



*Department of Biomedical Engineering
10900 Euclid Avenue
Cleveland, OH 4106*

Ohio Department of Development
Research Commercialization Program
Third Frontier Project
State of Ohio

January 9, 2010

Subject: 2010 OTFMIP LOI, 2010 OTFMIP LOI, OTFMIP2010@development.ohio.gov

Due: January 25, 2010

Case Western Reserve University and collaborating institutions intend to submit a proposal in response to the 2010, Ohio Third Frontier Medical Imaging Program.

Project Title: Biomedical Imaging

Estimated Grant Funds Requested: \$3,000,000

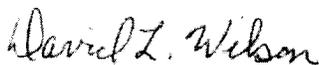
Lead Applicant Institution:
Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 44106

Contact person: David L. Wilson, PhD, Professor of Biomedical Engineering and Radiology,
david.wilson@case.edu, 216-368-4099.

Collaborating Institutions: There are a very large number of potential academic, research, and commercial institutions.

Summary: We will develop novel biomedical imaging equipment and software that will be important for commercialization in Ohio and for health care.

Regards,



David L. Wilson, PhD
Robert Herbold Professor of Biomedical Engineering & Radiology



Ohio Department of Development
77 South High Street
Columbus, Ohio 43215

December 21, 2009

RE: 2010 OTF MIP

Dear Sir or Madam:

Please be advised of our intent to submit a full proposal for the "Ohio Third Frontier Medical Imaging Program 2010". We note the following data concerning the prospective lead applicant:

Name: Imalux Corporation

Address: 11000 Cedar Road, Suite 250 Cleveland, OH 44106

Contact: Thomas F. Barnish, VP and CFO

Telephone: 216-502-0755 x 1004

E-mail: tbarnish@imalux.com

Collaborators: GVI Medical Devices, Preventive Oncology International

Grant Fund Request: \$1,000,000 with 1:1 matching funds, for total project cost of \$2,000,000

Project Title: Fourier Domain Optical Coherence Tomography Imaging System for Real-Time 3D Imaging of Epithelium for Pre-Invasive and Invasive Cancer

Summary of Proposed Topic:

Imalux and its collaborators will develop an enhanced imaging system based on their recently developed NIH-SBIR funded Fourier Domain Optical Coherence Tomography (FD-OCT) Imaging System. Imalux's FD-OCT system provides real-time, three-dimensional, cross-sectional visualization of tissue microstructure. This point-of-care system creates 3D images utilizing harmless near infrared light and produces spatial resolution on the order of 10-20 microns, surpassing conventional ultrasound imaging by an order of magnitude. As such, OCT enables detection of cancerous, pre-cancerous, inflammatory, and degenerative structural changes, and can aid in the differential diagnosis of these conditions. This imaging system will provide vital information to physicians during diagnosis, treatment and follow-up.

Using our previous studies of 2000 women screened for cervical cancer, we have shown that the relative brightness of the squamo-columnar junction (SCJ) epithelium correlates to the stage of cervical intraepithelial neoplasia (CIN) with statistical significance. In addition, studies of the

oropharynx indicate that the thickness of the epithelium is key in making the diagnosis of malignancy. The combination of a quickly generated 3D image, combined with automated brightness and depth of epithelium measurements and associated calculations will facilitate point-of-care assessment and guide surgery for patients with oral cancer, skin cancer and cervical cancer.

Imalux has shown the viability of OCT as a clinically relevant point-of-care imaging tool in a wide variety of medical applications, such as bladder cancer and laryngeal cancer, using its first generation time-domain model, the Niris. The Niris II Imaging System is scheduled for release in September 2010, and will offer multiple probe configurations and a faster scan time (8 frames/second). Both the Niris I and Niris II systems have limited use and functionality for the cervix and oral cavity as there is a highly-variable areas of interest that require comprehensive screening. The proposed FD-OCT system will be capable of utilizing probes and sheaths specifically designed for the cervix and oral cavity, and will have an integrated computer algorithm that will quickly provide data for suspicious areas based on depth of epithelium and brightness variations, leading to a rapid evaluation (an estimated 10 second examination for the cervix) that provides the much of the information necessary to make diagnostic and treatment decisions for early or pre-invasive cancer care. We believe this product will lead to improved patient care, decreased disease costs, and rapid market adoption.



Mike Burke
CEO, Imalux Corporation



CASE CENTER FOR IMAGING RESEARCH

January 22, 2010

The Ohio Department of Development
Technology and Innovation Division
77 South High Street, 25th Floor
Columbus, OH 43215

Re: 2010 OTFMIP LOI

To Whom It May Concern,

We plan to submit a proposal in response to your recent **OTFMIP_FY10_RFP**. We have been working on PET imaging of liver cancer for quite a while, and have reached point to start clinical translation. The title of our project is "[F-18]-fluoro-choline for Positron Emission Tomography (PET) imaging of hepatocellular carcinoma (HCC)". A summary of the project is given below.

The rate of incidence of primary liver cancers such as HCC is on the rise rapidly in this country due to hepatitis viral infection, fatty liver and many other risk factors. Clinical PET imaging with commonly used radiotracer, 2-[F-18]-fluoro-2-deoxy-D-glucose (FDG), a glucose analog, has been shown to be ineffective for imaging HCC due to a high false negative rate. Our pre-clinical studies on an animal model of hepatitis viral infection induced HCC showed a surprisingly good performance of [C-11]-choline, a small molecule PET imaging tracer, in detecting early stage HCC. However, due to the very short half life of C-11 (20 min), it is almost impossible to scale up the production for sharing with other research institutes or for wide range marketing by a vendor. But, the fluorinated version of choline looks very promising. A recent French study using [F-18]-fluoro-choline on 18 patients confirmed with HCC showed that not only it can detect HCC, which is sometimes missed by FDG, but it can also be used for staging since there is a difference in tracer uptake level as the disease progressed from early stage well-differentiated HCC to the later poorly-differentiated cancer. Therefore, we propose to team up with PETNET Solutions Inc to conduct a clinical trial here at University Hospitals Case Medical Center (Cleveland, Ohio). PETNET Solutions is a wholly owned subsidiary of Siemens Medical Solutions and operates the largest PET radiopharmaceutical production network with over 50 production and distribution centers (two in Ohio) worldwide. PETNET is the leader in commercial distribution and development of imaging biomarkers for PET scanning. This trial will be based on PET scans with fluoro-choline to derive quantitative indices as imaging biomarker for evaluating the true utilities of fluoro-choline that is applied to HCC: whether it will be good for early detection, or staging, or assessment of early response to the treatment. A team of key investigators/collaborators are assembled.

ZHENGHONG LEE, PH.D.
ASSOCIATE PROFESSOR, CASE CENTER FOR IMAGING RESEARCH AND DEPARTMENT OF RADIOLOGY
NUCLEAR MEDICINE, RADIOLOGY, UNIVERSITY HOSPITALS CASE MEDICAL CENTER
11100 EUCLID AVENUE • CLEVELAND, OH • 44106
PHONE: 216-844-7920 • FAX: 216-844-3106 • E-MAIL: ZXL11@CASE.EDU

From Case Western Reserve University (Lead Applicant)

PI: Zhenghong Lee, Ph.D.

Co-I: Yanming Wang, Ph.D. (Radiochemist)

Co-I: Afshin Dowlati, M.D. (Oncologist)

Co-I: Pierre Gholam, M.D. (Hepatologist)

The contact person for the Lead Applicant is *Cena Myers Hilliard* at
University Hospitals, Wearn B40

11100 Euclid Ave.

Cleveland, Ohio 44106

Cena.Myers@UHhospitals.org

Ph: (216) 844-8076

Fax: (216) 844-4987

From PETNET Solutions, Inc. (Commercializing Partner)

PI: Edward Plut, Pharm D.

The contact person for the partner is *David Haymond* at

104 Parkwind Court

Cary, NC 27519

david.haymond@petnetsolutions.com

Ph: (919) 362-1352

Fax: (919) 362-1244

We will have our hepatologist Dr. Gholam to recruit/prepare patients with HCC at different stages according to the inclusion criteria; For some of these patients who are candidates for treatment, Dr. Dowlati will implement the treatment regiments/schedules; Drs. Lee and Wang will produce [F-18]-fluoro-choline with cGMP standard for patient injection (PETNET will evaluate such production and improvement to ensure consistency with processes and procedures, which are required for cGMP and commercial scale up); Drs. Lee and Dowlati will oversee the PET imaging and treatment portions in the trial; Dr. Lee will finally be responsible for image processing and data analysis to derive quantitative indices as imaging biomarker for evaluating the true utilities of fluoro-choline for HCC. PETNET will evaluate the results of this trial to determine the commercial potential of the tracer and, if justified, will prepare their own IND and/or plan/support further clinical trials if needed to facilitate commercialization of this tracer.

The budget of \$900K will be requested from the OTF fund for the first two years of the project with a match of ratio of 1:1 for cost share. In addition, \$250K will be requested from WCF fund for a one-time capital purchase (also 1:1 cost share).

Sincerely,



Associate Professor, Radiology and Biomedical Engineering
and General Medical Sciences (Oncology, Pediatrics)
Case Center for Imaging Research

OTFMIP 10-904

Letter of Intent Ohio Third Frontier Medical Imaging Program (FY2010)

Lead Applicant: Neoprobe Corporation
425 Metro Place North, Suite 300
Dublin, OH 43017
Tel: 614-822-2320
Facsimile: 614-822-2321

Contact Person: Frederick O. Cope, Ph.D.
fcope@neoprobe.com

PROJECT TITLE: PHASE III CLINICAL STUDY SUPPORTING EXPANDED FDA CLAIMS FOR LYMPHOSEEK™, A MEDICAL IMAGING AGENT FOR SENTINEL LYMPH NODE MAPPING IN BREAST CANCER, MELANOMA, AND HEAD AND NECK CANCER.

Estimated Grant Funds Requested: \$1,000,000

Known Collaborators:

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
(614) 757-5000

Phylogeny, Inc.
4100 Regent St, Suite M-2
Columbus, OH 43219
(614) 448 9163

STATKING Consulting, Inc.
759 Wessel Drive, Suite 6
Fairfield, Ohio 45014
(513) 858-2989

Integrated BioScience Solutions
107 Fallenoak Court
Loveland, Ohio, 45140
(513) 260-5152

Project Summary:

Lymphoseek™ is a radiopharmaceutical where the intended use will be as a medical imaging agent for sentinel lymph node mapping; Lymphoseek provides tumor-associated lymph node identification both before and during surgeries delineating the extent of tissue removal in addition to the removal of patients' primary tumors. Sentinel lymph nodes are the first nodes reached by the lymphatic drainage from tumors and are important determinants of the evaluation of metastatic disease, treatment decisions and

patient prognosis. Specifically, sentinel lymph nodes are important determinants of whether or not a patient's cancer has spread into the regional lymph node drainage basin (nodal metastases).

