2019 NCI SBIR

INVESTOR INITIATIVES

COMPANY PROFILES

NATIONAL CANCER INSTITUTE
SBIR DEVELOPMENT CENTER

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COMPANY INFORMATION

BIOPHARMACEUTICALS

COMPANY	TECHNOLOGY TYPE	ORGAN/INDICATION
Adecto Pharmaceuticals	Monoclonal antibody against ADAM8	Multiple (1st indication: Triple Negative Breast Cancer)
Dualogics	Bispecific antibody pipeline	Multiple (Triple Negative, Breast Cancer; autoimmune indications)
GlyTR	Bispecific protein based immunotherapeutic targeting carbohydrate cancer antigens	Multiple
For-Robin	Monoclonal antibody against Thomsen-Friedenreich glycoantigen (TF-Ag)	Multiple (Breast-TNBC, Lung - SCLC, NSCLC)
Extend Biosciences	D-VITylation platform/long-acting Ghrelin peptide	Cachexia (Multiple cancer indications; other chronic diseases)
OncoNano Medicine	Ultra-PH sensitive, micelle-based imaging agents, therapeutics, & vaccines	Multiple (Breast, Head & Neck, Ovarian, Colorectal)
Zenopharm	Oral selective estrogen receptor degrader (SERD)	Breast Cancer
Keystone Nano	Bioactive cell messenger	Multiple (Lung, Pancreatic, Liver, AML)
Modulation Therapeutics	Actinium-225 radio labeled peptidomimetic	Metastatic cutaneous or uveal melanoma
ZetaGen (Fusologics)	Proprietary molecular pathway to grow bone	Multiple
SignaBlok	TREM-1 targeted standalone and combination immuno-oncology therapy	Multiple (1st indication: Pancreatic Cancer; Pigmented villondular synovitis)
Molecular Theranostics	Peptide-targeted MRI contrast agent	Multiple (Breast, Colon, Head & Neck, Liver, Pancreatic, Prostate)

THERAPEUTIC DRUG DELIVERY PLATFORMS

COMPANY	TECHNOLOGY TYPE	ORGAN/INDICATION
Advanced Chemo Technologies	Chemotherapeutic Drug Delivery Platform	Multiple (1st indication: Pancreatic)
NeOnc Technologies	Highly purified GMP-produced intranasal perillyl alcohol (POH) and a synthesized conjugate of temozolomide	Multiple (1st indication: Brain Cancer-gliomas, glioblastomas)
Privo Technologies	Nano-engineered Topical, Local Drug Delivery Platform	Multiple (1st indication: Oral Cancer)
TheraTarget	Polymer-based Carrier Platform for Solid Tumor Therapeutics	Multiple (Breast, NSCLC, Pancreatic, Ovarian)

DIAGNOSTICS/TOOLS

COMPANY	TECHNOLOGY TYPE	ORGAN/INDICATION
Abreos Biosciences	Therapeutic Drug Monitoring Platform	Multiple
bioSyntagma	Spatial Omics for Discovery and CDx	Multiple (1st indication: Melanoma)
Capio Biosciences	Biopsy-free biomimetic platform for CTCs	Multiple
Captis Diagnostics	Extracellular Vesicle-Based Liquid Biopsy	Multiple
Frontier Diagnositcs	Clinical assay for Accurate Diagnosis of Melanoma using IMS	Multiple (1st indication: Melanoma)
SynderBio	Targeted cell separation for research and diagnostics	Multiple (1st indication: Bladder Cancer)
Mirimus	Platform technology for the rapid creation of next-gen CRISPR/Cas9-RNAi mouse models	Multiple

COMPANY INFORMATION

DEVICES

COMPANY	TECHNOLOGY TYPE	ORGAN/INDICATION
Clarix Imaging	3D imaging device for intra-operative margin detection	Breast
Fischer Imaging	Slot scanning mammography technology	Breast
nView Medical	Real-time 3D imaging system	Multiple
Imago Systems	Image visualization software	Multiple (1st indication: Breast)
NE Scientific	Surgical guidance software for use during ablations	Multiple (1st indication: Liver)
Fibralign	Novel therapeutic device platform	Secondary Lymphedema
Cell Preservation Services	Cryoablation devices	Multiple (Pancreatic, Liver, Other GI tumors)
Madorra	Drug-and hormone-free treatment for vaginal dryness	Breast

DIGITAL HEALTH

COMPANY	TECHNOLOGY TYPE	ORGAN/INDICATION
Carevive Systems	End-to-end digital oncology clinical care platform	Multiple
Shade	Wearable UV sensor	Skin cancer

SHORT COMPANY SUMMARIES

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

Adecto Pharmaceuticals

ADAM8-TARGETED CANCER THERAPY

The ADAM8 protein is expressed on the cancer cell surface, downstream of the NF-κB family of transcription factors known to promote tumor growth, resistance to chemotherapy and metastasis. Consistently, ADAM8 is a critical driver of the growth and spread of many aggressive tumor types, including breast, stomach, colon, lung, liver and pancreatic cancers. Adecto's initial focus is on triple-negative breast cancer, with a plan to expand to other oncology indications. It is estimated that globally there are over 2 million patients with invasive ADAM8-driven cancers. Currently, there is no FDA-approved therapy for these patients or a diagnostic assay to identify them. Adecto is developing the first antibody-based therapy against ADAM8-positive cancers and a diagnostic assay to identify those patients most likely to benefit from inhibition of ADAM8.

LOCATION: BROOKLINE, MA
STAGE: PRE-CLINICAL DEVELOPMENT

Dualogics

BISPECIFIC ANTIBODY ENGINEERING

Dualogics is an RTP-based drug development company that specializes in engineering bispecific antibody therapeutics. Using the proprietary OrthoMab platform, we can generate bispecific antibodies with the characteristics of native human antibodies. Bispecific antibodies can engage two distinct antigens simultaneously, affording novel paths to immuno-modulation. Dualogics' most advanced drug candidate is a bispecific antibody for the treatment of acute graft versus host disease (GVHD) and other T cell mediated autoimmune diseases.

LOCATION: DURHAM, NC
STAGE: PRE-CLINICAL DEVELOPMENT

Extend Biosciences

D-VITYLATION PLATFORM TECHNOLOGY/ LONG-ACTING GHRELIN PEPTIDE FOR CACHEXIA

Cachexia is a complex metabolic syndrome characterized by involuntary weight loss, skeletal muscle wasting and impaired fat absorption that results in anorexia and a decrease in energy intake. Cachexia occurs frequently in the advanced stages of cancer and is associated with a worsened prognosis. There are no FDA-approved treatments for cachexia, and current strategies include appetite stimulation, which does not address the underlying cause of disease. EXT418 is a once-weekly, subcutaneously self-administered, long-acting ghrelin that increases food intake and restores muscle mass and grip strength in animal models of tumor-induced cachexia.

LOCATION: NEWTON, MA
STAGE: PRE-CLINICAL DEVELOPMENT

For-Robin

BREAST CANCER ANTIBODY IMMUNOTHERAPY

For-Robin, Inc, founded in 2012 and named in honor of the founder's sister who died at age 31 of breast cancer, is an antibody immunotherapy company whose primary mission is developing treatments for breast and lung cancer patients. Its proprietary technology (monoclonal antibody, JAA-F11 and humanized variants, hJAA-F11) targets all breast and lung cancer cell subtypes, including triple negative breast cancer where no targeted therapy currently exists. For-Robin is developing hJAA-F11 for adjunct therapy of breast and lung cancer either directly or as antibody-drug conjugates.

LOCATION: WILLIAMSVILLE, NY
STAGE: PRE-CLINICAL DEVELOPMENT

GlyTR Therapeutics

TACA-TARGETED IMMUNOTHERAPY PLATFORM

GlyTR Therapeutics is developing a novel immunotherapy platform technology that uniquely targets highly diverse cancer types, ranging from breast cancer to leukemia. GlyTR technology can overcome many of the shortcomings of current immunotherapies by binding to never-before targeted tumor associated carbohydrate antigens (targets) that are common to many cancer types. Widespread applicability of antibody based targeted cancer immunotherapies, such as bispecific proteins and CAR T cells, are limited by a lack of antigens and cost. TACAs are the most abundant and widespread cancer antigens known but are poorly targeted by antibodies. GlyTR technology (bispecific and CAR T) specifically targets TACAs, with a single GlyTR bispecific protein triggering the killing of diverse solid and liquid cancers.

LOCATION: IRVINE, CA
STAGE: PRE-CLINICAL DEVELOPMENT

Keystone Nano

BIOACTIVE CELL MESSENGER

Keystone Nano's lead product is the first clinical testing of a unique bioactive cell messenger that impacts cancer metabolism, upregulates the immune system, and increases sensitivity to standard chemotherapeutics. Follow-on technologies provide unique ways to deliver RNA as cancer therapies with safety, targetability, and efficacy. Keystone Nano's compound—Ceraxa—is currently testing at the highest plan dose level. Keystone Nano's technology is patent-protected to 2033, has orphan drug status in three indications, and is a trade secret-protected technology. Furthermore, Keystone Nano has a substantial lead in clinical testing and Ceraxa has not identified a Dose Limiting Toxicity in spite of increasing dose level by more than 500% from the starting point and has shown disease stabilization in 5 of 12 patients tested for more than 2 months.

LOCATION: STATE COLLEGE, PA
STAGE: IN CLINICAL TRIALS: PHASE I

Modulation Therapeutics

TARGETED RADIOTHERAPY FOR MELANOMA

Modulation Therapeutics is dedicated to the development of novel peptidomimetic drugs with reduced toxicity and increased efficacy for the treatment of cancers that are not cured by standard of care agents. The company has two major drug candidates now in aggressive development, with a focus on lead compound MTI-201, an Actinium-225 (Ac-225) radio-labeled peptide for the treatment of melanoma cancers. MTI-201 precisely targets the Melanocortin 1R expression on melanoma cancers and irradiates the tumor with a high dose of destructive energy, while sparing healthy tissue due to the short irradiation distance (only a few cell diameters). In vivo studies with mice have shown complete cure with a single bolus dose and very low toxicity even at the highest effective doses. MT-201 hits the melanoma target within 30 minutes of injection and then clears rapidly. MTI-201's 10 day half-life uniquely supports central quality-controlled manufacturing, with convenient express distribution to patient clinics throughout the world.

LOCATION: MORGANTOWN, WV
STAGE: PRE-CLINICAL DEVELOPMENT (PRE-IND COMPLETE; IND APPROVAL EXPECTED Q4 2019)

Molecular Theranostics

PEPTIDE-TARGETED MRI CONTRAST AGENT

MT218 is a small peptide-targeted MRI contrast agent specific to aggressive solid tumors for accurate early detection and risk-stratification of aggressive solid tumors. The targeted contrast agent is comprised of a small peptide of seven amino acids conjugated to a clinical macrocyclic MRI contrast agent Gd(HP-DO3A). MT218 has a T1 relaxivity of 5.5 mM-1s-1, nearly twofold of that of the corresponding clinical agent ProHance®. The effectiveness of MT218 has been demonstrated in animal models of aggressive breast cancer, colon cancer, pancreatic cancer, prostate cancer, and other types of solid tumors. MT218 can be readily implemented with the existing clinical MRI systems and protocols and does not require any new hardware or software settings.

LOCATION: CLEVELAND, OH
STAGE: PRE-CLINICAL DEVELOPMENT

OncoNano Medicine

ULTRA-PH SENSITIVE, MICELLE-BASED IMAGING AGENTS, THERAPEUTICS, & VACCINES

OncoNano Medicine has adapted unique, ultra-pH-sensitive micelle chemistry to design and develop an IV injectable, indocyanin green (ICG) based fluorescent imaging agent, ONM-100, for use by surgeons in intraoperative resection of solid tumors. The fluorescence is activated by the low pH microenvironment of tumors, which is the result of metabolic acid buildup (the Warburg effect) and is a hallmark of all cancers irrespective of their oncogenic phenotype—an attribute that provides the potential for ONM-100 to be used to image any solid tumor. Preclinical GLP studies and data from a Phase 1 first-in-human clinical trial have demonstrated that ONM-100 is safe (no drug-related adverse events) and is efficacious for imaging multiple tumor types studied to-date, which includes breast, head and neck, ovarian, and colorectal cancers in humans.

LOCATION: DALLAS, TX
STAGE: IN CLINICAL TRIALS: PHASE II

SignaBlok

TREM-1-TARGETED THERAPY FOR PANCREATIC CANCER AND PIGMENTED VILLONODULAR SYNOVITIS

SignaBlok is developing a novel therapy for pancreatic cancer (PC) and a rare joint tumor, pigmented villonodular synovitis (PVNS). Intratumoral inflammation characterized by the increased number of tumor-associated macrophages (TAMs) is associated with more aggressive PC and poor prognosis in patients with PC. SignaBlok's strategy is to inhibit tumor growth and improve patients' survival by suppressing intratumoral inflammation. To this aim, we use a proprietary SignaBlok (SCHOOL) 9-mer peptide (GF9) that inhibits TREM-1, an inflammation amplifier, that is expressed on macrophages including TAMs. The TREM-1-specific SCHOOL inhibitory peptide GF9 employs a new, ligand-independent mechanism of action that includes disconnection of TREM-1 from its signaling partner, DAP-12, in the cell membrane. GF9 self-inserts into the cell membrane, colocalizes with TREM-1, and can reach its intramembrane site of action from both outside or inside the cell. Other TREM-1 blockers (e.g., LR12 peptide, which is in development by SignaBlok's top competitor—Inotrem, France) all attempt to block binding of currently uncertain ligands of TREM-1 and have a risk of failure in clinics, while GF9 is advantageously ligand-independent.

LOCATION: SHREWSBURY, MA
STAGE: PRE-CLINICAL DEVELOPMENT

BIOPHARMACEUTICALS

Zenopharm

ORAL SERD FOR THE TREATMENT OF BREAST CANCER

Zenopharm is a startup pharmaceutical company founded in 2012 to commercialize innovative oncology therapeutics based on its patented platform technology. Zenopharm is developing transformational therapeutic solutions for the treatment of advanced or metastatic breast cancer. The company is currently advancing ZB716, an oral selective estrogen receptor degrader (SERD), to provide clinical benefits to breast cancer patients with metastatic disease. ZB716 is a chemically modified SERD, pharmacologically analogous to fulvestrant, but with high oral bioavailability. If clinically proven safe with equivalent or superior efficacy compared to fulvestrant, ZB716 has the full potential to replace fulvestrant as a monotherapy or a combination therapy for breast cancer patients.

LOCATION: NEW ORLEANS, LA
STAGE: PRE-CLINICAL DEVELOPMENT

ZetaGen Therapeutics

PROPRIETARY MOLECULAR PATHWAY TO GROW BONE

ZetaGen Therapeutics (previously Fusologics, Inc) is an early stage therapeutic device company, which is developing products that grow bone by activating a novel molecular pathway. Discovered fortuitously, ZetaGen is commercializing a proprietary, small molecule-based osteoinductive platform technology that addresses a large unmet need for several medial applications for which bone growth leads to optimal outcomes. There are 400,000 cases of bone tumors annually in the U.S. Successful outcomes for patients with bone metastases require bone healing and the reduction in bone associated morbidities (pathologic fracture). ZetaFuse is a small molecule-based drug-device combination product. Delivered locally to a surgical area, it can improve bone healing, limit bone destruction (resorption), and decrease local tumor growth.

LOCATION: SYRACUSE, NY
STAGE: PRE-CLINICAL DEVELOPMENT

Advanced Chemotherapy Technologies

NOVEL SURGICALLY IMPLANTED IONTOPHORESIS CHEMOTHERAPY DELIVERY SYSTEM

Advanced Chemotherapy Technologies (ACT) has developed a novel device for infusing chemotherapies directly into poorly vascularized tumors. Traditional approaches to overcoming poor tumor vascularity focus on delivering massive doses of systemic chemotherapies, resulting in toxic side-effects that force many patients to stop treatment. ACT has overcome these issues by developing a surgically implanted iontophoresis delivery system that delivers higher doses of chemotherapies directly into the tumor tissue while lowering systemic toxicity. This technology advancement enables ACT to develop new treatments with existing chemotherapies and to explore promising new compounds that may benefit from higher dosing with lower systemic toxicity.

LOCATION: RALEIGH, NC
STAGE: PRE-CLINICAL DEVELOPMENT

NeOnc Technologies

INTRANASAL DELIVERY OF THERAPEUTICS

NeOnc Technologies, Inc. (NTI) is an early-stage cancer biotechnology company focused initially on intranasal (delivery through the nose) inhalation and other non-traditional delivery of a novel, highly purified form of monoterpenes (oils from fruits and plants), alone or with other chemotherapeutic (cancer treatment chemicals) agents. It will initially be used in clinical research for second line or salvage treatment of malignant brain cancer (gliomas) and other aggressive brain cancer. The company's lead compound is NEO100, a highly purified GMP produced intranasal perillyl alcohol (POH) in Phase IIa trial for recurrent glioblastomas (GBM). The second compound is NEO212, which is a GMP synthesized conjugate of temozolomide (standard of care drug for gliomas) with POH.

LOCATION: WEST HOLLYWOOD, CA
STAGE: IN CLINICAL TRIALS: PHASE I

Privo Technologies

NANO-ENGINEERED TOPICAL, LOCAL DRUG DELIVERY PLATFORM

Privo Technologies has developed a nanoparticle-based platform technology to deliver targeted chemotherapeutics locally via topical administration, the initial indication being oral cancer. The treatment (PRV111 patch) is composed of biocompatible polymers and embedded with nanoparticles. Upon contact with tissue, the particles are released and retained by cancer cells to limit systemic toxicity. Privo's topical cancer patch has the potential to revolutionize the way many epithelium-based cancers are treated. Epithelium cancers such as oral, skin, and anal cancers can significantly benefit from high concentration of topical and local treatment with negligible toxicity.

LOCATION: PEABODY, MA
STAGE: IN CLINICAL TRIALS: PHASE I/II

TheraTarget

POLYMER-BASED CARRIER PLATFORM FOR SOLID TUMOR THERAPEUTICS

TheraTarget's goal is to introduce new, safe biodegradable copolymer drug-conjugates into the solid cancer market to treat, breast, non-small cell lung (NSCL), pancreatic, and ovarian tumors. Through patented polymer-drug delivery platform technology, TheraTarget can provide cancer patients an extensive track record of expertise in designing copolymer-anti-cancer drug combinations (copolymer-drug conjugates) that effectively deliver anti-cancer drugs to solid cancerous tumors. It can be utilized with a variety of already FDA approved chemotherapeutic agents to increase efficacy, reduce systemic toxicity and their costs, as well as improve quality of life. TheraTarget's lead candidate, KT-1, the second-generation HPMA copolymer-epirubicin conjugate, in combination with anti-PD therapy, may turn breast tumors from "cold" to "hot," and ultimately expand the number of patients that respond to immune checkpoint inhibitors. Its success will significantly impact the cancer immunotherapy field.

LOCATION: SALT LAKE CITY, UT
STAGE: PRE-CLINICAL DEVELOPMENT

Abreos Biosciences

VERITOPE PLATFORM FOR DOSE MONITORING

Biologic drugs are the largest growth segment of the pharmaceutical industry and are among the most expensive pharmaceuticals. Despite evidence of a relationship between blood drug levels and clinical efficacy for most of these drugs, dosing usually follows a one-dose-fits-all approach. As a result, roughly one quarter of patients do not receive or are incapable of receiving a fully efficacious dose and, conversely, as many as one third of patients are excessively dosed. Direct monitoring of drug levels in patients will disrupt the current dosing paradigms and enable precise, personalized dosing that can improve outcomes, minimize side effects, and reduce costs by dose sparing in patients that are currently excessively dosed. Abreos's core enabling technology is the Veritope platform, which is a proprietary reagent platform based on peptide mimetopes, termed Veritopes, that can specifically detect a given biologic drug by mimicking the natural target, including cell membrane bound proteins. They have developed an extensive Veritope pipeline against marketed biologic drugs. Veritopes specifically detect the target biologic drug in human samples such as whole blood and serum and can be implemented in lab-based assays such as ELISA or lateral flow assay (LFA) for point-of-care testing.

LOCATION: LA JOLLA, CA
STAGE: NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE

bioSyntagma

SPATIAL, MULTI-OMIC TISSUE ANALYSIS FOR DIAGNOSTIC SCREENING AND TREATMENT GUIDANCE

bioSyntagma is developing AI-enabled "Google Maps" for tissue that can physically map cells, gene mutations, proteins, and more from cancer patient biopsies (spatial, multi-omic). This generates a "Molecular Fingerprint" that quantifies features causing drug resistance to predict patient responses to targeted drugs and identify drug combinations that would overcome resistance and prevent relapse. A bioSyntagma test saves payers billions of dollars from trial-and-error treatments, helps Pharma companies enroll the right patients into clinical trials, and enables personalized medicine.

LOCATION: PHOENIX, AZ
STAGE: PRE-CLINICAL DEVELOPMENT

Capio Biosciences

BIOPSY-FREE BIOMIMETIC PLATFORM FOR CTCS

Capio Biosciences is a biotech startup focused on delivering high-value oncology diagnostics that can help inform patient care decisions and improve outcomes. It is developing an advanced platform called CapioCyte™ for clinically significant capture of circulating tumor cells (CTCs) from whole blood. By utilizing a biomimetic flow-based system and nanotechnology-mediated multivalent cell capture surface, CapioCyte™ delivers significantly greater capture sensitivity than other platforms currently available. This greater sensitivity results in enriched and viable CTCs for enumeration and post capture molecular analysis such as RNA-Seq, PCR, NGS, and FISH as well as culture expansion. Capio Biosciences is also developing a novel machine-learning-based software for fast and accurate CTC analysis.

