $5 million of National Cancer Institute (NCI) grants into significant (undisclosed) private angel investment to date, which has been used to achieve US FDA 510(k) clearance and growing sales.

Market and Commercialization Strategy:
Direct sales strategy with direct sales/marketing efforts designed to drive customer demand and wholesaler distribution channels leveraged in order to fulfill customer orders and accommodate real-time logistics and instantaneous ordering for hospital pharmacies. We are also leveraging a US-based contract manufacturing relationship in order to produce the product.

Technical & Competitive Advantage:
Halo is cleared for market in U.S. by FDA. Claims cleared by FDA for Halo labeling include: provision of superior fluid and vapor containment when subjected to multiple uses of the devices; provision of strong and secure attachment to the vial; very easy to use based on user feedback; involved fewer repetitive motions in preparing and administering a dose; minimal force required to install, which could reduce user fatigue caused by high installation forces. Corvida applied for European Union's CE Mark and is expecting approval in Q4 2016.

Regulatory Strategy & Intellectual Property:
29 patents allowed with broad claims coverage and 30 patents pending in countries including U.S., Australia, Canada, Europe, Israel, India, Japan, Mexico, and New Zealand.

Key Milestones:

Over-Subscribed Series B Financing	Mid-2015
US FDA 510(k) Market Clearance	Late-2015
Initial Sales & Repeat Orders	Mid-2016
Conversion of First Major National Cancer Institute-designated Comprehensive Cancer Center (CCC) Hospital	Late-2016

Capitalization History:

09/2011	Series A Financing	Angel, Venture, and Family Office	Private
07/2015	Series B Financing	Angel, Venture, and Family Office	Private
09/2016	2016 Convertible Note Bridge Financing	Angel, Venture, and Family Office	Private
2010-11	NCI SBIR Phase I Grant	National Cancer Institute	$250K
2012-14	NCI SBIR Phase II Grant	National Cancer Institute	$1.5M
2014-17	NCI SBIR Phase IIB Grant	National Cancer Institute	$3M

Use of Proceeds:
Corvida Medical seeking undisclosed Sseries C preferred equity growth financing by early-mid 2017 to fuel aggressive growth/expansion.

Key Team Members:
Kent Smith, MBA: CEO/President
20+ years of successful commercialization and leadership experience in the medical device start-up arena as well as with large corporations, such as American Hospital Supply and Baxter Healthcare. His previous roles at American include VP Operations, and at Baxter, President of Baxter Japan. Kent's experience also includes leading Suros Surgical from $0-30M in sales and a $300M (10x sales) exit.
Dana Schramm, BSME, MBA: COO
20+ years of experience in manufacturing, working at companies ranging from $1m to over $1B in sales. The last 17 years have been exclusively in Medical Device Manufacturing, managing teams of up to 100 people and holding executive positions in Engineering and Operations. His broad technical skills combined with his business acumen has propelled his career through positions of increasing responsibility up to his current role of Vice President of Manufacturing.
John Slump, BBA: CFO/Co-Founder

Privo Technologies / Nanotechnology Drug Delivery Platform

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

Company Overview (Clinical Impact and Value Proposition)

Privo Technologies is a biotechnology. Originally founded in MIT's Langer lab in 2010, the company now operates a facility in Peabody MA. 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 existing drugs within nanoparticles, and embeds the nanoparticles within the CTW body. When CTW is topically placed onto tissue, the nanoparticles are released, locally retained, and release encapsulated drugs in a controlled manner. CTW has been extensively developed, optimized and tested for the treatment of oral cancer and is also being developed for the treatment of anal/colorectal cancer.

Market and Commercialization Strategy

(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. Orphan designation is a collection of benefits awarded to companies which focus on rare diseases (fewer than 200,000 patients in the US), including an accelerated FDA review process, seven additional years of patent protection, tax exemptions, and smaller Phase III clinical trials.

Technical & Competitive Advantage

Due to high recurrence of OC, systemic chemotherapy is often ineffective due to the low dosage which reaches the tumor. Side effects include neurotoxicity, nephrotoxicity, hair loss, nausea, vision impairment and loss of hearing. Surgery is highly disfiguring, often ineffective, and highly expensive due to associated permanent disabilities. OC is also considered among the most expensive cancers to treat due to high costs associated with treatment. Privo's advantage is a higher concentration of drug administered directly to the tumor, where no systemic exposure or side effects occur. Privo's treatment includes only 2.0mg of cisplatin compared to 150mg administered systemically, however provides a higher concentration to the tumor than what is achieved systemically. CTW is also very inexpensive.

