

Commonwealth Research Commercialization Fund

Advancing Technology and Economic
Development in Virginia by Investing in Priority
Research and Commercialization Activities

ANNUAL REPORT

July 1, 2011 – June 30, 2012

Submitted by the Fund Administrator:
Center for Innovative Technology on behalf of the
Innovation and Entrepreneurship Investment Authority and the Commonwealth of Virginia

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Table of Contents

Executive Summary.....	3
Background	4
FY2012 Highlights.....	6
Fall 2011 Award Profiles	6
Commercialization Program	6
Eminent Researcher Recruitment Program	9
Facilities Enhancement Loan Program.....	10
Matching Funds Program.....	10
SBIR Matching Funds Program.....	15
Fall 2011 Declined Awards.....	29
Winter 2012 Solicitation	29
Commercialization Fund	30
Eminent Researcher Recruitment Program	30
Matching Funds Program.....	30
SBIR Matching Funds Program.....	31
Preparations for FY2013	31
Administration	31
APPENDIX A: Award Details	33
Fall 2011 Solicitation.....	33
Winter 2012 Solicitation	35
FY2012 Funding Totals.....	37
APPENDIX B: RTIAC Members.....	38

Executive Summary

In accordance with Code of Virginia Sections 2.2-22.33.1 G and 2.2-2221 (18), and on behalf of the Innovation and Entrepreneurship Investment Authority (IEIA), the Center for Innovative Technology (CIT) respectfully submits this report regarding the performance of the Commonwealth Research Commercialization Fund (CRCF) in FY2012. The CRCF accelerates innovation and company formation in the Commonwealth, while solving important state, national, and international problems through technology research, development, and commercialization.

During the 2011 session of the General Assembly, \$6 million was appropriated to CRCF for the purpose of advancing science- and technology-based research, development, and commercialization to drive economic growth in Virginia and to encourage collaboration among its institutions of higher education and partnerships between these colleges and universities and business and industry. CIT managed two FY2012 solicitations resulting in 47 awarded projects¹. These projects are performed by companies, universities, and research institutes across the state and are advancing technology commercialization aligned with Virginia's key strategic technology priorities as outlined in the Commonwealth Research & Technology Roadmap. CRCF leveraged the Commonwealth's \$5.85 million investment with \$12.7 million in matching funds. FY2012 CRCF awards tackle major challenges facing the state, the nation, and, in fact, humankind. For example, these latter projects are attempting to create groundbreaking diagnostics and treatment options for some of the deadliest and most challenging cancers, including brain cancer, pancreatic cancer, and renal cancer, and parasitic diseases that are pervasive and difficult to treat. The work the Commonwealth organizations are doing, with CRCF support, have the potential to have a profound and lasting benefit to society through job, intellectual property, and company creation in Virginia.

CRCF funds have helped Virginia-based organizations to gain additional large-scale funding. For example, as a result of their CRCF award, Paragon NanoLabs of Northern Virginia developed relationships with two large companies – Janssen Pharmaceuticals and Johnson & Johnson – for their work to treat brain tumors. This relationship led to additional funding and studies by the National Institutes of Health (NIH) and the Nanotechnology Characterization Laboratory (NCL). Similarly, the CRCF award to Phthisis Diagnostics, a small business in Charlottesville, was crucial to \$260,000 in private investment.

The FY2012 CRCF included five programs: Commercialization, Eminent Researcher Recruitment, Facilities Enhancement Loan, Matching Funds, and SBIR Matching Funds, for which \$2 million of the \$6 million FY2012 appropriation was specifically designated. Per legislative direction, awards made for CRCF projects must support technology sectors identified in the Commonwealth Research and Technology Strategic Roadmap. The Roadmap, a comprehensive planning tool Virginia leaders use to help determine research areas worthy of economic development and institutional focus, identifies technology sectors

¹ 47 projects were awarded in FY2012 although 51 projects were selected for funding; four organizations declined fall 2011 awards

with the most commercial promise and that will drive economic growth throughout the state. Eleven technology sectors were eligible for funding in FY2012.

CIT assessed interest in and demand for Commonwealth research and commercialization support through a Request for Information (RFI), issued to the research community and industry in June 2011. Findings demonstrated a pent-up demand from Virginia's private sector, academia, political subdivisions, research institutes, and federal labs; 144 entities across the state requested a total of \$120 million for 305 projects addressing such technology sectors as advanced manufacturing, aerospace, energy, information technology, and life sciences.

Following issuance of the RFI and in consultation with the technology community and the Administration – particularly the Secretariats of Education, Commerce & Trade, and Technology – CIT established the Research & Technology Investment Advisory Committee (RTIAC), a body created in 2011 legislation to recommend CRCF awards to IEIA and develop guidelines for the first FY2012 solicitation. RTIAC members are identified in Appendix B.

In total for FY2012, 181 eligible proposals were submitted from all of the Commonwealth's ten technology regions and from these submissions, 47 projects were awarded CRCF funding. Funded projects covered ten of the 11 technology sectors identified in the Roadmap as priorities eligible for CRCF funding. Many CRCF projects began well into the second half of FY2012; findings and work discussed in this report will reflect the recent starts. Outcomes of the progressed work will be included in more detail in the FY2013 Annual Report, along with such results as additional funds received through grants, contracts, and investments. The Fund Administrator will report on projects for up to five years after their period of performance in order to better capture commercialization results and economic outcomes, including job and company creation, and new revenues.

In addition to overseeing FY2012 solicitations, CIT submitted the FY2011 Annual Report in October 2011. This report discussed the two Commonwealth Technology Research Fund (CTRF) projects completed in FY2012: Eastern Virginia Medical School's *The Development of BioEclipse, the First Biologically Optimized Treating Planning System for Proton Radiotherapy* and Virginia Tech's *A Center for Community Security and Resilience*, and FY2012 planning by the Fund Administrator.

The Administration and General Assembly continue to support the mission of the CRCF. The FY2013 and FY2014 budgets each include \$4.8 million for the Fund. Planning is underway for the FY2013 opportunities.

Background

The Commonwealth Research Commercialization Fund (CRCF) is tied to the Commonwealth Research and Technology Strategic Roadmap, a comprehensive planning tool Virginia leaders use to identify

research areas worthy of economic development and institutional focus. Through a consultative process with Virginia's technology community, the Roadmap establishes priorities in key industry sectors that have commercial promise and will drive economic growth throughout the state. CRCF awards are only made to those projects that further the goals set forth in the Roadmap.

The five programs listed below were eligible for both rounds of FY2012 funding.

- **Commercialization Program**

This program incentivizes the commercialization of a product or service related to a qualifying technology. This program was particularly designed for collaborative projects that will have a demonstrable economic benefit to the Commonwealth and have a reasonable probability of enhancing the Commonwealth's national and global competitiveness.

- **Eminent Researcher Recruitment Program**

This program helps state institutions of higher education acquire and enhance research superiority through the hiring of eminent researchers whose research will be conducted in a qualifying technology. Collaboration and commercialization are important elements of this program.

- **Facilities Enhancement Loan Program**

This program was designed to help qualifying universities and political subdivisions establish and/or upgrade facilities used to commercialize qualified research or technologies, including those developed at the institutions and by Virginia's private sector. Award uses from this program include lease or credit guarantees.

