

Interventional Imaging, Inc.

Letter of Intent

Ohio Third Frontier Medical Imaging Program

2011

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:

“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

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

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 manufacturing 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.

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.

11-602



Letter of Intent
Ohio Third Frontier Medical Imaging Program (FY2011)

Lead Applicant:

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

Contact Persons:

Frederick O. Cope, PhD FACN CNS
Sr. Vice President, Pharmaceutical Research and Clinical Development
fcope@neoprobe.com

Project Title: RIGScan CRTM, A MEDICAL IMAGING AGENT FOR STAGING AND REAL-TIME INTRAOPERATIVE EVALUATION OF HEPATIC RESECTION IN METASTATIC COLORECTAL CANCER

Estimated Grant Funds Requested: \$1,150,000

Known Probable Collaborators:

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

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

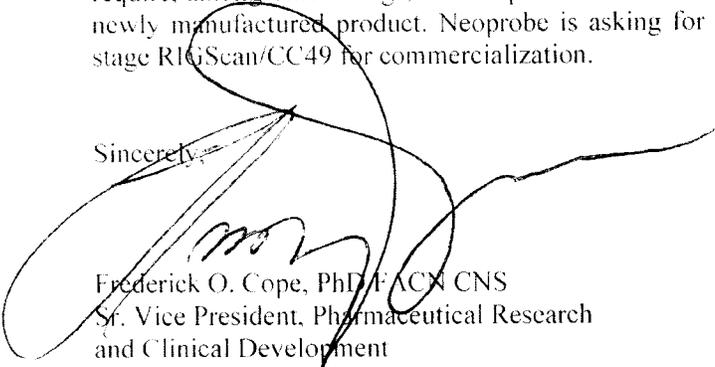
Integrated BioScience Solutions, LLC
107 Fallenoak Court
Loveland, Ohio, 45140
(513) 260-5152

Charles River Laboratories Inc (Spencerville Division).
640 N. Elizabeth Street
Spencerville, Ohio 45887
(419) 647-4196

RIGScan CR 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. Neoprobe, in collaboration with drug regulatory agencies, is undertaking major efforts to accrue additional data specific to the use of RIGScan in hepatic resection of metastatic colorectal cancer. More than 30% of all colorectal cancer patients present with hepatic metastasis. Prior performance of RIGScan/CC49 in hepatic metastasis evaluation and resection was outstanding and the new effort for RIGScan/CC49 approval focuses on the real-time intraoperative diagnostic resection/decision process of hepatic resection in these patients. Follow up data were collected from the patients in the previous Phase III trial indicating that RIGScan provided powerfully predictive information concerning patient outcome. In the intervening years since the previous trials, Neoprobe has continued to evaluate and develop clinical and regulatory strategies with the goal of reinvigorating the development of RIGScan/CC49. The reason for our tenacity is simple; there have been no products introduced or medical developments that we are aware of the development of which can compare in the improvement in the treatment of colon cancer patients. However, based on manufacturing innovations and regulatory process evolution, the opportunity to commercialize RIGScan/CC49 remains incredibly strong. Neoprobe has therefore decided make a major move forward with the RIGScan project and follow through with a Phase III trial in this patient population. Neoprobe has already taken steps to re-initiate production of the drug under GMP conditions to support clinical trials. However, this project will require, among other things, several preclinical studies and a Phase II/III clinical bridging study with the newly manufactured product. Neoprobe is asking for OTF support for these project efforts in order to stage RIGScan/CC49 for commercialization.

Sincerely,



Frederick O. Cope, PhD, F.A.C.N. CNS
Sr. Vice President, Pharmaceutical Research
and Clinical Development



Department of Biomedical Engineering

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

December 6, 2010

Letter of Intent

Ohio Third Frontier Medical Imaging Program (FY2011)

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 427, Mail Stop 7207
10900 Euclid Avenue
Cleveland, OH 44106
phone: 216-368-0187

Project title: Preclinical development of a targeted MRI contrast agent for an IND

Anticipated grants funds to be requested: \$1,500,000

Known collaborators:

Bracco
Hitron Technologies

Proposal Summary

Case Western Reserve University proposes to perform THE FDA required preclinical evaluations and development of a targeted MRI contrast agent for earlier detection and diagnosis of malignant tumors. The effectiveness of the agent to tumor imaging has been recently confirmed in animal tumor 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 agent
- GMP Materials synthesis in a FDA certified facilities;
- GLP preclinical toxicity evaluations;
- GLP preclinical pharmacokinetic study;
- Application for FDA approval of Investigational New Drug (**IND**) for the agent.

It is anticipated that the program will lead to the commercialization of the targeted MRI agent for earlier detection of malignant breast cancer in the US and worldwide.



11-604

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

December 6, 2010

Subject: 2011 OTFMIP LOI, OTFMIP2011@development.ohio.gov

Due date: December 14, 2010

Project Title: *Cardiac CT Perfusion*

Estimated Grant Funds Requested: \$1,000,000 TFRD funding, \$1,000,000 WCF funding

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: Philips Healthcare, University Hospitals Case Medical Center, and possibly other academic, research, and commercial institutions.

Summary: We will develop and evaluate a platform for assessing perfusion in the heart using CT. This far reaching project will include development of hardware, software, and image reconstruction, as well as animal validation studies and clinical evaluation. The result will be an important product for Philips Healthcare that will grow commercialization in Ohio and will aid detection and staging of cardiac disease, a major health problem for Ohioans.

Regards,

A handwritten signature in cursive script that reads "David L. Wilson".

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

11-605



25200 Chagrin Blvd
Suite No. 200
Cleveland, OH 44122

888-421-2536
www.mimsoftware.com

December 10, 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_FY11_RFP**. We have been working on PET imaging of liver cancer for quite a while, and have reached the point to start clinical translation. The title of our project is "Quantitative Positron Emission Tomography (PET) imaging for 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 from several other small molecule PET tracers, in detecting early stage, staging, patient selection/treatment planning, and therapy evaluation for HCC. However, there is a large variation in the methodology regarding how the imaging procedures are conducted, and more importantly, how the image data are analyzed during post-imaging image processing. Therefore, MIM Software Inc will team up with Case Western Reserve University to further develop MIM's quantitative package to aid clinical trials at University Hospitals Case Medical Center (Cleveland, Ohio). MIM Software is a private company located in Beachwood, Ohio. MIM is a leader in PET imaging software and has a reputation for developing innovative tools for image registration, segmentation, and assessment of response to cancer treatments.

The proposed trials will be based on PET scans to derive quantitative indices as imaging biomarkers for evaluating the true utilities of these scans 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 is assembled.



25200 Chagrin Blvd.
Suite No. 200
Cleveland, OH 44122

866.421.2536
www.mimsoftware.com

From MIM Software, Inc. (Lead Applicant)

PI: Dennis Nelson, Ph.D.

The contact person for the partner is *Aaron Nelson, M.D.* at
25200 Chagrin Blvd

Suite 200

Cleveland, Ohio 44122

asnelson@mimsoftware.com

Ph: (216) 455-0600

Fax: (216) 455-0601

From Case Western Reserve University (Academic Partner)

PI: Zhenghong Lee, Ph.D.

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

MIM led by Dr. Nelson will develop and evaluate their software package using the de-identified patient image data from the proposed trials conducted by Drs. Dowlati and Gholam to determine the commercial potential of the software package and will prepare their own IND and/or plan/support further clinical trials if needed to facilitate commercialization of their software. Dr. Lee will work with Dr. Nelson (MIM) for image processing and data analysis to derive quantitative indices as imaging biomarker for evaluating the true utilities of PET imaging for HCC.

The budget of \$1 million will be requested from the OTF fund for the first three years of the project with a match of ratio of 1:1 for cost share.

Sincerely,

Dennis Nelson

Dennis Nelson, Ph.D.

President

MIM Software Inc.



IMALUX[®]

MEDICAL IMAGING IN A NEW LIGHT[®]

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

11-606

December 10, 2010

RE: OTFMIP 2011

Dear Sir or Madam:

Please be advised of our intent to submit a full proposal for the "Ohio Third Frontier Medical Imaging Program 2011". The requested information is as follows:

Name: Imalux Corporation

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

Telephone: 216-502-0755 X1005

Contact: Paul G. Amazeen, Ph.D., Executive VP & CTO

E-mail: amazeen@imalux.com

Project Title: Commercialization of an Innovative Medical Imaging System for Early Cancer Detection

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

Collaborators: GVI Medical Devices, Twinsburg, OH and Cleveland Clinic

Summary of Proposed Topic:

Imalux with the assistance of our collaborators will develop and commercialize an enhanced imaging system based on our prior experience with the Company's first generation Optical Coherence Tomography (OCT) imaging system. Our first generation system established a platform technology (patented) and an FDA cleared product, the Niris® Imaging System, which has been clinically validated in cancer focused studies in over 40 prominent medical institutions, worldwide. Publications and conference proceedings from leaders in cancer diagnosis and treatment have noted the use of Niris as a unique contributor to early detection and consequent benefits to medicine. Feedback from these medical leaders, with their suggestions for enhancements, has established a firm basis for market acceptance. Imalux has shown the viability of Niris as a clinically relevant, safe, affordable, real time, easy to use, point-of-care imaging tool in a wide variety of medical applications, such as bladder, cervical and laryngeal cancers. Niris has the unique capability to utilize harmless infrared light to effectively image epithelial tissue where 60% of all cancers originate.

Funding from the OTF Medical Imaging Program will be used to accelerate the development and commercialization of an enhanced point-of-care system that is twelve times faster than the first generation Niris. The faster imaging speed and additional image capture and measurement accessories will enable an important new mode of operation where the clinician can smoothly and continuously scan tissue, rather than be limited to our current point-by-point optical biopsy. (This same scanning speed enhancement in Ultrasound drove that market to expand from millions to billions of dollars.) The enhanced Niris will address a large underserved segment of the imaging market by enabling users to identify structural abnormalities in epithelial tissue in real time. Neither visual observation nor other competing imaging modalities (CT, MRI, X-Ray, PET and Ultrasound) can identify such tissue structure changes associated with early cancer and other disease states. Health care professionals will utilize and benefit from the use of the enhanced Niris to improve patient care clinical and economic outcomes throughout the continuum of care from diagnosis to treatment to post-treatment surveillance.

To support market demand, Imalux and an Ohio-based commercial collaborator, GVI Medical Devices, will establish manufacturing, production, and after sale service support of the primary system hardware. Imalux will also substantially expand our current independent assembly facilities and employment in Ohio for production of our proprietary optical probes and accessories.. Cleveland Clinic will be a primary site for collaboration to conduct clinical validation. The accelerated growth of Imalux as a leader in the commercialization of an important new imaging modality application will complement and align with the objectives for Northeast Ohio's Medical Imaging Cluster.

The Niris Imaging System has the very real potential to become the imaging system of choice in the evaluation of epithelial tissue microstructure throughout the body – nose to lung, mouth to anus, kidneys to urethra, and skin. Support from the OTF Medical Imaging Program will assist Ohio-based Imalux to continue to expand employment and economic value by effectively addressing the clinical outcome and cost containment needs of the evolving health care market.

Paul G. Amazeen, Ph.D.
Executive VP & CTO
Imalux Corporation

11-607

 **SPECTRAL ENERGETICS**

Company Name: Spectral Energetics

Address: 3171B Beaver-Vu Drive
Beavercreek, OH 45434

Phone: (937) 320-5120

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

Project Title: Electromagnetic Medical Advisor (EMMA)

Grant Funds Requested: \$1M (Program Duration: 3 years)

Collaborators:

Wright State University School of Medicine

Wright State University LAR

Miami Valley Hospital

Anritsu Company, US operations

Steve Lockhart, MD, PhD, Biostatistics

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. This method has also been used to detect subdural and epidural hemorrhage. Our technology is also being investigated for application to the non-invasive monitoring of neuronal activity. 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 also 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 36-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 twelve-month period.