LOCATION: MADISON, WI
STAGE: PRE-CLINICAL DEVELOPMENT/IN CLINICAL TRIALS: EARLY FEASIBILITY, FEASIBILITY/PILOT

Captis Diagnostics

EXTRACELLULAR VESICLE-BASED LIQUID BIOPSY

Captis is developing a non-invasive lab service that will enable medical oncologists to provide actionable treatment management for solid tumor patients, which can significantly increase patient survival by guiding the therapy selection, therapeutic monitoring, earlier recurrence detection. The company's Extracellular Vesicle (EV)-based liquid biopsy tests will significantly improve cancer treatments, allow for better treatment control, enable early interventions, and change decision-making from reactive to predictive early interventions. Cancer cell derived EVs serve as biomarkers for early detection of cancer as they contain the genetic alterations found in the cancer cells of origin. There are no EV isolation products currently on the market that use the same principle. As a groundbreaking nanomaterial-based technology for EV isolation without the need for any bulk equipment, it can isolate EV with 80% efficiency in 15 minutes with high purity.

LOCATION: STATE COLLEGE, PA
STAGE: NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE

Frontier Diagnostics

CLINICAL ASSAY FOR ACCURATE DIAGNOSIS OF MELANOMA USING IMAGING MASS SPECTROMETRY

Frontier Diagnostics LLC (FDx) was founded to discover, develop, and commercialize innovative tissue-based diagnostics that improve patient care. The proprietary technology platform developed by the founders of FDx is Imaging Mass Spectrometry (IMS), a newly mature technology that combines the spatial information of microscopy with the unparalleled molecular specificity and sensitivity of mass spectrometry. IMS can produce thousands of molecular image maps in a single experiment that can be registered directly with specific anatomical features in the tissue. This capability complements existing pathology by adding objective diagnostic and prognostic capabilities based on the molecular expression rather than tissue morphology alone. This unique combination of capabilities positions IMS to revolutionize the $10 billion global clinical laboratory services market by providing pathologists access to a much-needed molecular technology.

LOCATION: NASHVILLE, TN
STAGE: PRE-CLINICAL DEVELOPMENT/DIAGNOSTIC TRIAL UNDERWAY FOR APPLICATION IN MELANOMA

Mirimus

PUSHING THE BOUNDARIES OF RNAI AND CRISPR TECHNOLOGIES

Mirimus develops RNAi and CRISPR/Cas9 genome editing platform technologies to screen for novel drug targets and genetically model therapeutic intervention in live animals and human cell lines. By exploiting RNA interference, a naturally occurring process that controls gene expression, they can reversibly silence specific gene targets and mimic drug therapy without the drug itself, enabling us to predict toxicities and evaluate efficacy in animals prior to drug development. Now with CRISPR/Cas9 genome editing available, Mirimus has synergized it with RNAi technology to give them speed and precision to engineer human disease models, both in animals and human cell lines, unlike before. By combining these powerful technologies, Mirimus moves beyond its competitors, engineering animals and companion cell-based models with enormous predictive power that will shape development of better tolerated therapies.

LOCATION: BROOKLYN, NY
STAGE: COMMERCIALLY AVAILABLE

DIAGNOSTICS/TOOLS

SynderBio

TARGETED CELL SEPARATION FOR RESEARCH AND DIAGNOSTICS

SynderBio is a life science instrumentation and diagnostic company that offers novel techniques to expedite and enhance cellular analyses by isolating desired cells for research or diagnostic purposes. Their patented approach uses biomechanical forces to process samples significantly faster and at a lower cost than traditional techniques, without the need for biochemical labels. SynderBio is pursuing two related but separate markets—sample preparation to provide high quality cell suspensions for single cell genomic sequencing (SCS) and cancer diagnostics by greatly improving sample preparation (i.e., tumor, biopsy, biofluid samples) to achieve enriched target cell content for fast, effective diagnosis through next generation sequencing (NGS) or via traditional pathology/cytology. SynderBio utilizes brief pulses of fluid shear stress to rapidly separate cells based on their intrinsic biomechanical differences. Current techniques require extensive preparation and rely on biochemical labels, while SynderBio's proprietary approach rapidly delivers viable, single target cells while removing dead/dying and undesired cell types.

LOCATION: CORALVILLE, IA
STAGE: NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE/PRE-CLINICAL DEVELOPMENT

Clarix Imaging

3D IMAGING DEVICE FOR INTRA-OPERATIVE MARGIN DETECTION

Clarix Imaging is positioned to disrupt the breast-cancer surgery market with volumetric specimen imager (VSI), a unique, portable 3D imaging-based solution for lowering the high re-operation rate of breast conserving surgery. Its imaging device and software application provides rapid and accurate margin assessment with an integrated workflow during breast-cancer surgery. This technology can significantly reduce the current 15-25% reoperation rate of breast-cancer surgery. Clarix's VSI has 90%+ demonstrated sensitivity and takes currently less than 5 minutes to complete the assessment, with a highly desired design feature that requires no change to existing operating room workflow and little training. With initial study data, the company expects that VSI can lower re-operations to less than 10%.

LOCATION: CHICAGO, IL
STAGE: CLINICAL TECHNOLOGY IN TESTING STAGE; FDA 510(K) SUBMITTED

CPSI Biotech

ENDOSCOPIC ULTRASOUND (EUS) CRYOCATHETER FOR ABLATION

CPSI Biotech, a private, integrative bio/medtech greenhouse company, develops and designs innovative cryo-medical devices for the ablation of targeted tissues. CPSI has developed innovative, minimally invasive cryoablation device platforms (GastroCS cryoablation console and FrostBite cryocatheter) for use with endoscopic ultrasound for the treatment of pancreatic cancer and other gastroenterological-based diseases. FrostBite is a novel game-changing ablation platform offering the ability to increase speed and effectiveness of "in situ freezing" (cryoablation), allowing for the targeted destruction of cancerous tissue in minutes compared to the hours currently required by surgical intervention. FrostBite not only effectively destroys the targeted lesion but reduces the risk of damage to surrounding tissue by delivering more precise destruction.

LOCATION: OWEGO, NY
STAGE: PRE-CLINICAL DEVELOPMENT

DEVICES

Fibralign

NOVEL THERAPEUTIC DEVICE PLATFORM FOR TREATMENT AND PREVENTION OF SECONDARY LYMPHEDEMA

Fibralign Corporation is a Stanford University spin-out that produces novel therapeutic medical devices to address major unmet medical needs. The company is already in commercial sales in the United States with its first product, the BioBridge® Collagen Matrix, a 510(k) cleared device that is based on Fibralign's proprietary Nanoweave® scaffolding technology. BioBridge's first target is treatment and prevention of secondary lymphedema, a global chronic disease that currently has no cure. Clinical benefit has already been demonstrated and a Stanford-led multi-site clinical study is currently underway for breast cancer-related lymphedema that is funded by an NCI SBIR bridge grant ($3 million). A compelling product pipeline has been established that includes treatments for peripheral nerve repair, peripheral artery disease, and volumetric muscle loss, each with preclinical benefit already demonstrated that has generated partner interest.

LOCATION: UNION CITY, CA
STAGE: IN CLINICAL TRIALS: PIVOTAL/COMMERCIALLY AVAILABLE

Fischer Imaging

SLOT SCANNING MAMMOGRAPHY TECHNOLOGY

Fischer Imaging's proprietary slot scanning technology doubles the resolution and contrast of today's mammography using less than half the X-ray dose. Traditional mammography uses cone beam radiation, which generates scattered radiation that blurs the images. MammoCAT™ uses a narrow, highly collimated, X-ray beam to scan the tissue in precise alignment with an inexpensive line-shaped detector. This method eliminates scattered radiation, resulting in images with double the contrast and resolution. MammoCAT™ also accommodates the natural shape of the breast, providing a painless, comfortable experience for the patient. The versatility of Fischer's technology permits multiple product configurations, ranging from an upright system in MammoCAT DM that can be upgraded to MammoCAT™ DBT to a prone, compressionless, full 360° imaging, to MammoCAT™CT that will allow screening, diagnosis, staging and biopsy in the same device. Conglomerates such as Hologic, GE, Siemens, Philips, Canon and Fuji are likely competitors. Their systems use cone beam radiation and large expensive 2D detectors that cannot match the resolution of Fischer's line detector. Their systems cannot provide the high contrast and low dose advantages.

LOCATION: WHEAT RIDGE, CO
STAGE: NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

Imago Systems

CONVERTING UNSTRUCTURED IMAGE DATA INTO STRUCTURED, HIGHLY INFORMATIVE VISUAL INTELLIGENCE

Imago's platform software solution, the Image Characterization Engine, Imago ICE™, utilizes the latest in machine learning to revisualize existing medical images. The basis of this technology is local micro-contrast convergence or simply "convergence". This digital imaging technique employs a sequence of transformations that cause relationships among neighboring pixel groups in an image to aggregate into predictable patterns that are consistent with the structure of whatever material is the subject of the image (human tissue, other animal tissue, or any other substance within an image), as well as consistent with the imaging modality that generated the image. As a result, each material is uniquely characterized and can be visually differentiated, using color and grayscale levels that are easily within the range of human vision. Integrated into the existing workflow, Imago ICE will securely provide a series of new visualizations enabling never-before-seen levels of detail and accuracy. It has been designed to reveal recognizable patterns, enabling clinicians to see very small or obscure lesions that would have otherwise been missed (false negatives) and bypass objects they might have otherwise mistaken for cancer (false positives). Clinicians will be better equipped to make more timely and accurate recommendations for optimal diagnosis and treatment.

LOCATION: LANSDOWNE, VA
STAGE: PRE-CLINICAL DEVELOPMENT

Madorra

DRUG- AND HORMONE-FREE TREATMENT FOR VAGINAL DRYNESS

Vaginal dryness results from a decrease in estrogen, caused naturally by menopause or artificially by cancer treatment. While many women use hormone-replacement therapy to relieve their symptoms, this is not an option for millions of women because of the health risks associated with hormones. Specifically, breast cancer survivors are contraindicated from using hormonal products because of the risk of cancer recurrence. While they experience some of the most severe symptoms, often at a younger age, breast cancer survivors are forced to make do with over-the-counter lubricants and moisturizers. Madorra is replacing pharmaceuticals with better, safer solutions for enormous unmet needs in the growing aging population. Madorra's first product is a revolutionary, drug- and hormone-free treatment for vaginal dryness. The simple, easy-to-use, at-home device will empower 1.8 million breast cancer survivors ($2B market opportunity) and 14.4 million post-menopausal women ($15B TAM) to improve their sexual health and quality of life.

LOCATION: PORTLAND, OR
STAGE: IN CLINICAL TRIALS: PHASE I/II AND EARLY FEASIBILITY, FEASIBILITY/PILOT

NE Scientific

SURGICAL GUIDANCE SOFTWARE FOR USE DURING ABLATIONS

NE Scientific has developed a software that accurately predicts the Radio Frequency Ablation (RFA) volume. The computed ablation volume is rendered using computer graphics fused to the CT image of the patient (acquired for example at the time of the procedure, according to the standard clinical workflow). The software additionally will identify the malignant tissues from contrast-CT images and build a model of their volume, which is also rendered fused to the CT image. The visualization of the tumor volume and of which part of this volume has been treated (in 2D and 3D views) allows the physician to understand in a simple and visual way whether parts of the tumor are still not necrotized, and if they can proceed to reposition the RF applicator and to treat those target tissues that are still untreated. The software will support multiple ablations by progressively accumulating in a "tissue damage map" the effects of each single ablation, and by updating the representation of which part of the tumor has been treated after each ablation. Through this approach—which integrates seamlessly with the current clinical workflow—physicians will be able to consistently treat medium and large tumors, without missing target tissues.

LOCATION: BOSTON, MA
STAGE: IN CLINICAL TRIALS: FEASIBILITY/PILOT; INITIAL COMMERCIAL RELEASE OF THE SOFTWARE EXPECTED IN 1H 2020

nView Medical

REAL-TIME 3D IMAGING SYSTEM

nView medical is an AI image creation startup with the mission to make surgeries safer, faster, and consistently accurate. nView's real-time 3D guidance system combines the accuracy of 3D imaging systems with the efficiency of fluoroscopic C-arms—the most common surgical imaging system—at a reduced radiation dose for patient and surgical staff. nView's 3D capable C-arm will be marketed as insta-3D. The system is similar to surgical C-arms in terms of positioning, mobility, and footprint, but provides 3D imaging and real-time 3D navigation. This technology can disrupt the image guidance market by displacing sales of C-arms, intraoperative 3D systems and surgical navigation systems. nView's technology can disrupt the $3.5 billion a year market of interventional imaging and image guidance, displacing technologies such as fluoroscopic C-arms, cath-labs, and surgical navigation.

LOCATION: SALT LAKE CITY, UT
STAGE: IN CLINICAL TRIALS: EARLY FEASIBILITY

Carevive Systems

END-TO-END DIGITAL ONCOLOGY PLATFORM

Carevive is an end-to-end digital oncology platform that seamlessly integrates into clinical and electronic health record (EHR) workflows to increase patient and provider engagement for improved health outcomes. Carevive's platform is centered on their proprietary Clinical Intelligence System, an algorithm-based engine that combines EHR data, evidence-based guidelines and patient-reported outcomes into one solution). Carevive licenses its PERFORM package to health systems that includes personalized treatment care plans, clinical trial screening, proactive symptom monitoring/management, survivorship care planning, and data analytic features to improve the health-related quality of life and survival of cancer patients, while increasing cancer service line revenues and improving clinic efficiencies. Carevive has 19 health system customers, which includes 600 clinician users who treat approximately 67,000 patients.

LOCATION: NORTH MIAMI, FL
STAGE: COMMERCIALLY AVAILABLE

Shade

WEARABLE UV SENSOR

Shade has developed the world's first and only ultraviolet detector that mimics the skin sensitivity to UVB and UVA rays. Shade's goal is to become the "UV-sensing engine" in wearable products, a multi-billion-dollar market segment, by selling the world's only accurate and low-cost UV index sensor. Shade already has an R&D agreement in place with Beiersdorf, a publicly-traded skincare company, which will conduct a pilot study with the sensor to support efficacy claims for their products. Shade's revenues have reached $250,000 per year (break-even) mostly from sales to clinical studies. Today, Shade's detector is too large and cumbersome to be easily incorporated in wearable devices (e.g., smart watches). With funding and the right hires, Shade plans to incorporate its detector technology into a package specifically designed for small devices.

LOCATION: NEW YORK, NY
STAGE: COMMERCIALLY AVAILABLE

ONE-PAGE COMPANY OVERVIEWS

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

Adecto Pharmaceuticals / ADAM8-Targeted Cancer Therapy

Nora Mineva | nora.mineva@adectopharma.com | 617-645-2931 | www.adectopharma.com

Company Overview (Clinical Impact and Value Proposition)

Adecto Pharmaceuticals is developing the first targeted therapy against ADAM8-expressing cancers and a companion diagnostic to identify patients who can benefit from it. ADAM8 is a novel cell surface target protein, which drives aggressive tumor growth and metastasis and is associated with poor patient survival. It has been implicated in several solid tumors, including breast, gastric, colon, liver, lung and pancreatic cancer.

Market and Commercialization Strategy

Based on current knowledge of ADAM8 expression in multiple cancers, and their reported prevalence, Adecto estimates the overall global market size for their therapeutic is ~2 million patients. The company plans to focus on triple-negative breast cancer (TNBC) as the first indication and then to expand to other malignancies. They plan to bring forward a strong data package to attract investors and/or a strategic pharmaceutical partner for full development through IND-enabling studies, clinical trials, and commercialization.

Technical & Competitive Advantage

Adecto's ADAM8 therapy is a first-in-class, monoclonal antibody that specifically and simultaneously inhibits the extracellular Metalloprotease and Disintegrin domains of ADAM8, which together drive its cancer promoting functions. Two top therapeutic candidates are in preclinical development. As single agents in TNBC mouse models, they decrease primary tumor growth, reduce metastasis, and extend survival. When added to chemotherapy, they significantly enhance treatment response. Adecto's ADAM8 diagnostic takes advantage of currently available technology (immunohistochemistry [IHC] of tumor biopsies). Two top IHC-grade diagnostic antibodies are also in preclinical testing. To date, there is no targeted treatment against ADAM8 cancers or a diagnostic assay for their detection marketed or in the pipeline. Several promising therapeutic agents are currently in different stages of clinical testing for TNBC. These target distinct mechanisms suggesting a possibility for combinatorial use with an anti-ADAM8 therapeutic.

Regulatory Strategy & Intellectual Property

Adecto plans to initially offer their therapy in combination with current standard-of-care chemotherapy for recurrent TNBC, which typically advances in 6-8 months, and evaluate progression-free survival. They will carry out Phase I/II safety and dose escalation studies starting with their antibody as a single agent and then in combination with chemotherapy in all-comers TNBC patients, while clinically validating the diagnostic assay. Patients with ADAM8-positive tumors would then be selected for a Phase III efficacy trial using the diagnostic assay (patients with brain metastasis will be excluded, as antibodies do not cross the blood brain barrier). Once efficacy is established, Adecto would expand to early TNBC, like other biologics on the market (e.g., Herceptin). A composition and a methods patent have been filed and the company has an Exclusive Option Agreement with Tufts University for this technology.

Key Milestones

Description	Date/Year
Early safety data for ADAM8 targeting and for chimeric therapeutic antibodies	12/2019
Identification and early validation of lead diagnostic antibody for immunohistochemistry of tumor biopsies	03/2020
Humanization and early safety testing of lead therapeutic antibody	05/2020
Identification of clinical entry path for therapeutic antibody	08/2020
IND from FDA	04/2022

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2016	Phase I NIH/NCI STTR grant	ADAM8 therapeutic antibody development	$416,490
2018	Phase II NIH/NCI SBIR grant	ADAM8 therapeutic antibody development	$2,002,084
2019	Phase I NIH/NCI SBIR grant	ADAM8 diagnostic development	$300,000

Use of Proceeds

Adecto is looking to raise $12M ($4M from government grants & $8M from investors or a strategic partner) for IND-enabling studies

Key Team Members

Gail Sonenshein, PhD: Founder & President

Internationally recognized expert on breast cancer; Received her PhD in Biology from MIT and is Professor at Tufts University.

Nora Mineva: Chief Scientific Officer

PhD in Pathology from Boston University School of Medicine; Expert in cancer biology

Adecto key advisors:

Business development: Susan Long, PhD (former VP of BD, Genzyme Corp.); John Tagliamonte, MBA (former VP of BD, ImmunoGen)

Therapeutic antibody development/evolution: Ann Marshak-Rothstein, PhD (Prof. of Medicine, UMASS Medical School); Phillipe Billiald, PhD (Prof. of Biochemistry, University of Paris-Sud)

Diagnostic development: Walter Carney, PhD (Former President & CSO Oncogene Science Diagnostics)

Medical oncology/Clinical trials: John Erban, M.D. (head of the Breast Health Program at Tufts Medical Center)

Dualogics / Bispecific Antibody Engineering

Ryan Hallett, CEO | ryan@dualogics.com | 919-391-0253| www.Dualogics.com

Company Overview (Clinical Impact and Value Proposition)

Dualogics is a drug development company focused on engineering innovative therapeutics to improve the life of patients in need. The company's core technology is a platform for making bispecific antibodies (OrthoMab) from any two existing antibody sequences and their expertise is in combining computational biology and directed evolution to select leads that have novel use. Dualogics has a growing pipeline focused on harnessing T cell biology; redirecting and activating T cells for oncology applications and inducing tolerance in autoreactive T cells for autoimmune indications. Leveraging the strengths of computational modeling and OrthoMab versatility, Dualogics has developed a computational pipeline for designing and displaying full-length bispecific libraries for high-throughput screening aimed at targeting areas of the bispecific market unreachable by current technologies.

Market and Commercialization Strategy

Dualogics' DLB program is focused on developing a T cell redirecting bispecific antibody for the treatment of metastatic breast cancer. This molecule redirects T cells to a unique glycoform of the MUC1 receptor found on $ER^+/HER2^-$, $PR^+/HER2^-$, and triple negative breast cancer cells for targeted cytolysis. Over 60% of these patient groups express high levels of antigen, making them suitable candidates for this therapy, which translates to an estimated market size of $4B. Using an FDA-approved diagnostic for the MUC1 glycoform, Dualogics has established minimum levels of tumor expression for cytotoxicity and will use the diagnostic readout to guide patient selection/inclusion allowing for future expansion into pancreatic cancers, which also express the MUC1 glycoform.

Technical & Competitive Advantage

Dualogics' core technology is the OrthoMab platform, a simple way to make bispecific antibodies from two existing antibody sequences. Heavy interest in bispecific antibodies has led protein engineers to develop several workarounds for achieving bispecificity, however, lack of compatibility and long, costly development times are becoming key limitations. The OrthoMab platform is a set of mutations that allow for the co-expression and correct assembly of a bispecific antibody from two existing mAb sequences. This means that antibody sequences generated from library screening, animal immunization, and human B cell sequencing can all be used to generate novel bispecific leads that retain the stability and manufacturability that have made traditional antibodies successful in the clinic.