Regulatory Strategy & Intellectual Property

Privo has 5 pending patent applications. Privo's primary patent is utility patent application US20140234212 A1. This application was filed by MIT, and Privo's CEO provided full funding for the project and is the first inventor on the application. Privo has 4 additional pending patent applications, including few for topical treatment of the GI tract, anal/colorectal cancer, multi-layered devices, and treatment kits.

Key Milestones (Achieved and Planned)

Approved for FDA's Orphan Designation (for oral cancer)	2015
Completed Privo's large in vivo study (54 hamsters, Privo's 4th in vivo study)	2015
File 5 provisional or pending patent applications	2016
Complete preclinical animal studies & Finalize clinical study design	2016
Secure over $6 million in additional private investment prior to clinical studies & Begin Phase I clinical trial	2017

Capitalization History

2016	Equity Investment	Private	$1,075,000
2015	NIH Grant Funding	National Cancer Institute	$2,500,000
2015	NIH Grant Funding	National Institute of Dental and Craniofacial Research (NIDCR)	$2,465,000
'13-'15	Other Grant Funding	National Science Foundation, MIT Deshpande Innovation Center, NIDCR	>$500,000
'10-'13	Founder personal funds	Manijeh N Goldberg	$470,000

Use of Proceeds

Initially, Privo plans to raise $6MM to support completing the FDA phase I safety study. Privo is also investigating a combination of phase I and II in order to obtain efficacy and safety results more efficiently. Privo's exit strategy includes partnering with a larger pharmaceutical company for completing phase III leading to NDA.

Key Team Members

Manijeh Goldberg, Ph.D, M.B.A: CEO

Over 20 years of experience in the biomedical industry, in large companies and startups (one was acquired for $275M); PhD in Biomedical Engineering, MS in Biomedical Enterprise from Harvard Medical School, MBA from MIT, and MS in Computer Science and Mathematics.

Michael Silverman, M.D.: CMO

Board-certified internist with decades of experience in biopharmaceutical industry clinical research, product development, and strategic planning. He has managed multiple pharmaceutical and biotechnology projects across a broad scope of therapeutic areas.

Ellen Milano: VP of Regulatory

Ellen Milano brings more than 40 years of extensive experience in Regulatory Affairs and pharmaceutical technical issues; expertise in product development, regulatory affairs, analytical development, QA/QC and compliance, QSR and PAI and diverse FDA submissions.

TeVido BioDevices / 3D Bioprinting for Custom Grafts

Laura Bosworth, CEO | bosworth@tevidobiodevices.com | 512-828-2596 | www.tevidobiodevices.com

Company Overview (Clinical Impact and Value Proposition)

TeVido BioDevices's platform technology uses proprietary 3D bio-printing processes and a patient's own living cells to build custom grafts that address significant unmet needs in the broad field of reconstructive surgery. TeVido's first product is a custom graft for nipple areola complex (NAC) reconstruction for breast cancer survivors. The NAC graft will have 1) a pigmentation layer designed to recapitulate the pigment of the lost nipple areola complex and 2) a projection built of volume-stable adipose (fat). ***TeVido's nipple graft is a permanent solution that eliminates the 1) flattening of the projection and 2) fading of the areola common in today's standard of care all in 3) one procedure rather than the multiple procedures over several months required today.*** This technology can also be used to address hypopigmentation or soft tissue deficiencies that often follow traumatic injury, burns, infection, tumor removal and can result from disease or congenital birth defects. The technology has additional licensing potential in tissue engineering and bioprinting.

Market and Commercialization Strategy

TeVido anticipates a Total Available Market for nipple reconstruction between $560-910M annually. Beyond nipple reconstruction TeVido's addressable market is estimated at $13B globally. TeVido will develop, manufacture and sell tissue engineered products with revenue derived from the sales of the graft itself, not the bio-printer. To lower risk, TeVido will look to key partnerships in sales, manufacturing and tissue collection. Sales will largely focus on plastic surgeons who recommend reconstructive options for patients.

Technical & Competitive Advantage

TeVido uses proprietary biofabrication techniques that deposit materials in precise locations which result in a custom tissue-engineered product. There are currently no universally accepted products available for nipple reconstruction, rather surgical procedures are used to create the "bump" and tattooing is used for the color. In order to achieve both pigmentation and a projection, with the existing solutions, (a minimum of) two procedures are required with a 3-month delay considered normal between them. TeVido plans to produce 1) a longer lasting and more predictably sized nipple projection, combined with 2) better and longer lasting color matching of the areola in 3) one procedure taking less than hour under local anesthesia rather than (minimum) 2 procedures over several months. **Longer term,** results from TeVido's pre-vascularized adipose grafts will more predictability address larger soft tissue deficits than fat injections can today and TeVido's pigmentation solutions leveraging autologous cultured cells will address larger defects with lower donor site impact than current treatments.