- **Matching Funds Program**

This program was designed to assist public and private colleges, universities, other research institutes, and federal labs in Virginia leverage federal and private funds designated for the commercialization of qualified research or technologies. These matching funds may advance research to readiness for intellectual property protection, private sector investment, and/or help to qualify institutions for funding competitions. Such funding also reflects the state's and institution's commitment to the project and their conviction in the feasibility and value of the proposed research.

- **SBIR Matching Funds Program**

This program was specially designed to advance technology commercialization by Virginia-based technology businesses that had won a Small Business Innovative Research (SBIR) Phase I award from the National Institutes of Health (NIH). This program also targeted the development of qualified research or technologies. In FY2012, \$2 million of the \$6 million appropriation was specifically designated for this program.

During the first solicitation, 91 eligible proposals were submitted from nine of the ten technology regions in Virginia. These submissions covered all eligible CRCF programs and ten of the 11 technology sectors; applications exhibited a particular emphasis on life sciences. Twenty-nine awards were extended to recipients in each of the five programs during the first solicitation, though four awards were declined, including the Facilities Enhancement Loan Program award. In total, awards were made to 20 organizations across the Commonwealth representing five regions and in three technology areas – life sciences, energy, and nuclear physics.

The second solicitation generated 90 eligible proposals from all technology council regions. These applications proposed work in ten of the 11 priority areas in all programs except for the Facilities Enhancement Loan Program. In this latter round, 22 awards were made to 20 organizations representing six regions of the Commonwealth. Awarded projects covered work in nine of the 11 eligible technology sectors: advanced manufacturing, aerospace, communications, cyber security, energy, environment, information technology, life sciences, and modeling and simulation.

FY2012 Highlights

CRCF selected 51 projects for funding with FY2012 monies, 47 of which were awarded. These projects and the work and accomplishments through this reporting period are profiled below. In the first of the two solicitations, 25 awards were made and the awardees are discussed alphabetically within their awarded program; four declined awards from the first solicitation appear at the end of this section. The 22 recipients of funding through the second solicitation, announced in early July 2012, began receiving awards and undertaking work in FY2013; these projects will be discussed in the FY2013 Annual Report.

Fall 2011 Award Profiles

Commercialization Program

Black Laboratories, LLC (CP-008)

ORGANIZATION: Black Laboratories, LLC
LOCATION: Hampton Roads
PROJECT TITLE: *Processing and Testing of Hydroformed SRF Cavities*
TECHNOLOGY SECTOR: Nuclear Physics
AWARD AMOUNT: \$91,922
AMOUNT SPENT: \$49,942
PARTNERS: Jefferson Lab (DOE nuclear and high energy physics facilities), Fermi National Accelerator Laboratory (Fermilab), ATI Wah Chang (AWC), Interlaken Technology Corporation

The Commercialization Program award for Black Laboratories is being used to commercialize superconducting radio frequency (SRF) cavity fabrication technology used in machines for nuclear and high-energy physics, free-electron lasers, fourth generation light sources, and rare isotope accelerators. Standard fabrication methods require a large number of electron beam welds, which are time consuming, expensive, and tend to contaminate the high-purity niobium metal used for these devices. Hydroforming, the new, advanced technology proposed by Black Laboratories, allows better performance, more efficient assembly, lower cost, and a more streamlined approach for the production of large numbers of cavities and components with geometries of nearly tubular shape.

The goals of this CRCF project are to advance commercialization by testing the prototype to determine the SRF properties of the first generation product and improving material properties for the second generation product. Excellent results will attract the endorsement of Fermilab and capital investment.

In this reporting period, Black Laboratories focused on testing and making modifications to the finished tubes and discussing acquisition of machinery to perform spinning and hydroforming operations previously done in Germany. The prototype SRF cavities are being tested at Jefferson Lab, the results of which will be shared with partners Fermilab, AWC, and Interlaken. Based on the outcomes of the testing, discussions with investors are planned for both improving tube material properties and establishing hydroforming facilities in Virginia. Black Laboratories will apply for Department of Energy (DOE) SBIR funding in October 2012 for the manufacturing of seamless SRF cavities.

Worldwide, the demand for low-cost, high-performance hydroformed SRF cavities is expected to be in the hundreds to tens of thousands of units, depending on the continuation of large government and international physics projects. At anticipated sales prices for \$30-40,000 for “as-formed” cavities, long-term market demand is projected in the range of tens to hundreds of millions of dollars.

HemoShear (CP-030)

ORGANIZATION: HemoShear
LOCATION: Charlottesville
PROJECT TITLE: *Interspecies Drug-Induced Vascular Injury (DIV) Consortium*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$250,000*
PARTNERS: Amgen Inc.

Due to HemoShear’s July 1, 2012 start date, an FY2012 progress report was not required. This project will be discussed in the FY2013 Annual Report.

*Award amount was revised from \$500,000 to \$250,000.

Phthisis Diagnostics, Inc. (CP-004)

ORGANIZATION: Phthisis Diagnostics, Inc.
LOCATION: Charlottesville
PROJECT TITLE: *Commercialization of Cryptosporidium/Giardia Molecular Diagnostic*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$499,477
AMOUNT SPENT: \$149,326
PARTNERS: Amresco, MDC Associates

The goal of Phthisis' Commercialization Program award is to develop a U.S. Food and Drug Administration (FDA)-cleared molecular diagnostic for use in clinical laboratories to detect intestinal infections that are currently or not easily or accurately diagnosed. DNA testing is faster, more sensitive, and less costly than currently used diagnostics. The product will test, simultaneously, for *Cryptosporidium* and *Giardia*, the two most commonly diagnosed parasites in the U.S., that cause about 2.3 million clinical infections each year, as well as *Entamoeba histolytica*. Including the third parasite will make this diagnostic test more attractive on the global market. Currently, no other companies are offering polymerase chain reaction (PCR)-based, FDA-approved clinical diagnostic tests for *Cryptosporidium*, *Giardia*, or *E. histolytica*.

The development of *R-Sphere*® *CGE Detect* will benefit economic growth in numerous ways, including improving the diagnosis of intestinal parasites; reducing diagnostic complexity of parasite diagnosis; generating tax revenues once the product is commercialized; increasing demand for parasite diagnosis, in turn increasing job opportunities in Phthisis, hospitals, and laboratories; and generating exports through international sales of this diagnostic.

Phthisis' work in this reporting period included market research to ensure this diagnostic meets the specific needs of the market, updating the product design based on this research, and preparing FDA-required documents. In addition, the firm presented DNA extraction methodology and molecular standard data at two scientific conferences, and, working with the Virginia Economic Development Partnership (VEDP), established distribution agreements in several key countries. Clinical trial work is projected to begin in October 2012, at which point Phthisis will self-certify the diagnostic to obtain a CE mark, thus enabling them to sell the product in the European Union. Once FDA approval is obtained, U.S. sales will begin.

Thus far, CRCF funding has supported three technical staff, one sales/development staff, and one administrative staff at Phthisis, with two additional support staff to be added with the product's commercialization.

RetiVue (CP-029)

ORGANIZATION: RetiVue
LOCATION: Charlottesville

PROJECT TITLE: *Bringing Affordable Retinal Screening Technology and Services to the Primary Care Physician*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$250,000
PARTNERS: University of Virginia (U.Va.)

Due to RetiVue's July 1, 2012 start date, an FY2012 progress report was not required. This project will be discussed in the FY2013 Annual Report.