Regulatory Strategy & Intellectual Property

The OrthoMab platform is covered by three patent filings, including one that was granted in 2018. These filings cover methods and amino acid mutations to the antibody scaffold that create orthogonal Fab interfaces and a heterodimeric Fc interface that guide the assembly of bispecific antibodies. Altogether, our IP allow the production of near native bispecific antibodies as well as a suite of antibody-like molecules, all of which have unique characteristics and distinct value. In 2017, Dualogics began filing product-specific patent applications that cover internally developed therapeutic molecules. We are aiming to complete a pre-IND meeting for our breast cancer program in 2020 and initiate a phase I/II study in breast cancer patients in 2022.

Key Milestones

Description	Date/Year
Triple Negative Breast Cancer lead enters lead optimization	Q2 2019
OrthoMab display launched for the optimization of DLC program (targets currently undisclosed)	Q2 2019
Cell line development begins for acute GVHD program (DLA)	Q2/Q3 2019
Commercial license for OrthoMab platform	Q3/Q4 2019

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2017	SBIR-NCI	Development of a bispecific antibody for triple negative breast cancer	$225k
2017-18	Loan	Company Inception and Strategic Research Loan from North Carolina Biotechnology Center	$325k
2016-19	Revenue	Partnerships around the OrthoMab platform and therapeutic programs	>$600k

Use of Proceeds

Dualogics is raising a Series A round of financing focused on bringing its internally developed therapeutic programs to the clinic and expanding its pipeline using a computationally-guided high-throughput bispecific display platform built around OrthoMab.

Key Team Members

Ryan Hallett, PhD: CEO & Co-Founder

Has built a revenue-generating business to power Dualogics internal R&D efforts; Spearheading Dualogics' co-development efforts with industry collaborators all over the world

Dennis McNamara, MBA: CBO

Experience in private and public equity financings which collectively have raised more than $150M; Former SVP/CBO of POZEN

Tim Jacobs, PhD: CTO & Co-Founder

Extensive experience in developing creative solutions to protein engineering and drug delivery challenges

Extend Biosciences – D-VITylation® platform technology

Tarik Soliman, CEO | tsoliman@extendbio.com | (732) 599-8580 | extendbio.com

Company Overview (Clinical Impact and Value Proposition)

Extend Biosciences is harnessing the biology of vitamin D to improve the pharmacokinetic properties of biologics. Using the D-VITylation® platform technology, they covalently attach vitamin D to the peptide or protein, which results in an extended half-life and improved absorption and bioavailability due to its interaction with vitamin D binding protein (VDBP), an abundant serum protein. Cachexia is a complex metabolic syndrome that occurs in the advanced stages of cancer and is associated with a worsened prognosis. There are no FDA-approved treatments for cachexia, and current strategies include appetite stimulation and exercise. One of Extend's pipeline products under this platform, EXT418, is a long-acting ghrelin that increases food intake and restores muscle mass and grip strength in animal models of tumor-induced cachexia. Extend's product will fulfill an unmet medical need by providing a drug that addresses the underlying biological mechanisms of cachexia.

Market and Commercialization Strategy

Worldwide, the cancer cachexia market was $1.63B in 2016, with an expected CAGR of 4.9-5.2%. Cachexia is also seen in people with almost any chronic disease (including AIDS, COPD, MS, RA, and CHF), and, therefore, Extend expects the total market in the years following approval to be much larger. Moreover, the market is projected to grow due to the increasing awareness of the importance of cancer supportive care, this complex metabolic syndrome, and due to the rising geriatric population. Extend is seeking pharma partners to assist with clinical trials and the regulatory approval process.

Technical & Competitive Advantage

Ghrelin, also known as the "hunger hormone", is an ideal therapeutic target for cachexia. Both animal and human studies have shown that exogenous administration of ghrelin stimulates the release of growth hormone, increases food consumption and muscle mass, and stimulates anti-inflammatory actions. However, in its native form, ghrelin treatment is limited by its short half-life and rapid deacylation to an inactive form. Furthermore, current dosing strategies require IV administration to produce a therapeutic effect. D-VITylation significantly lengthens ghrelin's half-life for much less frequent dosing, and increases subcutaneous bioavailability, allowing for self-administration. Importantly, the vitamin D modification is small enough to not interfere with peptide function. Competitor approaches that utilize other half-life extension strategies, such as PEGylation, cannot be used with peptides such as ghrelin because the conjugation results in loss of functional activity. Moreover, Extend has modified their ghrelin to be constitutively active to provide the maximum therapeutic effect. The company collaborated with Jose Garcia, MD, PhD, to demonstrate efficacy in a mouse model of cancer cachexia, where EXT418 increased lean body mass, fat mass, grip strength, and food intake, while having no effect on tumor size.

Regulatory Strategy & Intellectual Property

Extend plans to apply for Fast-Track designation and seek FDA approval for a drug-device combination (with an off-the-shelf self-injector pen to be introduced in Phase II/III). They aim to have a global regulatory strategy at an early stage in order to conduct trials that will produce data that will be acceptable to multiple regulatory authorities, thus minimizing cost and time to approval. EXT418 should be covered by medical insurance plans and the price should be in line with similar injectables. Extend's IP was conceived by the founders and assigned to the company. The company has several issued US patents and is prosecuting worldwide. The company will continue to file multiple follow-on patents to protect the additional composition of matter as well as other methods of use.

Key Milestones

Description	Date/Year
CMC – nonGMP batch	Jan 2020
GLP Toxicity – rat and dog	June 2020
IND filing	Nov 2020
FIH trials – NSLCL patients	Jan 2021

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2020-12	Seed Funding	Founders	$120K
2013-current	Grants & Contracts	SBIR Phase I/II: Dept. of Defense, NSF, NIH (NCI for this project; NIAID, NIDDK, NIAAA)	~$10M

Use of Proceeds

Extend is seeking a Series A round of $20M for the remaining IND-enabling studies and to enter Phase I and II clinical trials to show proof-of-concept in humans ($4M nonclinical, $1.5M Phase I, $11M Phase II POC + 3 years of operating costs).

Key Team Members

Tarik Soliman PhD: Cofounder and CEO

Expert on half-life extension technologies; Has done discovery work on two approved drugs (Lonquex® and Rebinyn®)

Laura Hales PhD: Cofounder and CBO

Expert in cancer biology; Was part of the team at Neotropix that brought a novel oncolytic viral therapy into the clinic

For-Robin, Inc. / Breast Cancer Antibody Immunotherapy

Kate Rittenhouse-Olson, CSO | krolson@buffalo.edu| 716-866-6941| www.for-robin.com

Company Overview (Clinical Impact and Value Proposition)

For-Robin is an antibody immunotherapy company whose primary mission is developing therapy for breast and lung cancer patients. The company's patented humanized antibody hJAA-F11 targets all breast cancer cell subtypes including triple negative breast cancer which currently has no targeted therapy, and also targets both non-small cell and small cell lung cancers. hJAA-F11 specifically targets the alpha-linked form of a disaccharide tumor marker, the Thomsen-Friedenreich glycoantigen (TF-Ag) a well-known antigen found on the surface of 80% of all carcinomas and not expressed on normal cells. JAA-F11 is expected to be safe as humans have small amounts of naturally-occurring antibody to the TF-Ag, indicating likelihood of safety at higher quantities.

Market and Commercialization Strategy

Of the more than 1.5 million new cancer cases in the US each year about 50% are expected to be targets for hJAA-F11. In 2018, 29 Mab and Mab-drug conjugates were licensed in the oncology market forming the basis of a multi-billion-dollar market for cancer immunotherapy. Mab therapy generally has less side effects than standard chemotherapy and radiation. For-Robin's main antibody competitor in breast cancer immunotherapy, Herceptin, treats only 25% of BrCa and generated $7 billion in sales in 2018 with a ~4% growth in market per year. The effective market for hJAA-F11 is potentially $22 billion. The company has been selected by NIH NExT program for a milestone driven partnership, beginning with NCI validation of the tumor targeting ability of hJAA-F11. Further NExT milestones include the current production of a cGMP cell line, producing cGMP Ab, safety testing and FDA IND preparation. In addition, we are analyzing the potential of imaging with radiolabeled hJAA-F11 as a companion diagnostic that would allow stratification of the appropriate patient population to treat, as well as a differential imaging for indeterminant lesions in lung cancer diagnosis.

Technical & Competitive Advantage

hJAA-F11 has potential to become the next blockbuster biologic for use in therapy for BrCa, since it is expected to target >80% of all BrCa. hJAA-F11 addresses the unmet need for treating the most aggressive triple negative BrCa that lacks estrogen, progesterone and Her2 receptors. JAA-F11 has reactivity against 88% of all BrCa and including triple negative BrCa. JAA-F11 was also shown to react with 84% of 235 tested lung cancer cases and shown to have in vivo efficacy against human non-small cell lung cancer and small cell lung cancer in vivo in SCID and nude mouse models as well in human tumor xenograft mouse models. The few options such as Keytruda and Opdivo for NSCLC immunotherapy carry serious risks and show an overall response rate of only 19% and 18% respectively. For-Robin projects to capture a large percentage of the unmet triple negative BrCa and and other BrCas and as well as SCLC and NSCLC.

Regulatory Strategy & Intellectual Property

For-Robin has five approved patents and one provisional patent. JAA-F11 is owned and patented by the University at Buffalo and exclusively licensed to For-Robin for commercialization. IP position is based on the novel design of the humanized antibodies composition and the resulting unique characteristics for ADCC and for internalization for tumor targeting and drug delivery.

Key Milestones

Description	Date/Year
Develop and validate tests for candidates for direct Ab supporting pre-IND animal testing	completed
Pre-IND meeting with FDA	12/31/2019
Develop GMP cell lines for lead candidates and produce cGMP material	04/01/2020
Obtain IND for FIH trial	09/31/2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2013-2020	Grants	NIH-NCI: 4 SBIR/STTR grants (Phase I and Phase II)	$2.61M
2013	Grant	UB/Bruce HolmesCatalyst	$50K
2013-2020	Grant	NYSTAR (total of 5 grants)	$121K

Use of Proceeds

For-Robin is seeking strategic partnerships with pharma partners and/or venture or angel funding to support the extended Phase I clinical trials in both lung and breast cancer therapy with naked humanized hJAA-F11 and/or clinical trials of differential imaging diagnostic applications of hJAA-F11 in lung cancer. The first in human clinical trials are anticipated to start in the Spring of 2021.

Key Team Members

Kate Rittenhouse-Olson, PhD, SI, ASCP: President & CSO 25+ years as University of Buffalo (UB) Professor & Biotechnology Program Director in Biotechnical and Clinical Laboratory Sciences; Has studied carbohydrate tumor associated antigens and TF-Ag since 1985

Sally Quataert, PhD: CEO Specializes in RQAP-GLP operational/strategic management; Experience in start-up vaccines, large pharma R&D, clinical translational research, and compliance/QA

James Olson, PhD - Chairman UB Distinguished Professor, specializing in toxicology and the environmental health sciences

GlyTR™ Therapeutics

GlyTR Therapeutics / TACA-Targeted Immunotherapy Platform

Raymond Zhou, CEO | raymondzhou@glytrtherapeutics.com| 916-612-9988 | www.glytrtherapeutics.com

Company Overview (Clinical Impact and Value Proposition)

GlyTR is an immunotherapy platform technology capable of targeting tumor associated carbohydrate antigens (TACAs) present in most cancer types, from breast cancer to leukemia. GlyTR overcomes many of the shortcomings of current immunotherapies by binding to never before targeted sugar antigens (TACAs) that are common to virtually all types of cancer and essential to cancer growth and metastasis. A single GlyTR molecule triggers T cell dependent killing of numerous cancer types.

Market and Commercialization Strategy

The global cancer therapeutics market is expected to reach $172.6 billion by 2022 from $121 billion in 2017, giving a compound annual growth rate (CAGR) of 7.4% from 2017 to 2022. Immuno-Oncology is one of the "hottest" areas of investment currently. GlyTR's timing is excellent and coupled with the unique ability to target most cancer types with one or two agents, it has the potential to dominate and greatly expand the Immuno-Oncology market. The company will leverage platform technology to achieve a good mix of products to develop internally plus licensing/selling to strategic pharma partners with footprints in immuno-oncology.

Technical & Competitive Advantage

The GlyTR2 bi-specific protein 1) binds Tn antigen with high sensitivity and specificity 2) triggers T cell dependent killing of blood and solid cancer cells in vitro with an ED50 as low as ~25pM 3) does not activate T cells in the absence of target cancer cells 4) reduced T cell leukemia tumor burden in the spleen of humanized mice by up to ~90% after 1 week of treatment while inducing a robust anti-tumor CD8+ T cell response 5) is stable in human plasma for 21hrs at 37°C 6) has a serum half-life of ~2hrs, the same as the FDA approved bi-specific protein Blinatumomab and 7) displayed no toxicity in preliminary testing using humanized mice, with no alterations in RBC, WBC, liver function, kidney function, electrolytes, cholesterol or muscle following 50ug/day x 2 days. The primary competition is from monoclonal antibody (mAB) based bi-specific immunotherapies, and engineered T cells (CAR T & TCR therapies). Theses therapies must engineer a specific mAB to a specific protein target on a specific cancer cell, a slow development path which results in one drug for one cancer. Moreover, the lack of cell surface protein antigens that are uniquely expressed/altered in cancer greatly limits the type of cancers that can be targeted by such therapies. GlyTR's technology does not need an engineered mAB to target its sugar antigens; which are abnormally expressed in multiple cancers and play an integral role in tumor growth and metastasis. Current CAR T therapies frequently target protein antigens that are expressed in normal cells, limiting usefulness to blood cancers, where bone marrow stem cells can re-populate the loss of normal blood cells following treatment. This is not possible with solid tumors. GlyTR can readily target both blood and solid cancers with a single therapeutic.

Regulatory Strategy & Intellectual Property

The composition of matter patent that covers the use of all sugar-binding proteins in combination with antibodies or intracellular signaling domains to generate bi-specific proteins or CAR T cells, respectively was filed in November 2017. GlyTR Therapeutics has an exclusive option agreement with pre-negotiated terms for a license of the IP owned by the University of California. GlyTR plans to prioritize cancers for clinical (human) studies based on best results in animal studies, specific unmet cancer needs, market size and ability to obtain FDA fast track and orphan drug status. GlyTR plans to obtain an IND by utilizing the same approach for CAR T cells given that GlyTR proteins are human specific and do not bind to lower primate T cells.

Key Milestones

Description	Date/Year
Obtain IND for GlyTR1 and/or GlyTR2 bi-specific proteins	2020/2021
Complete first in-human clinical trials for GlyTR1 and/or GlyTR2 bi-specific proteins	2023/2024
Complete CAR T animal and IND studies initiate human trials	2023/2024

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
10/2017	Angel (debt)	Bob Genthert	$100K
2018-2023	Cancer Moonshot Grant	NIH-NCI (Cancer Moonshot Grant and STTR Grant)	$3.7M
2016-2019	Internal Grants	University of California	$330K

Use of Proceeds

GlyTR is seeking $10-$15M in Series A funding for lead optimization, efficacy/toxicology studies in animal models, and operations.

Key Team Members

Raymond Zhou, PhD: CEO & Co-Founder

10+ years immunology research; Post-doctoral fellow at UC Irvine; published in *Nature Oncology*

Michael Demetriou, MD, PhD, FRCP(C)

17 years immunology research at UC Irvine; Has aquired ~$18M in funding; Published in *Nature*, *Cell*, *Nature Immunology*

Bob Genthert: Investor & Business Advisor

Successful entrepreneur at multiple start-ups; Raised $200M+ in financing; 35+ years of executive and finance experience

Keystone Nano / Developing novel cancer therapeutics

Jeff Davidson | jdavidson@keystonenano.com | 814-466-5080 | Keystonenano.com

Company Overview

Keystone Nano (KN) is an emerging biopharmaceutical company, building on technology licensed from Penn State University, and formed in 2005. KN has raised more than $16.3 million from a combination of pharmaceutical companies (18%), grants (62%) and equity investment (20%). KN's lead product is the first clinical testing of a unique bioactive cell messenger that impacts both cancer metabolism, upregulates the immune system, and increases sensitivity to standard chemotherapeutics. Follow on technologies provide unique ways to deliver RNA as cancer therapies with safety, targetability, and efficacy. KN's compound – Ceraxa – is currently testing at the highest plan dose level.

Market and Commercialization Strategy

KT plans to take the lead product through Phase II clinical testing and partner with a pharma or biotech company or carry on Phase III testing on their own with new infusions of capital. The Phase II study will investigate the use of Ceraxa as both a monotherapy and combined with the current standard of care in an adaptive clinical trial testing in three indications – lung cancer, pancreatic cancer and liver cancer. KN also has foundation testing to explore the efficacy of Ceraxa in the improved treatment of AML.

Technical & Competitive Advantage

KN's technology is patent protected to 2033, has orphan drug status in three indications, and is a trade secret protected technology. Furthermore, they have a substantial lead in clinical testing and Ceraxa has not identified a Dose Limiting Toxicity in spite of increasing dose level by more than 500% from the starting point and has shown disease stabilization in 5 of 12 patients tested for more than 2 months.

Regulatory Strategy & Intellectual Property

In addition to standard IP protections Ceraxa as a Nanotherapy is quite difficult to copy – as a complex nanostructure, companies seeking to compete are going to need to conduct clinical testing to demonstrate the equivalence of their formulations. KN has managed IND supporting studies, filed INDs, and managed clinical trials.

Key Milestones

Description	Date/Year
Completion of Phase I Solid Tumors Testing	Q2 2020
Initiation of Phase I / II AML Testing	Q2 2020
Initiation of Phase II Adaptive Solid Tumors Trial	Q3 2020
Completion of first Phase II solid tumors Trial	Q3 2021

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2005-2015	Grants, Pharma payments	Combination of pharmaceutical projects and grants	$250K to $500K per year
2016	Grants, Pharma payments	Above plus convertible notes	$1.9M
2017	Grants, Pharma payments	Above plus convertible notes	$875K
2018	Grants, Pharma payments	Above plus convertible notes	$838K

Use of Proceeds

KN is seeking $10 to $15 million to support the Phase II adaptive solid tumors trial and the Phase I / II AML study. This funding will allow the completion of the Phase II studies – facilitating partnership or next level financing (IPO, acquisition).

Key Team Members

Jeff Davidson, MBA: CEO
Founded KN, raised $16 million; founded PA Life Sciences
Chris Prior, PhD: Executive Chair
Built and sold two companies with proceeds of more than $500 million, raised over $75 million in financing
James Adair, PhD: CSO
Internationally recognized materials scientist
Mark Kester, PhD: CMO
Developer of Ceraxa, Director of UVA NanoStar; serial inventor
James Sharpe, MBA: VP of BD
Co-founded 3 biotech companies, negotiated over 40 transactions valued over $200 million and raised over $25 million

Modulation Therapeutics / Targeted Radiotherapy for Melanoma

Lori Hazlehurst, CEO| hazlehurst.modulation@gmail.com|304-293-3398| www.modulationtherapeutics.com

Company Overview (Clinical Impact and Value Proposition)

MTI develops safe and effective drugs for the treatment of cancers refractory to standard of care treatment options. As of Q4 2019, Modulation anticipates having 3 major first-in-class drug pipelines in early clinical or late pre-clinical stages of development. One of these drugs, MTI-201, an Actinium-225 radio labeled peptidomimetic for metastatic cutaneous or uveal melanoma treatment. precisely targets the Melanocortin 1R expression on Melanoma cancers and irradiates the tumor with a high dose of destructive energy while sparing healthy tissue due to the short irradiation distance (only a few cell diameters). *In vivo* studies with mice have shown complete cure with a single bolus dose and very low toxicity even at the highest effective doses. MT-201 hits the Melanoma target within 30 minutes of injection and then clears rapidly. MTI-201's 10 Day half-life uniquely supports central quality-controlled manufacturing with convenient express distribution to patient clinic locations throughout the world.

Market and Commercialization Strategy

The annual cost for treating melanoma has recently grown faster than the annual treatment costs for all other cancers combined. Over 1/3 of metastatic cutaneous and almost 100% of uveal melanoma patients do not respond to current therapies and will die within 6-12 months with currently available therapies. Foresight's technology niche market report for Modulation estimates a total addressable melanoma therapeutics market size at $5.64B by 2023. Modulation estimates a potential market share of >$1B for MTI-201 by 2023. The company is purposefully pursuing a lean yet agile entrepreneurial structure, that keeps overhead costs low while engaging high quality specialty expertise as needed in scientific founder-managed collaborative teams.

Technical & Competitive Advantage

Cutaneous and uveal melanoma remain one of the most chemotherapy-resistant malignancies. Unfortunately, uveal melanoma is not responsive to checkpoint inhibitor immunotherapy and thus patients have limited effective therapeutic choices. MTI-201 precisely targets the melanocortin 1 receptor (MC1R) expressed on 90 and 94% cutaneous and uveal melanoma tumors. The advantage of a peptidomimetic approach compared to an antibody approach for targeted radiotherapeutics is that the unbound therapeutic is rapidly cleared and thus increasing the therapeutic window. MTI-201 is based on the most specific MC1R-targeting ligand ever reported. MTI-201 is an agonist for the melanocortin 1 receptor, resulting in rapid internalization inside MC1R expressing melanoma cells. Targeted tumor cells or other tumor-related cells within 100 microns are irradiated with lethal alpha-particle emissions, but normal cells >100 microns or about 10 cells from the targeted cells are not exposed to lethal doses of radiation.