Lymphoseek will be used in conjunction with existing medical imaging instruments for pre-surgical lymphoscintigraphy (sentinel node mapping and lymphatic imaging) and during surgery (real time) to identify sentinel lymph nodes by use of a hand held gamma probe; such probes are classified and regulated by the FDA as class-I medical imaging devices. Previously completed preclinical studies and Phase I, II, & III clinical trials in human patients have determined that Lymphoseek performs as well or better than existing imaging agents for delineation of lymphatic drainage. These data will support an NDA submission to the FDA to gain approval for Lymphoseek to be marketed for this intended use. However, to reach the full potential of Lymphoseek as a commercial opportunity and to provide cancer patients with their best possible outcomes, Neoprobe is pursuing an indication for Lymphoseek for the specific intended use of *sentinel lymph node mapping and identification*.

Following discussions with the FDA and to win approval of the expanded claim for sentinel lymph node mapping and identification, Neoprobe is conducting an additional Phase III clinical trial in head and neck cancer patients to determine the false negative rate of Lymphoseek identified lymph nodes (comparing metastatic disease in sentinel nodes vs non-sentinel nodes). This trial will be a multicenter, open-label, nonrandomized, within-patient study of Lymphoseek for the detection of tumor-draining sentinel lymph nodes in patients with known cutaneous or mucosal squamous cell carcinoma of the head and neck. We estimate that 392 patients will be enrolled in this trial from numerous clinical study sites that will include The Ohio State University Medical Center and the Cleveland Clinic.

The endpoint of the work proposed in this application will be a supplemental NDA for FDA approval of the sentinel lymph node specific claims; however, the goal of this project is to maximize the commercial opportunity embodied in Lymphoseek and to enable significantly expanded and sustained revenue growth and profitability of Neoprobe and its corporate partners, including Cardinal Health (marketing and distribution partner, Dublin, OH) and to provide Ohioans with increased opportunities for high-skill/high-wage employment. Neoprobe and its corporate partner, Cardinal Health, have already committed to continue this effort beyond the efforts that will be supported by this proposal to bring Lymphoseek to its fullest fruition.



Department of Biomedical Engineering

Case Western Reserve University
Wickenden Rm 427
10900 Euclid Avenue
Cleveland, Ohio 44106-4912

Letter of Inten

Ohio Third Frontier Medical Imaging Program (FY2010)

Lead Applicant:

Department of Biomedical engineering
Case Western University
Cleveland, Ohio 44106

Contact Person:

Zheng-Rong Lu, Ph.D.
M. Frank and Margaret Domiter Rudy Professor
Department of Biomedical Engineering
Case Western Reserve University
Wickenden 309E, Mail Stop 7207
10900 Euclid Avenue
Cleveland, OH 44106
phone: 216-368-0187

Project title: A targeted Contrast Agent (TCA) for MR Imaging

Anticipated grants funds to be requested: \$1,000,000

Known collaborators:

LXD L.L.C
7630 First Place
Cleveland, Ohio

Proposal Summary

Case Western Reserve University proposes to develop a targeted contrast agent (TCA) for MRI imaging to enable earlier detection and diagnosis of malignant cancer. The effectiveness of the agent to distinguish the tumor from the normal tissue has been recently confirmed in animal models with MR imaging. The scope of this three-year project is to finish the following tasks:

- Optimization and scale-up of the synthesis of the contrast agents
- Material synthesis in a FDA certified facilities;
- Preclinical toxicity investigation;
- Preclinical pharmacokinetic/pharmacodynamic (PK/PD) investigation;
- Application for FDA approval on Investigational New Drug (IND)

It is anticipated that the program will lead to manufacturing and commercialization of a new MRI agent for early detection of cancer in US and worldwide.

OTFMIP 10-906



LETTER OF INTENT 2010 Ohio Third Frontier Medical Imaging Program

Lead Applicant:

Ricerca Biosciences, LLC
7528 Auburn Road
Concord, OH 44077

Contact: Heidi Nelson-Keherly, Ph.D.

Email: heidi.nelson@ricerca.com

Phone: 440-357-3088

Project Title: Establishment of retinal therapeutic development core based upon novel retinal imaging system.

Estimated Grant Funds to be Requested: \$1M

Known Collaborators:

Polgenix, Inc.

Utilizing this ODOD investment vehicle, Ricerca Biosciences will partner with Polgenix to establish a best-of-class retinal therapeutics drug development platform that will leverage and expand upon the companies' existing international pharmaceutical and bioscience commercial programs. Over the past four years, respective investments made by Ricerca and Polgenix have led to the construction of a state-of-the-art primate facility and an unparalleled retinal imaging technology that has recently been proven to deliver sub-cellular resolution of the primate retina in a safe and repeatable manner.

Through this partnership, the Companies will construct a 2-photon laser ophthalmoscope ("2PO") at Ricerca (Concord, OH) that will serve as the anchor of drug discovery and pre-clinical development offering by Ricerca to its established pharmaceutical and biotechnology corporate partners. In turn, Polgenix' product development program that is aimed at the establishment of the 2PO as a standard clinical intervention will greatly benefit from the established industrial utilization of the proprietary 2PO system. In addition to construction of the ophthalmoscope, the partnership will co-invest in the establishment of select animal models and analytical techniques tailored to the development of retinal therapeutics.

Ultimately, this collaborative will establish NEOhio as the preeminent site for the development of retinal and aligned neuroscience therapies that is currently nearing \$3 billion annually and is poised for immense growth based upon the prevalence of aging-related disorders.

OTFMIP 10-907

Letter of Intent for FY 2010 Ohio Third Frontier Medical Imaging Program

Lead Applicant: Case Western Reserve University School of Medicine

Address: 11000 Euclid Avenue, Wearn Bldg. B-42, Cleveland, OH 44106

Contact person: James P. Basilion, Ph.D., James.basilion@case.edu, 216-983-3264

Title: Associate Professor of Radiology and Biomedical Engineering

Project Title: Development of the "Buckeye": a device for imaging human tissues

Estimated grant funds: \$1M Industrial Collaborators: BioInVision Inc, and Akrotome Imaging, Inc.

This Letter of Intent is to notify the state of our intention to submit an application entitled "Development of the Buckeye: a device for imaging human tissues" This application is focused on developing an imaging device to enable technologies that are currently being tested in a clinical trial funded under a state BRCP award entitled "Therapeutic DNA Nanoparticles and Molecular Imaging "TDNMI". The previous BRCP award is focused on evaluating new applications of targeted compacted DNA and various imaging compounds and technologies. One of the research projects is significantly ahead of schedule and has developed a strong set of preliminary data that warrants funding to develop a follow-on human tissue imaging device for translation of a "technology package" to the clinic in 2-3 years.

Breast Cancer. In breast lumpectomy procedures, up to 60% of patients require re-excision to achieve clear margins, which are essential for effective treatment. Since frozen section samples are often inaccurate and permanent sections are not available for days after the operation, the effective assessment of tumor-free margins in resected breast tumor samples remains a significant unmet clinical need. Dr. James Basilion (Case Western Reserve University) and Dr. Matthew Bogyo (Stanford University) have developed a series of tumor selective probes and technology that allows the probes be topically applied to tissues *ex vivo* to identify the presence of cancer cells at tumor margins. This is performed in near real-time allowing the information to be used to inform surgical resection. These probes are optically silent but fluoresce after digestion by tumor-related enzymes, such as cathepsin L. A clinical trial designed to assess if molecular imaging technologies can be used to survey lumpectomy margins, partly funded by a Third Frontier award (see above), is underway and has is showing promising results. The limited data available demonstrates that the specificity and sensitivity of the technique to survey lumpectomy margins for cancer cell infiltrates is high (100% for each) on a per patient basis.

Current Need. The clinical trial underway utilizes topical application of quenched imaging probes and an imaging device. The Imaging device has been adapted for this use, but is not designed for this use and is significantly over-engineered. The purpose of this application is to design and test a low-cost imaging device that will meet the particular specifications for imaging of human samples and will be paired with the optimized imaging probe for product launch in 2012-2013. The development will be driven by researchers at Case Western Reserve University (lead institution), **Akrotome Imaging Inc.**, which will commercialize this technology package, and via a service contract with BioInVision Inc., that has experience in developing micro and macro-scopic imaging devices. Award funds will be used to further define the specification of the imaging device and to develop several prototypes with the aim at a marketable product to be paired with the imaging technology and launched in 2012-2013. *Potential Market Size: Lumpectomy sector, \$20-40 million per year. Other sectors (eg. prostate and skin cancers), each \$100-150 million yearly.*



January 22, 2010

Ohio Department of Development
Technology Division
77 South High Street, 25th Floor
Columbus, OH 43215

Dear Ohio Department of Development:

Please accept this letter of intent from Digital X-Ray Systems for our Fiscal Year 2010 Ohio Third Frontier Medical Imaging Program (“OTFMIP”) proposal.

Lead Applicant Name:	Digital X-Ray Systems
Address:	1333 Highland Rd. Suite F Macedonia, OH 44056
Telephone:	(330) 425-4400
Contact Person:	Mr. Edward Rawley, President
Contact Email:	e.rawley@classic-imaging.com
Project Title:	Development and Commercialization of a Digital X-Ray Retrofit Solution in Ohio
Estimated Grant Amount:	\$1,000,000
Known Collaborators:	To be determined

Summary of the Proposed Project:

Hospitals and medical facilities are transitioning from analog x-ray machines to the more cost effective, safe and expedient digital medical imaging technologies available on the market. The benefits of digital based imaging include the elimination of analog film and processing, limited hardcopy storage, the reduction of patient exposure to harmful radiation, and the creation of high quality images for faster and more accurate diagnosis.

One of the most popular mobile digital x-ray machines on the market is the General Electric model AMX-IV. This machine utilizes a digital detector plate tethered to the imaging machine. While offering a dramatic improvement over the analog system, the digital plate is heavy and permanently attached to the x-ray machine. Technicians often forego use of the inconvenient digital plate in favor of the more familiar analog process. The wire tether also poses a problem if the digital plate is mistakenly left beneath a patient as the machine is removed from the room, causing costly damage to the x-ray machine and possible harm to the patient.

Customers located across the globe have expressed a need for a wireless, digital plate that can be retrofitted to existing hospital x-ray equipment. In addition, a significant market need exists to retrofit older analog technology with a proprietary digital retrofit that is superior to current competitive offerings. Digital X-Ray Systems is a new Ohio company created to fulfill the demand for a cost effective digital retrofit solution to transition hospitals from analog to digital x-ray machines and overcome the inefficiencies of current digital x-ray machines on the market.