Our final twelve-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.



11-608

December 10, 2010

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

To whom it may concern:

This letter serves as our Notice of Intent to submit a grant proposal to the Ohio Third Frontier Medical Imaging Program.

Lead Applicant Name: Securus Medical Group, LLC
11000 Cedar Avenue
Cleveland, OH 44106

Contact Person: John Garibotto
President, CEO & Founder
Email: jgaribotto@securusmg.com
Phone: (617) 688-4408

Project Title: Development of clinical tools to improve the safety and efficacy of ablation therapy by providing real-time, non-contact, high resolution tissue temperature monitoring & mapping products

Estimated Funds Requested: \$1,000,000

Collaborators: Cleveland Clinic
Dr. Bruce Lindsay – Section Head of Electrophysiology
Cardiovascular Medicine - Heart & Vascular Institute
9500 Euclid Avenue / J2-2
Cleveland, OH 44195

Project Description:

Securus Medical Group, LLC is developing clinical tools to improve the safety and efficacy of ablation therapy. Cardiac and tumor tissue ablation use various forms of energy to remove or denature tissue in the treatment of arrhythmias and a variety of cancers. Commercially available ablation systems are prone to cause damage to the adjacent healthy tissue while delivering inadequate energy to the targeted site. Securus Medical's groundbreaking new products will provide the clinician with a non-contact, high resolution tissue temperature map to allow for the precise delivery of energy to the targeted site, thereby improving both the safety and efficacy of ablation therapy. The initial application of the technology will focus on esophageal temperature mapping, as a complementary product for the rapidly growing multi-billion dollar cardiac ablation market.

Atrial fibrillation (AF) is characterized by disorganized electrical impulses that originate in the left atrium and pulmonary veins. The result is an irregular heartbeat that may occur in episodes lasting from minutes to weeks or continuously for years. AF is often asymptomatic and is not, in itself, generally life-threatening. Atrial fibrillation



has shown to be an independent risk factor for both stroke and mortality and is associated with heart failure, hypertension, structural heart disease, and a number of other patient diseases and adverse conditions.

Over the past five years, catheter ablation of AF has evolved from an experimental procedure to one that is commonly performed throughout the world. Catheter ablation treatment for Atrial Fibrillation consists of accessing the heart by inserting a catheter through the veins in the groin and up to the left atrium. The Electrophysiologist uses the catheter to deliver energy to create a transmural lesion and destroy the abnormal electrical pathways in the heart tissue. Most procedures consist of isolating the electrical pathways emanating from the pulmonary veins, which are located on the posterior wall of the left atrium.

The use of extreme energy during cardiac catheter ablation procedures for the treatment of atrial fibrillation is prone to a serious and life-threatening complication known as atrioesophageal fistulas. Atrioesophageal fistula after catheter ablation occurs due to conductive heat transfer to the esophagus that causes transmural tissue necrosis. The close proximity of the esophagus to the posterior wall of the left atrium and the pulmonary veins presents a significant risk of injury to the esophagus during the application of energy to the cardiac tissue. Injury to the esophagus resulting in tissue necrosis can create a delayed opening in the esophageal wall, leading to the formation of a fistula between the atrium and the esophagus. The delayed onset of atrioesophageal fistulas combined with the rapid escalation of symptoms leads to a very high mortality rate (~80%).

To date, there are no products indicated for the monitoring or prevention of thermal injury of the esophagus during cardiac catheter ablation. The critical nature of atrioesophageal fistulas and lack of viable technology to monitor thermal spread to the esophagus force the clinician to make a trade-off between sufficiently ablating the cardiac tissue to ensure the fibrillation is treated and injury to the esophagus. Today the 6 month recurrence rate of catheter ablation to treat Atrial Fibrillation is over 50%. Imagine trying to walk to the edge of a cliff if you were blindfolded. The closer you can get to the edge of the cliff the greater you will be rewarded. This is analogous to what an Electrophysiologist is trying accomplish while performing cardiac catheter ablation. They want to treat the arrhythmia but they cannot “see” where the ablative energy is going. The ability to “see” will enable the clinician to ablate longer and more thoroughly resulting in improved long-term outcomes in the treatment of Atrial Fibrillation.

The Securus System will provide a non-contact, high-resolution video image of the esophagus showing the tissue surface temperature equivalent to thousands of discrete sensors. The device can be placed with minimal use of x-ray, and will not require repositioning during the course of the procedure. The system will include a thermal imaging probe, display unit and disposable sheath.

Funds are being sought to fund the prototype development and initial clinical evaluation of the esophageal thermal imaging system. The clinical evaluation in a suitable animal model will be conducted in collaboration with Dr. Bruce Lindsay and the Cleveland Clinic.



Lead Applicant: Hyper Tech Research, Inc.
Address: 539 Industrial Mile Rd., Columbus, OH 43228
Phone: 614-481-8050 Ext. 2452

Contact Person Larry Walley, email elwalley@hypertechresearch.com

Project Title: Manufacturing of Conduction Cooled Specialty MRI Magnets Using Magnesium Diboride Superconducting Wire

Estimated grant funds to be requested: \$1 million

Known collaborators: Eden Cryogenics, Inc.
Case Western Reserve University
Ohio State University

Project Description:

Project will develop, design, and manufacture magnesium diboride (MgB_2) superconducting magnet system for companies that sell MRI specialty systems. This project includes the manufacture of MgB_2 superconducting coils and vacuum cryostats. The magnet systems will be lower cost than current NbTi based MRI magnet systems and will be liquid helium bath free so they can be sited in more locations around the world. This project will provide MRI manufacturing system companies with the latest helium free superconducting magnet technology. The superconducting magnet system will be manufactured in Ohio using superconductor wire and cryostats that will also be manufactured in Ohio. This project will provide Ohio companies with the manufacturing capabilities to supply specialty MgB_2 based superconducting magnet systems for several specialty MRI applications.



Daniel F. Martin, M.D.
Chair, Cole Eye Institute

December 10, 2010

Letter of Intent Ohio Third Frontier Medical Imaging Program

To: Technology and Innovation Division, The Ohio Department of Development
From: Cleveland Clinic
Subject: Medical Imaging Program Letter of Intent

Please accept this correspondence as an indication of our intention to submit a proposal for the 2011 Ohio Third Frontier Medical Imaging Program. As required, information regarding our proposal follows.

- 1. Lead Applicant Information:**
The Cleveland Clinic
9500 Euclid Avenue
Cleveland, Ohio 44195
Tel: 216-445-7176
Fax: 216-445-2314
- 2. Contact Person:**
Neema Mayhugh, PhD, Director Commercial Affairs
Cole Eye Institute, CC Innovations
Phone: 216-445-7176
e-mail: mayhugn@ccf.org
- 3. Proposed Project Title:**
Ophthalmic Imaging Center (OIC)
- 4. Estimated Grant Funds to Be Requested:**
\$1,000,000
- 5. Known Collaborators:**
OptoQuest Corporation, Bioptigen, Peregrine Instruments, Leica, Case Western University
- 6. Summary of Proposed Project:** It is our intention to submit a proposal for the support of OptoQuest Corporation, a wholly owned spin-off of the Cleveland Clinic housed in The Ophthalmic Imaging Center (OIC), a comprehensive, multi-disciplinary center for commercialization of ophthalmic imaging technologies. Ophthalmic imaging has been revolutionized in the last half decade through the introduction of innovative imaging modalities such as Optical Coherence Tomography (OCT) and the growing use of remote image analysis for diagnosing and monitoring ophthalmic disease. In fact, OCT imaging is now standard of care for all patients with retinal disease and is fast becoming standard practice for diagnostic imaging of diseases of the front of the eye. Although

ophthalmic imaging is now used in some form to investigate almost all diseases of the eye, this is particularly the case in management of the leading causes of blindness in Americans including age-related macular degeneration and diabetic retinal disease.

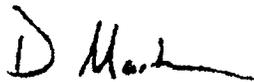
Previous to OCT, clinicians had only limited ability to image the eye through photography and crude ultrasonographic techniques. Now with the introduction of OCT, whole diagnostic and treatment paradigms are shifting to more precise and targeted methodologies. With remote monitoring, clinicians are now able to diagnose, manage and monitor patients more effectively and at less cost than ever before.

OptoQuest Corporation is focused on the commercialization of both front of the eye and back of the eye surgical imaging platforms. The company has developed a front of the eye OCT with elastography that allows surgeons for the first time to gain insight into the biomechanical properties of the eye prior to surgery. The company's other platform encompasses surgical imaging for the back of the eye, which will also for the first time allow surgeons use image guidance during retinal procedures. Both platforms will lead to better outcomes, decreased costs and a growth in market opportunity as more patients are served with customized care.

We have identified multiple commercial collaborators that have committed to take OptoQuest's developed products through commercialization to revenue generation. These collaborators have also agreed to fund operations that will not only sustain, but also grow the employment base for ophthalmic imaging in the State of Ohio.

The Cleveland Clinic has a long proven commercialization track record. In addition, ophthalmic imaging is still at the early stages of innovation when compared to most other medical imaging areas and that translates to virtually unlimited opportunities in this space. Because of this and the fortunate concentration in Northeast Ohio of arguably the brightest and most dedicated research talent in ophthalmic imaging, we feel this Center will see a many fold return in number of commercialization dollars brought to the state as well as impact on employment base and global reputation as a leading area for medical imaging.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "D. Martin".

Daniel F. Martin, M.D.
Chair, Cole Eye Institute

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

Dear Ohio Department of Development:

Please accept this letter of intent from Alpha CT, LLC to participate in the Fiscal Year 2011 Ohio Third Frontier Medical Imaging Program ("OTFMIP") Request for Proposal (RFP).

Lead Applicant Name: Alpha CT, LLC
4455 Glenbrook Road
Willoughby, Ohio 44094

Contact Person: Jeffrey Farmer, VP Marketing
Contact email: jfarmer@alpha-imaging.com
Telephone: 440-953-3800

Proposed Project Title: International Medical Imaging Product Development and Support Center

Estimated grant funds to be requested: \$450,000

Known Collaborators:

1. Foreign Medical Imaging Equipment Manufacturer, People's Republic of China
2. Established Medical Imaging Equipment Distributor, Willoughby, Ohio

Project Summary:

International and domestic medical device companies attempting to enter the US marketplace encounter difficulty finding independent distribution channels with the infrastructure needed to deliver the comprehensive technical and clinical support demanded by US-based customers. This limitation creates a significant barrier to commercialization for many small companies.

Foreign companies typically utilize offshore resources to provide training and support services for distributors and customers. Language barriers and travel costs can make training and support delivered from foreign centers ineffective in meeting customer and channel requirements in the US market.

Small, US-based device companies often lack the resources, experience and infrastructure to deliver ongoing service and clinical training to an expanded network of distributors. This limitation can inhibit effective product launch and limit national and international commercialization success.

December 13, 2010

Alpha CT, LLC proposes to develop an independent medical imaging equipment services and support center designed to support the commercialization of new products and simplify entry into the US marketplace for offshore and domestic medical imaging technology companies.

The center will create new, medical imaging industry jobs in Ohio, focused on the development and delivery of technical and clinical support services. These technical services are needed by both the distribution channels and the end users of the target company products. Proposed services include:

- Product Installation and Implementation Services
- Service Training on new medical imaging devices
- Clinical and applications training
- Technical and Clinical Help Desk Services
- Product configuration, staging and distribution
- Downstream Channel development and support
- Market insights generation for product roadmap planning

The proposed project addresses a common barrier to commercialization faced by domestic and international companies aspiring to enter the US medical imaging market. The project establishes important medical imaging infrastructure in Ohio to attract on-going capital investment and support sustainable job growth.