Eminent Researcher Recruitment Program

Virginia Tech (ER-002)

ORGANIZATION: Virginia Tech
LOCATION: Roanoke-Blacksburg
PROJECT TITLE: *Recruitment of Eminent Scholar in Heart Regenerative Medicine Research*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$250,000
AMOUNT SPENT: \$4,074
PARTNERS: Carilion Clinic

Virginia Tech partnered with Carilion Clinic to recruit Dr. Robert Gourdie, one of the leading scholars in the U.S. in the area of heart regeneration and wound healing research, to the Virginia Tech Carilion Research Institute (VTCRI). Dr. Gourdie's experience includes serving at the Medical University of South Carolina (MUSC) in Charleston as a South Carolina Board of Trustees' Eminent Scholar of Regenerative Medicine and Cell Biology, Professor of Regenerative Medicine and Pediatric Cardiology at MUSC, and Adjunct Professor of Biomedical Engineering at Clemson University.

Dr. Gourdie's research program combines innovative approaches to the study of the normal genetic and molecular processes that form heart and skin tissues with strategies for reactivation of those processes in conjunction with targeted stem cell activation to repair the heart after hypoxic/ischemic injury and the skin after mechanical injuries. This research uses a newly discovered process and gene/protein cascade common to both tissues. In addition to his academic program, Dr. Gourdie founded and is currently the CSO of a technology startup company in Charleston, FirstString Research Inc., which develops and brings to market for clinical testing new molecules and processes for wound healing and regeneration of injured skin and damaged heart tissue. FirstString Research Inc. is considering relocating the company and its six employees to the Roanoke area. Lastly, Dr. Gourdie has taken a leadership role for overseeing the research activities of the Emergency Medicine department at Carilion Clinic, thus further integrating the private partner (Carilion) to the public partner (Virginia Tech), in order to develop new collaborative research initiatives, foster technology transfer, and develop additional new intellectual property and start-up ventures in health research.

The project is on track with goals and schedule. Dr. Gourdie was recruited during the winter of 2012 and moved his research operation to Roanoke on June 1, 2012, one month ahead of schedule. Dr. Gourdie has begun to establish the new Center for Heart and Regenerative Medicine Research (CHRMR) at the VTCRI by setting up his own research laboratory, developing core research facilities, and actively participating in the recruitment of another recognized heart research scientist, Dr. Steve Poelzing, from the University of Utah School of Medicine; Dr. Poelzing arrived on August 8, 2012. In addition, Dr. Gourdie has been responsible for seven additional researchers joining the VTCRI. Over the course of the next three years, the CHRMR will continue to recruit an additional two to three heart and regenerative medicine researchers and their research support staff, further increasing the impact and research contributions of this endeavor, seeded by CRCF.

Securing additional funding was a key goal of Dr. Gourdie's recruitment to VTCRI. To-date, Dr. Gourdie has begun the transfer process for two NIH research grants from MUSC to VTCRI and Dr. Poelzing has begun the transfer of a third NIH grant. Between the two researchers, the current annual research funding portfolio is over \$700,000 per year. Dr. Gourdie has also submitted a major multi-institutional program grant and several other grants since arriving at VTCRI. Moving forward, Dr. Gourdie will establish the operations at CHRMR, recruit additional research staff members, submit at least one additional grant, and integrate the Carilion residents in heart and regenerative medicine research programs at the VTCRI over the next year. In addition, Virginia Tech will begin the search process next year for a third faculty research team leader in heart regenerative medicine and wound healing research.

Virginia Tech requested and received a no-cost extension through June 1, 2013 to facilitate final recruitment efforts, relocation of lab facilities, and transfer of research team personnel.

Facilities Enhancement Loan Program

In June 2012, Old Dominion University (ODU), the recipient of the only Facilities Enhancement Loan Program award in fall 2011, declined the \$500,000 award due to a variety of reasons, including the project's scaled-back size and revised timing. The award was for the Frank Reidy Research Center for Bioelectrics facility expansion.

Matching Funds Program

Old Dominion University (MF-010)

ORGANIZATION: Old Dominion University (ODU)
LOCATION: Hampton Roads
PROJECT TITLE: *A Nonchemical Approach for Creating Platelet Gel*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$100,000
AMOUNT SPENT: \$12,583
PARTNERS: N/A

The use of platelet gel to enhance healing in the U.S. has been growing at a steady rate, and new applications for it are being developed. Platelet gel is made from whole blood and is typically activated by thrombin, an enzyme that has several potential adverse effects. ODU researchers have developed a novel means to activate platelets and form platelet gel by utilizing specific electric fields, instead of chemical additives. This patented technology reduces or eliminates adverse effects associated with thrombin-derived platelet gel and would allow for the expansion of this therapeutic reagent. The proposed device will be compact to fit in a physician's office and the procedure can be done in as little as 15 minutes using the patient's own blood.

ODU has successfully used a novel, innovative, and proprietary time domain nanotechnology to activate platelets when preparing platelet gel. The platelets are activated without chemicals by generating non-ionizing radiation with nanosecond pulsed electric fields (nsPEFs or nanopulses) that are high in power and low in energy. A prototype ns pulsed power system for platelet activation has been designed, built, and tested, though pulsed platelet gel will require modifications of the design. The current prototype instrument, while compact enough for an office, is too heavy and cumbersome for widespread use. Therefore, the focus of this program is to develop an instrument/system that can facilitate widespread use of the technology.

There are two distinct products that will be marketed through work on this project. The first is the overall system, which includes the pulser and curvette holder. The second product is the disposable curvette. Thus far with CRCF funds, the ODU team has begun to test a smaller, lighter, and more portable instrument and has begun to design the curvette. ODU anticipates being able to place the system on the market within approximately two years.

Old Dominion University (MF-013)

ORGANIZATION: Old Dominion University (ODU)
LOCATION: Hampton Roads
PROJECT TITLE: *Development and Commercialization of Pulse Power Technology*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$100,000
AMOUNT SPENT: \$34,053
PARTNERS: Ethicon Endo-Surgery (EES)

This project is designed to build prototype pulse power systems and catheter electrodes and test them for efficacy in the treatment of cancer, using rat hepatocellular carcinoma (HCC) as a model, which grows and is treated directly in the liver. This project, at the Frank Reidy Research Center for Bioelectrics (CBE), proposes to find new treatments for cancer via pulse power technology using nanosecond pulse electric field (nsPEF). The objectives are to demonstrate a pulse power system for commercialization that can demonstrate efficacy for no growth for as long as six months in the rat model, which would represent a human survival time after treatment of approximately 12 years and to show whether, after

a six-week period of no growth or tumor elimination following nsPEF treatment, a challenge injection of the same HCC cells into the liver would grow. The absence of growth in the challenge injection would suggest that the nsPEF treatment was associated with a host response to reject further tumor growth.

It is anticipated that the pulse power systems, catheter electrodes, and nsPEF parameters will be developed to demonstrate efficacy of systems, electrodes, and treatment to provide sufficient pre-clinical data to justify clinical trials. Thus far, the ODU team designed and tested one pulse power system, as well as identified a set of nsPEF parameters using a previous electrode design that has demonstrated efficacy in the rat HCC model for six weeks, the longest time tested to-date. Research and testing results have shown that nsPEFs kill tumors from the inside out. The team will continue this work by maintaining short-term successfully treated animals for up to six months to show long-term efficacy of treatments established and demonstrated.