Regulatory Strategy & Intellectual Property

2 patents filed (PCT/US13.258338, PCT/US2014/062469) and 5 recent provisional patents. TeVido will be regulated as a HCT/P within FDA's CBER Division. There is low safety risk due to several design features and outcomes that are easily measured including nipple projection and areola color retention over time. After regulatory approval has been achieved, reimbursement will initially be through a cash market as we await appropriate billing codes.

Key Milestones (Achieved and Planned)

TeVido is in pre-clinical development phase with initial in vitro & animal data to support efficacy of this proposed product.

Primary Functionality of Bioprinter Complete	Q2 2017
Regulatory Strategy validated by FDA (or other appropriate agency)	Q4 2017
Pre-clinical proof of concept for nipple projection (0.5 cm graft)	Q1 2018
IND / IRB (as appropriate) approved for human studies for pigmented areola	Q2 2018

Capitalization History

12/2013 - 2/2016	SBIR Phase I & II	National Science Foundation	$1,102k
9/2014	SBIR Phase I	NCI	$150k
7/2015	Conv. Debt	MicroVentures	$110k
2014-15	Prizes/Misc	Livestrong Foundation Big C Competition, Texas New Ventures Competition, Indiegogo Crowdfunding	$84k
2016	ASEE Postdoc Fellowship	ASEE program funded by NSF for SBIR awardees	$150K

Use of Proceeds

Seeking $2M to cover 24 months of business operations that result in submission of IND to FDA (or other) for start of clinical trials on pigmentation capability. Use of funds are for 1) general business operations to support technology commercialization and 2) R&D costs including regulatory services and submission package development.

Key Team Members

Laura Bosworth, B.S. Met. Eng: CEO

Former Fortune 50 executive; has > 25 years of broad-ranging business and management experience

Scott Collins, Ph.D BME, M.S. BME, B.S.EE: President

Research activities focused on vascular formation and tissue engineering; experience in robotics and medical device design.

C4 Imaging, LLC / Positive-signal MRI Markers

Andrew Bright, President and CEO | abright@c4imaging.com | 609 933 5895 | www.c4imaging.com

Company Overview (Clinical Impact and Value Proposition)

C4 Imaging is a technology company focused on developing innovative medical devices that enable clinicians to more accurately perform image-guided procedures. The IP portfolio is centered on a proprietary positive-signal MRI contrast agent (C4) and associated encapsulation technology. C4 Imaging recently launched its first product, the Sirius™ MRI Marker. Sirius™ is the first commercially available positive-signal MRI Marker and is a permanently implantable medical device used in the management of prostate cancer. In prostate brachytherapy, Sirius™ MRI Markers are attached to radioactive seeds and inserted into the prostate. In doing so, physicians can view and evaluate seed placement utilizing MRI, allowing for a more accurate assessment of the quality of treatment. An accurate assessment of the treatment delivered is critical in optimizing patient outcomes. C4 Imaging is actively developing products that address significant opportunities outside of prostate cancer; with breast cancer biopsy and radiotherapy markers being the next target markets.

Market and Commercialization Strategy

C4 Imaging has entered into multiple supply agreements with companies serving the radiation oncology markets. These agreements address sales & marketing, as well as distribution, enabling C4 Imaging to focus its resources on development and regulatory progression, as well as identifying future strategic partners for additional marketing opportunities and potential licensing agreements.

Technical & Competitive Advantage

Current markers are usually metallic implants that depend on MRI signal voids for localization. Although useful as simple fiducial markers, these markers cannot precisely locate specific areas of interest in relation to surrounding anatomy. The C4 technology allows clinicians to incorporate MRI's optimal imaging in treatment assessment and ensure that planned treatment is precisely delivered.

Regulatory Strategy & Intellectual Property

C4 Imaging's regulatory strategy has focused on the approval of a liquid MRI agent encapsulated within an implantable medical device. This is a unique approach; consequently, an initial FDA clearance (510K) was needed to create a predicate on which to build a regulatory roadmap for future products that incorporate MRI alongside other imaging modalities (IE CT). The prostate MRI Marker is that predicate. The patent strategy reflects a mix of technological innovation and territorial applications that aim to prevent others from manufacturing, using, marketing or selling products protected by the relevant inventions. Key patents on both the core technology and its use have been awarded in the Americas, Europe, Japan and China.