Regulatory Strategy & Intellectual Property

GLP-compliant Tox studies, GMP-compliant synthesis studies, and IRB clinical protocols are complete. MTI-201 has received Orphan Designation by the FDA for uveal melanoma treatment. IND approval is expected in Q4 2019 and first in human clinical trials against metastatic uveal melanoma is expected to start later in Q4 2019 at the Moffitt Cancer Center. Modulation has two issued background patents and one pending application pending focused on the lead compound moving to the clinic.

Key Milestones

Description	Date/Year
First Clinical Trial for MTI-201	11/2019
Earliest Possible Marketing Approval for MTI-201	2022

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2013	Development Loan	Florida Institute for Commercialization	$300K
2015/2017	Contracts	NIH-NCI: Phase I/Phase II Contracts	$2.3M
2017	Angel Convertible Debt	WVU Research Corp	$220K

Use of Proceeds

MTI is seeking $2.5M in convertible debt to close within 6 months, plus another $2.5 M within 18 months to complete Phase II clinical trials in 2022. MTI expects to out license or partner with large pharma within 3 years. Revenues are expected to provide new investors with 10X ROI.

Key Team Members

Lori Hazlehurst, PhD: President, Co-founder

Associate Director of Cancer Research at West Virginia University; Worked on early development of Pixantrone

Mark McLaughlin, PhD: Executive Vice President, Co-founder

Professor of Medicinal Chemistry at WVU; Former Senior member of the Drug Discovery Department - Moffitt Cancer Center

William Dalton, MD, PhD

Former CEO of H. Lee Moffitt Cancer Center in Tampa, FL and current CEO, Founder and Board Chairman of M2Gen

Tim Hazlehurst: COO

35 years' experience as president of multiple companies leading M&A, R&D, Marketing, Sales and International Manufacturing

Molecular Theranostics / Peptide-Targeted MRI Contrast Agent

Yajuan Li, CEO | info1@ptheranostics.com |216-881-8389 | www.mtheranostics.com

Company Overview (Clinical Impact and Value Proposition)

Molecular Theranostics (MT) aims to develop and commercialize innovative imaging agents for the precise detection and characterization of aggressive tumors. Specifically, MT has developed a targeted MRI contrast agent (MT218) and a PET probe (MTP219) specific to an oncoprotein in tumor microenvironment for cancer imaging. The efficacy of the imaging agents has been demonstrated in different tumor models, including breast cancer, colon cancer, head and neck cancer, liver cancer, pancreatic cancer, and prostate cancer. The imaging agents are effective to provide early detection of small aggressive solid tumors and can differentiate aggressive tumors from benign tumors and tissues. The pre-clinical GLP safety data have demonstrated the safety of MT218. Commercialization of MT's technology will address the unmet clinical need of disease-specific imaging modalities for high-resolution and precise differential diagnoses, image-guided target-specific biopsies, and biopsy-free diagnosis, and will provide much needed non-invasive imaging assistance to the physicians for precision cancer management.

Market and Commercialization Strategy

The global contrast media/contrast agent market is expected to reach a value of $5.17 Billion by 2020 from an estimated value of $4.21 Billion in 2015. The US MRI contrast agent market was estimated by the Frost & Sullivan market research firm to be $400M for 2012. MT is currently performing the FDA-mandated safety studies of MT218 and will perform the first-in-man clinical trials once an IND is approved by the FDA. MT is also actively seeking collaboration and strategic alliance with major pharmaceutical companies specialized in imaging agents for later phase clinical trials and commercialization of the imaging agents.

Technical & Competitive Advantage

First, MT218 is a disruptive imaging technology for precision MR imaging of a spectrum of aggressive human cancer because there is no cancer-specific contrast agent available for clinical use. Second, MT218 is shows a major safety advantage of low effective dose. MT218 could effectively detect life-threatening tumors in mice at 0.02 mmol/kg, while ProHance or other Gadolinium based contrast agents could not, even at the clinical dose of 0.1 mmol/kg. Low dose of MT218 will reduce the existing agents' dose-dependent gadolinium accumulation in the brain. Third, MT218 has the potential to be used for risk-stratification and assessment of disease progression and therapeutic response, while no imaging technology approved can effectively address this unmet need.

Regulatory Strategy & Intellectual Property

MT has been working closely with the FDA to seek guidance for preclinical and clinical development of the imaging agents. MT has been following the FDA's guidelines to perform required assessments of the imaging agent to eventually acquire the FDA approval for marketing. MT has licensed the exclusive rights of the imaging agents from Case Western Reserve University.

Key Milestones

Description	Date/Year
Pre-IND meeting	07/2018
Completion of the FDA mandated preclinical safety assessment of MT218	12/2019
IND submission for clinical trials	06/2020
First-in-human clinical trial	08/2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2015	SBIR Phase I	Commercialization of the targeted MRI agent MT218	$0.25M
2016	Investment First Round	Commercialization of the targeted MRI agent MT218	$2.50M
2017	SBIR Phase II	Commercialization of the targeted MRI agent MT218	$2.00M
2019	Investment First Round	Commercialization of the targeted PET agent MTP219	$2.50M

Use of Proceeds

MT is seeking $5M to use toward the first-in-human clinical trials.

Key Team Members

Yajuan Li, PhD: PI & CEO

Adjunct Assistant Professor; Research scientist and pharmacist with experience and knowledge R&D and regulatory issues.

Zheng-Rong Lu, PhD: CSO & Co-Founder

Professor of Biomedical Engineering; Expert on molecular imaging and targeted imaging agents, drug delivery, and gene therapy.

Hui Zhu, MD, ScD: CMO & Co-Founder

Expert on urological tumor surgery; actively involved in planning of MT218 clinical trials and clinical development of the technology

Betty Kaneshiro, MBA: Vice President & Treasurer

30+ years' experience in healthcare administration and management; Expert in areas of finance, administration, HR management

Michael Tweedle, PhD: Member of MT's Scientific Advisory Board

Professor of Radiology; Former CEO of Bracco Research USA; has invented, developed, and translated several imaging agents, including ProHance®

OncoNano Medicine / Micelle-Based Imaging Agents, Therapeutics & Vaccines

Ravi Srinivasan, CEO | rsrinivasan@onconanomed.com| 408-476-1904 | www.OncoNanoMed.com

Company Overview (Clinical Impact and Value Proposition)
OncoNano has pioneered an ultra-pH sensitive micelle-based technology that, for the first time, promises to enable selective tumor targeting spanning a wide range of tumor types and can be used across the continuum of cancer care: Diagnosis, Staging, Surgery and Treatment. The technology is comprised of a library of proprietary, ultra-pH sensitive polymeric micelles that selectively identify and target cancerous tumors based on their universal property of acidic pH (aka the Warburg effect). The company's lead program, ONM-100, is in a Phase II trial for image-guided surgical resection of multiple tumor types, expanding from Phase I studies focused on breast, head and neck, esophageal and colorectal cancers, where it was shown to identify 100% of all tumors found by standard of care (SOC) and occult disease undetected by SOC in 30% of all patients studied. OncoNano is also pursuing preclinical programs for therapeutic applications using the micelle technology: (i) ONM-400 for selective delivery of micelle-encapsulated or -conjugated small molecules, antibody fragments, and cytokines to the tumor microenvironment to improve the therapeutic index of cancer therapy, and (ii) ONM-500 for antigen-containing micelle cancer vaccines that activate T-cell immune responses via the lymph nodes.

Market and Commercialization Strategy
Annually, the ~1 million cancer surgeries in the US and ~5 million cancer surgeries worldwide translate to a market for the ONM-100 imaging agent of ~$2B. Phase I results have established that the ultra-pH sensitive core technology behind the micelle platform is well tolerated and selectively identifies and targets many different tumor types. The emerging pan-tumor nature of ONM-100 opens the possibility of using the micelle delivery platform to carry payloads for therapeutic applications (ONM-400, ONM-500), and OncoNano is seeking partnerships to exploit its unique technology to improve upon existing and developmental treatments.

Technical & Competitive Advantage
OncoNano's ONM-100 imaging agent is an IV injectable designed to provide surgeons with real-time imaging of tumors during cancer resection surgery that is applicable to all tumor types regardless of their oncogenic phenotype. The mechanism of action relies on fluorescence activation triggered by the low pH nature of the tumor microenvironment compared to that of normal tissue. The concept of pH as a universal biomarker for tumors and associated the pH-based activation mechanism are being leveraged to develop micelles for therapeutic applications. The company's ONM-400 and ONM-500 micelle platforms offer the promise of tumor-specific delivery of cancer therapeutics and vaccines through either encapsulation or conjugation to the micelles with the potential to improve therapeutic outcomes.

Regulatory Strategy & Intellectual Property
ONM-100 is currently in a Phase II trial and has received Fast Track designation from the FDA. ONM-400 and ONM-500 are in preclinical studies. OncoNano has a broad portfolio of patents covering composition of matter and methods of use for the micelle technology with patent coverage extending beyond 2031.

Key Milestones

Description	Milestone	Date
ONM-100 Imaging Agent	End of Phase 2	2020
ONM-100 Imaging Agent	NDA Submission, Product Launch	2022
ONM-500 Cancer Vaccine	IND Submission	2021

Capitalization History
OncoNano has raised over $58MM to date including private venture financing ($35MM) and grants ($23MM).

Use of Proceeds
OncoNano will use its financing for the ongoing Phase II study of ONM-100 and the cancer therapeutic delivery platforms. The company was recently awarded its second grant from the Cancer Prevention and Research Institute of Texas (CPRIT) which will be used to advance the ONM-500 cancer vaccine. OncoNano is seeking partnerships to expand the application of the ONM-400 and ONM-500 micelle-based delivery platforms to improve the therapeutic window of cancer treatments and advance its lead product, the ONM-100 imaging agent, to an NDA.

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

SignaBlok, Inc. / Standalone and Combination Immuno-Oncology Therapy

Alexander B. Sigalov | sigalov@signablok.com | (203) 505-3807 | www.signablok.com

Company Overview (Clinical Impact and Value Proposition)

SignaBlok is developing a novel therapy for pancreatic cancer (PC) and a rare joint tumor, pigmented villonodular synovitis (PVNS). Only about 8.5% of 500,000 PC patients annually worldwide are alive 5 years after their diagnosis. PVNS patients have few treatment options, among them the only approved (hepatotoxic) drug and amputation. Internationally validated in multiple animal models in standalone- and combination-therapy treatment regimens and supported by world-renowned oncologists, SignaBlok's well-tolerable and non-cytotoxic TREM-1 therapy creates hope in PC and PVNS. Combined with standard chemotherapy, TREM-1 improves survival more than 3-fold versus chemo alone. Combined with standard immune checkpoint blockade (ICB) treatments, TREM-1 overcomes resistance to ICB. TREM-1 also presents a non-toxic alternative to chemotherapy in maintenance therapy cycles.

Market and Commercialization Strategy

The high unmet need market of PC and PVNS combined is around $2B+ per year with PC market projected to reach $3.4B+ by 2023 with CAGR of 7.54%. To quickly bring TREM-1 therapy to market, SignaBlok partnered with Translational Drug Development.

PVNS Strategy – *first indication*:

- Complete preclinical and submit IND; Advance to Phase I/II clinical trials
- M&A exit (e.g., 2011 Daiichi/Plexxikon PVNS deal of $935M; Pexidartinib approved in 2019)

PC Strategy– *second indication*:

- Submit IND; Advance to Phase I/II clinical trials (+ chemo, + immune checkpoint blockade, standalone as maintenance)
- Licensing to big pharma (e.g., 2014 Baxter/Merrimack PC deal of $970M+; Nanoliposomal irinotecan approved in 2015)

Technical & Competitive Advantage

Other TREM-1 blockers (Novo Nordisk's anti-TREM-1 antibodies, Inotrem's inhibitory peptide LR12; both not tested in cancer) all attempt to block binding of TREM-1 to its *still uncertain* ligand(s). In contrast, SignaBlok's first-in-class TREM-1 inhibitory peptide GF9 is advantageously ligand-independent. GMP-friendly formulation of GF9 into SignaBlok's lipopeptide complexes (LPC) extends GF9 circulatory half-life, provides targeted delivery *in vivo*, minimizes the off-target risk, and allows for potential oral delivery.

Regulatory Strategy & Intellectual Property

Regulatory pathway includes applications for Orphan Drug and Breakthrough Therapy designations. Fast Track Approval and Priority Review Voucher are possible. Acceptance into Real-Time Oncology Review (RTOR) pilot program is possible. Intellectual property handled by Medlen & Carroll, LLP covers composition of matter and methods of treating cancer.

Key Milestones

Description	Date/Year
Lead/Technology Optimization	04/2019 – 03/2020
GMP-Quality Lead	03/2020 – 06/2020
IND-Enabling Studies	06/2020 – 02/2021
IND Assembly/Filing	02/2021 – 05/2022

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2012/2015	NCI SBIR Phase I grants	Development of novel targeted agents in lung (2012) and pancreatic (2015) cancer	$0.44M
2017	NCI SBIR Phase I grant	First-in-class TREM-1 inhibitors in combination therapy for pancreatic cancer	$0.22M
2012-2018	NIH SBIR Phase I and II grants	Imaging of inflammation and TREM-1 therapy for multiple non-cancer diseases	$2.5M

Use of Proceeds

SignaBlok is looking for a strategic partner to take the technology through the pre-IND and IND-enabling studies and clinical trials process, which includes proof-of-concept studies *in vitro* and in animal models of lung, pancreatic, breast, brain and colon cancer, sepsis, atherosclerosis, retinopathy, alcohol-induced liver disease and rheumatoid arthritis.

Key Team Members

Alexander B. Sigalov, PhD – President of SignaBlok, Inc

Inventor of TREM-1 GF9 therapy. 35+ years in science and industry. 85+ publications and 16 patents and patent applications.

Robert Y. Chow – Partner, Foley Hoag's Business Department

SignaBlok's counsel. Experienced advisor at all stages of development.

Thomas C. Howerton, PhD – Partner, Medlen & Carroll, LLP

SignaBlok's patent attorney. Experienced attorney focused on biotechnology patent prosecution.

Stephen Gately, PhD – President and CEO of TD2, Inc

Extensive experience in the design and implementation of basic and clinical research studies.

Daniel D. Von Hoff, MD, FACP – Chief Development Officer of TD2, Inc

World-renowned leader in PC and PVNS. Was involved in the development of paclitaxel, gemcitabine, irinotecan, pexidartinib, etc.

Zenopharm / Oral SERD for the Treatment of Breast Cancer

Guangdi Wang, CEO | guangdi.wang@zenopharm.com | 504-236-5452 | www.zenopharm.com

Company Overview (Clinical Impact and Value Proposition)

Zenopharm focuses on the commercialization of innovative oncology therapeutics based on its patented platform technology. ZB716 is an oral steroidal SERD developed to overcome clinical limitations of fulvestrant, including poor bioavailability, injection-related side effects, slow therapeutic action due to long time-to-steady state drug concentration, and low clinical response rate in the treatment of patients with advanced breast cancer. ZB716 effectively enhances systemic drug exposure while bypassing first-pass metabolism of fulvestrant. In both wild type ER+ and ER mutant breast cancer cells, ZB716 blocks ER transcriptional activities, cell proliferation and degrades ER in a dose-dependent manner. Moreover, compared to fulvestrant, ZB716 has superior oral bioavailability and greater efficacy in blocking tumor growth in patient derived xenograft (PDX) breast cancer models.

Market and Commercialization Strategy

The current worldwide market size of the sole FDA approved SERD, fulvestrant, is $941M. As a first-line therapy, an oral SERD with greater drug exposure and faster action would bring immediate clinical benefits to patients in numbers significantly greater than those treated with fulvestrant in a second-line setting. The combined market of first line endocrine therapy drugs (tamoxifen, AIs, and fulvestrant) are estimated at $2.5B annually. Zenopharm will complete IND-enabling studies of ZB716 in Q4 2019 and submit an IND application in Q1 2020 while seeking to secure funding for a phase I clinical trial through three possible venues: 1) SBIR grant applications, 2) DoD breast cancer research program breakthrough level III grant application, and 3) third-party investment as matching fund for NCI SBIR phase IIB bridge grant. Upon meeting phase I endpoints, Zenopharm will seek to advance ZB716 through phase II, phase III, and NDA development by licensing ZB716 to pharma, collaborating with pharma, or venture capital investment.

Technical & Competitive Advantage

ZB716 is a chemically modified SERD pharmacologically analogous to fulvestrant, but with high oral bioavailability. If clinically proven safe with equivalent or superior efficacy compared to fulvestrant, ZB716 has the full potential to replace fulvestrant as a monotherapy or a combination therapy for breast cancer patients. Clinical evidence that drug exposure of fulvestrant may be insufficient has motivated efforts to develop orally bioavailable SERDs. More than 8 oral SERDs (GDC0810, GDC0927, GDC9545, AZD9496, LSZ102, RAD1901, G1T48, SAR439859) have entered clinical trials since 2013 of which two have been withdrawn (GDC0810 in 2017 and GDC0927 in 2018). Unlike fulvestrant and ZB716, these oral SERDs are all non-steroidal small molecules with mixed SERM/SERD activities that will not overlap the clinical utilities of ZB716 as an oral SERD and pure antiestrogen.

Regulatory Strategy & Intellectual Property

The first in human trial will be a Phase I, Dose Escalation Study of ZB716 in patients with ER Positive HER2- Negative Advanced Breast Cancer. Upon safety, tolerability, pharmacokinetic profile, and preliminary efficacy data in Phase I, a Phase II, Open-Label, Randomized Study of ZB716 vs. Fulvestrant in postmenopausal women with advanced or metastatic ER+ /HER2 - Breast Cancer will be conducted. Zenopharm has licensed the two patents that cover ZB716.

Key Milestones

Description	Date/Year
Pre-IND meeting and FDA responses	07/ 2019
cGMP manufacture of ZB716 substance	07/ 2019
GLP toxicity studies in rats and dogs	08/2019 – 11/2019
IND application	01/2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2017-2018	SBIR Phase I (NCI)	IND-Enabling Studies of ZB716, an Orally Bioavailable SERD	$296K
2018-2020	SBIR Phase II (NCI)	IND-Enabling Studies of ZB716, an Orally Bioavailable SERD	$1.9M

Use of Proceeds

Zenopharm seeks to raise $4 million to fund the phase I clinical trial of ZB716. Securing the proceeds will allow them to apply for SBIR Phase IIB bridge matching funds. Combined, the proceeds of $8M will pay for the trial and associated cost.

Key Team Members

Guangdi Wang, PhD: President & CEO

Formerly served as a full-time faculty directing laboratory research in small-molecule drug development for cancer therapy; Founded Zenopharm in 2012 and recruited a collaboration team to work towards the commercialization of ZB716.

Bridgette Collins-Burow, MD, PhD: Clinical Consultant

Medical oncologist and professor of medicine at Tulane School of Medicine

Harri Jarvelainen, DVM, PhD: COO

FDA regulatory expert serving as Zenopharm's toxicology and regulatory consultant.

James Bruno: CMC Consultant

Founder and president of Chemical and Pharmaceutical Solutions, Inc.

Zetagen Therapeutics / Proprietary Molecular Pathway to Grow Bone

Joe C. Loy, CEO | jloy@zetagen.com | 817-458-2270 | www.zetagen.com

Company Overview (Clinical Impact and Value Proposition)

Zetagen is an early stage therapeutic device company that has discovered and patented a new molecular pathway via a drug used and approved by the FDA since 1971 to safely help patients heal (grow bone) following spine, trauma, osteoporotic fractures, and dental surgery. ZetaFuse™ is also non-tumorigenic and suppresses cancer cell proliferation. The company has substantiated these claims via multiple animal studies (mice, rat, and rabbit) and *in vitro* hMSC and shared this data with the FDA in Q2-2019. Per the FDA's request, Zetagen is preparing for an *Early Human Feasibility Study* to be conducted in the first half of 2020 and will have human signaling data by Q4 2020. This data will be a value inflection point for the company and investors.

Market and Commercialization Strategy

Bone formation is critical to achieving successful outcomes in a number of high-volume procedures, such as lumbar spine fusion (450,000 US cases/year), dental implants (500,000 US cases/year), and bone cancer (400,000 US cases/year). These procedures are frequently supplemented with bone graft, which is currently a $5B domestic market / 7.5% CAGR. Zetagen will close their Series A round of financing with a raise of $8.5M on or before December 31, 2019. They are currently engaging and have commitments from industry specific venture capitalists that value the discovery, understand the clinical validation process, and ultimately want to see ZetaFuse™ brought to market.

Technical & Competitive Advantage

Zetagen's discovery, via a small molecule, opened a new molecular pathway that was previously unknown. By antagonizing the activity of the opioid growth factor receptor (OGFR) and up regulating the osteoblast function of the p21 transcription, grows quality bone while down regulating the osteoclast function to the *clinical benefit of suppressing tumor growth*. ZetaFuse™ has incorporated a small molecule which is osteoinductive and infused in a novel & patented collagen, bioceramic, osteoconductive carrier. This technology, ZetaFuse™, is delivered locally to a surgical area and can improve bone healing, limit bone destruction (resorption), and *decrease local tumor growth*. The current market leader relies on expensive biologic growth factors with a demonstrated safety risks that includes tumorgenicity, bone destruction (osteolysis) and bone growth outside the skeleton (heterotopic ossification). ZetaFuse™ can be used to treat primary malignancies or metastatic bone diseases, for which other products are currently blocked. And, ZetaFuse™ would provide significant value by generating bone through better biologic growth factors, it is anti-tumorgenic, anti-osteolytic, and significantly less costly to manufacture (8x) than the market leader.