The team is currently designing an electrode array that could be utilized through laparoscopic approach. A mid-term goal of this work is to establish nsPEF therapy as an effective therapy for liver cancer using the pre-clinical model, N1S1 rat HCC, and a long-term goal is to move nsPEF therapy to clinical trials, using pre-clinical studies as evidence of efficacy in cancer treatment. These strategies have the potential to establish ODU, CBE, and Norfolk, Virginia as the initiator of a new and novel cancer therapy that can be used alone or in combination with other treatment modalities.

Region 2000 Research Institute (MF-004)

ORGANIZATION: Region 2000 Research Institute
LOCATION: Region 2000
PROJECT TITLE: *Center for Safe and Secure Nuclear Energy*
TECHNOLOGY SECTOR: Energy
AWARD AMOUNT: \$100,439
AMOUNT SPENT: \$3,650
PARTNERS: AREVA, Nuclear Regulatory Commission (NRC), University of Virginia (U.Va.), Virginia Tobacco Commission

To address new technology and educational challenges in the next generation nuclear power plants, the Center for Advanced Engineering and Research (CAER), in collaboration with industry and university partners, created the Center for Safe and Secure Nuclear Energy (CSSNE) located at the newly established CAER research facility in Bedford County, Virginia. For this project, CAER's unique Human Performance Test Facility will provide expertise, personnel, and facilities to conduct human-in-the-loop research studies using nuclear power plant simulators available at the CAER. The Center is near two major nuclear power companies, AREVA and Babcock & Wilcox (B&W), and two major research universities, U.Va. and Virginia Tech. The Center is available to government, industry, and universities to impact design and regulatory matters associated with advanced reactor designs.

CAER matched the CRCF investment with equipment from the NRC and engineering support and cash from AREVA, funding from the Virginia Tobacco Commission, and Virginia’s Department of Housing and Community Development (DHCD). CRCF funding is being used to engage faculty and students from Virginia universities, including U.Va., Virginia Tech, and Virginia Commonwealth University (VCU); the work will allow CAER to inform the industry on how to design safe and “human-centered” nuclear power plants, strengthen the science and engineering programs at Virginia’s universities by offering research internships, and build a science and engineering workforce pipeline for the region and state. The overall objective of this effort is to fully realize a state-of-the-art advanced configurable control room facility that can provide technical licensing and regulation basis for next generation nuclear power plant control room design. The advanced control room of the CAER is the most critical element of the CSSNE concept, and is currently regarded by the nuclear industry as crucial to current and future research nuclear power plant designs.

CSSNE provides the Commonwealth with a facility that is unique in the U.S., with the capability to perform research, technology transfer, and education all in a single integrated site. Work began on this project on June 1, 2012.

University of Virginia (MF-014)

ORGANIZATION: University of Virginia (U.Va.)
LOCATION: Charlottesville
PROJECT TITLE: *Bone Imaging: Technology Development and Pilot Study*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$120,000
AMOUNT SPENT: \$36,363
PARTNERS: Rivanna Medical

Recently, medical imaging technologies have been developed at U.Va. to address the significant clinical need for technological advances that improve the efficacy of spinal anesthesia and diagnostic procedures. These ultrasound-based technologies circumvent many of the challenges associated with conventional ultrasound guidance of spinal anesthesia procedures. Rivanna Medical is the U.Va. spin-out company formed to commercialize the SpineFinder™, a medical device currently in development that incorporates these innovations for real-time 3D spinal bone renderings. By providing intuitive 3D views of the spine, the SpineFinder™ is anticipated to outperform 2D methods, such as fluoroscopy, while eliminating health risks arising from ionizing radiation and reducing procedure times. Rivanna Medical and U.Va. researchers hypothesize that a real-time, 3D view of spinal bone anatomy will reduce spinal anesthesia/diagnostic failures and their associated adverse health effects.

During this reporting period, the team was able to achieve a hand-held ultrasound prototype with custom electronics. The team also met preliminary accuracy, precision, and resolution specifications for *in vitro* 3D bone image reconstruction, as quantified in experiments using spine bone models embedded in tissue-mimicking gelatin. Key challenges going forward include translation from an *in vitro*

environment to *in vivo*, where high performance imaging is anticipated to be more difficult. The team has decided to perfect the imaging system using a pig model prior to commencing the planned observational pilot study – the final goal of the project.

The impact of the SpineFinder™ on success rates for spinal anesthesia procedures is expected to be significant. It is well documented that failures and complications in these procedures occur due to an inability to locate anatomical landmarks. By providing an intuitive visualization of spinal bone landmarks and an automated guide to identify needle insertion location, success rates should improve.

Virginia Institute of Marine Science (MF-005)

ORGANIZATION: Virginia Institute of Marine Science (VIMS)
LOCATION: Hampton Roads
PROJECT TITLE: *Near-Infrared Reflectance Spectrometry (NIRS) for Evaluation of Oyster Physiology in Selective Breeding*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$97,435
AMOUNT SPENT: \$48,366
PARTNERS: Virginia Tech

The aim of this Matching Funds proposal is to contribute to the continued growth of oyster aquaculture in the Chesapeake Bay and the East Coast by adding new capabilities for the quantification of commercially important traits. This work fits in the context of ongoing breeding and improvements by the Aquaculture Genetics and Breeding Technology Center (ABC) at VIMS. ABC has two principal selection goals: selective breeding in diploid oysters using quantitative genetics, and improvement of triploid oysters using traditional selection methods along with cytogenetics and analysis of heterosis among crosses. The oyster species used in this project is *C. virginica*.

Near-infrared reflectance spectrometry (NIRS) technology will give VIMS access to rapid determination of key traits in oysters, informing researchers about whether triploids will inherit and express attributes that were selected in the diploid, such as disease resistance and faster growth, which is critical to deciding breeding directions in the future. VIMS also expects to learn about the energetics of triploids that contribute to their advantage, attributes that could be selected to improve triploid performance. Furthermore, results will allow VIMS to quantify traits that are important to characterizing VIMS' lines and will be important to the ability to make sound recommendations to the industry on the various diploid lines available. For the species *C. virginica*, little work on triploids has been accomplished, so this project will establish a definitive baseline for relative performance among crosses and across strategically selected environments.

Thus far, CRCF funding has allowed VIMS to obtain and train on instrumentation, establish protocols for processing oyster samples, establish protocols for running chemical assays to calibrate the NIRS reading (through a subcontract with Virginia Tech), accumulate representative samples from different

physiological states to establish the range of conditions that researchers expect to encounter, and begin applying NIRS sampling to field samples of the National Sea Grant project. The next steps in this project include the intense acquisition of data, following the acquisition of the technology.

Virginia Tech (MF-016)

ORGANIZATION: Virginia Tech
LOCATION: Roanoke-Blacksburg
PROJECT TITLE: *Photovoltaic Inverter Development for Virginia Manufacturing Industries*
TECHNOLOGY SECTOR: Energy
AWARD AMOUNT: \$148,998
AMOUNT SPENT: \$61,124
PARTNERS: N/A

Currently, Virginia imports over half of its energy needs. To satisfy those needs and to accelerate economic growth, developing transformative energy is a must. The main purpose of this CRCF project is to commercialize the photovoltaic inverters developed under Virginia Tech’s Department of Energy (DOE) photovoltaic (PV) power conditioning project, which will produce ultra-high efficiency inverters and cost-effective PV system architecture. Inverters enable renewable energy to be integrated into the modern power grid. Today’s PV power conditioning systems cost about one dollar per watt, and the efficiency is typically around 95%.