Key Milestones (Achieved and Planned)

510K approval of MRI Marker for prostate brachytherapy	Q4 2013
510K approval of indications for multimodality breast biopsy marker and radiotherapy guidance marker	Q2, 2017

Capitalization History

Mth/yr	Funding	Provider	Amt
3/10	Investor	Private individuals	$2.0M
5/13	Investor	Private individuals	$1.5M
3/15	Investor	Private individuals	$0.5M
7/15	Grant	NCI SBIR	$1.3M

Use of Proceeds

C4 Imaging is looking to raise up to $2.0M. Funds will be used to complete ongoing product development and regulatory submissions. In addition, they will be used to upgrade current production assets; an upgrade will increase product throughput and reduce scrap rates, having a significant positive impact on cost of goods sold. Finally, C4 Imaging plans to fund strategic sales and marketing activity focused on key opinion leaders in the various market segments addressed by their new products.

Key Team Members

Andrew Bright, B.S.: President and CEO

Former VP of Global Sales & Marketing for GE Healthcare's brachytherapy business. He is an Applied Biology graduate with over 25 years of experience in commercial leadership roles within the medical device and life sciences industries, in both North America and Europe.

Steven J. Frank, M.D.: Founder and Chairman of the Board

Professor, Deputy Department Chair, Proton Center Medical Director and Director of Advanced Technologies at the MD Anderson Cancer Center. Dr. Frank is also the head of the prostate brachytherapy program at MD Anderson and is a recognized leader in prostate cancer treatment. He has developed or is the institution PI on 20+ clinical protocols and has 100+ peer-reviewed, published manuscripts.

Karen Martirosyan, Ph.D.: Co-founder and Chief Technology Officer

Dr. Martirosyan is a Professor in the Department of Physics and Associate Dean for Research and Graduate Education at University of Texas-Rio Grande Valley, Texas.

CellSight Technologies / PET Imaging Agent

Aruna Gambhir, CEO | agambhir@cellsighttech.com | 650-868-6650 | www.cellsighttech.com

Company Overview (Clinical Impact and Value Proposition)

CellSight is a clinical stage PET imaging tools company that can increase the probability of clinical success of immunotherapies by determining early in the therapeutic regimen if a cancer patient is responding. Cancer immunotherapies that harness the body's immune system to help fight cancer do not work for everyone, and up to 80% of patients undergoing immunotherapy are spending over $150,000 and investing 6 to 10 months on ineffective treatments. Our lead imaging tracer, [18F]-FAraG product name VisAcT, leverages existing health and PET imaging infrastructure but is specific for visualizing immune response. The goal of checkpoint inhibitors and most immunotherapies is to boost the number of activated T cells, which in turn kill the tumor. In activated T cells deoxyGuanasine Kinase (dGK) is overexpressed; dGK is a substrate for CellSight's VisAcT tracer that gets phosphorylated and trapped in cells that overexpress dGK. In the clinic a single dose of VisAcT is administrated into living subjects where it circulates to all cells in the body. The patient is then imaged in the PET scanner where the whole body image will show areas of concentration of the tracer correlating to tracer trapped in activated T cells, providing insight into the patient's immune response. A VisAcT scan early in the treatment regimen will provide clinicians valuable information to make treatment decisions. VisAcT was first discovered and developed in the Gambhir lab (Chair of Radiology at Stanford) and is exclusively licensed to CellSight. CellSight performed various preclinical studies, obtained an IND and is conducting Phase 1 clinical trials at University of California San Francisco. Our first target market is immuno oncology applications but since the tracer is specific to activated T cells it can be useful for other immune modulated diseases.

Market and Commercialization Strategy

The Immuno-oncology market according to a 2015 Barclays Research report is targeted to be $22B by 2023 and reached $2.5B in 2015 with sales of just Keytruda, Opdivo and Yervoy. CellSight is partnering with immunotherapy companies and noted academic clinicians to include VisAcT scans in standard of care and clinical trial immunotherapies to demonstrate utility of VisAcT scans as predictor of response to therapy. Positive results from VisAcT clinical trials will enhance pharma participation and clinical adoption. CellSight will also be working with healthcare systems like Kaiser to include immune response imaging as part of immunotherapy regimen to reduce ineffective treatments. CellSight is in discussions with radiopharmaceutical distributors to ensure VisAcT will be widely available. VisAcT can also be leveraged in preclinical development.

Technical & Competitive Advantage

A tracer that is relatively specific to activated T cells has wide ranging implications, as there are no imaging or noninvasive modalities that can visualize the last key steps in an immune response where activated T cells kill tumor cells. There are no tools to determine at an early timepoint if an immunotherapy regimen is working, the limited biomarkers that exist to prescreen patients prior to start of an immunotherapy regimen are not adequate. VisAcT use same equipment and infrastructure as the ubiquitous FDG tracer making product rollout and acceptance straightforward.