Digital X-Ray Systems will offer hospitals and healthcare organizations a complete digital retrofit package with enhanced wireless and digital equipment. Operating via a WiFi connection, the retrofit package is designed for all types of radiographic exams, in radiography rooms or on mobile imaging carts for use anywhere a digital image is required for patient diagnosis. It is particularly useful wherever portability is necessary, including unusual or difficult exposures, intensive care room and emergency rooms.

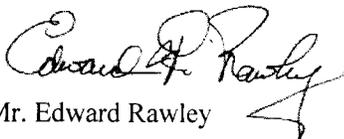
Digital X-Ray Systems and its Ohio collaborator are developing a proprietary interface technology (both the hardware and firmware) to communicate to and from a third party x-ray detector technology and another interface technology to communicate between the GE AMX X-Ray Machine's CPU and the hardware and firmware interface.

Digital X-Ray Systems and project collaborators are seeking Ohio Third Frontier funding to miniaturize these interface technologies so it fits seamlessly into the GE AMX footprint. This requires a complete reconfiguration (miniaturization) to accept the digital retrofit package. In addition, the miniaturization of these components significantly improves the manufacturing/retrofit time without degradation in processes or quality.

OTFMIP and match funding would also be used to further develop the Graphics User Interface Development following PACS & DICOM standards for compression and transmission of the image. The interface software in development also controls the KV/MA/time of the GE AMX machine. The project also involves removing the power converter, power supply, need for separate CPU box and touch screen LCD (master operator panel) and monitor configuration and board integration.

The proposed project and the resulting digital retrofit solution will enable hospitals and medical facilities to transition to digital imaging through retrofitted equipment, while gaining valuable wireless technology and an enhanced post processing user interface. The project will fulfill significant market need while enhancing the medical imaging cluster and its supply chain in the State of Ohio.

Sincerely,



Mr. Edward Rawley



Ohio Department of Development
Technology Division
77 South High Street, 25th Floor
Columbus, OH 43215

January 20, 2010

Dear Ohio Department of Development:

Thank you for the opportunity to submit this letter of intent for the Fiscal Year 2010 Ohio Third Frontier Biomedical Program ("OTFBP").

Lead Applicant Name: Lanx, Inc.
Address: 390 Interlocken Crescent, Suite 890
Broomfield, CO 80021-8053
Telephone: (303) 443-7500 x8482
Contact Person: Mr. Stuart Born, Director of Clinical Studies
Contact Email: stuart.born@lanx.com
Project Title: Lumbar Motion Monitor Commercialization in Ohio
Estimated Grant Amount: \$1,000,000
Known Collaborators: The Ohio State University and others to be determined

Summary of the Proposed Project:

Lanx, Inc. ("Lanx") was founded in 2003 by two physicians who created a patient focused culture of quality and innovation. As one of the largest privately held spinal companies in the U.S., Lanx is committed to providing spine surgeons innovative solutions for the challenges they face every day. Lanx proposes to culminate over 25 years of research and development by commercializing a diagnostic medical device in Ohio capable of quantifying the extent of a low back disorder by monitoring the motion functional characteristics (kinematic signature) of a patient's low back. This Lumbar Motion Monitor ("LMM") device provides a quantifiable functional assessment of lumbar spine disorders.

Lanx, Inc. will continue its partnership with the Biodynamics Laboratory at Ohio State University to commercialize the Lumbar Motion Monitor (LMM). The objective of the proposed OTFBP project is to move this innovative technology from the laboratory to the clinical environment to help clinicians more accurately diagnose low back pain. A more accurate diagnosis by physicians earlier in the clinical workup will result in fewer diagnostic medical scans and unnecessary surgeries. This will help reduce the extremely high cost associated with the treatment of lower back pain.

The LMM is a non-invasive device that a patient wears on a harness that takes measurements of the lumbar spine in motion. These spine motions represent a "motion signature" of the patient and this signature is believed to represent a "proxy" of important functional information relating lumbar spine functional status. The LMM has extensive scientific backing with over 40 peer reviewed journal articles to support its capabilities, including:

- Quantifying the extent of a low back disorder;
- Indicate the probable nature of the low back disorder (structural or muscular);
- Identifying need for further more expensive follow-up tests (e.g. MR imaging);
- Quantifying treatment success or failure and indicating when maximal medical improvement has been achieved; and
- Determining a patient's sincerity of effort.

When the kinematic signature is combined with the spine model under development by the OSU Biodynamics Laboratory, it will provide a surgeon with information never before available. The combination of these two projects will allow surgeons to conduct surgery 'in silico' and provide them with patient specific biomechanical

LANX

information to aid in their decision process to determine the best surgical option for their patient. Lanx has the exclusive rights to commercialize both the LMM and the spine model. Lanx is requesting a \$1,000,000 OTFBP grant to bring the device to full commercialization in the State of Ohio. Taken together, OTFBP and match funding will:

- Test and validate of the production version of the LMM;
- Achieve LMM FDA approval;
- Establish a fully staffed Lanx diagnostic division in Columbus, Ohio;
- Create marketing, sales and business development to support a formal product launch;
- Establish production capabilities; and
- Develop backend software systems to support both the interpretation and presentation of the LMM data and support company operations.

Collaboration with the OSU Biodynamics Laboratory provides Lanx with the engineering research expertise and investigations of low back pain causality that are essential to understanding the cause of low back pain. The OSU team provides a systems perspective which includes factors such as the occupational cause and the effect of muscle activity on spine loading.

Building upon a strong foundation of experience and knowledge in the biomedical sector, Lanx will successfully develop and commercialize a novel LMM device. The project aligns with the purpose, goals and objectives of the OTFBP. This project will benefit Ohio's robust biomedical cluster and generate continued technology based economic development throughout Ohio.

Sincerely,

Stuart Born
Director of Clinical Research
Lanx, Inc.

OTFMIP 10-910

January 23, 2010

Ohio Department of Development
Technology Division
77 South High Street, 25th Floor
Columbus, OH 43215

Dear Ohio Department of Development:

Please accept this letter of intent from Quality Electrodynamics, LLC for our Fiscal Year 2010 Ohio Third Frontier Medical Imaging Program ("OTFMIP") proposal.

Lead Applicant Name: Quality Electrodynamics, LLC
Address: 700 Beta Drive, Suite 100
Mayfield Village, OH 44143
Telephone: (440) 484-2225
Contact Person: Dr. Hiroyuki Fujita, President and CEO
Contact Email: hiroyuki.fujita@qualedyn.com
Project Title: 7-Tesla High-Density MRI RF Coil Development & Commercialization
Estimated Grant Amount: \$1,000,000
Known Collaborators: Case Western Reserve University and others to be determined

Summary of the Proposed Project:

Magnetic Resonance Imaging ("MRI") entered the market as a clinical diagnostic tool in the 1980's. Since then, significant advances in MRI technology have occurred, including enhancements to the images produced through the development of higher field strengths. The current clinical state-of-the-art machines are the 3-Tesla MRI and the more common 1.5-Tesla MRI. While these technologies have significantly advanced clinical diagnostic medicine, the evolution of MRI technology will continue to provide advances and improve medical diagnostics.

In contrast to the 1.5- and 3-Tesla devices, 7-Tesla systems are the next technological frontier offering a higher magnetic field providing sharper images and better insights into the smallest structures of the human body. The goal is to detect the risk or onset of illness at the earliest possible stage in a number of anatomies for improved diagnosis and more effective treatment strategies. While a limited number of 7-Tesla MRI systems are operational at research facilities around the world, these diagnostic systems are expected to be introduced in clinical settings in the near term.

Quality Electrodynamics ("QED") was started in 2006 with the vision to revolutionize medical imaging through advanced technical innovation in clinical diagnosis equipment. Since inception, QED has experienced significant growth, expanding from a 300 square-foot room on the campus of Case Western Reserve University to a 27,000 square-foot complex in Mayfield Village, Ohio. QED has become internationally recognized as a leader in the development of critical MRI component technology serving as the OEM supplier to Siemens Healthcare (Germany) and Toshiba Medical Systems Corporation (Japan). Forbes named QED 11th in the nation on the 2009 Forbes' list of "America's Most Promising Top 20 Companies." The State of Ohio also recently honored QED with a 2009 Governor's Excellence in Exporting Award.

HF



QED develops and manufactures MRI radiofrequency ("RF") detector coils in Ohio, for a number of anatomies to the specification of its MRI OEM customers for scanners sold to hospitals and healthcare institutions around the world. In addition, QED services and repairs RF coil products manufactured by specific MRI OEMs. RF coils are essential components of the MRI scanner for transmitting energy and receiving signals from the patient body in the MRI system. By providing a higher signal-to-noise RF coil, the doctor can see (i.e., diagnose) the patient's anatomies more clearly (e.g. cancerous tissues), which leads to earlier detection of serious medical conditions.

QED and its collaborators propose to build upon Ohio's investments in the state's medical imaging cluster and QED's proven expertise in MRI coil development and commercialization to develop 7-Tesla MRI coils for specific anatomies. QED's proposed OTFMIP project will support the continued development and commercialization of next generation RF coils for 7-Tesla MRI systems, while supporting the goals and objectives of the OTFMIP by accelerating the development and growth of the medical imaging industry in Ohio.

Sincerely,



Dr. Hiroyuki Fujita,
President & CEO



SPECTRAL ENERGETICS

Company Name: Spectral Energetics

Address: 1306 Research Park Drive
Beavercreek, OH 45432

Phone: (937) 320-5120 (V), (937) 320-5126 (F)

POC: Ronald G. Riechers, PhD, President (rr@spectralenergetics.com)

Project Title: Electromagnetic Medical Advisor (EMMA)

Grant Funds Requested: \$1M (Program Duration: 2.5 years)

Collaborators:

Wright State University School of Medicine

Wright State University LAR

Miami Valley Hospital

Thomas Hangartner, PhD

Steve Lockhart, MD, PhD

USAF/AFRL Materials Directorate

USAF/AFRL Sensors Directorate

Anritsu Company, US operations

Project Summary

Spectral Energetics has developed a handheld electromagnetic device, EMMA that aids in the diagnosis of two common trauma conditions, pneumothorax and hemothorax, and can perform this noninvasively. EMMA uses well established RF and microwave interrogating signals without the dangers presented by ionizing radiation. A prototype has been tested using a porcine model and the results are promising. It is planned to extend the capabilities of the existing EMMA prototype to aid in diagnosis of intracranial bleeding in closed head injuries. This project is designed to complete additional validation of EMMA performance in both animal and human models, and bring the unit to market. SE plans to use COTS equipment from an OEM and to assemble and test units in the future.

Our project will be accomplished over a 30-month period culminating in a unit ready for market. Each year will have specific tasks to be performed and provides decision points for the project. The following paragraphs describe the effort.