Regulatory Strategy & Intellectual Property

Zetagen has successfully completed several translational proof-of-concept models in mice, rat, and rabbit with regards to bone growth. In addition, they have completed several significant proof-of-concept models in mice implanted with tumor. Zetagen has an exclusive license for the technology, the patent for this technology has been issued, and several additional patents have been filed. A binding designation has been granted by the *FDA to regulate ZetaFuse™ as a device*, and the company has made significant progress on the medical grade prototype device.

Key Milestones

Description	Date/Year
Complete Series A Financing Round	12/2019
Complete testing of manufacturer grade product	03/2020
Finalize sterile package kit design and reagents	12/2020
Approval from FDA to begin GLP rabbit/sheep studies	03/2021

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2018	Seed Round	Friends and Family	$2.75M
2018	SBIR Grant	NIH-NCI	$300K

Use of Proceeds:

Zetagen is raising $8.5M Series A to complete GMP Product development, a GLP Study, and an Early Human Feasibility Study.

Key Team Members

Joe C. Loy: CEO

Distinguished career in Executive Management roles for companies including Stryker, NuVasive, and Pfizer/Leibinger

Nikhil Thakur, MD: President & Co-Founder

Board-Certified Orthopedic Spine Surgeon, specializes in adult reconstructive spine surgery; Published 25 articles and 6 chapters

Bryan Margulies, PhD: CSO & Co-Founder

Formerly an assistant professor of orthopedics, cell biology, and pharmacology at SUNY-Upstate; Research focuses on stem cell modulation to promote bone formation in all practice areas including bone sarcoma; More than 25 publications to his name

Advanced Chemotherapy Technologies / Local drug delivery

Tony Voiers, CEO | tvoiers@advancedchemotech.com | 919.368.0522 | www.advancedchemotech.com

Company Overview (Clinical Impact and Value Proposition)

Advanced Chemotherapy Technologies (ACT), a Delaware C-corp. based in North Carolina's Research Triangle Park, has developed a novel device for infusing chemotherapies directly into poorly vascularized tumors. In many cancers (such as pancreatic, head & neck, inflammatory breast, and others) the tumor is encased in avascular fibrous tissue that limits the penetration of intravenously delivered chemotherapies. In these cases it is common to try to overcome the poor vascularity by delivering massive doses of systemic chemotherapies, which result in devastating side effects that force many patients to stop treatment. ACT has overcome these issues by developing a surgically implanted iontophoresis delivery system that delivers higher doses of chemotherapies directly into the tumor tissue while lowering systemic toxicity. This technology advancement enables ACT to develop new treatments for existing chemotherapies and to explore promising new compounds that may benefit from higher dosing with lower systemic toxicity.

Market and Commercialization Strategy

Each year 53,000 people in the US are diagnosed with pancreatic cancer and their prognosis is extremely bleak, with a five-year survival rate of 7%. Surgery provides the best chance for these patients but curative surgery is not available to the 85% of patients - those with Stage 3 (locally advanced non-resectable) and Stage 4 (metastatic) disease. ACT plans to initially focus on treating the 24,000 patients diagnosed with Stage 3 cancer each year. These patients are ineligible for surgery because the tumor has expanded into nearby major blood vessels or nerves, which are vital structures that can not be removed. ACT's chemotherapy delivery approach has shown great promise in shrinking pancreatic tumors away from major blood vessels and nerves and making curative surgery possible for these patients. With an estimate price per procedure of $30,000, the total addressable market opportunity for pancreatic cancer is $720M. Additional opportunities in head & neck, sarcomas, liver, brain and inflammatory breast cancers bring the total potential patient population to 190K and push the market opportunity over $5B.

Technical & Competitive Advantage

The company founders, Professors Joseph M. DeSimone, PhD and Jen Jen Yeh, MD, have nurtured this invention at the University of North Carolina at Chapel Hill and have completed six extensive pre-clinical studies showing significant tumor reduction in pancreatic cancer and inflammatory breast cancer models which led to four publications in prestigious journals. In this study, a patient-derived xenograft (PDX) mouse model was used to compare tumor response between systemic administration of gemcitabine vs device administration of the gemcitabine. The study shows that 100% of tumors treated with ACT's device shrunk by an average of 40% while tumors treated with systemic gemcitabine grew an average of 240%.

Regulatory Strategy & Intellectual Property

ACT held a Pre-Sub meeting with the FDA and gained agreement on the regulatory path for its pancreatic cancer indication as a 505(b)2 application, and gained agreement on a modest, 3 phase clinical program with less than 300 total patients required for approval. The First-in-Human study, scheduled to begin in 2019, will focus on the safety of delivering gemcitabine to the pancreas. Upon successful completion of this Phase 1 study, ACT will conduct a dose escalation study to confirm the therapeutic dose, followed by a randomized trial to show improved outcomes. ACT has received funding from the National Cancer Institute through a FastTrack SBIR grant to fund the First-in-Human Study, with additional equity investments.

Key Milestones

Description	Date/Year
Demonstration of tumor volume reduction in a PDX pancreatic tumor model	Prior to Company formation
Development of implantable chemotherapy delivery system for human use	Q1-2019
Initiation of First-in-Human clinical trial	Q1-2020
Proof of principle preclinical studies in solid tumor models beyond pancreatic cancer	2021

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2017	Grant/Loan	NCI FastTrack grant/ Economic Development Loan from NC Biotech Center	$.2.4M
2017	Seed	Initial Seed Funding	$840K

Use of Proceeds

ACT is currently raising for $6.9M in Series A financing. The funds will be used for completion of First-in-Human clinical trial, design of device enhancements to prepare for 2nd clinical trial, trial planning for 2nd clinical trial, and proof-of-principle preclinical studies in solid tumor models beyond pancreatic cancer

Key Team Members

Tony Voiers, CEO – 29 years experience in medical device and pharmaceutical development
Bill Daunch, PhD, CTO – 25 years experience in medical device and material science development

NeOnc Technologies / Intranasal Delivery of Therapeutics

Thomas Chen, CEO| tchen68670@gmail.com| 310-606-9552| www.neonctech.com

Company Overview (Clinical Impact and Value Proposition) NeOnc Technologies, Inc. (NTI) is focused on novel platform technologies for "*reversibly opening*" tight gap junctions (i.e. Blood Brain Barrier/skin) to allow drugs to penetrate previously untouchable targets and reversing drug resistance. NTI's first therapeutic, NEO100, is in Phase lla clinical trial for treatment of malignant brain cancer (gliomas). Phase l has resulted in very encouraging outcomes. The platform technologies address multiple cancer indications such as Brain Cancers, Leukemia, Breast cancer, NSCLC, SCLC and Ovarian cancer. In the long term, this core technology can also address neurological and dermatological indications e.g. Parkinson's, actinic keratosis and melanoma.

Market and Commercialization Strategy

Progress towards commercialization is hinged on NTI's data which so far is quite encouraging. NTI has four patients surviving over a year in treatment (one is over two years) and three more approaching 6 months survival. When the Phase IIa data produces the same results as Phase 1, NTI will approach the FDA for drug approval. NTI is optimistic the FDA will be receptive since the treatment of gliomas has not advanced in fifty years. With drug approval, NTI will seek a partner to manufacture and distribute NEO100. Since NEO100 has demonstrated beneficial results with other cancers and CNS diseases, NTI is seeking partners to develop each of the indications. The glioma market was estimated as $465 million in 2016 and is expected to reach $1 billion by 2025. However, gliomas is only one of many indications where these platform technologies can be used.

Technical & Competitive Advantage

The company's lead compound is NEO100, a highly purified GMP produced intranasal perillyl alcohol (POH) in Phase IIa trial for recurrent glioblastomas (GBM). The second compound is NEO212 which is a GMP synthesized conjugate of temozolomide (standard of care drug for gliomas) with POH. By delivering medication directly to the brain, presumably via the olfactory and trigeminal nerve, intranasal delivery greatly reduces or eliminates the severe side effects associated with systemic delivery of cancer medications, which may be acute or chronic.Intranasal delivery via the proposed dispersion method may also enable the administration of current chemotherapies and other anti-cancer medications directly to the brain in combination with NEO100. Combination therapies will be tested using current anti-cancer drugs such as CPT-11, Avastin, and others.

Regulatory Strategy & Intellectual Property

Both NEO100 and NEO212 has been awarded Fast Track and Orphan Drug Status by the FDA. The company continues to enhance and expand its patent portfolio as necessary, both in the United States and overseas with continued research and legal defense.

Key Milestones

Description	Date/Year
License Agreement for NEO100	12/2020
Completion of Phase I Trial for NEO 212 TMZ-POH	12/2020
Completion of Phase II Trial for NEO100	06/2021

Capitalization History

YEAR	Grant, FundingRound, etc.	Description	Amount
Various	Series A	Friends & Family	$8.5M
2013	License Agreement	Foreign Biotech – Funded IND and Trial	$1.5M

Use of Proceeds

NTI is seeking $15M to complete Phase 2a study of the NEO100 product and to file an investigational New Drug (IND) application and begin Phase 1 clinical trials for its second drug, NEO212 (POH with temozolomide), maintain the intellectual property library, open its own laboratory, and pay other general corporate obligations.

Key Team Members

Thomas Chen, MD, PhD: Chairman & CEO

Physician, board-certified neurosurgeon, Director of Surgical Neuro-Oncology at USC; Published extensively on glioma biology and neurosurgery; Member of editorial board for *The Spine Journal* and review board for *Neurosurgery* and *Journal of Neurosurgery*

Vincent Simmon, PhD: Chief Regulatory Officer

30+ years' experience growing biotech companies and developing biotech products; Former Governor of the Emerging Companies Section of BIO and Director of the Chemical Industries Institute for Toxicology

Patrick Walters: CFO

Expert in finance and infrastructure for startups

Privo Technologies / Nano-engineered Topical, Local Drug Delivery

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

Company Overview (Clinical Impact and Value Proposition)

Privo has developed a nanoparticle-based platform technology to deliver targeted chemotherapeutics locally via topical administration, the initial indication being oral cancer. The treatment (PRV111 patch) is composed of biocompatible polymers and embedded with nanoparticles. Upon contact with tissue, the particles are released and retained by cancer cells to limit systemic toxicity. Epithelium cancers can significantly benefit from high concentration of topical and local treatment with negligible toxicity.

Market and Commercialization Strategy

The 5-year survival rate of oral cancer (OC) remains only 57%, and OC is one of the few cancers increasing in incidence both in the US and worldwide. By 2020, the annual worldwide OC incidence will increase 30%, and annual mortality will increase approximately 37%. Privo's strategy has been based on the reformulating already FDA approved drugs with well-known toxicity profiles (For oral cancer, Privo uses the drug cisplatin), ensuring that all other excipients are FDA Generally Recognized as Safe (GRAS) to minimize regulatory and testing costs, and using a nanoparticle synthesis method which eliminates any chemical changes to FDA approved ingredients which would increase regulatory scrutiny, and targeting a disease which qualifies for FDA's Orphan Designation.

Technical & Competitive Advantage

PRV111 is a 2cm x 2cm polymeric patch that contains nanoparticles loaded with chemotherapy designed to only permeate cancerous tissue and preserve healthy areas of the mouth. When placed on a tumor, it adheres to the surface and releases and retains the nanoparticles directly into the tissue. The nanoparticles are then taken up by cells and degrade to release their drug. This treatment is customizable to the tumor/lesion size and one or more patches can be used to fully cover larger tumors in multiple locations. Privo's patch administration takes approximately one hour versus the >6 hours of IV chemotherapy, improving clinical outcome by increasing patient compliance and quality of life, and reducing the need for intense clinical management, and postponing or eliminating the need for disfiguring surgeries. This can free up hospital beds and use far less of the clinician's time, resulting in hospitals being able to see more patients and reduce the per patient cost.

Regulatory Strategy & Intellectual Property

Privo's technology is from MIT's Langer lab, which is globally recognized for its translational science. Privo has 2 issued U.S. patents for this technology. In addition to the US, patents have been filed in several countries. Privo has 5 pending applications combined into one omnibus submission. Privo has obtained orphan designation for PRV111, and it is currently in a Phase 1/2 clinical trial at over 10 hospitals.

Key Milestones

Description	Date/Year
Complete Phase II Clinical Trial	2019
Large Pharma Partnership	2019
Begin Pivotal Phase III Trial	2020
Negotiate Product Licensing/Acquisition	2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2015	Grant	NSF Phase I SBIR	$180K
2015	Angel	Private Investment	$3M
2016	Grant	NIH-NIDCR Phase II SBIR	$2M
2016/2018	Grant	NIH-NCI Fast-track SBIR & Bridge Award	$5.3M

Use of Proceeds

Privo is currently seeking $30M for 2 clinical studies, one for its intraoperative chemotherapy trial (>$20 Billion market size) and its Phase 3 pivotal study, a large pharma company partner, or a combination thereof.

Key Team Members

Manijeh Goldberg, PhD, MBA, MS: CEO

25+ years industry experience; Founder of 5 medical startups; Expertise in nanotechnology developed at MIT's Langer Lab

Ellen Milano, VP of Regulatory

40+ years' experience in regulatory affairs and pharmaceutical technical issues

Donna Keith: Director of Manufacturing

20+ years of chemistry experience in FDA regulatory submissions, chemical/manufacturing control strategy and method validation

Jesse Hall, MD, FACP: Chief Medical Officer

20+ years' experience in biopharma, oncology drug development, and strategic clinical planning/management

Susan Szambelan, BS: Clinical Operations Consultant

20+ years' experience managing clinical trials for large institutions (Johns Hopkins, Genzyme, etc.)

TheraTarget / Polymer-based Carrier Platform for Solid Tumor Therapeutics

C. Matthew Peterson MD | petersoncmatthew@theratarget.com| 801-550-5400 | www.TheraTarget.com

Company Overview (Clinical Impact and Value Proposition)

TheraTarget holds the patent and licensing rights for a widely applicable polymer-anti-cancer agent delivery platform technology that dramatically improves the efficacy of traditional and novel anticancer agents by specifically targeting solid tumors, creating an immunogeneic tumor microenvironment, maximizing drug efficacy, and reducing adverse systemic effects.

Market and Commercialization Strategy

TheraTarget's goal is to introduce new, safe, biodegradable copolymer drug-conjugates into the solid cancer market to treat breast, non small cell lung cancer (NSCLC), pancreatic, and ovarian cancers which total nearly 600,000 cases and over 250,000 deaths per year, respectively. These markets currently total $34B annually ($18B breast, $14B NSCLC, $1.6B pancreatic and $1.4 B ovarian). In order to achieve a Pharma exit, Theratarget aims to complete animal toxicology, IND submission, and new patent protections leading to human trials in 2020.

Technical & Competitive Advantage

Recently, the use of immune checkpoint inhibitors has changed the landscape of cancer treatment, bringing hope for those suffering from various cancers. However, the major hurdle in clinical application is the low response rate, for example, less than 20% breast cancer patients respond to immune checkpoint inhibitors. KT-1, the 2nd generation polymer-epirubicin conjugate, can sensitize tumor to immunotherapy, remarkably expand the number of patients that respond to immune checkpoint inhibitors. Preclinical studies demonstrated KT-1 not only has stronger tumor-growth inhibition effect compared to free EPI, but also significantly activated tumor microenvironment as shown enhanced number of effector T cells. KT-1 treatment followed by anti-PD-1 therapy resulted in long-term antitumor effect (8/10 cured mice). The survival mice show Long-term Immune Memory Effects, can survive from re-challenge and no any metastasis was detected. KT-1 as monotherapy results in higher accumulation of drug in tumor site, reduces side-effect, leading to high efficacy, saving in time and cost, as well as improved quality of life.

Regulatory Strategy & Intellectual Property

Patent and licensing protection for the basic platform continues until 2031 with the opportunity for serial new patents available for combinations of new and off patent polymer-chemotherapeutic/-immunomodulating agents. Patent and licensing rights are held through the University of Utah's Technology and Venture Commercialization office. Animal toxicology, IND and new patent protections for KT-1 (di-block HPMA-epirubicin copolymer) for breast, NSCLC, pancreatic and ovarian cancers are 2020 goals resulting in human trials. HPMA polymer has been used clinically for 10 years and epirubicin has been in clinical use for 20 years suggesting a streamlined regulatory opportunity. This strategy can be replicated for various other anti-cancer and immunomodulating agents currently used clinically.

Key Milestones

Description	*Date/Year*
Incorporation of TheraTarget	2008
Licensing of Dr Kopecek's Di-block HPMA platform technology from the University of Utah TVC	2011
US patent of Dr Jindrich Kopeck's Di-block HPMA platform technology with Japan and EU Patents underway	2016
Patent applications for KT-1 Di-block HPMA platform epirubicin for use in breast, nsclc, pancreatic, ovarian cancers	2019-20

Capitalization History

Year	*Grant, Funding Round, etc.*	*Description*	*Amount*
2008	Founders	Founder equity (JK, HG, MA)	$30K
2010-9	STTR Grants (6)	(JK 1.7M, HG 1.7M)	3.4M
2011	TCIP	(JK)	$80K
2019	DOD	Submitted grant (JY/CMP/JK) and awaiting score	$250K
2018	Convertible Notes		$100K

Use of Proceeds

Theratarget is currently raising $450K for pre-clinical studies, to develop additional drug materials for use by the NCL which is conducting toxicology studies on KT-1, and to prepare for the pre-IND meeting with the FDA.

Key Team Members

Darwin Cheney, PhD: President & CEO

Former pharma executive; Expert in R&D process optimization and strategy/operations

Jeffrey Harps, MBA: CFO & VP of Business Development

Experience working with government, corporations, & start-ups; Led a start-up exit two years after founding the company.

Matthew Peterson, MD: Board Member

Expert in drug development; 20+ years' experience developing novel drug delivery systems to treat ovarian cancer

Abreos Biosciences / Veritope Platform for Dose Monitoring

Bradley Messmer, CEO | bmessmer@abreosbio.com | 858-248-9253 | www.abreos.com

Company Overview (Clinical Impact and Value Proposition)

Abreos Biosciences is focused on therapeutic drug monitoring of biologic drugs. Monoclonal antibodies (mAb) are used to treat cancers and other serious diseases. There is enormous pharmacokinetic variation across patients and evidence suggess that dynamic monitoring of mAb levels in the blood may improve outcomes and lower costs. Abreos has developed a proprietary reagent platform based on peptide mimetopes (Veritopes) that can detect a given biologic or biosimilar drug by mimicking the natural target. Veritopes specifically detect the target biologic drug in human samples and can be implemented in lab-based assays for point-of-care (POC) testing.

Market and Commercialization Strategy

Biologic drugs are increasingly used to treat oncology and autoimmune diseases. Seven of the top ten best-selling drugs are biologics, and the top three biologics in the world—Humira, Rituxan and Enbrel—have a combined worldwide revenue of over $35 billion. The mAb drug market already exceeds $100 billion and is one of the fastest growing pharmaceutical segments. Precision dosing of biologic therapeutics accounts for a fraction of the mAb drug market. If dose monitoring tests are priced at 3-5% of the price per unit dose of a drug, the US testing market for mAb drugs potential is $4B. The simple Veritope POC Lateral Flow Assay (LFA) tests Abreos has developed will enable physicians to optimize subsequent dosing decisions based on their patient's actual drug levels. The current NCI SBIR Phase II project aims to complete development of the LFA device for rituximab and integrate quantitative reader technology, followed by a clinical validation study at Northwestern University. By the end of Phase II (by Q3/2021), Abreos will generate a technical data package that will be included in their FDA de novo 510(k) submission.

Technical & Competitive Advantage

Only a handful of companies offer TDM tests for select biologic drugs. These are mostly limited to lab-based service and none of them are FDA cleared. Furthermore, there are no POC devices approved in the US for this application. Another disadvantage of the existing tests for biologic drugs is that they are primarily limited to the inflammatory bowel disease space. Abreos has developed an extensive Veritope pipeline, now consisting of 20 Veritopes, against marketed biologic drugs. Veritopes can be implemented in either lab-based tests or proprietary POC devices. The latter allows simple, rapid, and quantitative measurement of mAb drug levels in whole blood in <20 min. These devices are Bluetooth-enabled for easy and immediate data sharing with EHRs and the cloud.

Regulatory Strategy & Intellectual Property

The Veritope LFA POC device is a class II medical device and will be submitted to the FDA via the de novo 510(k) path. Abreos will also apply for a CLIA waiver to extend use to untrained individuals. Abreos has secured an exclusive license for the original patent awarded to UC San Diego in 2016. Additional patents have also been filed.