Regulatory Strategy & Intellectual Property

1 patent approved (US 9,011,817- Compounds and methods of making compounds.)

Key Milestones (Achieved and Planned)

Partnership with a major pharma to sponsor clinical trial	August 2016
Completion of Phase 1 clinical trial	Q4 2016
Image non oncology patient - RA or MS or GVHD	Q4 2016
Completion of Phase 2a clinical trial	Q4 2017

Capitalization History

2010	R01 Grant - UCLA	NCI	$720k
2010	Contract Phase I SBIR	NCI	$247k
2011	R01 Grant – MD Anderson	NCI	$1.1M
2013	Phase 2 SBIR	NCI	$1.5M
2016	Convertible note	TEEC, BioPacific Ventures, WSGR Investment	$370k

Use of Proceeds

Fund Phase 2 VisAcT imaging clinical trials with patients eligible for checkpoint inhibitors (lung, melanoma). Explore use in RA model.

Key Team Members

Sanjiv Gambhir, MD, PhD: Founder

Expert in molecular imaging; World renown imaging expert, Chair of Radiology dept. at Stanford

Aruna Gambhir, MS, MBA: CEO

Expert in business and marketing; Executive experience with multiple successful exits

Sam Quezada, MBA: COO

Expert in operations and IP; 30 years of business and operations experience

ON TARGET LABORATORIES
From Academia to Application

On Target Laboratories / Intraoperative Optical Imaging Agents

Marty Low, CEO | mlow@ontargetlabs.com | 484-477-1500 | www.ontargetlaboratories.com

Company Overview (Clinical Impact and Value Proposition)

On Target Laboratories specializes in the discovery and development of novel optical imaging agents that target and illuminate both diseased and healthy cells. The Company's technology provides surgeons a precise "lighted road map" to more effectively and efficiently diagnose and surgically treat diseased tissue ranging from cancer to autoimmune and inflammatory diseases. On Target's lead development candidate is OTL38, a modular agent comprised of a near infra-red (NIR) dye joined by a linker system to the targeting ligand folate. OTL38 has been proven safe in a phase 1 trial and effective in a completed phase 2 clinical trial for the treatment of women diagnosed with ovarian cancer and an investigator sponsored trial (IST) in over 75 lung cancer patients. The same proprietary NIR dye has been conjugated to additional ligands targeting receptors on prostate, brain, colorectal and other cancers [e.g. PSMA-targeted NIR agent (OTL78), CA IX-targeted NIR agent (OTL338)]. In addition, a photodynamic agent has been conjugated to a folate ligand (OTL228).

Market and Commercialization Strategy

On Target is focused on commercializing OTL38 for use in ovarian (2018) and lung (2020) cancers. The lead molecule for OTL78 has been identified and manufactured (GLP) in preparation for IND enabling studies. On Target will market and distribute its probes through well-established device partners.

Technical & Competitive Advantage

Technology	Companies	Status	Advantage of OTL38
Antibodies	ImaginAb	Preclinical	Dose 2hrs before surgery, higher affinity and specificity, lower CMC cost
Cleavable linkers	Avelas, Lumicell	Phase II	Dose 2hrs before surgery, higher affinity and specificity, lower CMC cost
Proteins	Blaze	Phase I	Dose 2hrs before surgery, higher affinity and specificity, lower CMC cost
Nonspecific dyes relying on leaky vasculature for tumor accumulation	Akorn (ICG), FLARE (ZW800), LI-COR (IR800)	Commercially available	Targeted, highly specific, will be available in the market for lower cost

Regulatory Strategy & Intellectual Property

On Target has 5 issued patents and associated PCT's and has 5 patents pending. These patents are associated with 4 different molecules (OTL38, OTL78, OTL338 and OTL228). OTL38 will be commercially available for ovarian and lung cancers in 2018 and 2020 respectively. OTL78 will be commercially available for prostate cancer in 2022. The other molecules (OTL338, OTLXXX) will be developed as soon as funds are available. Either independently or in combination these four molecules will cover most, if not all solid tumor cancers.