Sincerely,



Jeffrey P. Farmer
VP of Marketing
Alpha CT, LLC

11-612

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

To Whom It May Concern:

On behalf of my colleagues I am pleased to notify you of our intent to submit a proposal in response to the Ohio Third Frontier Medical Imaging Program 2011 RFP. Information specifically requested in the RFP is given on the next page with the project summary immediately following. If there are any questions, please do not hesitate to contact me.

Sincerely,



Raymond F. Muzic, Jr., Ph.D.
Associate Professor, Radiology and Biomedical Engineering
Raymond.Muzic@case.edu
Voice: 216-844-3543

Lead Applicant

Raymond F. Muzic, Jr., PhD
Associate Professor, Radiology, Oncology and Biomedical Engineering
Case Western Reserve University

Contact Information

Department of Radiology
University Hospitals Case Medical Center
11100 Euclid Avenue
Cleveland, OH 44106
Raymond.Muzic@case.edu
(216) 844-3543

Contact Person

Kelly Roberts, JD, CIP
Department of Radiology
Kelly.Roberts@UHhospitals.org
(216) 844-8275

Project Title

PET/CT and PET/MR scanner options for Positron Emission Mammography

Estimated Grant Funds to be requested:

\$ 1,000,000

Known Collaborators

University Hospitals Case Medical Center, Cleveland, OH

Case Western Reserve University, Cleveland, OH

Raymond F. Muzic, Jr., PhD, Associate Professor, Radiology, Oncology and Biomedical Engineering

Donna Plecha, MD, Assistant Professor, Radiology; Division Chief, Mammography; Director, Breast Imaging, Mammography

James K O'Donnell, MD, Professor, Radiology; Division Chief, Nuclear Medicine

Philips Healthcare, Highland Heights, OH

Piotr Maniawski, M.Sc., Director, Clinical Science – Nuclear Medicine

Project Summary

Attached

Project Summary - PET/CT and PET/MR scanner options for Positron Emission Mammography

Breast cancer is the second leading cause of death in 35 to 65 year-old women and one in eight women living in the U.S. will be diagnosed with breast cancer in her lifetime. If breast cancer is detected before it has spread to the lymph nodes or other parts of the body, the chance for a cure is over 95%. Herein we propose to develop and manufacture an option to enhance the sensitivity and accuracy of detecting and staging breast cancer with two forms of positron emission tomography (PET) scanners: the established dual-imaging scanner that combines PET with Computed Tomography (CT) and the emerging combination of PET with magnetic resonance (MR) imaging.

Background X-ray mammography is widely used to screen for cancer due to its wide availability, low radiation dose, low cost and its impact on decreasing mortality rates from breast cancer. Once cancer is detected, it may be further evaluated by biopsy or imaging studies. While biopsy has a critical role in managing cancer treatment, it is prone to false-negative results and causes the patient discomfort or pain. Dedicated positron Emission Mammography (PEM) imaging systems have been proposed as the imaging instrument of choice for this application. However, PEM systems have several disadvantages over standard PET scanners: non-3-dimensional images, non-quantifiable images, slightly improved but still less than desirable spatial resolution, long imaging times, and poor detection of lesions close to the chest wall. Combining the anatomic advantages of MR or CT with the functional aspects of PET imaging of the breast will improve the overall specificity while overcoming the pitfalls of PEM and therefore enhance the patient's health care by providing the physician with information needed to define the optimal, individualized treatment plan.

Improvements for PET Two major challenges of PET imaging of breast cancer are patient positioning and limited spatial resolution. The usual patient position used for PET, patient lying on her back (supine), is different from MR where it is necessary to have her lie on her stomach (prone) with the breasts hanging down in a positioning device and away from her chest wall. Consequently, the markedly different breast shape and positioning make it difficult to correlate metabolic PET images with anatomic MR or x-ray mammography images. With regard to spatial resolution, typical clinical workflows achieve spatial resolutions in the range of 6 to 10 mm. This is insufficient for early detection and characterization of small lesions.

Proposal We propose to **develop a PET breast-imaging package that could be sold as an option for PET/CT and PET/MR scanners** that addresses difficulties in positioning and limitations of spatial resolution described above. In addition, the package would be **more cost effective than a dedicated PEM device** that could be used only for breast imaging. Four key components of the project are: 1) development of an optimal patient positioning system for breast imaging, 2) optimization of imaging protocols for maximum spatial resolution, 3) development of faster PET reconstruction algorithms to enable clinically practical workflow, and 4) optimization and validation of clinical performance of this technique. The scanner options would be co-developed by Philips Healthcare and Case Western Reserve University. Clinical validation would be performed at the University Hospitals in Cleveland, Ohio. Manufacturing would be in the Philips Healthcare factory in Highland Heights, Ohio.

The Ohio Department of Development
Technology and Innovation Division
77 South High St., 25th floor
Columbus, OH 43215

December 14, 2010

Subject: 2011 OTFMIP LOI

Dear Sirs,

Medic Vision Imaging Solutions Ltd intends to submit a proposal in response to the FY 2011 Ohio Third Frontier Medical Imaging Program RFP. Attached please find a one-page summary of our proposed collaborative work with Dr. Robert Gilkeson of University Hospitals Case Medical Center and Case Western Reserve University.

Lead applicant information:

Name: Medic Vision Imaging Solutions Ltd.
Address: P.O. Box 15054, Matam Advanced Technology Center, Haifa, 31905, Israel
Phone #: +972-54-800-4500
Contact: Eyal Aharon, CEO.
Email: eyal@medicvision.com

Collaborator information:

1. Name: University Hospitals Case Medical Center
Address: Department of Radiology, 11100 Euclid Avenue, BSH 5056
Phone #: 216-983-4829
Contact: Robert Gilkeson, MD
Email: Robert.Gilkeson@UHhospitals.org
2. Name: Case Western Reserve University
Address: Department of Radiology, 11100 Euclid Avenue, BSH 5056
Phone #: 216-983-4829
Contact: Robert Gilkeson, MD, Professor of Radiology
Email: Robert.Gilkeson@UHhospitals.org

Proposed project title: "Clinical Validation and Commercialization of the SafeCT Low-dose CT Imaging System and the Establishment of North American Operations for Medic Vision Imaging Solutions Ltd."

Grant funds requested: \$1,000,000.00

Thank you for your consideration,



Eyal Aharon
CEO
Medic Vision Imaging Solutions Ltd.

MEDICVISION

IMAGING SOLUTIONS

Clinical Validation and Commercialization of the SafeCT Low-dose CT Imaging System and the Establishment of North American Operations for Medic Vision Imaging Solutions Ltd.

Since the inception of CT in the 1970's, its use has increased rapidly, revolutionizing diagnostic radiology. It is estimated that more than 70 million CT scans per year are performed in the United States, including at least 4 million for children. By its nature, CT involves relatively large radiation doses. The increasing number of CT scans performed and the associated radiation doses result in increased cancer risks in adults and particularly in children.

The need for CT dose reduction has become a prime focus for Radiology. To address this issue, various hardware and software features have been developed and incorporated in recent top-tier CT scanner models from major manufacturers, including image reconstruction software for processing of low-dose CT images. However, these solutions do not support the worldwide installed base of about 24,000 CT scanners.

To address the radiation risk, Medic Vision, a company specializing in turnkey solutions dedicated to the enhancement of diagnostic imaging, has developed the SafeCT, a novel universal product that enables up to 80% reduction in the ionizing radiation dose emitted from conventional CT scanners without compromising image quality or diagnostic confidence. Based on Medic Vision's proprietary patented image reconstruction algorithms, GiRR^{3D} (Generic iterative Retro Reconstruction in 3D™), SafeCT dramatically enhances the signal-to-noise ratio of low-dose CT images, providing dose-reduction functionality to existing CT scanner systems.

Medic Vision's SafeCT dose-reduction system has been evaluated at leading medical centers in Israel and USA in the past 12 months with over 250 patients tested. Some of the results were presented in two publications at the 2010 American Society of Neuroradiology (ASNR) annual meeting in Boston. These studies concluded that SafeCT allows for at least 50% dose reduction in brain CT scans, where the anatomy is most noise sensitive, and that routine use of SafeCT would decrease patient exposure to radiation. Commercialization of Safe CT is planned for the second half of 2011; it is pending FDA clearance (510k) and additional clinical studies, including the one proposed herein.

University Hospitals Case Medical Center and Case Western Reserve Universities, the collaborators in this proposal, have established global prominence in the field of imaging research and development and, in particular, the field of CT.

Our proposal will assess and fine-tune the SafeCT algorithms in conjunction with low-dose protocols for CT studies of various anatomies. SafeCT will be installed and integrated with the CT scanners at the collaborator's imaging facility. Low-dose protocols will be defined for different organs and the resulting images will be evaluated for image quality, visualization of structures and pathologies and for diagnostic quality. Low-dose SafeCT-processed images will be compared with full-dose studies as well as with low-dose images generated by recent top-tier scanners. The study will be performed at University Hospitals Case Medical Center under the supervision of Dr. Robert Gilkeson. Medic Vision, the lead applicant, will provide the SafeCT system and the professional support required.

The US CT market is the primary target for Medic Vision; the Israel-based company plans to open a principal place of business in the USA, to enable the distribution of low-dose SafeCT for use with installed CT scanners— well over 10,000 in the USA alone— as well as with many models of CT scanners currently on the market that have no recourse to safe and efficacious low-dose imaging. Medic Vision's proposed OTFMIP project will support the continued development and commercialization of SafeCT by developing low-dose protocols for CT scans and validating the clinical results, thus providing an innovative solution for the critical need to reduce radiation in CT scans performed by existing scanners.

Upon receiving the OTFMIP grant, the company will open its principal place of business in the state of Ohio. The proposed study and the establishment of Medic Vision's principal place of business will help bring to the state of Ohio new state-of-the-art image processing technologies along with high-quality research, and will help expand the state's technologically proficient workforce and global leadership position in the field of computed tomography.

Letter of Intent for FY2011 Ohio Third Frontier Medical Imagi

Lead Applicant's Name: Image IQ, Inc.
Contact Person: Dr. Amit VasANJI, Ph.D.
Address: Department of Biomedical Engineering
Cleveland Clinic Lerner Research Institute
Mailstop ND20
9500 Euclid Avenue
Cleveland, Ohio 44195
Office Phone: (216) 445-3411
Email: vasanja@ccf.org

Proposed Project Title: Expanding a State-of-the-Art Image Acquisition and Analysis Contract Research Organization to Support Life Science Research, Development and Discovery in the State of Ohio.

Estimated Grant Funds to be requested: \$800,000

Known Collaborator(s): Cleveland Clinic (CC)

Summary of the Proposed Project: In early 2011 the Cleveland Clinic is launching a commercial spin-out from an internal services center of their Lerner Research Institute (LRI). This spin out, named Image IQ Inc., will provide innovative and state-of-the-art image acquisition, processing, analysis and visualization services to clinical and commercial R&D endeavors in the Life Sciences industry. Over the past 7 years, as an internal department to LRI, Image IQ's client base (academic and commercial) has grown consistently through word-of-mouth referrals. Within the constraints of Cleveland Clinic corporate guidelines, the department could not increase its service offerings in order to accommodate a continually expanding user base.

As a newly formed Cleveland Clinic spin-off company, Image IQ addresses three specific life science markets:

- 1) Life Science Basic and Clinical Research Organizations (image acquisition device companies, research hospitals and institutions).
- 2) Pharmaceutical and Medical Device Companies (R&D and Product Development); and
- 3) Insurance Companies and Law Firms (Product Liability and Risk Management);

By offering a rare blend of biological, engineering and software development expertise, Image IQ enables its customers to accelerate research and product development, strengthen their risk management and product liability strategies and offers access to state-of-the-art imaging technologies. The company has the resources to provide researchers, clinicians, and commercial entities with multi-phase support including small animal research, clinical trial support and product failure retrospective studies (forensics).