The initial twelve-month period has two objectives, 1) validating the existing diagnostic algorithms in both porcine and human model, and 2) beginning initial market research. These objectives will be met by performing three tasks. A new animal test at WSU LAR will be undertaken to validate the diagnostic capabilities of the prototype in a blind test. This testing will be done using the existing protocol and EMMA prototype configuration. Concurrently SE and its collaborators will prepare the necessary protocols to begin a pilot study to test the diagnostic algorithms. SE will be assisted by WSU in the protocol preparation and conduct of the pilot study. The animal study will be limited to three months and the pilot study in humans to nine months. The remaining time in year one will be spent in analyzing the results from both tests. A decision to proceed to year two will be made based on these results.

Year two has one objective, 1) perform necessary hardware, software and firmware modifications to a candidate unit. This will be met by performing the following tasks SE will focus on the reduction of the prototype to a marketable unit based on existing RF handheld instruments, from the Anritsu Corporation. Our starting point is the Anritsu SiteMaster. Validated algorithms will be developed in a software format compatible with the SiteMaster microprocessor suite and installed on a unit for testing by Anritsu. Upon completion of the software development another animal test will be conducted to assure repeatability of the algorithm performance.

Concurrently SE will reduce the size weight and volume of the EMMA prototype antenna. This will include design, fabrication and testing the new antenna. Several designs will be investigated for mechanical, electrical and ergonomic performance and a single antenna will be selected for development. Additional RF hardware modifications will be performed during this period also. These efforts will be performed over a nine-month period and the remaining three months will be used to analyze the algorithm results and prepare unit(s) for the last six-month period.

Our final six-month effort has two objectives, 1) validating the capabilities of the market prototype unit, and 2) preparing the initial FDA documentation. These will be met by performing another human pilot study with the market prototype to collect data and compare to previous results. SE will begin the process of preparing FDA documentation during this period.

Letter of Intent Ohio Third Frontier Medical Imaging Program (FY2010)

Lead Applicant: Neoprobe Corporation
425 Metro Place North, Suite 300
Dublin, OH 43017
Tel: 614-822-2320
Facsimile: 614-822-2321

Contact Person: Frederick O. Cope, Ph.D.
fcope@neoprobe.com

Project Title: RIGScan™, A MEDICAL IMAGING AGENT FOR STAGING AND IMPROVED PROGNOSIS OF COLON CANCER PATIENTS

Estimated Grant Funds Requested: \$1,000,000

Known Collaborators:

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
(614) 757-5000

Phylogeny, Inc.
4100 Regent St, Suite M-2
Columbus, OH 43219
(614) 448 9163

STATKING Consulting, Inc.
759 Wessel Drive, Suite 6
Fairfield, Ohio 45014
(513) 858-2989

Integrated BioScience Solutions, LLC
107 Fallenoak Court
Loveland, Ohio, 45140
(513) 260-5152

Project Summary:

RIGScan is a radiolabeled monoclonal antibody (CC49) that recognizes the oncofetal antigen, tumor associated antigen 72 (TAG 72). TAG 72 is expressed on the surface of the large majority of colonic adenocarcinomas, invasive ductal carcinomas of the breast, non-small cell lung carcinomas, and epithelial ovarian carcinomas, as well as the majority of pancreatic, gastric, and esophageal cancers (*Can. Res.* 46, 3118, 1986). A previous human clinical trial of colon cancer patients, which was completed by Neoprobe

and its collaborators in 1997, indicated that RIGScan could be used for the intraoperative medical imaging of metastatic colorectal cancer. However, regulators asked for more data and the product was never released. Subsequently, follow up data were collected from the patients in the previous Phase III trial indicating that RIGScan provided powerfully predictive information concerning disease-free and overall survival. In addition, patients with RIGScan positive regional metastases that could be made RIGScan negative by surgical removal of the RIGScan positive tissue had significantly better outcomes than patients that could not be made RIGScan negative. With this information, a dialog was opened with the FDA resulting in the indication that Neoprobe needs to complete an additional confirmatory phase III study to gain FDA approval for a prognostic indication in colorectal cancer.

Neoprobe has decided to move forward with the RIGScan project and follow through with this additional phase III trial. However, before Neoprobe can begin this new phase III trial it must reactivate the RIGScan project, which has been inactive for many years. Reactivation of the project will require, among other things, reinitiating GMP manufacturing of the biologic product, repeating some of the preclinical studies and a Phase I bridging study with the newly manufactured product. Neoprobe is asking for OTF support for these project reinitiation/pre-Phase III efforts.

Letter of Intent Ohio Third Frontier Medical Imaging Program (FY2010)

Lead Applicant: Neoprobe Corporation
425 Metro Place North, Suite 300
Dublin, OH 43017
Tel: 614-822-2320
Facsimile: 614-822-2321

Contact Person: Frederick O. Cope, Ph.D.
fcope@neoprobe.com

PROJECT TITLE: DEVELOPMENT AND COMMERCIALIZATION OF AN ULTRA-SENSITIVE SMALL HAND HELD PROBE FOR INTEROPERATIVE REAL-TIME DETECTION OF HIGH ENERGY IMAGING ISOTOPES.

Estimated Grant Funds Requested: \$1,000,000

Known Collaborators:

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
(614) 757-5000

Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242
513-337-7000

STATKING Consulting, Inc.
759 Wessel Drive, Suite 6
Fairfield, Ohio 45014
(513) 858-2989

Integrated BioScience Solutions
107 Fallenoak Court
Loveland, Ohio, 45140
(513) 260-5152

Project Summary:

Fluorine-18 (^{18}F) is a high energy radioactive element commonly used to label medical imaging agents used in positron emission tomography (PET). Frequently, ^{18}F is formulated as fluorodeoxyglucose (^{18}F -FDG), which when injected into a patient, accumulates in cells undergoing rapid glucose metabolism, such as the brain, kidneys and cancer cells. With the accumulation of ^{18}F -FDG in cancer cells, PET imaging can be

used to identify possible locations to which a patient's cancer may have spread (metastasized) beyond their primary tumor. A surgeon will then use the PET image to guide biopsy or removal of putative primary and metastatic tumor(s) for pathological confirmation and determination of appropriate post-surgical treatments. To facilitate the identification and removal of the "hot-spot" visualized by PET, a surgeon's efforts may be dramatically enhanced by the use of a hand held gamma probe used in real time, intraoperatively.

The highly significant problem with the currently used probes is that they are markedly too large. ^{18}F emits a very high-energy gamma ray that deeply penetrates the crystals that are used to detect this photon. If the gamma ray passes through the crystal, it will not be detected. To overcome this detection problem, currently used probes have large crystals that can absorb the energy from a larger portion of the gamma rays. These large crystals require large shields to prevent detection of background radiation. The resulting instrument is far too large, requiring large incisions to be made in the patient, limiting the access of the probe to many interior parts of the patient and making it challenging for the physician to accurately delineate the location of the radiation source from diseased tissue. There exists a critical unmet need for smaller probes that overcome the limitations of the currently used devices where such devices are 1] very small, 2] highly sensitive, 3] highly directional without requiring excessive shielding, and 4] may be used with multiple isotopes (in addition to ^{18}F). We are seeking support from the OTF to develop such a probe using Neoprobe's new and proprietary gamma probe technology.

Neoprobe's solution for detecting emissions from radioactive substances during surgical or other procedures employs a "K-alpha" secondary emission response exhibited by materials when bombarded with photons emitted by high-energy radiation sources. This K-alpha response is produced when a photon from a relatively thin wafer of a select material is inserted between a target source of photon emissions and a detector which, in effect, converts the energy level of the target radiation (i.e., "primary photon emission") source to secondary emissions at a lower energy level, which greatly increases detector efficiency without resorting to thick detector crystals. The energy level of this K-alpha response is fixed for a given material, and is always lower than that of the excitation radiation that caused it. This greatly increases detector crystal efficiency without resorting to thick detector crystals or extensive shielding. The combination of a smaller crystal coupled with less required shielding enabling the construction of a much smaller probe.

Interventional Imaging, Inc.

Letter of Intent

Ohio Third Frontier Medical Imaging Program

2010

Lead Applicant: Interventional Imaging, Inc.
1120 Chester Ave., Ste 418
Cleveland, OH 44114

Contact Person: Vincent P. Kazmer
Chief Executive Officer
Interventional Imaging, Inc.
1120 Chester Ave., Ste 418
Cleveland, OH 44114
Email: vkazmer@i3mri.com
Phone: (216) 621-3632 Office
(330) 310-9037 Cell

Project Title:

“Manufacturing and Development, MRI Guided Treatment of Atrial Fibrillation”

Estimated Requested Grant Funds: \$1 Million

Known Collaborators: Case Western Reserve University
10900 Euclid Ave.
Cleveland, OH 44106

Dr. Jeffrey Duerk, Chairman, Biomedical Engineering
and Director, Case Center for Imaging Research, CWRU

Dr. Mark Griswold, Associate Professor, Radiology,
CWRU

Committed End-User: Valtronic Technologies
6168 Cochran Rd.
Solon, OH 44139

Attachment: A one-page summary of the project is attached.

Manufacturing and Development, MRI Guided Treatment of Atrial Fibrillation

Project Summary

Interventional Imaging, Inc. ("I3") has developed a new generation of MRI technology that enables improved and new therapies by delivering high-resolution interventional MR images and precise tracking capabilities. Targeting cardiovascular diseases, I3's intravascular products will aid clinicians at several steps in the treatment pathway, namely, early detection, therapy guidance, delivery and evaluation.

I3 was formed in co-operation with Case Western Reserve University ("Case"). The Case team has enjoyed a long-standing sponsored research agreement with Siemens Medical Solutions, and I3's core technologies are a result of this partnership.

Atrial Fibrillation or AF is the most common cardiac arrhythmia encountered in clinical practice. AF is a major precursor to congestive heart failure. Over 5 million people worldwide, including approximately 2.3 million people in the United States, are currently diagnosed with AF. In the United States, 1 in 4 people over the age of 40 have a lifetime risk of developing AF, and the incidence of AF increases strikingly with age. As the U.S. population ages – by the year 2015 approximately 14.8% of the population will be 65 and older – AF will exact a higher toll on the healthcare system.

I3's product for this procedure is a MR compatible catheter with ablation capabilities using RF energy and proprietary MR imaging micro-coils. Used in a MR field, I3's technology features will provide physicians with the capability to precisely track and thus place the ablation catheter and, subsequently, image tissue destruction to determine the success of this treatment for atrial fibrillation.