Key Milestones (Achieved and Planned)

OTL38 has been proven safe (phase 1 trial) and effective in ovarian (phase 2 trial) and lung (IST) cancers with potential in pituitary, and renal cancers (recently initiated IST's)

OTL38: Ovarian Phase III completed and NDA filed, Ready for sale	12/2017
OTL38: Data locked for phase 3 lung	12/2017
OTL78: Prostate, preclinical work completed and phase I completed, phase 2 initiated	3/2017
OTL338, OTLXXX: Phase 1 and several IST's in various indications completed	12/2017

Capitalization History

1/2011	Common	Single angel investor	$10.4M
3/2014	Preferred	Single angel investor + pension fund	$14.6M
4/2015	Convertible Debenture	Single investor+ pension fund + university fund	$6.9M

Use of Proceeds

To execute against milestones articulated above in "Key Milestones."

Key Team Members

Martin F. Low, MBA: **CEO**

Expert in strategic planning and business development; founded or co-founded seven companies

Timothy Biro, RPH, MBA: COO

Expert in venture capital and medical devices; was CEO of several companies & serves as on several boards

Sumith A. Kularatne, PhD: VP of R&D

Expert in drug design and delivery, Medicinal chemistry, and molecular biology

Spectral Molecular Imaging / Molecular Imaging

Daniel L. Farkas, Chairman & CEO | dlfarkas@gmail.com | 310-600-7102 | www.opmol.com

Company Overview (Clinical Impact and Value Proposition)

Spectral Molecular Imaging (SMI) is a pre-revenue company focusing on developing and bringing to market disruptive biomedical imaging devices aimed at saving lives and, simultaneously, costs by accurate, early diagnosis of cancer. We investigate patient tissues non-invasively, by a multimode combination of methods, anchored by hyperspectral imaging originally developed for satellite reconnaissance. These yield topologically resolved signatures of the targets, with high discrimination ability, and achieve histopathology-equivalent performance in living patients that reduces the risk of errors, while enhancing diagnostic acuity and specificity.

Market and Commercialization Strategy

Our lead product is SkinSpect, a multimode imaging dermoscope. The cost of treating an in situ melanoma is $4,648 while treatment of a stage IV melanoma is estimated to be $159,808. Considering the high incidence of melanoma the cost saving could be considerable. SkinSpect can provide fast and efficient characterization of potentially cancerous lesions that will help ensure early diagnosis and treatment. There are about 40,000 dermatologists worldwide, but there is shortage in many areas, with a need for better/faster diagnosis in that could be met by primary care physicians and surgeons equipped with tools like SkinSpect, with tele-consulting dermatologists.

Technical & Competitive Advantage

Proof-of-concept and testing of the methods' usefulness in clinical applications has been carried out in the CEO's academic labs, under two decades of significant (~$80 million, peer-reviewed) funding. The company's core competency is the molecular imaging technology combination that non-invasively quantifies the fundamental biological state of diseased tissue to couple early diagnosis and treatment, and guide them. Our primary competitive advantage is that SkinSpect will achieve a higher specificity than competing technologies, at comparable levels of sensitivity, by: (a) collecting more wavebands, over a greater range than other methods, at both polarizations, providing higher fidelity to current biological models for melanoma lesions; (b) being unique in allowing modeling of lesion depth (Breslow thickness), the single most significant indicator of the lethality of a melanoma; (c) combining 3 imaging modes and using intermodal cross-validation to improve the accuracy of skin component analysis. SkinSpect (1) has biological plausibility; (2) requires smaller clinical trials to validate compared to "black box" methods; (3) is applicable to other kinds of skin conditions (chronic wounds, non-melanoma skin cancers); and (4) is extensible to other tissue areas such as endoscopy, wound healing assessment and various surgical procedures.

Regulatory Strategy & Intellectual Property

We obtained regulatory approval in Canada in 2015. We have significant IP, issued (US # 5,796,512, # 5,841,577, # 7,428,048, and another 12 recently acquired) and pending (61/759,910; 61/846,525; PCT/US14/064410 and corresponding PCT applications).

Key Milestones (Achieved and Planned)

Complete clinical testing (UC Irvine, Memorial Sloan Kettering)	Q2 2017
Apply for FDA approval under 510(k) mechanism, European approval (CE Mark)	Q4 2016
Complete manufacturable prototype design (very similar to clinically tested current one)	Q4 2016
Extend device application domain from melanoma to many other skin diseases (e.g. basal cell carcinoma)	Q4 2016

Capitalization History

2010-11	Grant	USDHHS/QTDP/IRS	(DL Farkas PI)	$ 191,172
2010-13	Grant	NIH NCI R43/44	(DL Farkas Co-PI)	$ 795,430 ($271k SMI)
2010-16	Angels/management	Private		$2,050,600
2014-17	Grant	NIH NCI R43/44	(DL Farkas PI)	$1,599,944
2015-18	Grant	US Air Force STTR (I + II)	(DL Farkas PI)	$ 897,450

Use of Proceeds

We are currently raising $4-5 million, at a company valuation of ~$15 million (pre-money), to complete, within 12 months, (a) clinical testing at two locations (~100 patients); (b) obtainment of FDA approval under 510(k) mechanism; (c) obtainment of CE Mark and (d) identification of a contract manufacturer and beginning of production. With Canadian approval already at hand, sales can start immediately (Q4 2016). Some revenues could be direct, and some via partnerships/royalties. We expect healthy revenues within 12 months of the new funding, and be debt-free within 24 months, with significant profits. An exit scenario may involve acquisition by a medical device company.