Key Milestones

Description	Date/Year
Complete POC LFA based device	Q4/2019
Validate clinical performance	Q1/2020
FDA submission of first POC dose monitoring system	Q3/2020

Capitalization History

YEAR	Grant, Funding round, etc.	Description	Amount
2014-2016	6 Phase I SBIR/STTR Grants	NIH/NCI, NIH/NIAID, NIH/NIAMS	$1.26M
2016	Angel	UCSD Triton Fund + Private Individual	$725K
2017	Angel/Family Office	TLP, Private Individuals	$2.4M
2016-2018	Phase I & Phase II & Fast Track	NIH/NCI, NIH/NIAID	$4M

Use of Proceeds

Abreos is fundraising a Series A round for R&D, production, clinical studies, and regulatory approval of their first products. R&D efforts will expand the pipeline of Veritope reagents, lab-developed tests, and POC devices for the top-selling biologic drugs. Production of POC tests will support clinical studies in the US/EU and will generate vital data (clinical utility and cost-effectiveness).

Key Team Members

Bradley Messmer, PhD: Founder & CEO

Entrepreneur experienced in commercializing translational research in regional and international markets

Laura Ruff, PhD: Director of Research

Researcher with 20 years of experience in the fields of immunology, virology, cancer, and nanotechnology.

Ela Heussen, PhD MBA: Director of Corporate Strategy

Biotech specialist who has worked with numerous startups, strategy consulting (McKinsey & Co.), and impact investing.

Michael Williams: **Board Advisor**

Decades-spanning track record with various roles at Bristol Myers Squibb and Pfizer; Former Head of Global Marketing at Takeda

bioSyntagma / Spatial 'Omics for Discovery and CDx

David Richardson, CEO | david@biosyntagma.com | 415.236.0135| www.biosyntagma.com

Company Overview (Clinical Impact and Value Proposition)

bioSyntagma's mission is to eliminate trial-and-error cancer treatments through advanced diagnostics that predict response and acquired drug resistance. It's hardware for mapping patient biopsies enables discovery of microenvironment-based biomarkers, and its AI, the mPrint Mind™, enables predictive treatment recommendations. The company aims to displace existing companion diagnostics with a single test that will screen for multiple drugs and recommend combination treatments.

Market and Commercialization Strategy

bioSyntagma will sell discovery services to biotech and Pharma, and reimbursable Lab Developed Tests (LDTs) to oncologists. They provide biomarker discovery services for Pharma and will leverage those services to win co-development agreements for companion diagnostics (CDx). They are initially targeting development of an LDT for melanoma, a beachhead market worth $366M. bioSyntagma currently has a partnership in negotiation with an international life science company and is seeking additional partners. The company intends to grow the AI-enabled test to screen for response to many drugs at once, expanding beyond melanoma.

Technical & Competitive Advantage

The Molecular Fingerprint™ platform creates spatial (in-situ) 'omic maps of clinical tissues using any commercially available kit or chemistry. It can isolate single-cells, rare groups of cells, or large regions of interest (ROIs) from either fresh tissues or FFPE (formalin-fixed, paraffin embedded tissue), and produce maps of mutations, gene expression, etc. Compatibility with clinical samples, as well as with simultaneous NGS, PCR, and protein analysis, sets the technology apart from existing technologies and enables rapid penetration into the clinical market. Furthermore, rather than competing with existing NGS or reagent companies, bioSyntagma complements them by enabling their products for use for next-generation spatial analysis. The company's AI, the mPrint Mind™, is designed to ingest spatial 'omics maps to stratify patients based on their tumor microenvironment. Preliminary data on breast cancer patients has demonstrated a fundamentally new way of classifying breast cancer types based on microenvironment factors instead of traditional genetic subtypes (TNBC, HER2+, Luminal, etc.).

Regulatory Strategy & Intellectual Property

This technology is considered for research use only (RUO) as a discovery service to Biotech and Pharma. Development of companion diagnostics will be done in a CLIA certified lab where the CDx will be regulated as an LDT. The company may consider licensing opportunities as well. Aggregating spatial tissue maps from LDT customers will contribute to development of future AI-based diagnostics and, over time, their most valuable asset will be a database of spatial 'omic maps. bioSyntagma currently has exclusive licenses, company PCT patent filings, and trade secrets.

Key Milestones

Description	Date/Year
Demonstrated novel way to screen breast cancer patients based on spatial mapping	2019
Built prototype AI for stratifying patients	2019
Negotiating Strategic Partnership	2019
Integrate NCI Phase I SBIR technology into current mPrint platform	9/2019
Establish CLIA certified lab in Arizona	12/2019

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2016	Grant	Flinn Foundation Bioscience Entrepreneurship Grant	$30K
2017	Grant	NSF Phase I SBIR	$214K
2018	Grant	NIH-NCI Phase I SBIR	$200K
2018	Grant	NSF Phase II SBIR + supplemental funding for industry partnership	$910K

Use of Proceeds

bioSyntagma is raising $5M to 1) Market the company's discovery services to Pharma, 2) Win strategic partnership for immunotherapy CDx development, 3) Scale instrumentation and lab to meet demand, 4) Develop AI from prototype to beta.

Key Team Members

David Richardson, PSM: CEO

Expert in medical devices with 9 years' experience in R&D; Has developed and launched multiple software packages and has brought multiple medical devices through the FDA, including a complete hip replacement system.

Dmitry Derkach, MD, PhD: CSO

20 years' clinical and research experience in drug/bioassay development, validation, and implementation; Expert in Molecular and Cellular Biology

Colleen Ziegler: Director of Operations

Capio Biosciences Inc. / Biopsy-Free Oncology Diagnostics (CTCs)

Andrew Wang, CEO | a.wang@capiobiosciences.com |608-441-8375 | www.capiobiosciences.com

Company Overview (Clinical Impact and Value Proposition)

Capio aims to address the significant unmet need for predictive biomarkers and liquid biopsy technologies in oncology. Most cancers do not have a biomarker that can be utilized for assessing disease status, which can increase cost of care and decrease patient quality of life. Moreover, advances in personalized cancer care and immune-oncology require real time information on the tumor biology. Capio Biosciences has developed a novel biopsy-free biomimetic platform for capture, enumeration, and subsequent analysis of circulating tumor cells (CTCs). CapioCyte™ has higher clinical correlation than other technologies and is well suited for bundled reimbursement with the potential to save costs by identifying patients not responding to treatment, and by reducing expensive and inconvenient imaging and biopsy visits.

Market and Commercialization Strategy

Initially, CapioCyte™ will be launched for Research Use Only (RUO) with appropriate labeling and marketing activities including reaching out to key cancer centers and research labs to create awareness and demand. The FDA-cleared indications for use for CapioCyte™ will be initially targeted for monitoring therapy response and prognosis in patients with stage II-IV Head and neck squamous cell carcinoma (HNSCC) and Non-small Cell Lung Cancer (NSCLC). The estimated US market size for the two indications is approximately $286M. Physicians will be able to utilize CapioCyte™ results to help inform their treatment decisions. Capio is currently conducting clinical research studies in collaboration with multiple institutions in the US, which also aligns with clinicians and scientists to gain early insight and promote potential clinical significance.

Technical & Competitive Advantage

CapioCyte™ uses a patented flow surface for CTC capture to induce cell rolling that slows the cells down and improves capture. CapioCyte™ concurrently uses a mixture of antibodies bound to nanoscale dendrimers to better capture tumor cells. This enables multivalent binding that greatly increases binding avidity and provides at least a 10-fold increase in capture efficiency when compared to other published data utilizing other technologies. Because CTCs captured using CapioCyte™ are viable, downstream analysis and culture expansion can offer real-time information on cancer's genomic, epigenetic, transcriptomic, and proteomic state.

Regulatory Strategy & Intellectual Property

Capio will file for an IDE with the FDA to enable the platform to be used in clinical trials to produce clinical data to support a pre-market notification submission to FDA for 510(k) clearance to market CapioCyte™ as an in-vitro diagnostic (IVD). The clinical laboratory improvement amendments (CLIA) pathway will also be explored. Capio has exclusively licensed a strong portfolio of IP related to CapioCyte™ technology from the University of Illinois and have licensing agreements with UNC and Wisconsin Alumni Research Foundation (WARF) for additional IPs. To date, there have been 21 patent applications globally (7 issued and 14 pending), covering surface compositions, polymer chemistry, flow chamber designs, and clinical indications of CapioCyte™ technology.

Key Milestones

Description	Date/Year
Close Series B Financing	Q4 2019/Q1 2020
Lock down final design of CapioCyte™ flow chamber, ready for initial manufacturing and scale-up	Q1/Q2 2020
Complete production of CapioCyte™ design verification/clinical builds for IUO purposes	Q3/Q4 2020
Execute at least one external partnership with biotech/pharma/reference lab	2020/2021

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2016	Series A	Equity	$2.9M
2018	Grant	SBIR Phase I	$175K

Use of Proceeds

Capio Biosciences is currently seeking additional Series B funding of $12MM-$15MM and expects to close this additional funding in Q4 2019 or Q1 2020. Funding will be used to complete development of breadboard prototypes of the CapioCyte™ Analyzer and Flow Chamber, followed by alpha and validation units for final testing, debugging, and optimization. They will then be able to build RUO units for initial commercialization and Investigational Use Only (IUO) units to be used in clinical trials.

Key Team Members

Andrew Wang, MD: Acting CEO & Co-Founder

Associate Professor in Radiation Oncology at UNC; Postdoc Fellowship under Prof. Robert Langer (MIT) & Dr. Farokhzad (BWH)

Seungpyo Hong, PhD: President & Co-Founder

Professor of Pharmaceutical Sciences at UW; Completed postdoc training in Prof. Robert Langer's lab (MIT)

Steven Miller: Chief Business Officer

30+ years of global experience in medical devices with proven track record launching 50+ products, including CellSearch®

Captis Diagnostics / Extracellular Vesicle-Based Liquid Biopsy

Hongzhang He, CEO | hongzhanghe@gmail.com | 949-878-2679 |

Company Overview (Clinical Impact and Value Proposition)

Captis is developing a non-invasive lab service that will enable medical oncologists to provide actionable treatment management for solid tumor patients, which can significantly increase patient survival by guiding the therapy selection, therapeutic monitoring, earlier recurrence detection. The company's Extracelluar vesicle (EV)-Based liquid biopsy tests will significantly improve cancer treatments, allow for better treatment control, enable early interventions, and change decision making from reactive to predictive early interventions.

Market and Commercialization Strategy

It is projected that the global extracellular vesicle (EV) research products market is projected to reach $264 million by 2024 from $91 million in 2019, at a CAGR of 23.8%. Currently, more patients die due to lung cancer than the next three most deadly cancers combined. Captis plans to work with oncologists and key opinion leaders from research-oriented cancer centers to validate EV-based liquid biopsy product's clinical utility in therapy selection, therapeutic monitoring, earlier recurrence detection of solid tumor through clinical trials. Captis will also develop the laboratory developed tests (LDTs) and set up a Clinical Laboratory Improvement Amendments (CLIA)-cleared lab to provide liquid-biopsy diagnostic testing service for oncologists to have the actionable lab report.

Technical & Competitive Advantage

Most current EV isolation approaches are impractical in clinical settings due to inherent shortcomings (e.g. lengthy procedure, low yield, and poor purity). The patent-pending lipid nanoprobe system for EVs isolation developed by Captis Diagnostics leverages the fundamental structural characteristics of EVs, their outer bilayer lipid membrane, to efficiently and rapidly isolate them. There are no EV isolation products currently on the market that use the same principle. As a groundbreaking nanomaterial-based technology for EV isolation without the need for any bulk equipment, it can isolate EV with 80% efficiency in 15 minutes with high purity.

Regulatory Strategy & Intellectual Property

The company's goal is to develop and provide the diagnostic service to oncologists with actionable results. Captis has two approaches for the regulatory process: 1) For genes with known clinical utility, they will develop the LDTs tests and discuss with CLIA to establish a CLIA lab and provide lab services to oncologists. 2) For gene tests with unknown clinical utility, they will discuss with FDA and go through Class III 510(k) clearance to validate the clinical utility of the tests. Captis Diagnostics has four patents in liquid biopsy and two granted patents for circulating tumor cell capture along with patent applications for the lipid nanoprobe system for EVs isolation.

Key Milestones

Description	Date/Year
Optimization and lock down on performance characteristics and components	Q2 2019
Build a quality plan for commercialization (QC and controls)	Q4 2019
Commercial product	Q2 2020
Build evidence (analytical validation, clinical validation, clinical utility, health economics)	Q4 2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2018	Grant	Penn State Research Foundation	$75K
2018	Grant	NIH-NCI Phase 1 award	$300K
2019	Grant	NIH I-Corps Program	$55K

Use of Proceeds

Captis plans to compete for a $2M SBIR phase II and secure angel funding and venture capital for a total of about $6M to develop and commercialize their product at the current stage. Captis will use the funding to support the clinical trials in both analytical verification and clinical utility validation. They will first focus on non-small cell lung cancer (NSCLC).

Key Team Members

Hongzhang He, PhD: CEO

10+ years' experience working in the molecular diagnostic field; Has been trained in start-up business development in the TechCelerator from Penn State, Y combinator Startup School, and NIH I-Corps programs.

Siyang Zheng, PhD: Founder

Associate Professor at Carnegie Mellon University, with 15+ years' research experience in cancer diagnosis through liquid biopsy.

Mark Myslinski: Consultant:

Life science and diagnostics industry veteran with a combination of large company and entrepreneurial experience

Chandra Belani, MD: Consultant

30+ years' clinical experience; Translational investigator developing personalized therapies/combined modalities for lung cancer

Frontier Diagnostics | Clinical Assay for Accurate Diagnosis of Melanoma using IMS

Jeremy Norris | Jeremy.norris@frontierdx.com | 615-970-2361 | www.frontierdiagnostics.com

Company Overview (Clinical Impact and Value Proposition)

Currently, there is no effective tissue-based assay that can definitively discriminate benign lesions from malignant melanocytic tumors, likewise no tissue-based assay exists for prognostic classification. Frontier Diagnostics (FDx) is currently developing and validating a clinical assay to provide a highly accurate diagnosis of melanoma using direct tissue analysis by MALDI imaging mass spectrometry (IMS). This assay will provide additional molecular measurements that will directly support pathologists in the diagnosis of melanoma when a conclusive diagnosis cannot be reached using the classical approaches.

Market and Commercialization Strategy

There will be an estimated 192,310 new cases of melanoma in 2019. However, the rate of over-diagnosis of melanoma has been reported to be as high as 90%. Since failure to diagnose melanoma poses both medical and legal risks, there exists a significant incentive for over-diagnosis and classifying ambiguous lesions as melanoma. Considering the increasingly large number of biopsies (>3M/year to rule out melanoma), this represents a significant problem that is likely to negatively impact patient care and resulting in substantial costs to the healthcare system. If diagnosed early, removal of melanoma costs approximately $1,800 per patient, with an excellent survival rate. However, treatment costs increase substantially as the melanoma advances, rising to well in excess of $150,000 per patient. More importantly, the long-term health of the patient is compromised if chemotherapy is administered to patients who are incorrectly diagnosed with melanoma.

Technical & Competitive Advantage

IMS is a unique and proprietary platform technology that generates highly multiplexed protein expression panels directly from thin tissue sections while retaining spatial information. FDx has exclusive license for this technology from Vanderbilt. The successful development of this technology and commercial launch of MelanoMap will create numerous opportunities for the development of new tests by FDx. IMS provides anatomical pathologists with the tools to probe tissues directly to determine the molecular makeup of specific cells groups of cells without the use of antibodies. This technology is a paradigm shift in anatomic pathology that provides pathologists with new, highly specific tools to carry out their vital work. This innovative approach to tissue pathology will be applied to numerous disease areas and will make significant improvements to patient care.

Regulatory Strategy & Intellectual Property

This assay will be developed and launched within a CAP/CLIA accredited laboratory. The FDx founders have developed patented and patentable technologies and filed multiple patent applications through Vanderbilt related to instrumentation, software, consumables, and application methods for the MALDI mass spectrometry in diagnostics. FDx has an exclusive license to the key patents that enable IMS for diagnostics. This includes 3 issued patents. Two additional patent applications have been filed by FDx that claim the use of IMS to diagnose all types of skin lesions, broadening the protection beyond the diagnosis of Spitzoid lesions.

Key Milestones

Description	Date/Year
Completion of validation cohort for MelanoMap	Q3 2019
CLIA Licensure and CAP Accreditation	Q3 2019
MelanoMap Launch	Q4 2019
CMS Reimbursement	2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2016	Series A	Series A investment received from angel investors	$1M
2018	Grant	NIH-NCI SBIR award	$2.3M

Use of Proceeds

The company is raising a $4M Series B round for the completion of clinical development of MelanoMap and launch of assay, continued publications and healthcare economic studies, CMS reimbursement positioning, and continued IP prosecution.

Key Team Members

Jeremy Norris, PhD: Co-Founder, President & CEO

Managing Director of The National Resource for Imaging Mass Spectrometry; Former VP of R&D, Protein Discovery, Inc.

Richard Caprioli, PhD: Co-Founder & Chief Scientific Officer

Primary inventor of and world's foremost authority on MALDI Imaging Mass Spectrometry

Jason Robbins, MD: Chief Medical Officer & Laboratory Director

Dermatopathologist/dermatologist; Partner at Pathology Associates of St. Thomas; Founding Partner of Nashville Skin & Cancer

James Stover, PhD: Director, Business Development & Regulatory Affairs

Experienced healthcare executive; Former Head of BD at Aegis Sciences Corp; Founder/President of Diagnovus

Mirimus / Pushing the Boundaries of RNAi and CRISPR Technologies

Prem Premsrirut | prem@mirimus.com | 646-221-5960 | www.mirimus.com

Company Overview (Clinical Impact and Value Proposition)

Mirimus is a pioneer in the development of powerful research tools and applications for the biomedical industry. The company is comprised of leaders in both RNA interference and CRISPR/Cas genome editing technologies and they have invented unique platforms to rapidly engineer preclinical models for drug discovery. Mirimus has revolutionized human disease modeling by synergizing technologies that together accelerate genetic manipulation to create sophisticated *in vitro* cell-based and animal model systems to study disease processes and therapeutic strategies. Their expertise in model creation will advance research capabilities, with technology to silence gene expression and mimic the effects of small molecule therapeutics in live animal models.

Market and Commercialization Strategy

Mirimus has engagements with several large pharma companies to develop preclinical research platforms for their internal discovery and toxicology groups. In addition, Mirimus is partnered with Charles River Laboratory. Mirimus is seeking capital to launch its new RNAi rat platform, Mirattus™ and to expand their production capabilities to rat models. Rat models are preferred rodent models for toxicity studies due to more physiological similarities to humans and are frequently used in disease areas such as cardiovascular and neurological diseases. They are looking for equity partners to provide the bridge funding necessary to build a successful enterprise with strong IP and research portfolio.

Technical & Competitive Advantage

Mirimus is the only company with deep expertise in both CRISPR/Cas and RNAi technologies. Each technology has unique advantages and limitations, and Mirimus' ability to combine the two technologies creates even more powerful tools for research. Notably, Mirimus has created a method to increase the efficiency of site-specific transgene insertion by up to 50-fold, giving Mirimus an enormous advantage over competing entities. Advancing their know-how to the rat model system places Mirimus far beyond the competition, as there are limited players in the field of rat modeling. Combined with the RNAi platform, Mirimus will be able to generate some of the most sophisticated, precise, and predictive models.

Regulatory Strategy & Intellectual Property

Mirimus licenses core RNAi IP from its founding institution, Cold Spring Harbor Laboratory. In addition, Mirimus holds patent applications to protect its methods to generate RNAi rat models. Furthermore, Mirimus is spearheading an effort to redefine cow milk and remove components that may lead to autoimmune related neurological diseases and has put forth provisional applications to protect this IP. Mirimus also holds a trademark for the Mirimus logo and name, as well as Mirattus.

Key Milestones

Description	Date/Year
Successful completion of large pharma CRISPR/RNAi project & initiation of follow-on project	2019
Publication of CRISPR/RNAi mouse model cohort development and cancer modeling	01/2020
Development of RNAi rat platform and proof-of-concept of functionality	04/2020
Strategic financial partnership with CRL for commercialization and marketing of rat models	08/2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2011	Series A	Funding by Topspin Partners	$2M
2013-2016	Series A.a	Funding by Topspin Partners	$2.8M
2014/2017	Grants	NIH-NCI SBIR Phase I and II	$1.63M
2018/2020	Grant	NIH-ORIP Phase I (awarded) and Phase II (expected)	$2.25M

Use of Proceeds

Mirimus is seeking $2.5M (for 15% equity stake) to expand facilities, continue patent prosecution of existing applications, and completion of proof-of-concept research for RNAi rat models.

Key Team Members

Prem Premsrirut, MD/PhD: Founder & President/CEO

Seasoned CEO with 9 years' experience, Expert in cancer biology, genetic engineering, molecular biology, and medicine

Stephen Chang, PhD: Business & Commercialization Strategist

Experienced entrepreneur who has started 10+ companies; Expert in stem cells, genetics, and business development

Scott Lowe, PhD: Founder/Consultant

30+ years' experience in caner research and mouse models

SynderBio / Targeted Cell Separation to Accelerate Cancer Diagnosis

Mike Cable, CEO | mike@synderbio.com| 510-599-6154| www.synderbio.com

Company Overview (Clinical Impact and Value Proposition)

SynderBio offers novel techniques to expedite and enhance cancer diagnosis and research efforts using a novel, targeted cell separation technology. Their patented approach performs rapid sample cleanup using a simple benchtop instrument that delivers intact, viable target cells without biochemical labels. SynderBio has confirmed product-market fit in single-cell sequencing (SCS) sample preparation and cancer diagnostics. With advances in sequencing technology and a growing number of SCS platforms now on the market, there is increasing need for high quality sample preparation techniques. SynderBio's technology achieves a higher yield of single, viable target cells and faster, effective removal of undesired components, all in a single instrument.