The team’s goal with this work is to reduce the PV inverter cost to 10¢ per watt and to increase the inverter efficiency to higher than 99% for production-ready PV inverter products. The cost reduction will be achieved through highly integrated design and collaboration with the semiconductor industry. The efficiency improvement will be achieved by adopting Virginia Tech’s proprietary soft-switching techniques. During this reporting period, the team prepared three invention disclosures, which will be filed once hardware prototypes are proven. In addition, Virginia Tech has secured DOE continuation funding of \$800,000 for a Phase III program focused on PV inverter development and commercialization.

The project capitalizes on the work in energy technology at Virginia Tech to address the state’s growing energy needs, while fostering local job creation.

SBIR Matching Funds Program

AFrame Digital, Inc. (SBIR-012) (Final)

ORGANIZATION: AFrame Digital, Inc.
LOCATION: Northern Virginia
PROJECT TITLE: *Continuous Fall Risk Monitoring System: Walking vs. Activities of Daily Living*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$49,997
AMOUNT SPENT: \$49,997

PARTNERS: Vinson Hall Retirement Community, University of Virginia (U.Va.), George Mason University (GMU)

The recognition and isolation of activities of daily living (ADL) provide an objective measure of patient performance and functional assessment that can be used in a wide variety of applications, including medication adherence, chronic disease management, and behavioral management for psychological health and wellness. For this SBIR Matching Funds project, AFrame Digital, Inc. conducted secondary data analysis on the activity and video data made available during their NIH SBIR Phase I project. In addition, they also increased the marketability of their MobileCare Monitor system by validating classification and characterization of patient activity in real-time using non-intrusive wearable sensors.

The research resulted in a system that can automate a major labor-intensive task in healthcare – the assessment of a patient’s functional capacity over time and at a given point in time. In addition to data analysis, the project team conducted an extensive U.S. Food and Drug Administration (FDA) 510(k) regulatory review with experts who provided guidance on requirements for clearance of the system.

The CRCF project extended the system’s previous utility beyond walking identification into automated algorithmic classification by activity level of other actions, such as running, sitting, sleeping, reading, eating, etc. The purpose of the project was to validate a means of translating tri-axial acceleration data from the wrist into a physical activity value that was correlated with metabolic equivalent of task (MET) values, and could accurately differentiate between active, moderately active, and inactive activity. The ability to classify activities into different activity levels supports the dual goals of healthcare cost reduction and improved care by providing more automated recognition of ADLs. Automated activity level assessment of an individual over time can assist nurses in evaluating patients for eligibility and potential admission to institutional facilities and programs or their capacity for continued independent living. Automated activity level assessment can also facilitate ongoing monitoring of a patient’s overall health status.

During this reporting period, AFrame Digital researchers submitted an abstract on the NIH SBIR Phase I project for consideration of publication and presentation at the mHealth Summit in 2012. The research team plans to submit at least two more abstracts for upcoming conferences, and AFrame Digital has been asked to participate in the mobile Health Information Management Systems Society (mHIMSS) workgroups based on recognition of the merit of AFrame Digital’s recent research activities, publications, and awards. Finally, the company has been working on preparing intellectual property protection strategies for its systems.

Next steps to advance the system include finalizing the algorithm in the watch so that it matches the parameters determined to be optimal during the study. The finalized algorithm will be made available to commercial customers in the next release cycle. AFrame Digital secured an SBIR Phase II award that will begin in October 2012, and results of this CRCF award will be used to track the activity level of 30 participants with heart failure and 30 healthy participants. Each participant will be monitored using the watch device 24 hours a day for six months; additionally, participants will take surveys reporting on their

activity and sleep and will sleep on a bed sensor. The data is intended to further validate the results of the CRCF study by comparing the activity level determined using the watch and the output of the bed sensor with self-reported activity and sleep behaviors.

The NIH SBIR project required collaboration among Vinson Hall Retirement Community in McLean, Virginia, U.Va., and AFrame Digital. The CRCF project was expanded to include GMU. Three Virginia-resident engineering students were hired as research assistants or engineering technicians and were provided with technical and scientific mentoring by senior AFrame engineering and research personnel. At least two students will continue on as AFrame employees.

Alexander BioDiscoveries, LLC (SBIR-016)

ORGANIZATION: Alexander BioDiscoveries, LLC
LOCATION: Charlottesville
PROJECT TITLE: *Novel Anti-Viral Agents to Treat Influenza*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$50,000
AMOUNT SPENT: \$33,000
PARTNERS: University of Virginia (U.Va.) School of Medicine

Yearly influenza epidemics and occasional pandemics are a continuing world-wide public health challenge; currently available vaccines and anti-influenza drugs are only partially effective in prevention and treatment and they suffer from viral resistance. Therefore, an urgent, immediate, and global need exists for anti-influenza therapeutics that attack unexploited aspects of viral biology. Alexander BioDiscoveries is developing new drugs that can combat influenza virus infection in humans. The company is developing a series of influenza virus inhibitors with highly potent broad-spectrum activity in cell culture and mouse models, leading to pre-clinical investigational new drug (IND)-enabling studies.

Alexander BioDiscoveries' work on advanced medicinal chemistry resulted in highly active compounds with broad-spectrum activity against a variety of seasonal and laboratory influenza strains. The researchers found, however, a wide variability in drug sensitivity among various recent seasonal strains supplied by the Center for Disease Control (CDC). Future plans include additional medicinal chemistry to tackle variation in sensitivity among seasonal strains, as well as direct biochemical approaches to drug-protein binding assays, which will allow the team to directly assess binding affinity for many target molecules. The company is currently preparing a Phase II application for December 2012; if funded, it will support extensive *in vivo* testing and pharmacokinetics.

BioSpherex LLC (SBIR-009) (Final)

ORGANIZATION: BioSpherex LLC
LOCATION: Northern Virginia
PROJECT TITLE: *Development of an LH-PCR Based Diagnostic for Inflammatory Bowel Disease*

TECHNOLOGY SECTOR: Life Sciences

AWARD AMOUNT: \$50,000

AMOUNT SPENT: \$50,000

PARTNERS: Metabiomics Corporation, George Mason University (GMU) Microbiome Analysis Center, Virginia Commonwealth University (VCU) Medical Center

The purpose of this CRCF project was to support the further development of SBIR Phase I research, a follow-on NIH SBIR Fast-Track proposal, and an NIH “Grand Opportunities” grant research project – projects that have high short-term impact and high likelihood of enabling growth and investment in biomedical research and development, public health, and healthcare delivery. This work sought to develop and test novel human microbiome (HMB) molecular diagnostic and prognostic tests and support vector model (SVM) to accurately diagnose and differentiate Irritable Bowel Syndrome (IBS) from Inflammatory Bowel Disease (IBD), two commonly encountered gastrointestinal disorders that account for a significant proportion of visits to primary care physicians and gastroenterologists. The proposed *in-vitro* diagnostic (IVD) will also diagnose clinical subclasses of these diseases, including Crohn’s Disease (CD) and Ulcerative Colitis (UC), forms of IBD. The proposed tests will provide timely, low-cost, non-invasive, and accurate methods for routine early diagnosis of IBS and IBD, reducing reliance on costly and invasive colonoscopy examinations and improving therapeutic outcomes for patients.