As life science R&D and product development becomes increasingly complex, and as the FDA adopts stricter guidelines for establishing product safety and efficacy, high-end application specific (customized) image acquisition, analysis and visualization services will become the cornerstone of medical product innovation.

If awarded, grant monies from this proposal will be used to staff and procure additional leading-edge imaging equipment to augment the current capabilities of Image IQ. It is anticipated that with the new equipment and expert staff, Image IQ will require regular increases in staffing levels to grow and execute its business model. The positions that would be created will be high-

Letter of Intent for FY2011 Ohio Third Frontier Medical Imaging Program

paying, professional positions which will help retain the biomedical talent in the Northeast Ohio area. Image IQ will use Ohio Third Frontier funds to purchase key capital assets (e.g. *ex vivo* microcomputed tomography scanner and state-of-the-art automated digital microscope) and hire the necessary full-time employees to extract value from these assets and to accelerate the growth of its customer base within Ohio as well as attracting high-value contracts from outside the state.

11-615

December 14, 2010

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

Dear Ohio Department of Development:

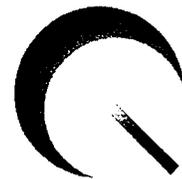
Please accept this letter of intent from Quality Electrodynamics, LLC for our Fiscal Year 2011 Ohio Third Frontier Medical Imaging Program ("OTFMIP") proposal.

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 & CEO
Contact Email: hiroyuki.fujita@qualedyn.com
Project Title: **Development and Commercialization of a Novel Imaging System to Determine Organ Viability**
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, including non-proton spectroscopy.

Organ transplantation is another vital area of significance in the healthcare industry because successful transplants and grafts cure a vast number of terminal diseases. For example, excised kidneys, for which demand has been increasing worldwide, to treat rising instances of renal failure, must remain in an icebox and in constant perfusion while awaiting transplant to keep them "alive." The long waiting list for kidney transplants (83,095 according to the United Network for Organ Sharing) has pressured the medical community into the use of non-standard donors, including donors after cardiac death as a source of additional organs. This trend has increased the need to determine the viability of the chosen kidney contained in the perfusor prior to the transplant into the patient. Preliminary clinical results indicate that the likelihood of kidney transplant success can be better understood by imaging other nuclei in the kidney through the use of MRI.



HF QED

Quality Electrodynamics ("QED") was founded 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 MRI component and system technology, ranked 11th in the nation on the 2009 Forbes' list of "America's Most Promising Top 20 Companies," and ranked 193rd in the nation of the 2010 *Inc* Magazine's list of "America's Fastest-Growing Top 500 Private Companies." In the category of "Healthcare," QED was named 13th in the nation of the list.

QED develops and manufactures MRI radiofrequency ("RF") detector coils for a number of anatomies and RF system 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.

For the FY2011 OTFMIP project, QED and its collaborators will propose to build upon Ohio's investments in the state's medical imaging cluster and QED's proven expertise in MRI coil and system development and commercialization to develop a high-field MRI system to determine donor organ viability prior to transplant. QED's proposed OTFMIP project will support the continued development and commercialization of novel high-field MRI system for monitoring an organ's viability prior to transplant, 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





1470 Enterprise Parkway
Twinsburg, OH 44087

p. **330.963.4083**
f. 330.963.4084
www.gvimd.com

December 14, 2010

FY2011 Ohio Third Frontier Medical Imaging Program (OTFMIP)
Ohio Department of Development
Technology Division
77 South High Street, 25th Floor
Columbus, Ohio 43215-6130
OTFMIP2011@development.ohio.gov

Lead Applicant

GVI Medical Devices, Inc.
1470 Enterprise Parkway
Twinsburg, Ohio 44087
Telephone 330-963-4083
Fax 330-963-4084

Contact Person

Mr. Geoffrey Cochrane
geoff.cochrane@gvimd.com
330-283-2334

Project Title

Expansion and Enhancement of Cardiac Nuclear and Molecular Imaging Product Line

Budget Request Estimate

\$950,000

Collaborators:

Emergency Room Diagnostics, LLC
The Cleveland Clinic
Valtronics Corp.

Attachment A Project Summary Expansion and Enhancement of Cardiac Nuclear and Molecular Imaging Product Line

GVI Medical Devices is a Twinsburg, OH based manufacturer and has been developing and shipping clinical nuclear medicine and molecular imaging products for 9 years. The funding applied for will allow GVI to leverage its existing patented technology and products (fully FDA cleared) in the development of additional products which address the clinical and competitive requirements of existing as well as emerging markets, both domestic and international (export).

Project Overview:

- Utilize latest available technology and expertise existing and/or under development at GVI as well as local collaborators (e.g. Valtronics) to enhance core imaging capabilities as follows:
 - Implement a compact, modular, light weight and extensible form acquisition/detector form factor with enhanced imaging capabilities that can be used in a broad range of products for domestic and export markets.
 - Enhance manufacturability thru best practices in order to increase the potential for local manufacture as well as over all competitiveness in cost sensitive markets (domestic and emerging).
 - Improve overall ruggedness, internationalization, serviceability and reliability.
- Implement a general purpose image acquisition and processing architecture (hardware and software) which can be leveraged in a broad range of clinical nuclear and molecular imaging products.
- Finalize the development and implementation of new and proprietary advanced image processing and visualization algorithms/technology that provides improved connectivity, enhanced workflows and productivity as well as improved diagnostic quality.



Ohio Third Frontier Medical Imaging Program

Letter of Intent The Ohio State University

Lead Applicant: The Ohio State University Office of Sponsored Programs
1960 Kenny Rd.
Columbus, OH 43210

Proposal Title: **Digital Imaging Analytics**

Budget Request (Estimated):

Capital:	\$ 400,000
<u>Operating:</u>	<u>\$ 600,000</u>
TOTAL:	\$1,000,000

Collaborators: American Health Technology (Mark Plaskow)

Contact: Michael V. Knopp, MD, PhD
The Ohio State University
Department of Radiology
395 W. 12th Ave, Room 430
Columbus, OH 43210

Phone: 614-293-9998

Fax: 614-293-9275

Email: knopp.16@osu.edu

Biomedical imaging technology requires a continuum of technological components starting with a device and imaging probe to generate images to the need of capable, and preferably quantitative, readouts. The continuous progress in the device and imaging probe technology necessitates even more rapid progress on the analytical side of medical imaging. With this innovative program, we intend to introduce an integrated portfolio of commercial products that are based upon advanced digital technologies to provide new capabilities with the focus of a continuum to use imaging as a hallmark of noninvasive diagnostics in an area of personalized medicine from multi-modal radiological imaging to digital pathology. We have identified a considerable unmet need of Ohio's technology partners in this promising, high-growth potential technology area that can rapidly capitalize on the globally interconnected market opportunities to lead to significant commercial employment and development opportunities in Ohio within the time frame required by the Medical Imaging Program.



Sandra Simon Halliburton, Ph.D.
Cardiovascular Imaging Scientist

Cleveland Clinic
9500 Euclid Avenue
Cleveland, OH 44195
216-444-2200

December 14, 2010

REF: Letter of intent for Ohio Third Frontier FY2011 Programs in Medical Imaging

Cleveland Clinic in collaboration with Philips Healthcare is very excited about the opportunity to submit a proposal for the Ohio Third Frontier FY2011 Program in Medical Imaging.

We are proposing to develop an Automated Radiation Dose Reduction Algorithm & Workflow for CT Scanning. 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

- Cleveland Clinic, 9500 Euclid Avenue, Cleveland, Ohio, 440 444-2200

Collaborators for the project include

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

Lead Applicant contact information, including email address:

- Sandra S. Halliburton, Ph.D., Imaging Institute, Cleveland Clinic, Cleveland, Ohio
Email: hallibs@ccf.org; phone 216 445-9447

Collaborator contact information, including email address:

- Jamie Valliant, Director, Product Marketing – Computed Tomography - Philips Healthcare, Cleveland Ohio
Email: jamie.valliant@philips.com; phone 440 483-7605

• Scott Pohlman, M.S., Director, Clinical Science – Computed Tomography - Philips Healthcare, Cleveland Ohio

E-mail: scott.pohlman@philips.com; phone 440 483-4398

Proposed project title:

- Automated Radiation Dose Reduction Algorithm & Workflow for CT Scanning

Estimated grant funds to be requested:

- \$ 1,000,000

Sincerely,
Cleveland Clinic (Cleveland),

Sandra S. Halliburton / Lisa Cleugh on behalf of Sandra
Sandra S. Halliburton, Imaging Scientist, Imaging Institute

Halliburton

Automated Radiation Dose Reduction Algorithm & Workflow for CT Scanning

Heightened concern regarding the increase in radiation exposure to the public from medical imaging, namely computed tomography (CT), and the associated biologic risk has motivated the desire for radiation reduction strategies that minimize radiation exposure while maintaining diagnostic image quality. A practical means of achieving this goal with existing scanner technology is modification of the x-ray tube voltage and tube current on the basis of patient size as appropriate for a given clinical indication for the CT scan. The x-ray tube voltage and/or tube current can be reduced for slimmer patients significantly lowering radiation exposure without a loss in diagnostic image quality. The consequence of selecting x-ray tube voltage and tube current values that are too low for a given patient size and clinical indication is excessive image noise and a non-diagnostic scan. The consequence of selecting x-ray parameter values that are too high is exposing the patient to an excess amount of radiation.

Automatic tube voltage and tube current selection is not, however, available on all CT systems (namely, tube voltage selection is not available on CT scanners manufactured by Philips). Development of an automated x-ray parameter selection tool provides a unique opportunity for the Cleveland Clinic and Philips to partner in an Ohio-based collaborative project. Cleveland Clinic and Philips believe such a tool should be integrated into the scanner platform and sold to all customers desiring to routinely reduce the delivery of radiation without compromising diagnostic quality and workflow.

Proof of concept has been demonstrated through an offline, non-integrated software tool developed by Cleveland Clinic. This tool has been applied to a large number of patients in pilot studies and has demonstrated the ability of the customized algorithm to provide more consistent results with respect to noise across patients compared to technologist-only selection of parameters. The benefits are so great that the tool is now in daily use at the Cleveland Clinic on cardiovascular patients. Its limitations are that it is not integrated and, thereby, negatively impacts workflow, and that it does not completely address quality assurance issues.

The purpose of the proposed project is to develop algorithms and workflow with the following end-user benefits:

1. An objective means of automatically determining the appropriate (dose influencing) x-ray parameters for each patient for a given CT examination.
2. A simple workflow utilizing information routinely acquired at the start of each CT examination.
3. Consistency in dose values in clinical departments having multiple operators and challenging patient types.

In addition to the aforementioned clinical benefits of this novel technology, the collaboration between the Cleveland Clinic and Philips will facilitate job creation in northeast Ohio through the research, design, implementation, and training associated with the resulting new systems.

Grant: 2011 OTFMIP LOI

11-619

Ohio Third Frontier Medical Imaging Program

Lead Applicant: Francis Michael Walsh, M.D., MBA, CPE, FACPE, FCAPE (Distinguished)

Phone Number: 419-534-3251; 419-350-4852

Contact Person: F. Michael Walsh, M.D.