Market and Commercialization Strategy

The company's three-product pipeline employs their platform technology (instrument/disposable cartridge): Product 1, SCS Sample Prep, sold to academic and research laboratories, improves sample preparation for laboratory research applications including the rapidly growing SCS market (launch 2021). The global cell separation market is projected to reach $7.89B by 2021 and the US SCS research applications market was $1.1B in 2017. Product 2, Advanced Cytology to enhance detection of bladder cancer recurrence via urine-based cytology, decreases the need for invasive, painful cystoscopy, currently required 4x/year in bladder cancer surveillance (launch 2022). The US bladder cancer surveillance market is projected to reach $1B by 2020. Product 3, Cancer Molecular Diagnostic, will rapidly prepare biopsies for genetic analysis (launch 2023). The global cancer diagnostics market is currently $35B. By first targeting a research-only market, SynderBio has a fast path-to-market and directly reaches key researchers. Early revenue will be reinvested.

Technical & Competitive Advantage

SynderBio has a unique approach to improving the sample clean-up process that is significantly faster (10 minutes vs 40+ minutes using approaches like MACS or FACS) and greatly outperforms the competition in terms of yield, enrichment, and purity of the resulting sample. SynderBio has demonstrated consistent, effective sample preparation using a range of cancer cell types, as well as stem cells and neurological cells. In addition to outperforming FACS and MACS, SynderBio's unique ability to disaggregate cell clusters while eliminating dead/dying cells ensures maximum retention of scarce clinical samples. SynderBio's benchtop instrument rapidly isolates target cells, delivering intact, viable cells ideal for genetic testing, pathologist review, and R&D efforts. The company's solution ensures higher-quality input for NGS, leading to better detection of genetic markers and faster delivery of actionable reports to oncologists and patients.

Regulatory Strategy & Intellectual Property

SynderBio has contracted firm Canopy Medical to develop the regulatory plan. Canopy Medical has helped confirm the direct path to market for Product 1, and the 510(k) clearance-to-market pathway for Products 2 and 3. SynderBio's has an issued patent that covers the method for isolating viable cancer cells from a sample that comprises a mixture of cancer and normal cells. The company also has PCTs pending that describe the incorporation of this method into a benchtop instrument, with additional claims and capabilities related to the selective removal of cells from a cell suspension using mechanical lysis. These three patents are owned by the University of Iowa and exclusively licensed to SynderBio (with rights to sublicense).

Key Milestones

Description	Date/Year
Benchtop instrument and disposable cartridge designed; key modules tested; ready for large-scale manufacturing	2019
Technology tested on broad range of cancer types including clinical samples; third party validation	2015-present

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2016	Grant	Proof of Commercial Relevance Fund, Iowa VentureNet	$25K
2017	Grants	NIH-NHGRI SBIR Phase I / NIH-NCI STTR Phase I	$525K
2019	Accelerator Program	Participant in SkyDeck Accelerator, UC Berkeley	$100K

Use of Proceeds

SynderBio is seeking a $1.5M to work with key companies and researchers to perform product evaluations, using feedback and insights to finalize the first product for launch, and to launch SCS Sample Preparation instrument & disposable cartridge.

Key Team Members

Mike Cable, PhD: CEO

Exec at Fovi Optics, Nanomix, Xradia, Matrix Sensors; Key employee at Xenogen ($31M revenue, acquired for $80M)

Michael Henry, PhD: President

Senior Scientist at Millennium Pharmaceuticals, Deputy Director of the Holden Comprehensive Cancer Center

Sarah Vigmostad, PhD: CTO

Expertise in fluid mechanics, mechanobiology, and medical devices; 10 years' experience advising engineering teams and start-ups

Clarix Imaging / 3D Imaging-based Device to Lower Re-operation Rate

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

Company Overview (Clinical Impact and Value Proposition)

Clarix Imaging, a Chicago-based startup company, is developing a volumetric specimen imager (VSI), a unique, portable 3D imaging-based solution for lowering the high re-operation rate of breast conserving surgery. Clarix possesses an IP-protected unique technology, a world-class development and advisory team, and has successfully raised private investment in addition to NIH grants.

Market and Commercialization Strategy

There are about 6,000 hospitals and outpatient centers performing breast lumpectomy procedures in the US, representing a $500 million/year market. The global market for VSI is estimated to be $2.5 billion. Clarix has formed close partnership with leading US medical centers for early adoption and clinical-efficacy evaluation. Following initial launch in the US, Clarix plans to enter other strategic markets including Europe, China, and India. In addition, Clarix plans to expand the specimen imaging technology platform to cover other key applications in surgical oncology.

Technical & Competitive Advantage

Currently 15% - 25% of the annual 200,000 breast lumpectomy surgeries performed in the US fail to complete tumor removal in the first attempt, thus requiring additional surgeries resulting in poor patient outcomes and significant cost burden. A key reason for the high re-operation rate is the lack of a fast and accurate method for identifying incomplete tumor resection (i.e., positive margin) during the surgery. 2-D specimen radiography, the current standard of care technique for intra-operative margin assessment, has only ~50% sensitivity and takes ~30 minutes to complete. In contrast, Clarix's VSI has 90%+ demonstrated sensitivity and takes currently less than 5 minutes to complete the assessment, with a highly desired design feature that requires no change to existing operating room workflow and little training. With initial study data, we expect that VSI can lower re-operations to less than 10%.

Regulatory Strategy & Intellectual Property

With a seed round of $4+ million NIH award and private investment, Clarix has developed an optimized prototype for FDA 510(K) submission scheduled for August, and final product launch by Q4 of 2019. While VSI uses mostly off-the-shelf hardware components, Clarix has obtained exclusive rights to the IP owned by University of Chicago (UC), which protect the image reconstruction algorithms and possesses IPs of innovative system designs. These IPs uniquely enable the high-resolution, real-time imaging application. The company is aggressively growing its own IP portfolio for protecting product-specific features.

Key Milestones

Description	Date/Year
FDA 510(K) Submission	08/2019
Product Launch	12/2019
First commercial product delivery	03/2020
Expand to China and Europe	12/2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2017	SBIR Phase I	NIH-NCI	$225K
2018	SBIR Phase II	NIH-NCI	$2M
2018	Angel	Angel - Undisclosed	$2.2M

Use of Proceeds

Clarix is looking to raise $8M series-A (private investment & nondilutive grants) by 6/2020 for manufacture transfer, marketing, and expanded clinical trials, and $20M series-B in 2022 for scaled manufacturing, global marketing and sales.

Key Team Members

Xiao Han, PhD: Co-Founder & CEO

14 years of experience in medical and industrial imaging; former PhD student of Xiaochuan Pan

Xiaochuan Pan, PhD: Co-Founder & CSO

Professor of radiology at University of Chicago; leading authority on medical imaging with 30 years of experiences

Kirti Kulkarni, MD: Clinical Advisor

Breast Radiologist at University of Chicago with 13 years of clinical experiences

Arthur Lerner, MD: Clinical Advisor

Founder of the American Society of Breast Surgeons and former Board Member of Hologic

Maryellen Giger, PhD: Scientific Advisor on Machine Learning/AI

Pioneer of radiology AI with 30 years of academic research and start-up company experiences including R2 (acquired by Hologic Inc) and Quantitative insights (acquired by Paragon Biosciences

Paul Chang, MD: Scientific Advisor on Imaging Informatics

An inventor of PACS and world leader of radiology informatics; Co-founder of Stentor (acquired by Philips in 2005 for $280 million)

Cell Preservation Services / EUS Cryocatheter for Ablation

John Baust | jmbaust@cpsibiotech.com | 607-687-8701 | www.cpsibiotech.com | www.gicryo.us

Company Overview (Clinical Impact and Value Proposition)

CPSI Biotech, a private, integrative bio/medtech greenhouse company, develops and designs innovative cryo-medical devices for the ablation of targeted tissues. CPSI has developed the GastroCS cryoablation console and *FrostBite* cryocatheter, a minimally invasive cryoablation device platform for use with endoscopic ultrasound (EUS) for the treatment of pancreatic cancer and other gastroenterological-based diseases. This EUS-guided treatment will overcome several problems related to the surgical, laparoscopic or transcutaneous approaches used today, including reducing pain, surgical complications and treating non-resectable tumors.

Market and Commercialization Strategy

Pancreatic cancer cases in the US and Germany will increase to 60,000 and 30,000 by 2022, respectively. More than 95% of the individuals diagnosed with pancreatic cancer will die within five years. CPSI intends to carry out the development of a robust pre-alpha system which is poised for transition into industrial design and alpha product build for pre-clinical studies and FDA 510K submission. To advance the development and commercialization efforts of the technology, CPSI and GI Cryo, a spinoff of CPSI, have partnered wherein GI Cryo has licensed the GastroCS and *FrostBite* technologies to lead commercialization effort. Preliminary conversations with RBC Medical regarding commercial product finalization have taken place.

Technical & Competitive Advantage

The *FrostBite* system will be the first truly versatile, user friendly, minimally invasive ablation system for the targeted ablation of pancreatic and liver cancer. Currently, there are four main competitive therapeutic categories: surgery, chemotherapy, radiation and (most pertinently) radiofrequency (RF) ablation. RF is used as the energy source of choice for the catheter ablation treatment of unresectable pancreatic cancer. However, RF limitations include charring and the risk of thermal injury and collateral damage to non-targeted organ structures. As a result, alternative energy sources, such as cryo, for ablation of unwanted pancreatic tissues are being sought. Testing results showed a >2cm lethal zone in 3 minutes; nearly 4X faster than today's commercial cryotechnologies.

Regulatory Strategy & Intellectual Property

GI Cryo has obtained exclusive worldwide license to the nitrogen-based GastroCS cryoconsole and the *FrostBite* EUS Cryocatheter IP portfolio for Endoscopic GI procedures in humans from CPSI Holdings. Under the agreement, GI Cryo also has exclusive license to a second cryoablation technology, supercritical nitrogen, developed by CPSI, providing a dual technology approach and added IP protection. This portfolio currently includes 20 issued and 25 pending patents worldwide. Additionally, CPSI is working with Guideline Medical to oversee implementation of the quality system and to manage the FDA 510K regulatory process.

Key Milestones

1. Prototypes Developed 2. Patent Protection 3. Pilot Pre-clinical Study completed at Johns Hopkins 4. DFM/Mfg/Regulatory Partners	Milestone Schedule - Description	Date/Year
	Acquisition of Financing for GI Cryo	01/2020
	Phase 1 – FrostBite finalization, pre-clinical studies, CE & UL submission, first-in-humans,	01/2021
	Phase 2 – FrostBite manufacture, 510(k) submission, sales launch in Europe	01/2022
	Phase 3 – 510(k) approval, sales launch in US; expand indication to stomach or esophagus	08/2022

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2012	Tech Sale	Cryosystem sale to EndoPharma	$3M
2014	Grant	NIH-NCI Phase I award for FrostBite P1	$ 225K
2015	Grant	NIH-NCI Phase I award for EsoAblate P1	$ 278K
2016	Grant	NIH-NCI Phase I award for ERASE P1	$ 295K
2017	Grant	NIH-NCI Phase II award for FrostBite P2	$1.73M

Use of Proceeds

GI Cryo is currently seeking $8 million in investment to finalize development of the product, complete animal and the limited human trials necessary for 510(k) approval and commercialization. Once the technology is commercialized, GI Cryo projects a corporate M&A value approaching $150M. In the absence of corporate acquisition, GI Cryo will ramp up of sales facilitating rapid growth of revenues targeting upwards of $50 million within five years of completion of the product launch plan.

Key Team Members

John Baust, PhD: Founder & CEO

Expert in business, engineering, and science with a history of success in asset sale management and technology development.

P. Jay Pasricha, MD: Medical Director

Expert in the clinic, business and startup tech development; wide success as a physician, medical director and serial entrepreneur.

Kristi Snyder, PhD: Director of Operations

Expert in startup operations, marketing, and science; success in corporate management and product marketing/launch.

Rich O'Hara, MBA: Financial Advisor Expert in finance and proven track record in startup corporate finance.

Fibralign / Novel therapeutic device platform, Secondary Lymphedema

Greg King, CEO | gking@fibralignbio.com | (415)902-4721 | www.fibralignbio.com

Company Overview

Fibralign Corporation is a Stanford University spin-out that produces novel therapeutic medical devices to address major unmet medical needs. The company is already in commercial sales in the US with its first product, the BioBridge® Collagen Matrix, a 510(k) cleared device that is based on Fibralign's proprietary Nanoweave® scaffolding technology. BioBridge's first target is treatment and prevention of Secondary Lymphedema, a global chronic disease that currently has no cure. Clinical benefit has already been demonstrated and a Stanford-led multi-site clinical study is currently underway for breast cancer-related lymphedema that is funded by an NCI SBIR bridge grant ($3M). A compelling product pipeline has been established that includes treatments for peripheral nerve repair (PNR), peripheral artery disease (PAD) and volumetric muscle loss, each with preclinical benefit already demonstrated that has generated partner interest.

Market and Commercialization Strategy

Fibralign will initially focus BioBridge in US and Europe on addressing treatment of cancer-related acquired lymphedema (15 million cases worldwide) and prevention of the disease, where preclinical and clinical benefit has already been demonstrated. Fibralign is working closely with KOLs in this field in US, Europe, and Asia. The company will engage with strategic partners for further expansion of reach in these and additional markets (Japan, ROW) and to advance product pipeline.

Technical & Competitive Advantage

Despite their limitations, conservative therapies (compression, wraps, physical therapy, massage, etc.) remain the primary treatment option for lymphedema. These therapies are non-curative, time consuming, provide limited relief, and are very costly. Fibralign Nanoweave® technology platform provides the means for creating ("printing") 3D nano-scaffolding which precisely mimics human tissue structure. This technology has been proven to directly influence desired cell behavior for repairing diseased tissue and can be further be utilized as a "bioreactor" combination device that provides a sustained localized delivering of cells and gene therapy for precisely targeting therapy. The end-to-end production system has been fully developed and implemented in the Company's GMP facility. BioBridge®, in conjunction with microsurgical procedures that have advanced in addressing this disease but are not considered curative, will greatly improve outcomes, providing the opportunity to reverse the disease.

Regulatory Strategy & Intellectual Property

Fibralign is engaged with regulatory experts for US and Europe and a strategic partner for Japan. BioBridge already has an initial 510(k) clearance as a surgical mesh and will utilize the NCI-funded clinical study to expand the indication of use for treating lymphedema. CE mark is currently in process. ISO 13485 certification secured. The company has a strong IP position established with 26 total patents issued and 8 additional patents pending. Nanoweave® and BioBridge® are registered trademarks of Fibralign.

Key Milestones

BioBridge received 510(k) clearance (K151083), ISO certification
Commercial revenue (reimbursed) revenue
Clinical benefit and safety demonstrated
Completed Pilot Clinical Study, multi-site clinical study underway (NCI funded) for Breast cancer related lymphedema
Strategic partnership established
Previous winner of prestigious **Medtech Innovator** award

Capitalization History

Equity financing	$8.2M
Non-dilutive funding (NCI, DoD, NSF, partner NRE)	$8.1M

Use of Proceeds

Fibralign is raising a $12M investment round to complete lymphedema clinical studies in US and Europe, expand commercial sales in US & Europe, develop pathway for Japan and other markets, advance product pipeline in PNR, PAD and drug delivery, establish partnerships to support market execution and production, and develop next-gen manufacturing capability.

Key Team Members

Greg King: CEO/President
Michael Paukshto, PhD: CTO & Co-Founder
David McMurtry: VP Manufacturing, Co-Founder

Fischer Imaging / Slot Scanning Mammography Technology

Shabbir Bambot, CEO | sbambot@fischermti.com | 678-907-4711| www.fischerimaging.com

Company Overview (Clinical Impact and Value Proposition)

Fischer Imaging is developing MammoCAT™, a next generation advanced mammography and breast imaging technology. The higher resolution and contrast of this slot scanning technology (SST) will reduce the number of missed cancers and unnecessary callbacks. The lower dose will produce a safer test and the pain free compression will improve patient compliance. This platform technology can be applied to Digital breast Tomosynthesis MammoCAT™ DBT, the company's second product and a fully integrated Computed Tomography system MammoCAT™ CT, that will use the same gantry as the other devices in a prone configuration where the breast is held without compression and will perform full field, 360 degree, imaging at the same dose as standard digital mammography.

Market and Commercialization Strategy

300,000 women are diagnosed with Breast Cancer (BC) and 40,000 succumb to BC each year in the US. Worldwide, BC deaths exceed 500,000. 90% of women diagnosed at the earliest stage survive compared to only 15% diagnosed with advanced disease. Today's mammography misses almost half the cancer cases in young women and women with dense breasts (about half the population) and is inaccurate for the rest. The Mammography Equipment market in the US exceeds $5.0B with annual service and sales and service >$1.0B with an addressable volume of over 50 million procedures a year. Market trends point to more than 10% CAGR in this opportunity. Fischer has invested over $4.5M in the development of their technology. A 510(k) approval is expected in 18 months post-Series A funding for MammoCAT™ DM, their first product, with production shipments 6 months thereafter.

Technical & Competitive Advantage

Traditional mammography uses cone beam radiation which generates a lot of scattered radiation that blurs the images. MammoCAT™ uses a narrow, highly collimated, X-ray beam to scan the tissue in precise alignment with an inexpensive line shaped detector. This method eliminates scattered radiation resulting in images with double the contrast and resolution. MammoCAT™ also accommodates the natural shape of the breast providing a painless, comfortable experience for the patient. The versatility of Fischer's technology permits multiple product configurations ranging from an upright system in MammoCAT DM that can be upgraded to MammoCAT™ DBT to a prone, compressionless, full 360° imaging to MammoCAT™CT that will allow screening, diagnosis, staging and biopsy in the same device. Conglomerates such as Hologic, GE, Siemens, Philips, Canon and Fuji are likely competitors. Their systems use cone beam radiation and large expensive 2D detectors that cannot match the resolution of Fischer's line detector. Their systems cannot provide the high contrast and low dose advantages.

Regulatory Strategy & Intellectual Property

Fischer has granted patents in the US and Europe and has completed an internal "freedom to operate" review. MammoCAT DM is regulated as a Class II device requiring a 510(k) submission. The FDA's 510(k) guidance on FFDM includes the use of slot scanning technology allowing for a relatively fast FDA approval. MammoCAT™ DBT, and MammoCAT™ CT are currently regulated as Class III devices requiring a longer regulatory process (PMA).

Key Milestones

Description	Date/Year
Complete prototype development, testing, and validation	Q3 2019
NIH Phase II grant application	09/2019
Series A raise of $5M	12/2019

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
Pre-2015	Prior Investment	Angel Investors	$4.5M
2016	Seed Funding	Founders Capital	$1M
2018	Grant	NIH-NCI SBIR Phase I award	$300K

Use of Proceeds

Fischer is seeking $5M in a Series A round to use toward industrial design, clinical prototypes, clinical research, salaries (7 people, 2 years), facilities (2 years), FDA submission, legal/insurance, packaging and shipping validation, marketing, and product launch.

Key Team Members

Shabbir Bambot, PhD: CEO & Co-Founder

Serial entrepreneur with 11 US patents; Founded multiple medical device companies in cancer diagnostics and imaging

Wes Rogers: COO & Co-Founder

20+ years' experience in medical devices and device commercialization (Medtronic, TEI Biosciences)

Mike Tesic, PhD: CTO

30+ years developing imaging devices (Picker and Delphinus); 17 issued patents; Father of SenoScan slot scanning mammography

Webster Stayman, PhD: Advisor

Expert in PET/SPECT/CT image reconstruction; Associate Professor at the Johns Hopkins School of Biomedical Engineering

Imago Systems, Inc. / Taking the guesswork out of image analysis

Robert Boyce, CCO | robert.boyce@imagosystems.com | 908-625-3295 | www.imagosystems.com

Company Overview (Clinical Impact and Value Proposition)

Imago has developed a software platform for visualizing cancer from cells to tumor in any imaging methodology. Their patent pending software will be used for visualizing, characterizing, and differentiating structural patterns in existing digital images. Imago's Image Characterization Engine (Imago ICE™) is a set of multidimensional image processing algorithms which provide visual differentiation of structures in breast tissue through the post-processing of existing 2D digital mammograms, including full-field digital mammogram (FFDM), and synthetic 2D, generated from 3D-DBT. In addition, the company will launch a veterinary medicine product to be commercialized in 2020. The product will utilize existing X-Ray images to detect cancers as well as ligament damage.

Market and Commercialization Strategy

There are 39 million mammograms performed annually in the US on roughly 18,000 mammography machines. Imago will sell its software platform directly to hospital systems and radiology clinics. The product will be cloud based or available on premises. It can be used with the output from any mammography machine (2D or 3D). Imago will offer a standard SAAS model. The veterinary business will also be cloud based and sold as an SAAS model.