This project is the next phase in the commercialization of I3's product. I3 and its collaborator, Case Western Reserve University, have developed and tested the MRI micro-coil platform technology and developed the ablation catheter for treatment of atrial fibrillation. The current phase of development is funded by the Global Cardiovascular Innovation Center at the Cleveland Clinic. The next phase in I3's commercialization plan includes the following:

1. Establishment of a supply chain for product components in NE Ohio.
 - a. Electrical components including micro-coils, micro flexible circuit boards and safety PCB's will be sourced from companies such as Valtronic Technologies in NE Ohio.
 - b. Durable components such as injection molded handles, cables, connectors and tubing will be manufactured in NE Ohio.
2. Relocation of manufacturing from Minnesota to Ohio.
 - a. Establishment of assembly and quality control operation with technical staff in NE Ohio.
3. Integration of I3's ablation catheter into Siemens MR systems at CWRU.
4. Integration of I3's ablation catheter into an EP system at CWRU.
5. Completion of animal tests to confirm system integrations and prepare for clinical tests.

This project will establish I3 as a medical device manufacturing company in NE Ohio and provide a high volume source of MR-compatible RF ablation catheters for the treatment of atrial fibrillation.

January 22, 2010

Ohio Department of Development
Technology and Innovation Division
77 South High Street, 25th Floor Columbus, Ohio 43215-6130

Dear Sir,

With this Letter of Intent we are pleased to inform you that we plan to submit an application for the Wright Project in response to the Ohio Third Frontier Advanced Energy Program Fiscal Year 2010 Request for Proposals.

Lead Applicant: Case Western Reserve University, 11100 Euclid Ave, Cleveland, OH 44106

Contact Person: Yanming Wang, PhD: yxw91@case.edu 216 844 3288
Jeffery Duerk, PhD: duerk@case.edu 216 368 6047

Project Title: Case PET Center

Estimated Grant Funds to be requested: \$2,000,000

Collaborators: Case Western Reserve University and University Hospital System
Cleveland Clinic
General Electric Healthcare, Siemens Inc, Philips Medical Systems
Biomedical, Structural, Functional & Molecular Imaging Enterprise
MIMVista, Clear Image Technologies
Fused Multimodality Imaging, Interventional Imaging,
QED, PETNET, Neomed, Cardiolnsight

Description: Over the past decade, in part due to the Wright Capital Projects, Ohio has entered a new round of vigorous technology-based economic development. Substantial investments have been made to further strengthen biomedical research and commercialization in Ohio. As results, many new drugs have been developed and new start-up companies have been established. In this process, biomedical imaging plays a key role in efficacy evaluation and validation of new drugs and therapeutic interventions.

Case Western Reserve University has proven itself a national leader in biomedical imaging, which is equipped with the start-of-the-art imaging facilities represented by the newly established Case Center for Imaging Research (CCIR). CCIR is designated to support biomedical research in northeastern Ohio through a variety of imaging modalities such as magnetic resonance imaging (MRI) and nuclear imaging such as positron emission tomography (PET). MRI and PET are two key imaging modalities, which are capable of translational studies. They complement each other in terms of resolution and sensitivity. While MRI provides primarily anatomic information with high resolution, PET provides primarily functional information at molecular level with high sensitivity. So far, we have established a strong MRI facility through collaboration with academic institutions and commercial companies in Ohio. In this application, we propose to establish a PET facility as part of CCIR, which will become the core facility for drug discovery and development.

The new laboratory facility is expected to serve as "green house" of biomedical research and commercialization in Ohio over the next few years. It will assist in drug discovery and development within existing Ohio companies. It will also become a driving force in creation of 50-100 new jobs for Ohioans through establishment of several new start-up companies. The mission of the new PET facility is to support pharmaceutical development in Ohio. It will have the following functions: 1) conduct drug screening and evaluation based on the existing PET imaging technologies; 2) identify new PET imaging technologies for commercialization; 3) develop new PET imaging agents for diagnosis and efficacy evaluation of emerging therapeutic interventions.

The new PET facility will be managed by the CCIR and staffed by professional and technical personnel ranging from faculty, physicians, licensed nuclear pharmacists, engineers, radiochemists, and technicians. The facility will be built on Case Western Reserve University campus. This project is a collaborative effort between Case Western Reserve University/University Hospital System, University Hospital System, the University of Toledo, General Electric Healthcare, Siemens, Philips Medical Systems, Biomedical, Structural, Functional & Molecular Imaging Enterprise, MIMVista, Clear Image Technologies, Fused Multimodality Imaging, Interventional Imaging, QED, PETNET, Neomed, and Cardiolnsight.

Medical Skin Imaging Device (MSID)

Visual skin assessment based on relevant features of the underlying biology is a mainstay for effective clinical care. However, current methods are limited. There are frequently no “universal standards” for normal skin integrity and color, making protocols difficult to implement uniformly across institutions. Drawbacks also include low reproducibility, variation even among skilled, experienced observers, and low reliability. These methods lack the ability to quantify the skin’s condition, prohibiting the clinician’s ability to diagnose skin-related ailments and monitor treatment efficacy. Electronically and quantitatively recording the skin’s condition would aid in staging skin-related illnesses that affect a number of medical disciplines such as plastic surgery, wound healing, dermatology, endocrinology, oncology, and burns. Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), and ultrasound are used routinely to image the body for signs of disease and injury. Researchers and commercial developers continue to advance these imaging technologies to produce improved pictures of internal organs and bony structures. Clinical use of these technologies to diagnose and monitor subsurface tissues is now a routine part of medical practice. However, these imaging systems cannot provide information about the skin (stratum corneum, epidermis, and dermis).

Our proposed effort will result in a low-cost system for digitally recording the skin’s condition. We present a bedside, handheld imaging device for geometrically mapping and diagnosing skin disorders, diseases, and injuries by combining three-dimensional color surface scanning with enhanced perfusion imaging, digital color photography, thermal imaging, and near infra-red sensing. Multi-modal scanning may allow inexperienced operators to accurately diagnose skin related injuries and illnesses, and transmit detailed electronic images to remote experts for further analysis, and fusion with CT or MRI. The proposed technologies are low-cost, robust, portable, and accessible to the point of care. As a platform, this system will find utility in many medical disciplines as new capabilities and protocols are applied. Plastic, reconstructive and trauma surgeons, dermatologists, practitioners, wound care specialists and bedside nursing will all benefit from an integrated, multimodality imaging device with rapid data analysis capability to permit treatment decision making in real time. This device can be readily integrated into the electronic medical record technology.

Our multidisciplinary team represents a broad foundation of development in key areas required for success of this project and we are well positioned to develop an assistive system for diagnosing disease and anomalies related to skin conditions. With the evolution of microprocessors, surface mount components, diode light sources, and photo-ICs, photonic instruments have become smaller, lighter, battery-operated devices with improved capability. Our goal is to make the proposed diagnostic imaging platform portable with a modular design to accommodate additional imaging modalities as they are further developed.

In summary, our mission is particularly relevant at the present time when the emphasis is in improving outcomes across the spectrum of racially, socially and economically diverse patients. The health care system will continue to be pressed to quantify the effectiveness of various common treatments, such as those involving wounds, burns, pressure ulcers, and irritant dermatitis. To do so requires the development and implementation of objective quantitative skin assessment methods that are effective across the diverse patient population, as well as affordable and useful at the bedside and in clinic settings.

Lead Applicant:

Total Contact, Inc.
Jennifer Whitestone, President
41 N. Main Street
Germantown, OH 45327
(937) 855-6107
jen@totalcontact.com

Collaborators:

Point Source, Inc.
Cincinnati Children’s Hospital Medical Center

requesting: \$1,000,000



January 24, 2010

Subject: Ohio Third Frontier Medical Imaging Program Request for Proposals

Dear Ohio Third Frontier Medical Imaging Program RFP Manager:

This letter confirms the intent for Accelerated Data Concepts, LLC to pursue a project under the Ohio Third Frontier Medical Imaging Program. The required information is provided as follows:

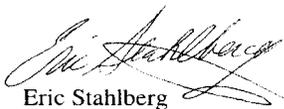
Applicant Name: Accelerated Data Concepts, LLC
Applicant Address: 3916 Marsha Drive, Columbus, OH 43207
Applicant Phone Number: 614-309-8661
Contact Person: Eric Stahlberg
Contact Person Email: estahlberg@acceleratedata.com
Estimated Funds Requested: \$400,000
Known Collaborators: The Research Institute at Nationwide Children's Hospital

Project Name: Accelerated Pathology Image Analysis and Transfer Engine (APIATE)

A separate one page project description is on the second page of this letter of intent.

We look forward to the final submission and appreciate the opportunity the state of Ohio has created for small businesses to grow and prosper in the state.

Sincerely,



Eric Stahlberg
Accelerated Data Concepts, LLC
www.acceleratedata.com

Project Name: Accelerated Pathology Image Analysis and Transfer Engine (APIATE)

Project Description:

Unstructured, semi-structured and image data are increasingly part of the medical analysis and treatment workflow as electronic medical records are increasingly integrated across hospitals, medical offices, imaging centers and patients. Unfortunately, the network bandwidth required to move this information in a timely manner is frequently insufficient to allow use of the information at full resolution.

Fortunately, new parallel and accelerated computing technologies are increasingly able to affordably provide the necessary computing power at or near the point-of-acquisition, enabling faster and more effective upstream processing of medical image information.

The purpose of this project is to develop a new product that will be introduced into the workflow for medical imaging to accelerate the secure movement and diagnostic capability of medical image and clinical data.

Accelerated Data Concepts will be working with its growing commercial and academic partners to develop and commercialize a new product that will use established and emerging standards combined with emerging accelerated computing technologies to significantly speed the acquisition, processing and distribution of medical image data.

The product will initially focus on digital pathology as a currently underserved yet increasingly important sector of the medical imaging diagnostic industry that can be greatly impacted by advances in the proposed areas. The product plans future extensions and support to enhance other image acquisition modalities (e.g. MRI, CT, PET, etc.) and secure data integration.

Philips Healthcare

January 22th, 2010

REF: Letter of intent for Ohio Third Frontier FY2010 Programs in Medical Imaging

Philips Healthcare in collaboration with Case Western Reserve University & University Hospitals Health System is very excited about the opportunity to submit a proposal for the Ohio Third Frontier FY2010 Program in Medical Imaging.

We are proposing to develop a PET/CT scanner optimized for quantitative myocardial blood flow assessment. As requested a short description of the project is provided as an attachment to this letter.

The prospective lead applicant's name, address, phone number is:

- Philips Healthcare, 595 Miner Rd., Highland Heights, Ohio, 440 483-3000

Contact person, including email address for the contact:

- Piotr J. Maniawski, Director, Clinical Science - Nuclear Medicine
- E-mail: piotr.maniawski@philips.com; phone 440 483-7616

Proposed project title:

- PET/CT scanner optimized for quantitative myocardial blood flow assessment.