Specifically, the objective of this CRCF project is to further develop and demonstrate the technical feasibility of a novel SVM for differential diagnosis and classification of IBD and non-IBD clinical cases. Data and results from this interim research will be used to support an NIH SBIR Fast-Track proposal to be submitted in December 2012. This SBIR Fast-Track proposal, if successful, could provide the needed financial resources to advance the commercialization of the now patented HMB diagnostic methods.

The next steps in BioSpherex’s commercialization plan involve increasing grant and contract revenues, and raising private investment capital, to continue clinical research and trials.

Gencia Corp. (SBIR-014) (Final)

ORGANIZATION: Gencia Corp.

LOCATION: Charlottesville

PROJECT TITLE: *Treatment of Sepsis Bioenergetics Using a Protein Biologic*

TECHNOLOGY SECTOR: Life Sciences

AWARD AMOUNT: \$50,000

AMOUNT SPENT: \$50,000

PARTNERS: The Jackson Laboratory

Sepsis and related multiple organ dysfunction are major causes of mortality and morbidity, responsible for over 215,000 deaths per year in the U.S. Despite growing understanding of the pathomechanism of sepsis, treatment options are still limited primarily to antibiotics, glucocorticoids, and supportive

measures. There is wide consensus that mitochondrial dysfunction, so-called cytopathic hypoxia, develops over the course of sepsis and becomes the defining feature of the late stage of the process. Experimental manipulations, such as over-expression of transcription factors that enhance mitochondrial biogenesis, TFAM, have been found effective in models of sepsis, but clinical applications are hampered by lack of suitably powerful pharmacological biogenesis stimulators.

During the CRCF SBIR Matching Funds project, Gencia developed a recombinant form of human TFAM (rhTFAM), modified to allow it to traverse cellular barriers and to be specifically imported into mitochondria. Gencia researchers tested whether rhTFAM was capable of reversing the cytopathic hypoxia observed in a lipopolysaccharide (LPS) model of sepsis. Specifically, the aims of the project were to determine if rhTFAM treatment ameliorates inflammation, mitochondrial function, and cell death in HepG2 and human primary liver cells challenged with LPS and to determine whether rhTFAM treatment alters mortality in c57/b16 mice challenged with LPS. Confirmation of a beneficial effect of rhTFAM in LPS models of sepsis would pave the way for SBIR Phase II work, where rhTFAM would be used in the cecal ligation and puncture (CLP) model of sepsis. Gencia intends to submit a Phase II proposal to the National Institute of Allergy and Infectious Disease (NIAID) in December 2012. Moreover, this CRCF project helped support key milestones necessary to move the rhTFAM towards and investigational new drug (IND) filing with the U.S. Food and Drug Administration (FDA) and commercialization.

HemoSonics, LLC (SBIR-017)

ORGANIZATION: HemoSonics, LLC
LOCATION: Charlottesville
PROJECT TITLE: *Development of Quality Control System for In-Vitro Assessment of Hemostasis*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$49,734
AMOUNT SPENT: \$8,467
PARTNERS: University of Virginia (U.Va.), BioLyph LLC

Coagulopathy, defined as disturbance of the physiologic balance between bleeding and clotting, is often observed in the five million patients affected by chronic liver disease (CLD). Clinical evaluation and management of coagulopathies in CLD patients remains poorly understood. Improved diagnostic tools are needed to assess bleeding and clotting risks in patients and guide routine clinical decisions. Unfortunately, currently, there is no viable comprehensive test able to provide accurate diagnosis and guide management of coagulopathy for CLD patients.

HemoSonics, LLC is developing a point-of-care (POC) instrument, the Global Hemostasis Analyzer (GHA), to directly quantify the function of different hemostatic components, enabling appropriate selection of treatment. The GHA is based on sonorheometry (SR), a patented ultrasound-based technology that can rapidly quantify the hemostatic process and aid in early coagulopathy identification. The GHA will help the surgical team administer the correct treatment, will help the hospital save costs by reducing

unnecessary transfusions, will help the blood bank save blood products, and will help improve the patient's care.

The CRCF investment furthered development and commercialization goals by designing and validating an appropriate quality control (QC) system to be used with the GHA analyzer; the device is currently in the beta stage of design. The team conducted experiments with QC materials from two vendors and discovered that while each vendor's materials provided useful information for instrument calibration, individually they did not provide a complete set of measurements. The team and selected vendor are finalizing the development of a set of QC materials that will provide all the required measurements for optimal system calibration. The availability of this system is critical for the regulatory approval and ultimately the commercial success of this product.

To-date, HemoSonics has raised \$3 million in angel funding in addition to over \$2 million in NIH and other federal grants. The latest \$2 million in angel funds is dedicated to product development, as is \$868,000 in an SBIR Phase II project that started September 2011 and will run for two years. These funds are specifically targeted at developing a production-ready beta instrument. Through CRCF and other funding, HemoSonics positively impacted workforce development in the Commonwealth by hiring two undergraduate interns from U.Va., an office manager, and a research engineer over the course of this project. HemoSonics plans to hire additional personnel to manage the clinical trials and prepare for market launch. Once the company enters sales, teams will be built out for accounting and finance, customer service, sales and marketing, and IT; HemoSonics estimates the creation of 30 jobs for their Virginia-headquartered business.

HemoSonics, LLC (SBIR-018)

ORGANIZATION: HemoSonics, LLC
LOCATION: Charlottesville
PROJECT TITLE: *Reagent Optimization for In-Vitro Assessment of Hemostasis*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$49,994
AMOUNT SPENT: \$8,467
PARTNERS: University of Virginia (U.Va.), BioLyph LLC

Over 60% of the 600,000 patients undergoing cardio-pulmonary bypass (CPB) procedures in the U.S. each year experience intra- and post-operative bleeding. Several transfusion treatment options are available to surgeons, however, there is no global hemostasis test available at the point-of-care (POC), which is able to guide the best treatment option. Current clinical practice is iterative blood product transfusion and subjective evaluation of bleeding. This process is slow and proven to over-transfusion, resulting in increased risk of immunological reaction, infection, and unnecessary expense.

HemoSonics, LLC is developing a POC instrument, the Global Hemostasis Analyzer (GHA) to directly quantify the function of different hemostatic components, enabling appropriate selection of treatment.

The GHA is based on sonorheometry (SR), a patented ultrasound-based technology that can rapidly quantify the hemostatic process and aid in early coagulopathy identification. In addition, it's faster, more compact, easier to use, and offers information not available in similar devices. The GHA, currently in the beta stage of design, has multiple benefits. It will help surgical teams administer the correct treatment, hospitals decrease costs by reducing unnecessary transfusions, blood banks save blood products, and will help improve patient care.

The goal of HemoSonics' second CRCF SBIR Matching Funds award was to further the development and commercialization goals by identifying, optimizing, and validating a set of lyophilized reagents to be pre-loaded and used within each test consumable cartridge of the GHA instrument. CRCF funding allowed HemoSonics to conduct experiments with reagents specifically selected to provide as much information as possible of all components of the coagulation cascade in an effort to better guide patient treatment options. The team also determined the appropriate concentrations of each reagent and will collaborate with BioLyph LLC to manufacture these reagents in a format that will be small, easy to load into cartridges, and appropriate for long storage. The next step in this project is to obtain lyophilized reagents and load them into consumable cartridges for testing. The first product release is anticipated for mid-2014 in Europe and Canada and within the first quarter of 2015 in the U.S.