Key Team Members

Daniel L. Farkas: Chairman & CEO

Extensive academic credentials (Fulbright scholar, led National Science and Technology Ctr. at Carnegie Mellon U., was vice chairman for research at Cedars-Sinai) and significant entrepreneurial experience; co-started 10 companies, and none of them have failed.

Carla Mann: CEO (from this quarter)

Has very significant (C-level) business and regulatory experience.

N. Mackinnon

Has scientific and corporate experience in medical device; obtained FDA approval for an oral cancer detection device in 21 days.

Adherence Health / Adherence & Outcomes Mgmt Solutions

Barbara Rapchak, Founder | barb@leapoffaith.com | 815-861-1767 | www.emedonline.com

Company Overview (Clinical Impact and Value Proposition)

Adherence Healthcare is a digital health company focused on commercializing its proprietary solution for medication non-adherence which is a $317 billion/year healthcare problem. The company's initial product, eMedonline®, is a Software-as-a-Service, platform that creates a real-time "conversation" between patients and providers around medication adherence and related outcomes. We are a leader in improving adherence with increases achieved in multiple randomized-control clinical studies from 50% to 95+%. Our solution also collects outcomes data that would otherwise be lost and has contributed to a reduction in hospital readmissions. We are pioneers in applying Natural Language Processing (NLP) and medical terminologies to capture and map adherence and outcomes data to standard clinical codes sets to create a shared language for existing health and pharmacy information systems. This unique benefit provides the common foundation for data exchange (interoperability), interpretation, and actionable results needed for cost effective quality care. Payers and providers win big with adherence due to a significant reduction in healthcare costs (as high as 48%) and an increase in quality scores, which contribute to higher payments.

Market and Commercialization Strategy

We estimate our target market—five or more drugs per day—to be worth $4.9 billion/year. The total addressable US market—one or more prescribed drugs per day—is valued at $79 billion/year. We have multiple channel opportunities including hospitals, Accountable Care Organizations, extended care, home health care agencies, population health service providers, primary care physicians, chronic care specialists, pharmacy, specialty pharmacy, pharmacy benefit managers, and biopharma companies. We are presently engaged in commercial discussions with a population health service provider focused on diabetes and two premier medical centers for managing high risk/cost patients.

Technical & Competitive Advantage

eMedonline is a systems innovation that integrates smartphones, a server, the cloud, and behavioral informatics to optimize both adherence and outcomes. It consists of a mobile device application and a web-based server application that collects data sent to it by the device about patient-specific dosing events. The server application lets clinicians view summarized results data and provides a platform for disease management and data mining. Medication sensing with RFID, NFC, or bar codes is available if needed. eMedonline serves as a Mini-Patient Record providing medication and health status, and offers unique adherence and outcome data-mining opportunities. Our platform permits easy expansion as a solution for broader adherence issues—remote monitoring of physiologic measures, scheduled appointments, exercise, diet, remote monitoring.

Regulatory Strategy & Intellectual Property

1 patent approved (US 7002476) for a Medication Management System and 1 provisional (No. 61767365) for a System and User Interface for Displaying Patient Medical Record Information that Incorporates a Body Map. No regulatory clearances are required.

Key Milestones (Achieved and Planned)

Adherence Health has completed critical development and clinical milestones and is now preparing to validate its business model.

Revenue Model Validation	2016
Clinical Validation : >95 % Adherence with up to 27 doses/day	Completed
NIH Human Factors Testing	Completed
Ethnographic Research: ID Adherence & Engagement Triggers	Completed

Capitalization History

2003-16	SBIR Grant & Contracts	NIH National Institute on Aging, National Cancer Institute	$3.3M
2005-16	Outside Investments	Intelligent Medical Objects, McKesson, others	$0.83M

Use of Proceeds

We are seeking $8M in Series A Preferred to commercialize eMedonline. 61% of the funds will be used for commercialization; 39% for continued product development

Key Team Members

Barbara Rapchak, B.S.: Founder and Chief Innovation Officer

Expert in Digital Health and Medication Adherence and drug development; Founder of LOF technologies with 25 years specializing in the development and application of digital platforms that elicit patient behavior change. Recipient of the Tibbetts Award

Thomas Loarie, B.S.: Chairman and CEO

Expert in Digital Health and Medical Technology; Former Baxter executive who has supported and/or led numerous development stage health related companies since 1984, and has brought 20+ innovative products across eleven medical specialties to the market.