Estimated grant funds to be requested:

- \$ 1,000,000

Known collaborators are:

- Case Western Reserve University (Cleveland, Ohio) & University Hospitals Health System (Cleveland, Ohio)
 - Raymond F. Muzic, Jr., PhD, .Associate Professor, Radiology, Oncology and Biomedical Engineering
 - James K. O'Donnell, M.D. Director, Division of Nuclear Medicine, University Hospitals of Cleveland, Professor of Radiology, Case Western Reserve University, Cleveland, Ohio)

Sincerely,

Philips Medical Systems (Cleveland), Inc., a Philips Healthcare company

**Piotr
Maniawski**

Digitally signed by Piotr Maniawski
DN: cn=Piotr Maniawski, o=ou,
email=piotr.maniawski@philips.com
, c=US
Date: 2010.01.25 07:55:10 -05'00'

Piotr Maniawski, Director, Clinical Science, Nuclear Medicine

Philips Medical Systems (Cleveland), Inc.,
a Philips Healthcare company
595 Miner Road
Cleveland, OH 44143
Tel: (440) 483 3000

PET/CT scanner optimized for quantitative myocardial blood flow assessment

Coronary artery disease (CAD) is the leading cause of death worldwide. While the symptoms and signs of CAD are noted in the advanced state of disease, most individuals with coronary artery disease show no evidence of disease for decades as the disease progresses before the first onset of symptoms, often a "sudden" heart attack, finally arises. Myocardial perfusion imaging is the gold standard for the diagnosis of CAD. Physicians perform more than 10 million myocardial perfusion studies a year in North America.

Myocardial perfusion imaging is typically performed with single photon emission computed tomography (SPECT) and, to a limited degree, positron emission tomography (PET).

PET technology offers several advantages over SPECT in cardiac applications. PET's improved diagnostic accuracy can be attributed to its superior sensitivity, the more homogenous spatial resolution of the PET/CT scanner and the routine use of attenuation correction with PET.

Unlike PET, SPECT myocardial perfusion assessment is only relative. One can evaluate the difference in perfusion between various segments of the myocardium but not the actual blood flow (in mL/min/g). Consequently, if a patient has a uniform reduction in blood this can be detected by PET but not by SPECT. If absolute quantification of the myocardial perfusion is available, PET has the edge over SPECT in evaluating multivessel CAD and balanced ischemia.

The purpose of the proposed project is to develop a PET/CT scanner that is optimized for quantitative myocardial blood flow assessment. Three key components of the project can be defined as:

1. Optimization of image acquisition detector and electronics to allow for optimal patient dose
2. Development of fast time of flight PET reconstruction algorithms to enable clinically practical workflow
3. Optimization and validation of absolute blood flow and coronary flow measurement

Today's PET/CT systems are optimized for qualitative imaging but have severe limitations for quantification. In particular, there is no commercial scanner capable of quantitative measurements while following widely accepted imaging guidelines issued by American Society of Nuclear Cardiology*.

The proposed scanner would be co-developed by Philips Healthcare and Case Western Reserve University, clinical validation would be performed at the University Hospitals Health System and manufacturing would be in the Philips Healthcare factory in Highland Heights, Ohio.

We believe that this project uniquely addresses the program goals by investigating adaptation and modification of the existing devices (PET/CT scanners) in order to address a specific issue of image quantification.

** ASNC IMAGING GUIDELINES FOR NUCLEARCARDIOLOGY PROCEDURES PET myocardial perfusion and metabolism clinical imaging: Vasken Dilsizian, Stephen L. Bacharach, Robert S. Beanlands, Steven R. Bergman, Dominique Delbeke, Robert J. Gropler, Juhani Knuuti, Heinrich R. Schelbert, Mark I. Travin, Journal of Nuclear Cardiology, July 2009 (in effect until 2014)*



OTFMIP 10-919

www.bioinvision.com

781 Beta Dr. Ste E
Mayfield Village, OH 44143
Phone: (216) 373 1500
Fax: (216) 201 9375
Email: inquiry@bioinvision.com

Ohio Department of Development
Research Commercialization Program
Third Frontier Project
State of Ohio

January 25, 2010

Subject: 2010 OTFMIP LOI, 2010 OTFMIP LOI, OTFMIP2010@development.ohio.gov

Due: January 25, 2010

BioInVision, Inc. and collaborating institutions intend to submit a proposal in response to the 2010, Ohio Third Frontier Medical Imaging Program.

Project Title: Biomedical Imaging in Ohio
Estimated Grant Funds Requested: \$3,000,000

Lead Applicant Institution:

BioInVision, Inc.
781 Beta Drive, Suite E
Mayfield Village, OH 44143-2360

Contact person: Debashish Roy, PhD, Principal Engineer, droy@bioinvision.com, phone: 216-373-1500

Collaborating Institutions: Collaborating institutions are Case Western Reserve University, Ohio manufacturers, commercial partners, and potentially a large number of additional academic and research institutions.

Summary: We will create new biomedical imaging systems to be manufactured in Ohio. It will be more robust, have improved resolution, and higher throughput as compared to previous systems. We will deliver a commercially ready device to at least one of our collaborating institutions.

Regards,

A handwritten signature in black ink that reads "Debashish Roy".

Debashish Roy, PhD
Principal Engineer
BioInVision, Inc.

Lead Applicant:	Midmark Corporation 60 Vista Drive, P.O. Box 286 Versailles, OH 45380-0286 1-800-643-6275	Contact Person:	Thomas Schwieterman, M.D., Director of R&D 60 Vista Drive, P.O. Box 286 Versailles, OH 45380-0286 937-526-8722 tschwieterman@midmark.com
Estimated Grant Funds Requested:	\$1,000,000.00	Collaborators:	TBD

Project Title: Improving Access to and Protocols for Using Imaging in the Diagnosis and Treatment of Obstructive Sleep Apnea

Company Summary: Based in Versailles, OH, Midmark is a privately-held, physician-led, manufacturer of medical equipment and cardiovascular diagnostic devices. Midmark has four divisions, all of which are healthcare-focused: medical, dental, imaging, and veterinary. Midmark serves the front line of today's health-care system, predominantly the office-based physician and office-based dentist. Midmark products can be found in well over 90 percent of ambulatory physician offices and a majority of dental offices. Through our Progeny subsidiary, Midmark is the leading manufacturer of intraoral x-rays systems in the US, and offers a full line of x-ray, digital sensor and intraoral camera products worldwide. Our company vision is to be, "A global leader providing products and services for the healthcare provider, integrating value-added technology for efficient and effective patient care."

Project Summary: Lateral cephalometric radiography and panoramic technology have long been used in clinical practice with obstructive sleep apnea patients, however these technologies are limited in their ability to show soft-tissue and three-dimensional views. An emerging body of research shows promise for the relatively new technology of cone-beam computed tomography (CBCT) scanners when used for craniofacial imaging in the diagnosis and treatment of obstructive sleep apnea (OSA). According to a recent paper, "[CBCT] clearly shows high contrast between bone, teeth, empty space and soft tissue in general. It is ideal to show the patency of the airway related to the position of the hard tissue structures of the skull. The spatial resolution is also much greater than conventional CT."¹ We believe that we can lower the cost of imaging, while accelerating its use with OSA patients, which will lead to improved patient outcomes.

Use of CBCT by dentists and other physicians for the diagnosis and treatment of OSA is limited by a lack of awareness, cost barriers, and limited experience with the technology. We believe that dramatic improvements can be made to help OSA patients get the care they need if provided with a cost-effective and comprehensive solution integrating imaging, a range of third-party OSA diagnostic and therapeutic devices, and emphasizing collaborative care plans. The proposed solution will be complemented by our market leading cardiovascular diagnostic devices (ECG, holter, spirometer). Our unmatched device integration with over ninety electronic medical record systems will ensure the clinical data created becomes part of the patient's electronic medical record and can be leveraged to help minimize long term cardiovascular diseases.

The primary benefits of the proposed solution will be:

- Improved access to imaging technology by lowering costs and increasing awareness of its application to OSA
- Improved detection and treatment of OSA through the development and use of CBCT protocols
- Improved care-coordination of OSA between dentists, doctors, and specialists, and patients
- Improved compliance to OSA therapies with virtualized care management strategies that compliment and augment the efforts of the patient's local care team
- Significant contributions to clinical data about OSA, enabling comparative effectiveness of various diagnostic and therapeutic options for treating OSA
- Reduced healthcare system costs through proactive management of OSA and the reduction of long term morbidities known to be consequences of inadequate sleep apnea treatment.

We are actively working to identify the right collaborators for this project from our network of contacts in Ohio.

¹ Lohse AK, Scarfe WC, Shaib Fi, Farman AG. Obstructive sleep apnea-hypopnea syndrome: Clinical applications of cone beam CT. Australasian Dental Practice. Sep/Oct 2009;104-114.



The future of radiotherapy.

#2 Thermo Fisher Way, Oakwood Village, Ohio 44146

The Ohio Department of Development
Technology and Innovation Division
77 South High Street, 25th Floor
Columbus, OH 43215

Subject: 2010 OTFMIP LOI

Dear Sirs,

ViewRay Incorporated intends to submit a proposal in response to the FY 2010 Ohio Third Frontier Medical Imaging Program RFP. Please find attached a one page summary of our proposed collaborative work with Dr. Robert Brown of Case Western Reserve University.

Lead Applicant Information

Name: ViewRay Incorporated
Address: #2 Thermo Fisher Way, Oakwood Village, Ohio 44146
Phone #: 216-925-2546
Contact: John L. Patrick, PhD, MBA
Email: jlpatrick@viewray.com

Collaborator Information

Name: Case Western Reserve University
Address: Department of Physics, 204 Rockefeller Building, Case Western Reserve University, 10900 Euclid Avenue, Cleveland, OH 44106-7079
Phone #: 216-368-4010
Contact: Robert W. Brown, PhD
Email: rwb@case.edu

Proposed Project Title:

"Real-time volumetric MR imaging for the reconstruction of dose delivery"

Grant funds requested: \$1,000,000.00

Thank you for your consideration,

A handwritten signature in black ink, appearing to read "John L. Patrick", written in a cursive style.