INCOGEN, Inc. (SBIR-003) (Final)

ORGANIZATION: INCOGEN, Inc.
LOCATION: Hampton Roads
PROJECT TITLE: *Commercialization Strategy for Cancer Biomarker Intellectual Property*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$49,915
AMOUNT SPENT: \$49,915
PARTNERS: N/A

INCOGEN, Inc. provides software and professional services to life and clinical researchers to optimize the analysis, mining, and management of large, heterogeneous data sets. Since its 1998 start, INCOGEN has developed a large and growing list of clients – including corporations, institutes, and laboratories – who utilize their custom informatics solutions and user-friendly, multi-platform discovery tools. In this CRCF SBIR Matching Funds project, INCOGEN conducted market research and commercialization planning for the intellectual property being developed during their current NIH Phase II project. Although INCOGEN has extensive experience commercializing its software products, the commercialization of clinical intellectual property, such as the cancer biomarkers in this project, comprises a new set of challenges that required additional research to develop the best strategy and business plan.

During the market research portion of their work, INCOGEN issued a survey to collect and analyze information about consumers, competitors, and the effectiveness of marketing programs in order to determine the feasibility of commercializing the discovered biomarkers, test interest in renal cancer-specific biomarkers, explore biomarker competition, and develop competitive strategies. Results from

this survey validated their current and prospective work, leading researchers to prepare a commercialization plan to provide resources to find the best strategy for bringing INCOGEN's biomarker research and intellectual property to the market. The discovery of potential biomarkers and therapeutic strategies for the company's integrative biological study of renal cell carcinoma offers clinically-relevant intellectual property that can be licensed to pharmaceutical companies and INCOGEN is in a prime position to capitalize on the intellectual property obtained from this project; initial contacts are currently being investigated. Furthermore, work from this CRCF project will help facilitate the company's plan to pursue subsequent and additional funding.

Indoor Biotechnologies, Inc. (SBIR-010) (Final)

ORGANIZATION: Indoor Biotechnologies, Inc. (IBI)
LOCATION: Charlottesville
PROJECT TITLE: *Multiplex Array for Mold Biomarkers*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$50,000
AMOUNT SPENT: \$50,000
PARTNERS: University of Virginia (U.Va.) Lymphocyte Culture Center, Radix Biosolutions, Luminex Corporation

Mold exposure is associated with a broad range of health effects, including allergic respiratory disease, infection, pulmonary diseases, chronic fatigue syndrome, lethargy, and migraine headaches. Several different mold species have been implicated in causing disease and this, in combination with the diverse health effects, has made it difficult to establish clear relationships between mold exposure and health. Currently there are no established guidelines for mold exposure, due in part to lack of valid quantitative exposure-assessment methods. IBI is developing a sensitive immunoassay for the detection of biomarkers for multiple mold species commonly found in water-damaged buildings. The Multiplex Array for Mold Biomarkers (MAMB) is an expandable, high-throughput assay that measures specific and unique allergens or other antigens from various mold species and would make large-scale studies for mold exposure possible. The MAMB currently measures six mold allergens or antigens and has been evaluated as a method for detecting molds in environmental samples.

This CRCF award furthered IBI's progress towards commercializing the MAMB as a mold exposure assessment method, successfully bridging the gap between IBI's SBIR Phase I study from 2010 and their pursuit of SBIR Phase II funding in 2012. Using CRCF funds, IBI conducted MAMB validation studies, worked towards adding a sixth mold species to the MAMB panel, and marketed and promoted the technology at two out-of-state conferences. In addition to the scientific advances made at IBI's laboratory, CRCF funding supported antibody production services provided by the U.Va. Lymphocyte Culture Center.

Further work will allow IBI to expand the MAMB to include up to ten mold species commonly found in water-damaged buildings. To facilitate this effort, IBI applied for a National Institute of Environmental

Health Sciences (NIEHS) SBIR Phase II grant in August 2012. The specific aims of this Phase II project are to expand the MAMB to a ten-plex by developing antibodies to antigens from additional molds commonly found in water-damaged buildings; clone and express mold antigens from *A. versicolor*, *S. chartarum*, and *P. chrysogenum*; and environmental exposure assessment using the MAMB. The MAMB will be validated by measuring molds in samples from well-defined environmental studies of asthma in New York City and in New Orleans. IBI intends to commercialize the MAMB as an extension of the existing and highly successful product and service line of MARIA, a test for multiple indoor allergens that was commercialized in 2008.

Demonstrating that the MAMB can measure mold exposure is the key element in successful commercialization. Previous work has suggested that high levels of mold growth (spore counts) are required to be detected by immunoassay tests, even if the tests are highly sensitive, because the levels of antigens in spores are low. Thus, an important aspect of MAMB development is the availability of environmental samples of known spore concentrations. To validate the MAMB, IBI will partner with several prominent labs in the U.S. that collect environmental samples. Product validation by these labs and other research groups yield the potential for outside investment and commercial success.

To accommodate IBI's anticipated growth, the company recently purchased a new building in Charlottesville that will more than double the space currently available for its operations. The new facility provides the infrastructure for continued growth, commercial development, and new production facilities and offices. Additional space available for lease will provide an option for other growing technology businesses to stay in Virginia and may attract new business to the Central Virginia area.

iTi Health, Inc. (SBIR-008)

ORGANIZATION: iTi Health, Inc.
LOCATION: Charlottesville
PROJECT TITLE: *Comparing Imaging Agent Modalities for Optimal Detection of Pancreatic Cancer*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$50,000
AMOUNT SPENT: \$22,093
PARTNERS: University of Virginia (U.Va.) Emily Couric Cancer Center

iTi Health received two SBIR Matching Funds awards and, in its first award, the company is developing a targeted imaging agent for the early detection of pancreatic cancer. The imaging agent binds to the highly validated marker of pancreatic cancer, plectin, which is expressed specifically in pancreatic cancer and its precursor lesions (though not in benign, inflammatory conditions of the pancreas). An imaging agent targeting this marker has been tested extensively in stringent animal models and has demonstrated the ability to image very small tumors. In this CRCF project, iTi Health is testing the two most sensitive imaging modalities for optimal characteristics for early diagnosis. Single photon emission computer tomography (SPECT) and positron emission tomography (PET) are both radionuclide-based

imaging modalities with the ability to allow sensitive detection of small tumors; each has distinct advantages, and this project is testing the use of the plectin imaging agent in both settings to determine which modality has the optimal characteristics for success in human clinical testing.

To address considerable limitations in the current standard diagnostic work-up, iTi Health is developing a novel molecularly targeted imaging agent to the biomarker plectin. SPECT imaging is a common imaging modality with a highly distributed instrumentation base and is commonly available in the local clinic setting, making it a highly accessible imaging test for doctors in rural settings. Through this project, iTi is investigating the utility of plectin imaging using PET imaging and has been awarded a distinct SBIR to pursue early-stage comparative studies of SPECT vs. PET. Compared to SPECT imaging, PET imaging has increased resolution, which could translate into diagnosing smaller tumors, and a lower associated cost of goods. PET, however, is much less accessible and is mostly associated with major medical centers.