Email Address: fmwalsh@clm-pml.com

Project Title: Diagnostic Electronic Medical Record Imaging Technologies

Estimated Grant Funds: \$800,000.00

Known Collaborators: 1) The Toledo Hospital; 2) The Toledo Clinic, Department of Oncology; 3) ProMedica Cancer Institute, Toledo, OH; 4) Toledo Radiological Associates; 5) Consultants in Laboratory Medicine of Greater Toledo, Inc.; 6) Sepetys & Associates, Ann Arbor, MI; 7) The University of Toledo College of Medicine, Department of Pathology; 8) Bioimagine, Division of Ventana, Roche Holdings, Sunnyvale, CA; 9) Aperio, Vista, CA; 10) M L Holdings, LLC, Bay Harbor, MI

Summary of the Proposed Project: (See separate page below)

Grant: 2011 OTFMIP LOI

Ohio Third Frontier Medical Imaging Program

Project Title: Diagnostic Electronic Medical Record Imaging Technologies

Summary of the Proposed Project:

To further develop a diagnostic cockpit, integrating radiology and anatomic pathology images, laboratory medicine, molecular markers and clinical oncology with patient data to improve the specificity, sensitivity, accuracy and turn-around of testing results generated by multiple and unrelated diagnostic images. The diagnostic integration model concept has been designed by CMIT in conjunction with Bioimagene prior to its sale to the Ventana Division of Roche. Ventana has indicated no interest in pursuing to image integration other than in pathology. The project requires the implementation of digital pathology along with the development of multiple interfaces incorporating the diagnostic images from the radiology information system and PAC system. The images are then applied to specific diagnostic protocols and order sets that have been designed by multi-disciplinary groups so as to standardize diagnostic testing and interpretation of diagnostic images. CMIT and its partners are developing diagnostic algorithms that will allow for the interfacing of multiple information systems including multiple images using cloud technology. The integration will yield a specific patient-focused and comprehensive report generated by a physician which addresses potential discrepancies and correlates multiple diagnostic images to the specific disease process. The report has a defined CPT code and is reimbursed by third-party carriers including Medicare and Medicaid. The prototype has previously been marketed and found to be relevant, widely accepted (95% acceptance of using physicians) and reimbursable. To expand the market applicability, it is required to create a diagnostic engine that will allow for the image data integration into a multi-screened workstation creating the diagnostic cockpit. The physician will thus have the ability to view all pertinent radiographic and other images from MRI and PET as well as digital images from gross pathology, microscopic slides, and molecular imaging.

The funding has been achieved from private sources, Small Business Administration loans, and bank financing. Commercialization of the project is estimated to be within six months and the company has identified and qualified clients throughout the United States. Exit is designed either through initial public offering or acquisition by a partner or another entity in the diagnostic electronic arena. The company is incorporated as Consultants Managing Information Technology Inc., 3170 W. Central Avenue, Toledo, OH 43606, with Employer Identification Number: 27-4227379.

The next component of the commercialization is the integration of the diagnostic images from The Toledo Hospital's Breast Clinic using digital mammograms and MRI's, along with digital images of: 1) the gross core biopsies, and 2) microscopic detail which will have image overlay to establish that the biopsies, in fact, were taken from the location specifically identified by the interpreting radiologist. Future integration of diagnostic images from other tissue sources to incorporate multiple fields of oncology utilizing the multi-disciplinary teams of the ProMedica Cancer Institute to establish the appropriate protocols is planned for mid-2011.

The product is designed to address the non-integration and piecemeal to haphazard fashion that diagnostic imaging reports are generated by different sections of the Department of Radiology, other radiology providers, clinical laboratories and the Department of Pathology, including external consultants. The diagnostic imaging data sets received in variable formats without comprehensive correlation often lead to repeat or inappropriate testing or therapeutic regimes that are less than efficacious. The product is designed to streamline information into a diagnostic EMR that reduces unnecessary or delayed testing or inappropriate therapy by correlation of the multiple images to the patient's medical condition. The use of diagnostic images obtained from different image modalities in conjunction with a multi-disciplinary interpretative approach yields a consistent, final report. This significantly enhances the multiple and at times discrepant reports that can be rendered when viewing imaging technology on an individual image basis rather than in context with the overall patient condition.

11-620



Marc F. Pelletier
VP-Chief Scientific Officer
11,000 Cedar Ave, Suite 270
Cleveland, OH, 44106-3008

Tel: 216-231-2679
marc.pelletier@aeromics.com

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

Subject: 2011 OTFMIP LOI, OTFMIP@development.ohio.gov

Due: January 18th, 2010

Aeromics, LLC and collaborating institutions intend to submit a proposal in response to the 2011 Ohio Third Frontier Medical Imaging Program

Project Title: "Development of AQP4 Radio-Ligands for Imaging the Blood-Brain Barrier."

Estimated Grant Funds Requested: \$2,250,000

Lead Applicant:

Aeromics, LLC
11000 Cedar Ave,
Cleveland, OH 44106

Contact Person: Marc F. Pelletier, Aeromics, LLC. 216-231-2679

Collaborating Institutions: Aeromics will collaborate with Case Western Reserve University, as well as other academic, research and commercial institutions.

Summary: Please see attachment for 1 page summary.

Sincerely,

Marc F. Pelletier

VP-Chief Scientific Officer

Project Summary

Brain injuries from trauma and cerebrovascular disease are a major cause of patient disability and mortality in the United States. Each year nearly 800,000 Americans suffer a new or recurrent stroke (“brain attack”). Stroke is the third leading cause of death with 137,000 annual fatalities. It is the leading cause of disability and has an annual medical cost of about \$70 billion. Furthermore, traumatic brain injury (TBI) is responsible for ~1.7 million hospitalizations and ~50,000 deaths each year.

A major contributor to brain injury, especially secondary injury from either a traumatic or vascular event, is cerebral edema (CE)—increased brain water content. This may lead to increased intracranial pressure (ICP), and decreased cerebral perfusion pressure (CPP) with initiation of further necrotic and apoptotic processes. Patients that endure the period of increased ICP (~2 - 4 days) are likely to survive the underlying brain injury but often with poorer functional outcomes. Edema is also a major contributor to damage caused by several other CNS pathologies such as: **traumatic spinal-cord injury**, **bacterial meningitis**, and—for sojourners to high altitude—**acute mountain sickness**.

Central in the development of cerebral and spinal-cord edema is the H₂O channel aquaporin-4 (AQP4) at the blood-brain barrier (BBB) and glia limitans (Fig 1). AQP4 is an attractive drug target because AQP4-null mice show substantially improved survivability over their wild-type counterparts in experimental models of ischemic stroke, retinal ischemia, bacterial meningitis and water intoxication.

Aeromics’ long-term goal is to modulate H₂O transport and gas permeability across the BBB. In an NINDS/NIH Phase I SBIR program (1R43NS060199), we developed a high-throughput assay for blockers of AQP4-mediated H₂O entry. In a pilot screen of 21,000 compounds, we identified 6 hits in 4 structural classes. We have also developed two sensitive kinetic bio-assays (based on electrical impedance and light scattering) that we are currently using to determine structure-activity relationships (SARs) on these molecular hits as part of an ongoing Phase II SBIR program (2R44NS060199).

Our unique approach was gleaned from the observation that several AQPs—including AQP4—are not only water channels but also gas channels. AQP4’s O₂ and CO₂ permeabilities may explain the up-regulation of AQP4 in the potentially viable penumbra that surrounds the irreversibly injured “ischemic core” in a stroke. In an exciting development, the Boron Lab at Case has shown that H₂O and CO₂ take different pathways through the AQP4 homotetramer, with H₂O moving through the four conventional aquapores (center of each monomer) and CO₂ moving through the central pore, which is formed at the interface of the four monomers (Fig 1). Molecular dynamics simulations predict that O₂ takes the same route as CO₂. Indeed, the Boron Lab finds that it is possible to block H₂O permeability in AQP1 while preserving CO₂ movement through the central pore. Replicating this result for AQP4 in a drug for humans could substantially improve the clinical outcome in all of the conditions noted above by reducing edema without compromising O₂ delivery to the tissue.

Current methodologies for imaging the BBB rely on mass transport measurements and arterial spin labeling that are not functionally targeted and of limited resolution. In this proposal, Aeromics plans to develop radioligands for AQP4, thus directly targeting an integral component of the BBB. To reach our goal we will:

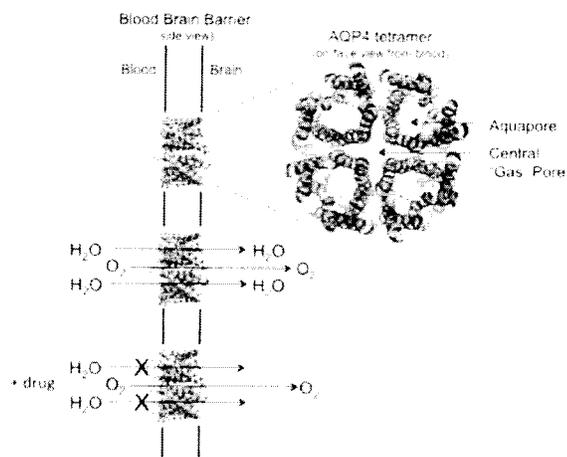
Aim 1: *Develop short and long half-life AQP4 radio-ligands using existing Aeromics AQP4 antagonists.* Leveraging compounds identified in our drug discovery program for AQP4, we will (1) utilize medicinal chemistry to improve ligand-binding affinities, (2) develop radio-labeled ligands with short (i.e. ¹⁸F, t_{1/2} = 110 min) and long (i.e. ¹²⁴I, t_{1/2} = 4.2 d) half-life tracers and (3) validate AQP4-ligand interactions using *in vitro* binding assays.

Aim 2: *Develop novel short and long half-life AQP4 radio-ligands.* To ensure that enough compounds are available to transition through later stages in the development of biomolecular imaging agents, we will perform a high-throughput screen to identify additional chemical structures. As in Aim 1, medicinal chemistry will be performed to optimize AQP4 affinity, and radio-ligands will be validated using *in vitro* binding assays.

Aim 3: *Proof of Principle Pilot Studies using rodent MicroPET.* We will assess AQP4 radio-ligand binding *in vivo* using the MicroPET facility at Case Western Reserve University. We will test leads for direct AQP4 interaction at the BBB *in vivo* and perform differential binding studies using a three compartment ligand-binding model and Logan plots to develop molecular imaging of AQP4.

Developing Aeromics’ current leads and identifying new core structures will allow development of molecular and clinical imaging reagents for the BBB and new techniques to further understand *in vivo* anatomy, pharmacology and pathology of AQP4 in brain injury.

FIG 1 H₂O AND GAS PERMEABILITY THROUGH AQP4 AT THE BBB





17700 Oakwood Village, Columbus, Ohio 43240

December 13, 2010

The Ohio Department of Development
Technology and Innovation Division
77 South High Street, 25th Floor
Columbus, OH 43215
OTFMIP2011@development.ohio.gov

2011 OTFMIP Letter of Intent

Dear Administrator,

ViewRay Incorporated along with its collaborator, Case Western Reserve University, intends to submit a proposal in response to the 2011 Ohio Third Frontier Medical Imaging Program. The summary of the proposed project is found on the following page.

Project Title: Development and Commercialization of Novel Image-Guided Therapy Systems

Estimated Grant Funds Requested: 1 proposal for \$1,000,000.00

Lead Applicant: ViewRay Incorporated

Address: 2 Thermo Fisher Way
Oakwood Village, Ohio 44146

Telephone: 440-703-3210

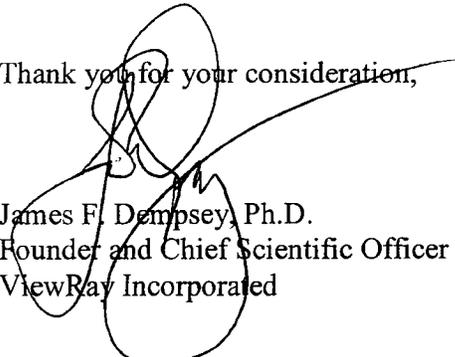
Contact Person: James F. Dempsey, Ph.D.