John L. Patrick PhD, MBA
Sr. VP Engineering

Title: Real-time volumetric MR imaging for the reconstruction of dose delivery

ViewRay Incorporated, located in Oakwood Village Ohio, is developing an advanced technology to cure cancer patients: the world's first truly real-time image guided radiation therapy system. This unique technology can continuously see inside the patient during radiation delivery. This information is provided seamlessly, non-invasively, and with zero additional radiation dose to the patient. Radiation therapy is the most cost effective form of cancer treatment available today, representing a growing \$3 billion global market, where 2/3rd of cancer patients in the US are receiving radiation therapy as part of their treatment regimen. However, current technology has a tremendous shortcoming limiting its effectiveness as a treatment: it cannot determine where the dose is actually being deposited in a patient's body when the radiation beam is on. The human body inherently and inevitably has internal organ motion that causes the tumor to be in different positions when treatment occurs. This movement is often significant enough to cause the radiation to miss the intended target and healthy tissue can be repeatedly and unnecessarily irradiated, leading to more side effects and fewer cures. Radiation oncologists currently lack the tools to solve this problem. Despite the fact that today's image guided radiation therapy or "IGRT" systems can generate a field of radiation with high precision to a non-moving target, they cannot ensure that the treatment is accurately delivered in the presence of organ motion. In essence, all available forms of state-of-the-art radiotherapy systems, including intensity modulated radiation therapy or "IMRT", tomotherapy, proton and heavy-ion therapy, suffer from this limitation of precision without accuracy.

In this application we propose providing both precision and accuracy in the determination of actual dose received in the patient by acquiring a stream of dynamic volumetric images simultaneous to the actual treatment while the beam is on and reconstructing the delivered dose to the patient. The temporal and spatial resolution requirements will be determined by a rigorous application of information theory to dose distribution and physiologic data on organ motion. The MRI data is combined with the control system record of the treatment and an *a priori* Monte Carlo simulation model of radiation transport and dose absorption that models the device, deforming patient tissues, and the MRI magnetic field to provide a quantitative estimate of the delivered dose to the patient's moving tissues. Moving and deforming phantoms and high-resolution dosimeters will be used to validate the process.

We propose to collaborate with the Prof. Robert W. Brown's Applied Computation & Applied Physics Research Group, which has collaborated with members of ViewRay's team for over 25 years.

ViewRay's unique approach promises to improve the efficacy and efficiency of radiation therapy and represents the first sustainable competitive advantage in the radiotherapy market in over 30 years. This gives the physician the knowledge of the actual dose delivered to the patient and the ability to ensure that the tumor receives its full prescription. The same information may enable the treatment of tumors previously thought too difficult to treat. Ultimately, this advance can lead to increased cure rates and decreased side effects.



EXCMR, Ltd.
2481 Sandover Rd. Columbus, OH 43220
excmr@excmr.com
(614) 306-5502

January 22, 2010

Ohio Department of Development
Technology and Innovation Division
77 South High Street, 25th Floor
Columbus, OH 43215-6130

Re: LOI Ohio Third Frontier Medical Imaging Program

Dear Ohio Department of Development:

This letter serves as notification of our intent to submit a project proposal to the Ohio Third Frontier Medical Imaging Program for Fiscal Year 2010.

Lead Applicant: EXCMR, Ltd.
Address: 2481 Sandover Rd
Columbus, OH 43220
Telephone: 614-306-5502
Contact person: Orlando P. Simonetti, PhD
Chief Executive Officer
Email: orlando.simonetti@excmr.com

Project Title: An In-State Multi-Center Evaluation of Treadmill
Exercise Stress Cardiac Magnetic Resonance

Estimated Funding Request: \$1,000,000 Third Frontier R&D Fund
\$ 360,000 Wright Capital Fund

Known Collaborators: The Ohio State University
Case Western Reserve University Hospitals
The Christ Hospital, Cincinnati
Siemens Healthcare, Inc.

Project Summary:

EXCMR, Ltd. is an Ohio State University Technology Commercialization Company (UTCC) founded in 2008 to develop and commercialize technology that enables treadmill exercise stress cardiovascular magnetic resonance imaging. To date, EXCMR has successfully developed and implemented a totally MRI compatible treadmill and other equipment and software necessary for exercise stress MRI. Initial feasibility testing at The Ohio State University Medical Center in normal human subjects and patients with known or suspected coronary artery disease has shown this novel new diagnostic imaging test to be superior to existing nuclear SPECT technology. The proposed project will outline a plan for the next phase of clinical testing extending to several other leading centers for cardiovascular medicine in Ohio. Ohio State University will serve as the core lab coordinating data acquisition and analysis. Siemens Healthcare will support the implementation of appropriate imaging hardware and software at each of the sites. This project is not only anticipated to support the commercialization of the MRI-compatible treadmill and other technology manufactured in central Ohio by EXCMR, but will also highlight the strength of Ohio as an innovation leader in both medical imaging and cardiovascular medicine.

Sincerely,



Orlando P. Simonetti, PhD

CEO

EXCMR, Ltd.

Hansen, Andrew

From: Craig Hartz [chartz@aurumdx.com]
Sent: Monday, January 25, 2010 12:29 PM
To: OTFMIP2010
Subject: 2010 OTFMIP LOI
Attachments: Project Title submitted to ODOT for Third Frontier Funding Jan 25 2010.doc

To Whom It May Concern:

Please accept this communication of Aurum Dx LLC, an Ohio Corporation, as our desire and intent to participate in the RFP being extended by the Third Frontier Medical Imaging Program.

Aurum Dx LLC's Lead Applicant and direct contact is;

Craig L. Hartz
Aurum Dx LLC
453 South High Street, Suite 101
Akron, Ohio 44311
(330) 754-1377 ext. 111
(800) 574-1277 ext. 111
(888) 476-3250 ext. 111 FAX
(330) 671-8469 Cell
CHartz@aurumdx.com

The proposed Project Title is "The Commercialization and Use of Ultrasound by the Primary Care Physician to Advance Detection of PAD Under Current and Existing CPT and ICD-9 Coding Structures of Reimbursement".

The initial estimate for Grant Funds requested is \$1.0 Million.

Other known Collaborators include;

Kate Robson, B.S., RDCS, RCVT, FASE
Aurum Dx LLC
453 South High Street, Suite 101
Akron, Ohio 44311
(330) 754-1377 ext. 160
(800) 574-1277 ext. 160
(888) 476-3250 ext. 160 FAX
KRobson@aurumdx.com

Mark E. Krohn
Aurum Dx LLC
453 South High Street, Suite 101
Akron, Ohio 44311
(330) 754-1377 ext. 130
(800) 574-1277 ext. 130
(888) 476-3250 ext. 130 FAX
MKrohn@aurumdx.com

Robert J. H. McManus
Aurum Dx LLC
453 South High Street, Suite 101
Akron, Ohio 44311
(330) 754-1377 ext. 120
(800) 574-1277 ext. 120
(888) 476-3250 ext. 120 FAX
RMcManus@aurumdx.com

William G. Hartz
Aurum Dx LLC
453 South High Street, Suite 101
Akron, Ohio 44311
(330) 754-1377 ext. 120
(800) 574-1277 ext. 120
(888) 476-3250 ext. 120 FAX
WHartz@aurumdx.com

You will find attached a one page brief of the project proposed and other collaborators.

Respectfully yours,

Craig L. Hartz

CEO and Founding Partner

Aurum Dx LLC

(330) 754-1377 ext. 111

(800) 574-1277 ext. 111

(888) 476-3250 ext. 111 FAX

(330) 671-8469 Cell

CHartz@aurumdx.com

Project Title submitted by;

Aurum Dx LLC™



The Commercialization and Use of Ultrasound by the Primary Care Physician to Advance Detection of PAD Under Current and Existing CPT and ICD-9 Coding Structures of Reimbursement

This project is to commercialize the research and development conducted by Aurum Dx LLC, which has successfully adapted ultrasound technology and the other modalities required in the evaluation, diagnosis and treatment effectiveness of PAD, one of the earliest forms of atherosclerosis.

One major and significant element of the research and development conducted by Aurum Dx LLC was the capability to comply with the requirements of current and presently existing CPT and ICD-9 requirements for provider reimbursement.

The commercialization of this effort will support an organization needing 150 to 200 full time employees in the Northeastern Ohio Area directly and additional supplemental employment for the assembly and delivery companies in the next 4 years.

This growth opportunity is being fostered by the movement acceptance and need for Healthcare Information Technology supporting CMS initiatives defined by the standard of “Meaningful Use” and EMR capabilities. It also addresses the need to intervene early with the most costly chronic diseases such as heart attaches and strokes.

Collaborative efforts are currently in place and underway with the Quantum Group and CINA-US both having the need and provider base to meet our goal of producing 500 units for delivery during our first year of production. Both firms have also offered to participate in the testing and validating of the production units produced by Aurum Dx LLC.

To Advance Clinical Performance

January 25, 2010

The Ohio Department of Development Technology and Innovation Division
77 South High Street, 25th Floor
Columbus, OH 43215

Subject: 2010 OTFMIP LOI

Dear Director,

Simbionix USA Corporation is pleased to inform you of our intent to submit a proposal in the Biomedical area for the OTFMIP2010 Request for Proposals. Following is our contact information and project summary:

Administrative Information

Lead Applicant: Simbionix USA Corporation

Address: 7100 Euclid Avenue, Suite 180 , Cleveland, OH 44103
Phone 216.229.2040 Fax 216.229.2070

Contact Person: William E. Lewandowski

Phone 216.229.2040 ext 102
Email: bill@simbionixusa.com

Project Title: Development of Advanced Virtual Reality Planning, Training and Performance Sustainment Systems for Minimally Invasive Endovascular Procedures

Estimated Budget: \$3,000,0000. Simbionix will match any funds provided by the State of Ohio to meet the estimated budget amount.

Collaborators: Currently under negotiation

Project Summary

Simbionix USA Corporation is a "for profit" corporation headquartered in Cleveland, Ohio. It produces a wide range of virtual reality medical simulations. In 2009, it commercialized an innovative, patient specific simulation product to assist interventionalists in planning and practicing carotid stenting. This product, the Simbionix PROcedure Rehearsal Studio™, accepts a patient's CT and MRI scan data from a CD or local PACS, server. It then generates a digital 3D model of the patient's clinically relevant anatomy from the scan data. When this model is imported into the Simbionix ANGIO Mentor™ (its full-feature simulator for endovascular procedures) the result is a simulation containing a model of the patient's anatomy that replicates the visual, auditory and tactile aspects of the carotid stenting procedure, for that particular patient. It enables hands-on practice of all aspects of the carotid stenting procedure, including angiography and stenting, balloon and embolic protection device placement and deployment.

Simbionix™

To Advance Clinical Performance

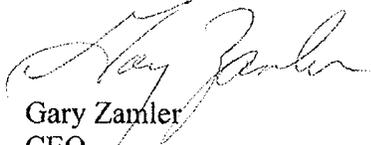


A revolutionary aspect of the Simbionix PROCEDURE Rehearsal Studio™; is that the process of importing a patient's CT data into the simulation can be easily accomplished by the clinician, or assistant, using Simbionix's proprietary modeling software. This ability to rapidly create a simulated case from actual patient data not only supports Mission Rehearsal for that particular case, it also has the potential of creating an unlimited library of simulated carotid stenting cases for training and analysis. This effectively indefinitely extends the utility of the Simbionix ANGIO Mentor™ as a training device (which is manufactured for Simbionix by Astro Manufacturing & Design of East Lake, Ohio) and provides an interventionalist with a planning opportunity far beyond that offered by using conventional imaging systems alone. For now, not only can the interventionalist see the patient's anatomy, he or she can practice the procedure, in the simulator, using the actual tools. This integration of sight, sound, hearing and touch, combined with the ability for real-time practice on the patient's anatomy, creates a powerful synergistic effect in improving clinical performance. Simbionix has also applied for FDA approval for using PROCEDURE as an integral component of the diagnostic process.