Technical & Competitive Advantage

Imago's ICE Reveal software will provide more accurate screening, less exposure to radiation and contrast media, reduction of emotional stress due to a reduction in false positive diagnosis, and earlier identification of abnormalities to allow for earlier treatment and better outcomes. Imago examined the technology's algorithmic performance metrics utilizing 1,249 images. Correct pattern matches were recorded, only if the Imago ICE algorithms indicated the same area of the mammographic image as was indicated by the ground-truth for that image. Sensitivity for abnormal pattern matching was 95%. Specificity for normal cases when multiple Imago ICE algorithms were used (Color Island, Relief, Low Density, and High Density) to eliminate positive reads was 98.7%. Imago has completed validation work in the field with 11 radiologists reviewing mammograms alone and mammograms with Imago ICE software.

Regulatory Strategy & Intellectual Property

Imago is seeking an FDA clearance to commercialize its Imago ICE Reveal software. Given that the risk is moderate (Class II) and that there is not a clearly defined predicate device, Imago will pursue a *de novo* classification from the FDA. They will conduct multi-reader, multi-case clinical trials in support of our submission. The company has filed two patents on its technology and maintains several trade secrets.

Key Milestones

Description	Date/Year
Initiate clinical trials for mammography	07/2019
Submit de novo package to the FDA	01/2020
FDA de novo clearance for mammography	07/2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2016	Friends and Family	Convertible Debt	$430K
2017-2018	Seed Round	Convertible Debt	$3.5M

Use of Proceeds

Imago Systems is currently raising $6.25M in a Series A financing round to conduct a Pilot Clinical Study and Pivotal Clinical Study and complete *de novo* application process, to complete Veterinary Medicine and Mammography products, to commercialize the business (development of white papers, third-party validation and publication for Mammography), and to launch the Vet franchise.

Key Team Members

Thomas Ramsay: CEO, CTO, & Co-Founder

Imaging expert with 10 patents in optics, image processing, and computer-based machine learning

James Hallihan: EVP & Co-Founder

20+ years' advanced technology sales and management experience, working with both manufacturers and business partners

Robert Boyce: CCO

Launched several medical devices while at J&J where he was VP Sales and Marketing at Independence Technology

Travis Brooks: CFO

Experience leading teams through periods of growth, transition, and challenges; Worked with Liberator Medical Supply to grow the business from $9.5 million in annual sales to $81.6 million.

Susan Alpert, MD, PhD: Regulatory and Board of Directors

Principal of a consultancy to companies placing products into the US healthcare market; Former SVP of Global Regulatory Affairs at Medtronic and VP Regulatory Sciences at CR Bard

Madorra / Drug- and Hormone-free Treatment for Vaginal Dryness

Holly Rockweiler, CEO | holly@madorra.com| 314-239-3059| www.madorra.com

Company Overview (Clinical Impact and Value Proposition)
Madorra is developing a product intended to treat vaginal dryness associated with vaginal atrophy. Their system is a prescription, non-invasive, non-hormonal medical device that engages the body's natural mechanism for lubricating the vaginal canal. Madorra's device is easy to use so women can comfortably treat themselves at home. After a few weeks of non-invasive, non-stimulating therapy, women are enabled to reclaim their health and sexual wellness.

Market and Commercialization Strategy
Madorra's first product is a hormone-free device intended to treat vaginal dryness. The non-invasive, home-use system (reusable and disposable) could potentially empower 1.8 million breast cancer survivors ($2B market opportunity) and 14.4 million post-menopausal women ($15B TAM) to improve their quality of life and sexual health without hormones and messy lubricants. Madorra's clinical evidence shows compelling results and robust interest. Further, Madorra's recurring revenue from the single-use disposable, and out of pocket purchase approach predicts significant ROI without reimbursement risk. Madorra completed their Series A round, led by OneVentures, to fund their pilot clinical trial and enrollment of the pivotal trial for FDA clearance.

Technical & Competitive Advantage
The Madorra therapy system eliminates the risks associated with hormonal treatment methods and the inconvenient application of artificial lubrication. In a related space called vaginal rejuvenation, a laser ablation device, MonaLisa Touch, is marketed by Cynosure. Their approach burns vaginal tissue, driving production of new cells. The procedure has no FDA approval for vaginal dryness, is performed in the clinic, and is expensive at $3000 for the first treatment. Cynosure and six other vaginal rejuvenation companies garnered warning letters from FDA last summer compelling them to stop advertising their devices for treatment of vaginal dryness. Madorra is differentiated from these companies first and foremost by clinical evidence specifically targeting vaginal dryness. In addition, Madorra's non-invasive approach, home use, and lower price point put distance between Madorra and the competition. Other "wellness" competition claiming to treat vaginal dryness have not sought FDA approval, casting doubt on their treatments' effectiveness.

Regulatory Strategy & Intellectual Property
Madorra is a clinical-stage company with clinic-ready prototypes and three completed clinical studies. These studies demonstrated the device's mechanism of action and reduction of vaginal dryness symptoms. Madorra is reproducing these results on a larger scale to support their FDA IDE and De Novo submissions. They have two pending patents and are submitting their third. The first was filed by the CEO when she was a fellow in Stanford's Biodesign program. The technology is fully licensed for use to Madorra.

Key Milestones

Description	Date/Year
Complete Human Factors clinical trial	2019
Complete pilot clinical trial	2020
Complete pivotal (IDE) clinical trial	2021
Submit De Novo application to the FDA & receive clearance	2021

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2016-2018	Prize awards & Grants	Stanford, NSF, NIH, other	$3.5M
2015/2017	2 Seed Rounds	Angel Investors (convertible note)	$1.5M
2018-2019	Series A	OneVentures + Angels (Equity)	$4.2M

Use of Proceeds
Madorra has closed their oversubscribed Series A of $6.7M. The Series A and grants fund Madorra through the pilot clinical trial as well as the pivotal clinical trial enrollment.

Key Team Members
Holly Rockwieler: Founder & CEO
Extensive experience in medical device development, user-centric design, and feasibility research at Boston Scientific and as a Stanford Biodesign Fellow; 15+ medical field patents; BS and MS Biomedical Engineering from Wash U, St. Louis
Stephanie Kaplan: COO
30+ years' experience in medical device start-ups and established companies driving successful transition from early-stage R&D to manufacturing to market; BSIE from The OSU and MBA in management of technology and operations from UC Berkeley
Bryan Flaherty, PhD: CTO
30+ years' experience in medical devices, specializing in early de-risking of technology; 15+ years leading product development at start up medical device companies; BSME from UC Davis and MS and PhD in Bioengineering from University of Illinois

NE Scientific / Surgical Guidance Software for Use During Ablations

Andrea Borsic, CEO | aborsic@ne-scientific.com | 857-880-2028 | www.ne-scientific.com

Company Overview (Clinical Impact and Value Proposition)

NE Scientific (NES) aims to improve precision in the ablation of tumors by providing guidance software like what is available in radiotherapy (but lacking in radiofrequency ablation – RFA and microwave ablation - MWA). Currently, the company is focused on a first product for guidance of liver RFA - a procedure where, because of lack of computerized guidance, physicians fail to treat completely the volume of the tumor in 24% of cases for medium tumors (3-5cm) and in 58% of cases for large tumors (>5cm), leading to recurrence after the treatment.

Market and Commercialization Strategy

NES will initially focus on hepatic tumors (the main application of RFA) with lung, kidney, and prostate tumors to follow. Approximately 900 physicians practice RFA in the US and a similar number in Europe. 50,000 tumor ablation procedures are conducted annually in the US for oncological purposes. The tumor ablation market is the fastest growing segment of non-vascular interventional radiology, with an estimated growth of 4.5% per year. The value of this market is expected to reach $1.5 trillion by 2023. NES aims to release a first and simplified software for RFA and MWA treatment for liver and lung tumors by the end of 2019. A more sophisticated software for liver/lung RFA in 2020, and a more sophisticated for liver/lung MWA in 2021.

Technical & Competitive Advantage

The software developed by NES uses a computational core which simulates RFA physics and estimates accurately the volume of the ablation. This volume is shown fused to CT images during the procedure, together with a representation of the tumor volume NES is currently developing a similar software for MWA. NES has been the first entity in the world to demonstrate that the required computations can be performed in real-time by using GPU acceleration technologies. This achievement permits the adoption in the operating room of this guidance technology.

Regulatory Strategy & Intellectual Property

NES has filed two patent applications designed to protect methods for modeling the ablation volume. In a clinical study NES has validated the ablation prediction models against data collected from 20 liver cancer patients undergoing RFA. Through a clinical trial scheduled to start in September 2019 at the Dartmouth Hitchcock Medical Center the company will assess the effective reduction in the local recurrence of the tumors. NES is currently developing a reimbursement strategy where the monetary value produced after each use of the software is shared between NES, the insurance companies, and the hospitals.

Key Milestones

Description	Date/Year
File 510(K) for a first product (simplified guidance software)	08/2019
Obtain IRB approvals for a clinical trial	08/2019
File 510(k) for a second product (advance guidance software)	08/2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2014	SBIR Phase I	NIH-NCI	$220K
2017	SBIR Phase II	NIH-NCI	$1.42M
2019	Grant	Johnson & Johnson QuickFire Lung Cancer Innovation Challenge award	$250K

Use of Proceeds

NES is looking to raise an investment of $3.5 million. Proceeds will be utilized for developing initial commercial activities in US (60%) during Q1-Q2/2020 and for supporting the product development pipeline (40%). The long-term goal is to commercialize products globally through strategic partnerships. The development in the short term of a small US-based sales team aims at gaining direct customer feedback and at demonstrating market traction. Partnerships for commercialization in China and Europe will be developed in the course 2020/2021.

Key Team Members

Andrea Borsic, PhD: Founder & CEO

15 years of experience in biomedical engineering and scientific computing; Former Dartmouth faculty member who assisted in developing new imaging modalities for detecting breast and prostate cancer

Eric Hoffer, MD: Co-Founder & CMO

Director of Vascular and Interventional Radiology at Dartmouth-Hitchcock Medical Center for 10 years; 25 years of experience in full-time interventional radiology practices during which he performed thousands of CT-guided interventions

Peter Savas: Chairman Board

19 years of CEO experience; Recruited as Chairman CEO of Aderis Pharmaceuticals in 2000 where he raised $45 million in new capital; Has attracted world-class directors/advisors including Nobel Laureates Paul Greengard and Sir James Black.

nView medical / Real-Time 3D Imaging System

Cristian Atria, CEO| cristian.atria@nviewmed.com| 801-712-6367| www.nviewmed.com

Company Overview (Clinical Impact and Value Proposition)

nView medical is an AI image creation start-up with the mission to make surgeries safer, faster, and consistently accurate. By leveraging model based imaging and machine learning, nView's imaging scanner provides 3D images instantly, analyzing them on the fly to provide step-by-step guidance to surgeons. nView's technology can disrupt the $3.5B/yr market of interventional imaging and image guidance, displacing technologies such as fluoroscopic C-arms, cath-labs and surgical navigation. nView plans to first launch in pediatric orthopedic applications with an expansion into adult and soft tissue applications.

Market and Commercialization Strategy

To date, nView has received $5.4M in funding, including $2.7M in non-dilutive grants. The NIH funded research continues the development of nView's patented technology by making the prototype viable for soft tissue visualization and for the adult segment. Preliminary results from the company's Phase I NIH research shows good visualization of lung tissue, soft tissue discrimination, making the technology promising not only for bone tumors, but also for lung tumor resections and liver tumor ablations when previously marked with contrast agents.

Technical & Competitive Advantage

nView medical's real-time 3D guidance system combines the accuracy of 3D imaging systems with the efficiency of fluoroscopic C-arms (the most common surgical imaging system) at a reduced radiation dose for patient and surgical staff. The system is similar to surgical C-arms in terms of positioning, mobility and footprint, but provides 3D imaging and real-time 3D guidance.

Regulatory Strategy & Intellectual Property

nView's first intraoperative scanner is 510(k) cleared and was validated based on successful cadaveric imaging. Two fully functional prototypes have been built (one is installed at Johns Hopkins Bayview Medical Center) and the second generation prototype intended for human use is currently in process. The first live cases are planned by year-end of 2019. The foundational patent has been issued in the US, and a pipeline of 4 additional patents is in process in the US and internationally.

Key Milestones

Description	Date/Year
Product launch in pediatrics at POSNA	05/2019
510(K) approval	07/2019
First live patients - expected	2H 2019

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2014	Pre-seed	GE/Danaher executives	$100k
2014-2018	Grant – Phase I/Phase II	NSF	$1.4M
2015-2017	Grants	State Of Utah	$500K
2017	Grants – Phase I	NIH-NCI	$275K
2018	Seed	Fusion Fund (VC), GE & Medtronic executives, including NSF matching	$1.2M
2019	Convertible notes	Fusion Fund (VC), Dr. Kevin Foley, Johnson & Johnson executive	$2M
2019	Grants	NCC-PDI (FDA), Amazon	$150K
2020	Series-A	Expected VC round	$6M

Use of Proceeds

The company has currently reached its target for a bridge to Series-A convertible note round and is funded to start commercialization in the pediatric segment and file follow-on 510(k)s. The company is expected to raise additional $6M in Series A in 2020 to expand its commercialization efforts in pediatric and to address the adult market.

Key Team Members

Cristian Atria, MBA: Founder & CEO

20 years of industry experience in surgical imaging, including with GE Healthcare where he had a successful track record developing products; Ran GE Healthcare acquired start-up in Computer Aided Surgery as General Manager (Visualization Technologies Inc).

Lisa Last: COO

16 years' experience (GE Healthcare), multiple 510(k) & successful FDA audits, including lifting a consent decree with the FDA

Carine Henderson, MBA: Director of Business Development

12 years commercialization experience: product launches in pharma with AstraZeneca and Valeant Pharmaceuticals as well as oncology treatment devices and hospital equipment; Recipient of Rep of The Year Award and Today's Woman Scholar Award

Carevive Systems / End-to-end Digital Oncology Platform

Madelyn Herzfeld, CEO | maddy@carevive.com| 305-778-1870 | www.carevive.com

Company Overview (Clinical Impact and Value Proposition)

Carevive is an end-to-end digital oncology platform that seamlessly integrates into clinical and electronic health record (EHR) workflows to increase patient and provider engagement for improved health outcomes. The platform is powered by real-world evidence: clinical data and electronic patient-reported outcomes (e-PROs). Carevive licenses their PERFORM package to health systems which includes personalized treatment care plans, clinical trial screening, proactive symptom monitoring/management, survivorship care planning, and data analytic features to improve the health-related quality of life and survival of cancer patients, while increasing cancer service line revenues and improving clinic efficiencies. They have 19 health system customers, which includes 600 clinician users who treat approximately 67,000 patients.

Market and Commercialization Strategy

Carevive is one of a handful of cancer care management technologies, an industry estimated to be a>$600M. Carevive has a direct sales team and a channel partnership that licenses their technology in US, with plans for global expansion. Many of the health system customers are now joining Carevive OPT-INTM, a provider network working with Carevive and life science companies to build tumor-specific data registries and conduct clinical research requiring our patient experience data. The oncology real-world evidence/ePRO market size is >$1B today and growing. Life science companies need Carevive's data because CMS and the FDA are placing significant value in the patient-reported experience for new drugs coming to market. While new therapies are expensive to develop and deliver, they are believed to provide significant benefit to patients with minimal options today. As such, the market is trending towards early market approval of new cancer therapies, with the possibility of providing strong clinical data and patient-reported experience data in the real-world setting to maintain drug approval and receive favorable reimbursement. There are approximately 300 oncology drugs in Phase III development (over 3,000 in total), growing at 10% annually.

Technical & Competitive Advantage

Carevive is the only company bringing e-PROs into an EHR so clinicians can better manage their cancer patients. The company believes their cancer care management technology has the most robust features, supporting clinicians and their patients from diagnosis through survivorship. Through provider use of the software, Carevive can collect clinical and longitudinal PRO data to uniquely quantify the real-world cancer patient experience. The company can do this because of the proprietary relationship they have with Cerner, who are both investors and business partners. Together, they have built proprietary clinical data transactions and workflow functionality needed to make PRO integration into the EHR feasible for a busy clinic. Through Carevive's provider business, they can provide a rich and unique dataset to the life science industry more efficiently, accurately, comprehensively, and cost effectively than other cancer data aggregators.

Regulatory Strategy & Intellectual Property

Carevive is focused on Regulatory Compliance and Data Security. They only employ vendors with HITRUST and SOC2/3 credentials, and routinely pass the stringent privacy and security audits required by our Provider clients. As a software company, they've elected to treat their IP as a trade secret rather than apply for patents.

Key Milestones

Description	Date/Year
PROmpt/ePRO General Availability (GA) Release	07/01/2019
Automation Code Set/Updated Content Management Release	10/01/2019
Advanced Analytics Module Release	06/01/2020

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2013/2016	Series A, B	Cerner Corp., HLM Ventures, Long River Ventures, Co-founders, Family/Friends	$16.5M
Various	Grants	Genentech, BMS, Celgene, Takeda, others	$6M
2018	SBIR Fast Track Contract	NIH-NCI: CDS for symptom management	$1.725M

Use of Proceeds

Carevive is looking to secure two new life science strategic investors to complement the current financial investment partners and Cerner. Proceeds will be used to build the data registries and patient-centered outcomes research to scale so they can quickly penetrate the life science RWE market.

Key Team Members

Madelyn Herzfeld: CEO, 20 years managing oncology-related businesses
Stan Norton, 20+ years as healthcare data Chief Technology Strategist
Mordecai Kramer: VP, Data Generation & Outcomes, 24 years in life sciences clinical research business development
Ethan Basch, MD: Scientific Advisory Board Director, Leader in Patient-Reported Outcomes Health Services Researcher

Shade / Wearable UV Sensor Mimicking Skin Sensitivity to UV Exposure

Emmanuel Dumont, CEO | em@shade.io | 347-896-2017 | www.wearshade.com

Company Overview (Clinical Impact and Value Proposition)

In the US, skin cancer is the most commonly diagnosed cancer (5M people per year). Its annual cost is over $8B per year and it is deemed a major public health problem by the US Surgeon General. Shade, a spin-off from the Jacobs Technion-Cornell Institute, has developed the world's first and only ultraviolet detector that mimics the skin sensitivity to UVB and UVA rays. Our NCI-funded trial showed that, in a high-risk population, there is 5x decrease in the incidence rate ratio of non-melanoma skin cancer for patients wearing the Shade UV sensor. Our data will be submitted for publication at the end of 2019.

Market and Commercialization Strategy

Shade's goal is to become the "UV-sensing engine" in wearable products, a multi-billion-dollar market segment, by selling the world's only accurate and low-cost UV index sensor. Shade already has an R&D agreement in place with Beiersdorf, a publicly-traded skincare company, who will conduct a pilot study with the sensor to support efficacy claims for their products. Shade's revenues have reached $250K/year (breakeven) mostly from sales to clinical studies. Today, Shade's detector is too large and cumbersome to be easily incorporated in wearable devices (e.g. smartwatches). With funding and the right hires, Shade plans to incorporate its detector technology into a package specifically designed for small devices.

Technical & Competitive Advantage

Many companies have attempted at commercializing a wearable UV sensor for health, but they have failed to reach a meaningful accuracy. They are on average 10x less accurate than the Shade sensor because they do not mimic the skin sensitivity to UV exposure, which we achieve by combining special optics and machine-learning. We published our accuracy data in IEEE Life Sciences Conference. Recently, L'Oreal launched the "My Skin Track UV Sensor" but Shade testing shows that it is as inaccurate as the other competitors (data not published).

Regulatory Strategy & Intellectual Property

Shade's IP strategy has been to protect, as broadly as possible, every aspect of the semiconductor, embedded algorithms, design, and user interfaces of our product. The bulk of the IP applications were filed in the summer of 2016, one month before Apple's first application on the same subject matter and six months before Google's first application on the same subject matter. Shade intends to remain in the "wellness device" category of FDA and will limit their marketing claims to the ones allowed in that category.

Key Milestones

Description	Date/Year
Deliver on Phase I and II of our signed R&D agreement Beiersdorf	Q2 2019
File additional patents on the detector technology	Q3 2019
Raise series A	Q4 2019

Capitalization History

YEAR	Grant, Funding Round, etc.	Description	Amount
2014	Grant	Weill-Cornell	$100K
2016	Seed	Angels and early-stage VC	$1.9M
2017	Contract	NIH-NCI	$1.5M
2018	Grant	NSF	$225K

Use of Proceeds

Shade is looking to raise $2M to develop a package that could be tested and used by most wearable device companies (e.g. smartwatches, skincare companies, etc.). The features would include: 1) operate at a low voltage (< 2.8 V), 2) consume very little power, 3) are "surface-mount", as opposed to "through-hole", and 4) incorporate an analog-to-digital converter and a standard interface ("I2C") to connect to the wearable device's microprocessor.

Key Team Members

Emmanuel Dumont, PhD: Founder & CEO

Expert in optics; Proven success in IP roadmap and technology development; Former postdoc researcher in the "Runway" program of the Jacobs Technion-Cornell Institute; PhD in biophysics from Columbia University; Former investment banker on Wall Street.

Peter Kaplan, PhD: CTO

30+ years' experience in skin measurement studies at Unilever

Barry Cheskin: Investor in Shade and advisor

Founder and CEO of PowerVision, a company that was recently acquired; Former President and CEO of NanoGram Devices Corp. which he sold to its largest competitor nine months after arriving in the position; Former President and CEO of RITA medical systems, which he grew to $18M in sales after taking it public in 2000

NATIONAL CANCER INSTITUTE
SBIR DEVELOPMENT CENTER