Contact Email Address: jfdempsey@viewray.com

Known Collaborator: Case Western Reserve University

Summary of Proposed Project: Please See following page

Thank you for your consideration,



James F. Dempsey, Ph.D.
Founder and Chief Scientific Officer
ViewRay Incorporated

Summary of Proposed Project by ViewRay Inc.

ViewRay, Inc. is a privately held medical device company creating a novel image-guided radiation therapy system for the treatment of cancer. ViewRay's current technology merges established Magnetic Resonance Imaging (MRI) technology with optimized cobalt-60 radiotherapy, and is designed to be the world's first real-time image guided radiotherapy system. Both MRI and radiotherapy are growing markets, and ViewRay has already secured an agreement with Washington University in St. Louis for preclinical testing and validation. Presently, ViewRay is working to secure clearance for commercial distribution of this system.

We propose to develop new proprietary image-guided therapy techniques that will expand the capabilities of ViewRay's system and broaden the scope of potential end users. ViewRay's collaboration with Case Western Reserve University will take advantage of advanced engineering and technical design and development capabilities.

ViewRay's novel system and unique expertise provide a sustainable competitive advantage and pose an opportunity for strengthening the medical imaging and radiotherapy industry in Northeast Ohio by addressing unmet clinical needs in a market with high growth potential.



1470 Enterprise Parkway
Twinsburg, OH 44087

p. **330.963.4083**
f. 330.963.4084
www.gvimd.com

December 14, 2010

FY2011 Ohio Third Frontier Medical Imaging Program (OTFMIP)
Ohio Department of Development
Technology Division
77 South High Street, 25th Floor
Columbus, Ohio 43215-6130
OTFMIP2011@development.ohio.gov

Lead Applicant

GVI Medical Devices, Inc.
1470 Enterprise Parkway
Twinsburg, Ohio 44087
Telephone 330-963-4083
Fax 330-963-4084

Contact Person

Mr. Geoffrey Cochrane
geoff.cochrane@gvimd.com
330-283-2334

Project Title

Pre-Clinical Multi-Modality Small Animal Imaging System

Budget Request Estimate

\$1,000,000

Collaborators:

The Cleveland Clinic
Valtronics Corp.

Attachment A Project Summary Pre-Clinical Multi-Modality Small Animal Imaging System

GVI Medical Devices is a Twinsburg, OH based manufacturer and has been developing and shipping clinical nuclear medicine and molecular imaging products for 9 years.

GVI proposes to finalize development and take to market a family of SPECT, PET, CT pre-clinical (animal) imaging systems for use in pharmaceutical development and biomedical research. The systems make use of advanced acquisition and reconstruction technology that has been under development at GVI since 2006. A common hardware platform (computing and gantry) and software (acquisition, reconstruction, and visualization) architecture allows GVI to cost effectively configure these as either single modality devices or in any multi-modality (SPECT/CT, PET/CT, SPECT/PET, SPECT/PET/CT) combination.

The SPECT subsystem will utilize GVI's advanced clinical detector technology, which, in combination with the aforementioned acquisition and reconstruction, delivers state of the art sensitivity and resolution at a significant cost advantage over other pre-clinical systems on the market. Time-to-market, product cost, and technical risk will be further reduced by leveraging GVI's clinical product expertise, technology and manufacturing processes.

The lower cost, flexible, high performance family of systems that we propose is well positioned to effectively address the increasing demand for pre-clinical imaging in the development of pharmaceuticals.



Medical Skin Imaging Device

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 medical disciplines such as plastic surgery, wound healing, dermatology, endocrinology, oncology, trauma, and burns. Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), and ultrasound are used routinely to image inside 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 stratum corneum, epidermis, and dermis layers of the skin.

Our proposed effort will result in a portable, high tech, but 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 robust 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 accuracy and 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 a time when the emphasis is on 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, skin diseases, 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, 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

Hansen, Andrew

From: Craig Hartz [chartz@aurumdx.com]
Sent: Tuesday, December 14, 2010 1:29 PM
To: OTFMIP2011
Subject: 2011 OTFMIP LOI
Attachments: Project Title submitted to ODOD for Third Frontier Funding Dec 14 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

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KRobson@aurumdx.com

Mark E. Krohn

Aurum Dx LLC

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MKrohn@aurumdx.com

Robert J. H. McManus

Aurum Dx LLC

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(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;



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, CLI and ALI the earliest forms of atherosclerosis and some of our most costly chronic diseases for our population.

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, delivery, and on going support over the next 3 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 diabetes, heart attaches and strokes.

Collaborative efforts are currently in place and underway with the Quantum Group, InfoCision, Enovate, a major telecommunication vendor, multiple companies skilled and certified to read and report on the procedures and suppliers of medical modalities and information technology component suppliers. Some of these collaborators are based in Ohio with major employee bases and others will be providing us with materials and resources critical for us to meet our goal of producing 500 units for delivery during our first year of production.



11-625

AllTech Medical Systems America, Inc.

The Ohio Department of Development
Technology and Innovation Division
77 South High Street, 25th Floor
Columbus, OH 43215
OTFMIP2011@development.ohio.gov

2011 OTFMIP Letter of Intent

To the Program Officials:

AllTech Medical Systems America, Inc., in conjunction with its partner institution detailed below, intends to submit a proposal in response to the 2011 Ohio Third Frontier Medical Imaging Program.

Project Title: Development of a Novel Spectrometer as a Critical Component of a High-Performance, Low-Cost Total MRI System.

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

Lead Applicant: AllTech Medical Systems America, Incorporated
6551 Cochran Road
Solon, Ohio 44139

Contact Person: Michael Thompson, Ph.D.
Michael.Thompson@alltechmedusa.com

Known Collaborator: Case Western Reserve University

A one-page description of the proposed project follows.

Respectfully submitted,

Michael Thompson, Ph.D.
AllTech Medical Systems America, Inc.

**6551 Cochran Road
Solon, OH 44139
Telephone: (440) 424-2240 Fax: (440) 424-2255**



AllTech Medical Systems America, Inc.

PROJECT DESCRIPTION

AllTech Medical Systems America, Inc. has created a revolutionary high-performance, low-cost total MRI system that improves on the capabilities of existing systems while reducing cost by 30%. Last year AllTech launched its innovative ECHOSTAR Centauri 1.5 Tesla system, disrupting the existing market and allowing AllTech to enter underserved, emerging markets with high growth potential.

AllTech has capitalized on the Northeast-Ohio strong engineering, technical and manufacturing base to develop its first-generation spectrometer, which can be considered the MRI "brain" that connects the main magnet, gradient system, RF, and interfacing components, and controls pulse sequence design and signal processing. All aspects of the spectrometer, both hardware and software, were created, developed, tested, manufactured and exported from Solon, Ohio.

The spectrometer is a critical component of AllTech's system and its capabilities will allow AllTech to gain a sustainable advantage over its competition. We propose to develop the next-generation spectrometer, optimizing electronics and detection systems to address the new demands of emerging markets and leveraging the existing engineering base to strengthen the medical imaging industry in Northeast Ohio.

**6551 Cochran Road
Solon, OH 44139
Telephone: (440) 424-2240 Fax: (440) 424-2255**



11-626

Ohio Department of Development
Third Frontier Medical Imaging Program
77 South High Street
Columbus, Ohio 43215

Letter of Intent
Ohio Third Frontier Medical Imaging Program (FY2011)

Lead Applicant: Kettering Health Network

Contact Person: Jason G. Parker, Ph.D.
Innovation Center
Kettering Health Network
3535 Southern Blvd
Boonshoft Tower, 4th Floor
Kettering, OH 45429
(937) 395-8483
jason.parker@khnetwork.org

Project Title: An Automated Human-Machine Interface for Patient Communication in the Magnetic Resonance Imaging Environment

Funding Request: \$1,000,000.00

Collaborators: Siemens Medical Solutions, Inc.

Project Summary: Magnetic resonance imaging is a loud, time consuming, and space-restricted diagnostic imaging modality and can be a challenging procedure for sick patients. Furthermore, emerging functional MRI techniques require patients to engage in specific, highly controlled repetitive tasks which may create stress and fatigue and potentially lead to early-termination of the procedure. The purpose of this work is to commercialize an automated human-machine interface for patient communication and engagement in the MRI environment that has recently been developed at the Kettering Health Network. The system uses standard functional MRI hardware to provide patients with information related to the length of their scan and time remaining in the procedure, as well as entertainment options such as interactive picture slideshows, radio, and television. The system also offers functional MRI tasks that show patients movies of the task to be performed (such as repetitive clenching of the fist), audio and visual cues for beginning and completing tasks, countdown clocks for task repetition, and the number of repetitions remaining. We have demonstrated that the system reduces patient stress levels and promotes procedure completion, while maintaining the high-quality anatomical and functional imaging capabilities of MRI.



526 South Main St. #812
Akron, Ohio 44311
www.fmimaging.com
330.253.0200
December 14, 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

Lead Applicant: FMI Technologies Inc.
526 South Main Street #812
Akron, Ohio 44311

Administrative Contact: William K. McCroskey
President/CEO
Direct Voice: 330-253-0200 x402
william.mccroskey@fmimaging.com

Technical Contacts: William D. Dickinson – Dir. R&D
Direct Voice: 330-253-0200
bill.dickinson@fmimaging.com

Project Title: “Commercialization of the ScintiStar Cardiac LPX PET/CT for Myocardial Perfusion Imaging and CT Calcium Scoring for Global Markets”

Estimated Grant Funds to be Requested: \$1,000,000.00 for Project
\$1,000,000 Wright Funds for ScintiStar Cardiac LPX PET/CT at the **“Global Center of Multi-Modality Imaging for the Heart, Brain, Breast, and Bones.”**

Known Collaborators:

1. **Lantheus Medical Imaging:**, Stephen Haber PhD, Senior Director of Business and Corporate Development, 331 Treble Cove Road, N. Billerica, MA 01862 Tel: 978-671-8357
2. **Cleveland Clinic:** – Thomas Marwick MD Cardiovascular Medicine 9500 Euclid Ave. Cleveland, Ohio 44195
3. **Akron General Medical Center:**, Tim Stover MD – President Outpatient Service, George Litman MD- Cardiologist-Heart & Vascular Center, Leslie Tobias MD- Cardiologist- Heart & Vascular Center, Vinayak Hegde MD –Cardiologist, Robert Anthony, Technology Transfer Office, 400 Wabash Ave., Akron, Ohio 44307 (330) 344-7285

4. **Summa Health System**, Ken Berkovits, MD – Chairman of Summa’s Department of Cardiology; Steven Schmidt PhD, VP for Clinical Research & Innovation; Daniel Finelli MD – 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 Director of Nuclear Medicine/PET, Martin Satter PhD –Physicists Nuclear Medicine, 3535 Southern Blvd. Kettering, Ohio 45429 (937) 298-4331
6. **University of Dayton – Electro-Optics Program:** – Joseph Haus PhD Director, 300 College Park, Dayton, Ohio 45402
7. **Wright State University:** – Computer Science & Engr. Arthur Goshtasby Professor and Director of Graduate Program- Imaging registration and fusion software, 3640 Colonel Glenn Hwy, Dayton, Ohio 45435 (937)775-5170
8. **Akron Biomedical Corridor:** – Robert Bowman- Deputy Mayor, Akron, and **Akron Global Business Accelerator:**, Mike LeHere – Accelerator CEO, Terry Martell – Director of Operations and Bus. Dev., 526 South Main St., Akron, Ohio 44311
9. **Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM):**, Walter Horton, VP for Research, Neels Van der Schyf, Professor and Chair, Pharmaceutical Sciences, 4209 State Route 44, PO Box 95, Rootstown, Ohio 44272 (330)325-6290

Project Summary:

FMI is proposing a demonstration program for commercialization of its ScintiStar Cardiac LPX PET/CT systems. FMI’s technology for commercialization is small footprint highly sensitive molecular imaging system for cardiovascular diseases. FMI has developed unique multimodal imaging with 3 systems in one that is 1/5 the cost and 1/5 the size as compared to current whole body PET/CT systems. FMI and its clinical and medical imaging collaborators desire to show the imaging capability at Ohio’s academic medical centers and community hospitals. This program will enable FMI to obtain FDA 510k approval on the systems and sell units. With FDA 510k approval, FMI will be producing the units in Ohio along with other 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.