Based on our success for developing and commercializing PROCEDURE for carotid stenting, we would now like to extend this product to include versions for abdominal aortic aneurysm (AAA) stenting, thoracic aortic aneurysm (TAA) stenting and coronary stenting. This would include research, development, and FDA submissions for extending the functionality for both our PROCEDURE Rehearsal Studio™ and ANGIO Mentor™. This project, if funded, will not only generate jobs at both Simbionix headquartered in Cleveland, Ohio, Astro located in East Lake, Ohio, but also increased jobs for Northeast Ohio in general. It will also provide valuable tools for interventionalists that will significantly enhance their ability to treat patients in a timely and effective manner.

Please let me know if you need any additional information.

Best regards,



Gary Zamler
CEO

Simbionix USA Corporation



526 South Main Street #812
Akron, Ohio 44311
(330)253-0200
Fax : (330)-253-0201
www.fmimaging.com

January 25, 2010

Ohio Department of Development, Technology and Innovation Division
Attention: Ohio Third Frontier Medical Imaging Program
77 South High Street, 25th Floor
Columbus, Ohio 43215

Dear Sirs:

FMI Technologies Inc. (FMI) is pleased to submit this letter of intent to submit a proposal in response to the Ohio Third Frontier Medical Imaging Program Fiscal Year 2010 Request for Proposals.

Lead Applicant: FMI Technologies Inc.
526 South Main Street
Akron, Ohio 44311

Administrative Contact: William K. McCroskey
President FMI
Direct Voice: (330) 253-0200 x402
William.mccroskey@fmimaging.com

Technical Contacts: William Dickinson, Ph.D., Director, R&D
Direct Voice: (330) 253-0200 x405
Bill.dickinson@fmimaging.com

Project Title: "Commercialization of Organ/Disease Specific Cardiac and Neurologic PET/CT/SPECT Molecular Imaging Systems for Global Markets: A Value Proposition Demonstration."

Estimated Grant Funds to be Requested: \$1,000,000.00

Known Collaborators:

1. **The Ohio State University – Wright Center of Innovation in Biomedical Imaging**, Michael Knopp, M.D., Ph.D., Novartis Chair of Imaging Research; Robert McKenny, Ph.D., Research Assistant Professor, 2050 Kenny Road, Columbus, Ohio 43210, (614) 293-9998
2. **Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM)**, Walter Horton, Ph.D., VP for Research; Neels Van der Schyf, Ph.D., Professor and Chair, Pharmaceutical Sciences, 4209 State Route 44, PO Box 95, Rootstown, Ohio 44272, (330) 325-6290
3. **Akron General Medical Center**, David Peter, M.D., Chief Medical Information Officer; Jack Mitsifer, M.D., President Inpatient Service; George Litman, M.D., Cardiologist - Heart & Vascular Center; Leslie Tobias, M.D., Cardiologist - Heart & Vascular Center; Robert Anthony, Technology Transfer Office, 400 Wabash Ave., Akron, Ohio 44307, (330) 344-7285
4. **Summa Health System**, Steven Schmidt, Ph.D., System Director of Research; Kyle Allen, D.O., Chief, Division of Geriatric Medicine; Daniel Finelli, M.D., Neuroradiologist, Chairman Dept. of Radiology; Ilene Shapiro, Summa Foundation Office of Strategic Business Development, Professional Center South, Suite G-1, Summa Akron City Hospital, 525 East Market Street, Akron, Ohio 44304, (330) 375-4045
5. **Kettering Medical Center**, Joseph Mantil, M.D., Ph.D., Director of Nuclear Medicine/PET; Martin Satter, Ph.D., PET Physicist, Nuclear Medicine, 3535 Southern Blvd. Kettering, Ohio 45429, (937) 298-4331
6. **Wright State University, Department of Computer Science & Engineering**, Arthur Goshtasby, Professor and Director of Graduate Program and founder of Image Registration and Fusion Systems, 3640 Colonel Glenn Hwy., Dayton, Ohio 45435, (937) 775-5170
7. **The Cleveland Clinic, Cleveland Clinic Neurological Institute**, Michael Philips, M.D., Neuroradiologist; Michael Modic, M.D., Neuroradiologist & Director of the Neurological Institute; Richard Rudick, M.D., Neurologist, Cleveland Clinic Main Campus, 9500 Euclid Ave., Cleveland Ohio 44195, (216) 444-0557
8. **Lantheus Medical Imaging**, Steve Haber, Ph.D., Senior Director of Business and Corporate Development, 331 Treble Cove Road, N. Billerica, MA 01862, (978) 671-8357
9. **AVID RadioPharmaceuticals**, Alan Carpenter, Ph.D., J.D., VP of Business Development & Regulatory Affairs, Philadelphia, PA, (215) 298-0701
10. **Akron Global Business Accelerator**, Mike LeHere, Accelerator CEO; Terry Martell, Director of Operations and Business Development., 526 South Main St., Akron, Ohio 44311, (330) 375-2173
11. Others To Be Determined

Project Description Summary:

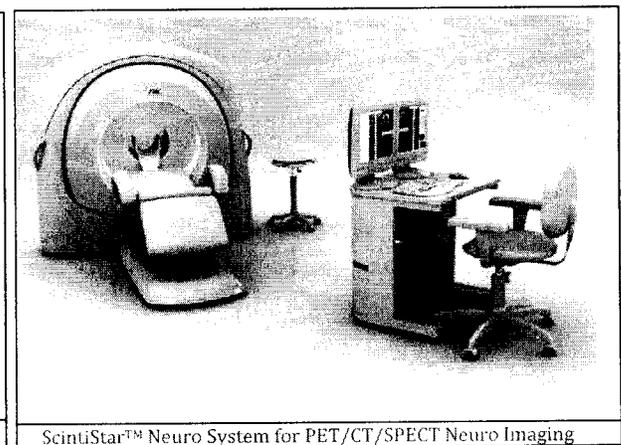
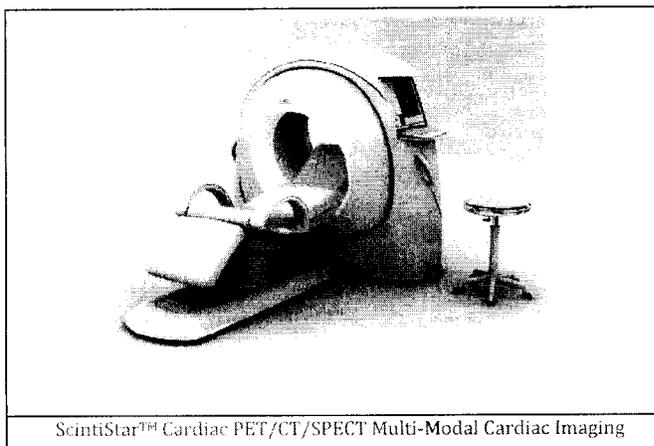
FMI is proposing a demonstration program for commercialization of its ScintiStar™ Cardiac and ScintiStar™ Neuro PET/CT/SPECT systems. FMI's technology for commercialization is a small footprint highly sensitive molecular imaging system for cardiovascular diseases and neurological diseases including stroke, memory loss, dementia, and Alzheimer's. FMI has developed a unique imager combining 3 modalities: Positron Emission Tomography(PET), Computed Tomography(CT), and Single Photon Emission Tomography(SPECT). This system is 1/5 the cost and 1/5 the size of current whole body PET/CT systems. FMI and its imaging and molecular isotope collaborators desire to demonstrate the imaging capability at Ohio's academic and community hospitals. This program will enable FMI to complete development work and obtain FDA 510k approvals for the systems. Pending FDA 510k approval, FMI will be producing the units in Ohio and draw on other Ohio based medical imaging supply chain businesses. With this program FMI will create 300-400 jobs with global utilization of the ScintiStar™ Systems over the next 5 years.

The Ohio Third Frontier funds requested for FMI and it's collaborators will enable FMI to start sales of it's ScintiStar™ Systems worldwide and attract additional venture capital to build a strong growing company with job creation in several regions of Ohio.

Problem:

- Lack of cost effective small footprint organ specific PET/CT/SPECT medical imaging systems for cardiovascular disease and neurological disease
- Need for PET/CT/SPECT molecular imaging with 1.5mm spatial resolution and improved sensitivity for early asymptomatic disease detection.
- Need for early cardiovascular disease detection and neuro-degenerative disease detection to reduce medical health care costs and improve outcomes.

Solution:



- Improved imaging resolution (3-10x) and sensitivity with the ScintiStar™ Cardiac System performing PET/CT/SPECT myocardial perfusion imaging (MPI) utilizing the new PET F18-MPI imaging agent, Rb-82, and Tc-99 Sestamibi.
- Dynamic morphological vascular flow imaging with the ScintiStar™ Cardiac PET/CT System performing low dose Cardiac CT angiography and CT cardiac calcium scoring.
- Brain imaging with the ScintiStar™ Neuro System for PET/CT/SPECT utilizing new amyloid plaque detection PET imaging agents for Alzheimer's disease and PET F18-FDG glucose metabolism imaging for brain neuro-health.
- Stroke and vascular flow imaging with the ScintiStar™ Neuro System performing volume CT angiography and Tc-99 ECD SPECT imaging.
- An innovative paradigm combining cost effective imaging technology with disease specific imaging agents to improve management of cardiovascular and neurological diseases world wide.

Program Projected Plans:

- Build and install a ScintiStar™ Cardiac and a ScintiStar™ Neuro system for clinical validation of cardiovascular and neurological molecular, functional, and morphological imaging at collaborator sites.
- Demonstrate the clinical value and the market value proposition for the ScintiStar™ Cardiac and ScintiStar™ Neuro systems.
- Submit FDA 510k applications for approval of the ScintiStar™ Cardiac and ScintiStar™ Neuro systems.

FMI's commercialization of the ScintiStar™ Cardiac and ScintiStar™ Neuro for organ specific imaging is a key outcome of this proposed work to create high technology medical imaging jobs in the state of Ohio.

FMI and its respective collaborators have developed the medical imaging supply chain to support the development, marketing, and sales of this novel technology.

Regards,



William K. McCroskey
President/CEO
FMI Technologies Inc.