Thomas Kanar, B.A., CPA: Chief Financial Officer

Seasoned life science and software financial executive who began his career with Price Waterhouse.

Lumme / Wearable Tech for Smoking Cessation

Akshaya Shanmugam, Program Manager| akshaya@lumme-labs.com| 413-362-4080

Company Overview (Clinical Impact and Value Proposition)

Lumme Inc. helps people quit smoking by providing just-in-time interventions. Lumme's technology combines wearable sensors, machine learning, and behavioral psychology to automatically detect when the user smokes and extract factors associated with each user's smoking pattern in order to predict a relapse. This information is then used to deliver timely and contextually appropriate interventions in the form of text messages or therapist phone calls. The intervention protocol is designed by Dr. Sherry McKee, director of the Yale Tobacco Treatment Clinic and implemented by a team of scientists from UMass Amherst. A pilot study with 19 subjects has already shown smoking event detection with greater than 95% accuracy. In collaboration with the Yale School of Medicine, Lumme has commenced a national scale clinical trial to quantify the improvement in success rate their technology can offer. The ability of the technology to offer the right help at the right time would not only aid users to quit the habit, but also improve abstinence rates.

Market and Commercialization Strategy

Existing behavioral programs such as quitlines have a low success rate of 10%. Individual counselling has high dropout rates due to costs and time commitments. This data clearly points out the need for a scalable & individualized quit program, creating a unique niche for Lumme. Lumme plans to offer this as an essential part of a wellness strategy to reduce health care expenses for companies and employees. Insurance companies, corporate wellness companies, and human resources department at self-insured companies will be used as channels to tap into this segment. As a part of Lumme's customer discovery, other customer segments such as pharmaceutical companies, smoking cessation clinics, researchers, and direct-to-consumer models are also being explored.

Technical & Competitive Advantage

Lumme's technology is divided into three parts: Detection, Prediction, and Prevention. Existing smoking detectors such as Quitbit, CReSS, and mPuff detect smoking by using bulky special purpose hardware. Lumme uses a commodity wearable sensor to monitor hand movements and decodes the characteristic signature of smoking. The prediction technology employs deep learning algorithm to identify triggers by associating factors such as time of the day, location, and social interactions with the user's smoking behavior. With this data, the prevention technology delivers customized intervention such as text message or calls with suggestions to handle the craving. Existing mobile apps require users to manually log each smoking event to track behavior and delivers intervention only upon request. Lumme's solution enables unobtrusive, automated detection of smoking and seamlessly integrates personalized therapy into user's daily lives. The company is exploring expansion of the technology to detect and monitor individuals with eating disorders, obesity, and other addictions.

Regulatory Strategy & Intellectual Property

Lumme's technology falls under the FDA guideline of Mobile Medical Apps for which they will exercise enforcement discretion. Lumme has initiated the process to file a patent on the automated behavior monitoring and intervention technology.

Key Milestones (Achieved and Planned)

Lumme has developed a prototype for smoking detection that works with commercial smartwatches available in the market.

Development of smoking detection and prediction algorithms [Completed]	Feb, 2016
Development of app and web interface [Completed]	July, 2016
Study to validate prediction model [In progress]	Aug 2016
Study to validate intervention protocol [Planned]	Oct 2016
Study to validate the complete platform and measure quit rates [Planned]	Jan 2017

Capitalization History

9/2015	SBIR Phase II	NIH/NCI	$1.5M

Use of Proceeds

Lumme plans to expand their team by hiring business experts to develop and test business strategies and marketing plan. Once the results from the clinical trial are obtained, the company also plans to hire a sales team to commercialize the technology. In order to expand the team and scale up, Lumme would have to raise $2M in the next fiscal year.

Key Team Members

Abhinav Parate, Ph.D.: Head of R&D

Expert in detecting health behaviors and developing analysis methods for understanding triggers of individual behavior; responsible for the design and coordination all technical aspects of the project.

Akshaya Shanmugam, Ph.D.: Program Manager

Expert in the design of biosensors and health monitoring devices; handles the company's finances, business strategies, and overall progress of the project.

Sherry McKee, Ph.D.: Consultant

Extensive experience conducting clinical trials for tobacco dependence; will be responsible for developing the intervention protocol and monitoring the clinical study.