Also, FMI and its collaborators are applying for Ohio Third Frontier Wright Project funds to establish a section in the “**Global Center for Multimodality Imaging for the Heart, Brain, Breast, and Bones.**”

Program Projected Plans:

- Build and install a ScintiStar Cardiac for clinical validation of cardiovascular molecular, functional, and morphological imaging at collaborator sites.
- Show Value Proposition for the ScintiStar Cardiac

- Submit FDA 510k application for approval of the ScintiStar Cardiac LPX PET/CT system.
- This clinical validation will enable sales in the US, Europe, and China.

“Global Center for Multimodality Imaging of the Heart, Brain, Breast, and Bones”
in Akron’s Biomedical Corridor.

- Focused development for anatomical and molecular imaging for the heart, brain, breast, and bones.
- Fused modalities include FMI’s PET,CT, SPECT with its ScintiStar Programs.
- New program for ScintiStar PET/MR imaging of the brain, heart, and breast.
- Ohio medical imaging cluster development with global networks to China, Germany, and Finland.

FMI’s commercialization of the ScintiStar Cardiac LPX PET/CT 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 the medical imaging supply chain in mind to support the development, marketing, and sales of this novel technology.

Regards,

William K. McCroskey
President/CEO
FMI Technologies, Inc.



526 South Main St. #812
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330.253.0200
December 14, 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

Lead Applicant: FMI Technologies Inc.
526 South Main Street #812
Akron, Ohio 44311

Administrative Contact: William K. McCroskey
President/CEO
Direct Voice: 330-253-0200 x402
william.mccroskey@fmimaging.com

Technical Contacts: William D. Dickinson – Dir. R&D
Direct Voice: 330-253-0200
bill.dickinson@fmimaging.com

Project Title: “Commercialization of the ScintiStar Neuro LPX PET/CT/SPECT for Neuro Stroke, Tumor, Dementia, and Alzheimer’s Imaging for Global Markets”

Estimated Grant Funds to be Requested: \$1,000,000.00 for Project
\$1,000,000 Wright Funds for ScintiStar Neuro LPX PET/CT/SPECT at the **“Global Center of Multi-Modality Imaging for the Heart, Brain, Breast, and Bones.”**

Known Collaborators:

1. **Cleveland Clinic** – Neurological Institute – Micheal Phillips MD- Vice Chairman, Research and Academic Affairs, Imaging Institute 9500 Euclid Avenue, Cleveland, Ohio 44195
2. **Summa Health System**, Kyle Allen MD, Chief, Division of Geriatric Medicine; Steven Schmidt PhD, System Director of Research; Daniel Finelli MD – 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
3. **Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM)**, Walter Horton, VP for Research, Neels Van der Schyf, Professor and Chair, Pharmaceutical Sciences, 4209 State Route 44, PO Box 95, Rootstown, Ohio 44272 (330)325-6290

4. **Ohio State Wright Center of Innovation:** Michael Knopp MD, PhD –Director, Wright Center of Innovation, Robert McKenney-PhD, 395 W. 12th Avenue, Room 430, Columbus, Ohio 43210 (614)293.9998
5. **Kettering Medical Center** , Joseph Mantil Director of Nuclear Medicine/PET, Martin Satter PhD –Physicists Nuclear Medicine, 3535 Southern Blvd. Kettering, Ohio 45429 (937) 298-4331
6. **University of Dayton – Electro-Optics Program** – Joseph Haus PhD Director, 300 College Park, Dayton, Ohio 45402
7. **Wright State University** – Computer Science & Engr. Arthur Goshtasby Professor and Director of Graduate Program- Imaging registration and fusion software, 3640 Colonel Glenn Hwy, Dayton, Ohio 45435 (937)775-5170
8. **Akron Biomedical Corridor** – Robert Bowman- Deputy Mayor, Akron, and **Akron Global Business Accelerator**, Mike LeHere – Accelerator CEO, Terry Martell – Director of Operations and Bus. Dev., 526 South Main St., Akron, Ohio 44311

Project Summary:

FMI is proposing a demonstration program for commercialization of its ScintiStar Neuro LPX PET/CT/SPECT systems. FMI's technology for commercialization is small footprint highly sensitive molecular imaging systems for Neurological diseases. FMI has developed unique multimodal imaging with 3 systems in one that is 1/5 the cost and 1/5 the size as compared to current whole body PET/CT systems. FMI and its clinical and medical imaging collaborators desire to show the imaging capability at Ohio's academic medical centers and community hospitals. This program will enable FMI to obtain FDA 510k approval on the systems and sell units. With FDA 510k approval, FMI will be producing the units in Ohio along with other medical imaging supply chain businesses. With this program FMI will create 100-150 jobs with global utilization of the ScintiStar Systems over the next 5 years.

Also, FMI and its collaborators are applying for Ohio Third Frontier Wright Project funds to establish a section in the "**Global Center for Multimodality Imaging for the Heart, Brain, Breast, and Bones.**"

Program Projected Plans:

- Build and install a ScintiStar Neuro LPX PET/CT/SPECT for clinical validation of Neuro molecular, functional, and morphological imaging at collaborator sites.
- Show Value Proposition for the ScintiStar Neuro
- Submit FDA 510k application for approval of the ScintiStar Neuro LPX PET/CT/SPECT
- This clinical validation will enable sales in the US, Europe, and China.

“Global Center for Multimodality Imaging of the Heart, Brain, Breast, and Bones”

in Akron's Biomedical Corridor.

- Focused development for anatomical and molecular imaging for the heart, brain, breast, and bones.
- Fused modalities include FMI's PET, CT, SPECT with its ScintiStar Programs.
- New program for ScintiStar PET/MR imaging of the brain, heart, and breast.
- Ohio medical imaging cluster development with global networks to China, Germany, and Finland.

FMI's Commercialization of ScintiStar Neuro LPX PET/CT for organ specific imaging is key outcome of this proposed work to create high technology medical imaging jobs in the State of Ohio.

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

Regards,

William K. McCroskey

President/CEO
FMI Technologies, Inc.



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Ohio Department of Development
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Attention: Ohio Third Frontier Medical Imaging Program
77 South High Street, 25th Floor
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Lead Applicant: FMI Technologies Inc.
526 South Main Street #812
Akron, Ohio 44311

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

Technical Contacts: William D. Dickinson – Dir. R&D
Direct Voice: 330-253-0200
bill.dickinson@fmimaging.com

Project Title: “Commercialization of the ScintiStar Mammo LPX PET/CT for Breast Cancer Imaging for Global Markets”

Estimated Grant Funds to be requested: \$1,000,000.00 for Project
\$1,000,000 Wright Funds for ScintiStar Mammo
LPX PET/CT/SPECT at the “**Global Center of
Multi-Modality Imaging for the Heart, Brain,
Breast, and Bones.**”

Known Collaborators:

1. **Akron General Medical Center:**, Tim Stover MD – President Outpatient Service, Andrew Fenton MD – Breast surgeon, Daniel Guyton MD – Dir. Surgery , Robert Anthony, Technology Transfer Office, 400 Wabash Ave., Akron, Ohio 44307 (330) 344-7285
2. **Summa Health System**, Douglas Trochelman, MD – Medical Director of Oncology, Summa Health System’s Cooper Cancer Center; Gary Williams, MD – Surgeon; Victoria van Fossen, MD – Surgeon; Steven Schmidt PhD, VP of Clinical Research & Innovation; Daniel Finelli MD – 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

3. **Ohio State Wright Center of Innovation:** Michael Knopp MD, PhD –Director, Wright Center of Innovation, Robert McKenney-PhD, 395 W. 12th Avenue, Room 430, Columbus, Ohio 43210 (614)293.9998
4. **Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM),** Walter Horton, VP for Research, Neels Van der Schyf, Professor and Chair, Pharmaceutical Sciences, 4209 State Route 44, PO Box 95, Rootstown, Ohio 44272 (330)325-6290
5. **Kettering Medical Center** , Joseph Mantil Director of Nuclear Medicine/PET, Martin Satter PhD –Physicists Nuclear Medicine, 3535 Southern Blvd. Kettering, Ohio 45429 (937) 298-4331
6. **University of Dayton – Electro-Optics Program** – Joseph Haus PhD Director, 300 College Park, Dayton, Ohio 45402
7. **Wright State University** – Computer Science & Engr. Arthur Goshtasby Professor and Director of Graduate Program- Imaging registration and fusion software, 3640 Colonel Glenn Hwy, Dayton, Ohio 45435 (937)775-5170
8. **Akron Biomedical Corridor** – Robert Bowman- Deputy Mayor, Akron, and **Akron Global Business Accelerator**, Mike LeHere – Accelerator CEO, Terry Martell – Director of Operations and Bus. Dev., 526 South Main St., Akron, Ohio 44311

Project Summary:

FMI is proposing a demonstration program for commercialization of its ScintiStar Mammo LPX PET/CT systems. FMI's technology for commercialization is small footprint highly sensitive molecular imaging systems for Breast diseases. FMI has developed unique multimodal imaging with 3 systems in one that is 1/5 the cost and 1/5 the size as compared to current whole body PET/CT systems. FMI and its clinical and medical imaging collaborators desire to show the imaging capability at Ohio's academic medical centers and community hospitals. This program will enable FMI to obtain FDA 510k approval on the systems and sell units. With FDA 510k approval, FMI will be producing the units in Ohio along with other 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.

Also, FMI and its collaborators are applying for Ohio Third Frontier Wright Project funds to establish a section in the **“Global Center for Multimodality Imaging for the Heart, Brain, Breast, and Bones.”**

Program Projected Plans:

- Build and install a ScintiStar Mammo LPX PET/CT for clinical validation for Breast molecular, functional, and morphological imaging validation at collaborator sites.
- Show Value Proposition for the ScintiStar Mammo LPX PET/CT
- Submit FDA 510k application for approval of the ScintiStar Mammo

- This clinical validation will enable sales in the US, Europe, and China.

“Global Center for Multimodality Imaging of the Heart, Brain, Breast, and Bones”

in Akron’s Biomedical Corridor.

- Focused development for anatomical and molecular imaging for the heart, brain, breast, and bones.
- Fused modalities include FMI’s PET,CT, SPECT with its ScintiStar Programs.
- New program for ScintiStar PET/MR imaging of the brain, heart, and breast.
- Ohio medical imaging cluster development with global networks to China, Germany, and Finland.

FMI’s Commercialization of ScintiStar Mammo LPX PET/CT for organ specific imaging is key outcome of this proposed work to create high technology medical imaging jobs in the state of Ohio.

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

Regards,

William K. McCroskey

President/CEO
FMI Technologies, Inc.



526 South Main St. #812
 Akron, Ohio 44311
www.fmimaging.com
 330.253.0200
 December 14, 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

Lead Applicant: FMI Technologies Inc.
 526 South Main Street #812
 Akron, Ohio 44311

Administrative Contact: William K. McCroskey
 President/CEO
 Direct Voice: 330-253-0200 x402
William.mccroskey@fmimaging.com

Technical Contacts: William D. Dickinson – Dir. R&D
 Direct Voice: 330-253-0200
bill.dickinson@fmimaging.com

Project Title: “Commercialization of the ScintiStar Orthopedic LPX PET/CT for Bone Disease and Bio Materials Imaging for Global Markets”

Estimated Grant Funds to be requested: \$1,000,000.00 for Project
 \$1,000,000 Wright Funds for ScintiStar Mammo
 LPX PET/CT/SPECT at the **“Global Center of
 Multi-Modality Imaging for the Heart, Brain,
 Breast, and Bones.”**

Known Collaborators:

1. **Turku University Central Hospital:** Hannu Aro MD PhD, Dir. Orthopedics, Turku, Finland
2. **Austen BioInnovation Institute:**, Dr. Frank L. Douglas, Austen BioInnovation Institute in Akron, 1 South Main Street, Suite 401, Akron, OH 44308
3. **Akron General Medical Center:**, Tim Stover MD – President Outpatient Service, George Litman MD- Tom Tompson MD - Orthopedics, Robert Anthony, Technology Transfer Office, 400 Wabash Ave., Akron, Ohio 44307 (330) 344-7285
4. **Summa Health System,** Kyle Allen MD, Chief, Division of Geriatric Medicine; Steven Schmidt PhD, System Director of Research; Daniel Finelli MD – 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. **Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM)**, Walter Horton, VP for Research, Neels Van der Schyf, Professor and Chair, Pharmaceutical Sciences, 4209 State Route 44, PO Box 95, Rootstown, Ohio 44272 (330)325-6290
6. **Kettering Medical Center** , Joseph Mantil Director of Nuclear Medicine/PET, Martin Satter PhD –Physicists Nuclear Medicine, 3535 Southern Blvd. Kettering, Ohio 45429 (937) 298-4331
7. **University of Dayton – Electro-Optics Program** – Joseph Haus PhD Director, 300 College Park, Dayton, Ohio 45402
8. **Wright State University** – Computer Science & Engr. Arthur Goshtasby Professor and Director of Graduate Program- Imaging registration and fusion software, 3640 Colonel Glenn Hwy, Dayton, Ohio 45435 (937)775-5170
9. **Akron Biomedical Corridor** – Robert Bowman- Deputy Mayor, Akron, and **Akron Global Business Accelerator**, Mike LeHere – Accelerator CEO, Terry Martell – Director of Operations and Bus. Dev., 526 South Main St., Akron, Ohio 44311

Project Summary:

FMI is proposing a demonstration program for commercialization of its ScintiStar Orthopedic LPX PET/CT systems. FMI's technology for commercialization is small footprint highly sensitive molecular imaging systems for Bone diseases. FMI has developed unique multimodal imaging with 3 systems in one that is 1/5 the cost and 1/5 the size as compared to current whole body PET/CT systems. FMI and its clinical and medical imaging collaborators desire to show the imaging capability at Ohio's academic medical centers and community hospitals. This program will enable FMI to obtain FDA 510k approval on the systems and sell units. With FDA 510k approval, FMI will be producing the units in Ohio along with other medical imaging supply chain businesses. With this program FMI will create 100-150 jobs with global utilization of the ScintiStar Systems over the next 5 years.

Also, FMI and its collaborators are applying for Ohio Third Frontier Wright Project funds to establish a section in the **“Global Center for Multimodality Imaging for the Heart, Brain, Breast, and Bones.”**

Program Projected Plans:

- Build and install a ScintiStar Orthopedic LPX PET/CT for clinical validation for Bone and muscle molecular, functional, and morphological imaging validation at collaborator sites.
- Show Value Proposition for the ScintiStar Orthopedic LPX PET/CT
- Submit FDA 510k application for approval of the ScintiStar Orthopedic LPX PET/CT

- This clinical validation will enable sales in the US, Europe, and China.

“Global Center for Multimodality Imaging of the Heart, Brain, Breast, and Bones”

in Akron’s Biomedical Corridor.

- Focused development for anatomical and molecular imaging for the heart, brain, breast, and bones.
- Fused modalities include FMI’s PET,CT, SPECT with its ScintiStar Programs.
- New program for ScintiStar PET/MR imaging of the brain, heart, and breast.
- Ohio medical imaging cluster development with global networks to China, Germany, and Finland.

FMI’s Commercialization of ScintiStar Orthopedic LPX PET/CT for organ specific imaging is key outcome of this proposed work to create high technology medical imaging jobs in the State of Ohio.

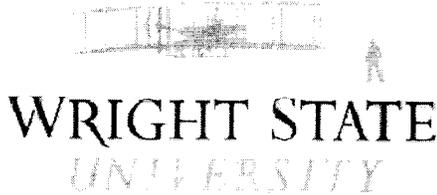
FMI and its respective collaborators have the medical imaging supply chain in mind to support the development, marketing, and sales of this novel technology.

Regards,

William K. McCroskey

President/CEO
FMI Technologies, Inc.

11-631



Dayton, Ohio 45435
(937) 775-2425
Fax: (937) 775-3781
E-mail: marianne.shreck@wright.edu
14 December 2010

Lead Applicant: Wright State University (WSU)
3640 Colonel Glenn Highway
Dayton, OH 45435-0001

Contact Name: Elliott Brown, Ph.D.
elliott.brown@wright.edu
937-775-4903

Title: Development of a High-Power THz Medical Imager
Estimated grant funds requested: \$2,000,000 over three years

Known Collaborators: Cleveland Clinic (Dr. Maria Siemionow), Teraphysics Corp.

Executive Summary:

Wright State University, in collaboration with the Cleveland Clinic and Teraphysics Corporation, wishes to submit a \$2 million proposal to the Ohio Third Frontier Medical Imaging Program to bolster the development of the terahertz imaging in Ohio. Our project will develop and ultimately commercialize a high-powered terahertz medical imaging system. Over the last 10 years, research on terahertz interactions with biomolecules and soft tissue has grown exponentially, and has demonstrated the immense potential of terahertz radiation within medicine. For example, terahertz imaging has already been shown to detect basal cell carcinoma and breast ductal carcinoma without any additional markers, not to mention the ability to provide valuable non-destructive testing of pharmaceutical agents and pill coatings.

The primary limitation of the field, in research and industry, is the availability of a high-powered terahertz imaging system which would remove the practical barriers to market entry. With our partner organizations, we intend to leverage our respective expertise to create the world's first high-powered THz imaging system, and build upon an infrastructure of terahertz activity Ohio has already fostered. The system will operate both in continuous-wave and pulsed mode so will provide range information with very high resolution (1 mm or better) as well as sensitive amplitude and phase information related to the biochemical and physiological state of soft tissue.

11-632

Tursiop Technologies, LLC

December 13, 2010

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

Dear Sir/Madam,

This Letter Of Intent serves to express our interest in submitting a proposal in response to the Request For Proposals in connection with the Ohio Third Frontier Medical Imaging Program for Fiscal Year 2011.

Information required in this connection is provided below.

Lead Applicant: Tursiop Technologies, LLC
Address: 11000 Cedar Ave. Suite 280, Cleveland OH 44106
Phone: 216-658-4521
Contact Person: Dr. Raju Viswanathan
Email address: raju@tursiop.com
Proposed Project Title: High-performance nanotechnology-based imaging coils for prostate imaging applications
Estimated funds requested: \$ 1,000,000
Collaborator: Philips Healthcare, 595 Miner Road, Highland Heights, OH 44143

A project summary is attached on the next page.

Please let me know if further information is needed.

Yours sincerely,



Raju Viswanathan, Ph.D.
Chief Technology Officer
Tursiop Technologies, LLC

Tursiop Technologies, LLC

Project Summary:

High-performance nanotechnology-based imaging coils for prostate imaging applications

This project seeks to develop high-performance MRI prostate imaging coils using Tursiop's proprietary nanomaterial technology, as a highly effective tool for enhanced image-based MRI diagnosis of disorders of the prostate, and for radiation therapy planning applications in this context.

Magnetic Resonance Imaging (MRI) is the imaging modality of choice in many medical diagnostic applications, particularly in the case of soft tissue imaging where an excellent range of contrast is possible with MRI. This is very relevant in the case of prostate imaging, where image quality, patient comfort, and patient access are significant factors in growing this application. While the recent introduction of high field open systems (e.g., the Panorama 1T system) by Philips Healthcare permits several key improvements in patient comfort and patient access, there is an unmet need for high quality imaging coils for signal acquisition in imaging the prostate. Internally used (endorectal) high performance imaging coils can provide increased diagnostic value to the physician. In the endorectal context, a coil for fast, high-resolution imaging can deliver quality diagnostic images while minimizing patient discomfort. An optimized internal prostate imaging coil or coil array can provide diagnostic images of the prostate for obtaining three dimensional information for biopsy guidance and/or radiation therapy planning. Since the prostate tends to be generally visible as diffuse images, high resolution of structure is particularly important for identifying lesions and boundaries.

Tursiop recently published imaging results from a nanomaterial-based endorectal prostate imaging coil at 1.5T where a doubling of Signal-to-Noise Ratio (SNR) was demonstrated compared to a conventional state-of-the-art commercial coil of similar form factor. This effort can be leveraged to produce an optimized endorectal coil for imaging with the Panorama 1T open access system. We will develop and evaluate coils for prostate imaging with this high field open system to provide high quality MR imaging. With its demonstrated imaging advances, Tursiop can provide a significant boost to the development of MR prostate imaging applications.

The primary endpoint of the project is a high performance prostate imaging coil at a field strength of 1T that can offer very good SNR performance for optimized prostate imaging beyond that possible with conventional commercial coils available today. The coils developed as part of this project will be carefully evaluated to arrive at an optimized design with substantial clinical utility. The project is anticipated to directly arrive at a commercial solution for enhanced imaging of the prostate while maintaining patient access and comfort with this high field open system.

OHIO THIRD FRONTIER MEDICAL IMAGING PROGRAM – OTFMIP 2011

Principal Investigator: Ravi Srinivasan, President
Project Title: MRI Compatible, Neonate Imaging Sub-System (MR-NISS)
Collaborators: TBD
Estimated Request: \$1 million

ABSTRACT:

Moving critically ill newborns and small infants outside of their controlled environment without adequate life sustaining and support mechanisms outside of their clinical departments for effective diagnosis is risky. Most moderate, severely ill babies are left in the hospital clinical departments until they stabilize, albeit at sub-optimal radiological diagnosis resulting in little or no clinical intervention. It is important with early diagnosis effective clinical interventions are possible in these cohorts which can save lives. The societal impact is immense.

An overall goal is to permit non-invasive high resolution brain, spine, cardiac imaging of critically ill premature neonates and infants, safely, without the use of ionizing radiation. We intend to accomplish high-resolution imaging using magnetic resonance (MR), obviating the need for radiation (CT) and invasive diagnostic procedures.

We propose the MRI Compatible Neonate Imaging Sub-System (MR-NISS) intended to facilitate safe transport of pre-term, term newborns and small infants, so effective diagnosis/prognosis is possible using MRI. The MR-NISS shall consist of life sustaining equipments such as a transport/MRI neonatal incubator and ventilator for uncompromising care; vital signs monitoring equipment; a custom infant sized MRI coil that fits inside the incubator for optimum MRI diagnosis including support accessories (such as tanks, hoses, nasal canula setup etc) necessary during transport and the MRI procedure.

A successful project will extend effective diagnosis to infants and newborns using MRI which in turn may permit prompt interventions which in turn can save lives. This we believe will be of a substantial benefit to mankind. The market opportunity extends from dedicated Children's hospitals, university based teaching hospitals, community hospitals to birthing hospitals and stand-alone clinics worldwide.

Advanced Imaging Research, Inc. dba SREE MEDICAL SYSTEMS
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Cleveland, OHIO 44114 USA
Ph: 216-426-1461
Fax: 216-426-1180
www.sreemedical.com "Dedicated to Peds"