With the ability to sensitively and specifically detect pre- and post-metastatic disease and accurately stage pancreatic cancer, plectin-targeted imaging has the potential to transform the practice of pancreatic cancer diagnosis. iTi Health expects that the plectin-targeted agent will replace the multi-imaging steps necessary currently, resulting in a work-up that is significantly faster and less expensive. The molecular information provided by the plectin imaging step should result in significantly increasing accuracy of the diagnosis and staging decisions. Moreover, a plectin-targeted imaging agent has the potential to enable the monitoring and early detection in high-risk patients, as well as assessment of response to chemotherapy.

iTi Health, Inc. (SBIR-006)

ORGANIZATION: iTi Health, Inc.
LOCATION: Charlottesville
PROJECT TITLE: *Developing a SPECT Imaging Agent for Early Diagnosis Pancreatic Cancer*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$50,000
AMOUNT SPENT: \$40,905
PARTNERS: University of Virginia (U.Va.) Emily Couric Cancer Center

This project, the second of two SBIR Matching Funds awards for iTi Health, focuses on developing a novel targeted imaging agent for the detection of pancreatic cancer using a single photon emission computed tomography (SPECT). A targeted imaging agent for the early detection, staging, treatment stratification, and measurement of response to therapeutics could transform the current standard-of-care for diagnosing and treating pancreatic cancer, a clinical setting with a serious and unmet need. In fact, pancreatic ductal adenocarcinoma (PDAC) is the fourth deadliest cancer with a five-year survival rate of less than 5%, with 75% of patients dying within year one of diagnosis. This dire prognosis has remained unchanged for the last 40 years and current standard diagnostics are slow, costly, and inaccurate in determining whether cancer exists and the best treatment option.

Plectin, the targeted imaging agent, has been extensively characterized in numerous, highly stringent preclinical animal models. This biomarker can sensitively and specifically detect tumors and accurately stage pancreatic cancer, thus having the potential to transform the practice of pancreatic cancer diagnosis. Plectin is expected to replace the multi-imaging steps currently necessary, resulting in a work-up that is significantly faster, less expensive, and more accurate. Furthermore, a plectin-targeted imaging agent has the potential to enable monitoring and early detection in high-risk patients, as well as assessment of response to chemotherapy. During a pre-investigational new drug (IND) meeting with the Food and Drug Administration (FDA), a defined set of manufacturing requests for advancement of this SEPCT agent was put forth. This CRCF SBIR Matching Funds proposal will support these FDA requests and propel this transformative, first-in-class SPECT agent for clinical studies at U.Va.'s comprehensive cancer center.

iTi Health is subcontracting portions of the SBIR/CRCF project to U.Va Emily Couric Cancer Center. ITI's three SBIR awards allowed hiring of two full-time employees and two part-time employees. The company's next steps include raising additional funds from private investors and submitting an SBIR Phase II award by the end of 2012, which would potentially fund early clinical development of the imaging agent.

LC Technologies, Inc. (SBIR-007)

ORGANIZATION: LC Technologies, Inc.
LOCATION: Northern Virginia
PROJECT TITLE: *Eyetracking Comprehension Assessment System (ECAS): Improving Validity of Comprehension Assessment for People with Brain Injury*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$49,922
AMOUNT SPENT: \$4,946
PARTNERS: Ohio University

The goal of LC Technologies' SBIR Matching Funds project is to develop and test the feasibility of an eyetracking system for assessment of language comprehension in people with stroke and brain injury. Most people who have had a stroke or brain injury have deficits that may impair their ability to respond or to respond correctly when traditional tests of linguistic comprehension are administered. This novel assessment system, called the Eyetracking Comprehension Assessment System (ECAS), will enhance the validity of language comprehension testing for people whose comprehension is poorly or inaccurately assessed via traditional assessment methods.

ECAS is a computer-based testing procedure that presents a patient with a series of trial situations and observes his/her resulting eye activity. Each situation begins with a verbal stimulus that presents a circumstance and, simultaneously, a set of four alternative visual images is displayed in the corners of the computer screen, each having varying degrees of semantic relationship to the audible stimulus. Eye

tracking technology (Eyefollower) measures how the patient visually scans the images and the trial is scored by evaluating how the patient's scan path converges to the "target" image, or the image with the greatest semantic relationship to the verbal stimulus. The ECAS concept utilizes the intrinsic dynamics of the eye-mind relationship to evaluate the patient's comprehension of the trial's subject matter. The auditory and visual stimuli induce viewing patterns that expose a person's underlying comprehension abilities. Ultimately, ECAS allows clinicians to gain information about comprehension that is currently unavailable for severely inexpressive patients and other patients who are difficult to diagnose.

In this reporting period, the CRCF funds allowed LC Technologies to formulate a list of pupilometry metrics expected to be useful in the ECAS system and build computer software to compute these metrics. Pupilometry metrics may help to expand the applicability of the system to those who do not have sufficient vertical and horizontal eye movement for the fixation-based system to work and may increase the confidence in and/or precision of the current gaze-based assessments. The next step is to execute pupil-parameterization code on ECAS data previously collected in Phase I of the NIH SBIR project. The resulting pupil-parameter values will be correlated with known comprehension deficits to determine the potential value of using pupilometry data to predict comprehension deficits. LC Technologies also is compiling ECAS descriptive material to use in discussions with potential customers to ensure the final product will meet the needs of those customers and ultimately be a product profitable to both the company and user institutions.

LC Technologies requested and received a four-month no-cost extension to continue evaluating alternate organizations to host ECAS training in China.

Parabon NanoLabs, Inc. (SBIR-001)

ORGANIZATION: Parabon NanoLabs, Inc.
LOCATION: Northern Virginia
PROJECT TITLE: *Mixed-Ligand Targeting of a Nano-Pharmaceutical Against GBM Stem Cells*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$50,000
AMOUNT SPENT: \$15,480
PARTNERS: University of Virginia (U.Va.)

Parabon NanoLabs, Inc. developed a project to focus on drugs designed to enable the treatment of primary malignant glioma (brain) tumors, which are among the deadliest of all cancers, and also currently without effective treatment options. Parabon's product, Essemblix™, allows scientists to direct the exact placement of every atom within the compound, which provides rational drug design capabilities. This CRCF project augments an NIH SBIR Phase I project to provide funds for business/investor development and to assist the company with its preparation of the associated SBIR Phase II proposal. In addition, CRCF funds were expended for intellectual property protection.

Based on business development efforts made possible by CRCF funding, an opportunity was generated that encouraged NIH to extend the SBIR Phase I period of performance, thus delaying the preparation of the Phase II proposal. Specifically, Parabon NanoLabs developed a relationship with scientists at Janssen Pharmaceuticals, a Johnson & Johnson company, and together the two organizations approached the Nanotechnology Characterization Laboratory (NCL), a federal laboratory jointly supported by NIH, the U.S. Food and Drug Administration (FDA), and the National Institutes of Standards and Technology (NIST), to inquire whether NCL would perform immunotoxicity studies on Parabon Essemblix™ nano-carriers of the variety being investigated in the SBIR Phase I project. The results from such studies showing the safety of Essemblix™ constructs is essential for Janssen to license the technology. NCL agreed to fund the studies and NIH agreed to fund the required materials as a supplement to the Phase I project; NCL is slated to begin the studies in late September or early October 2012.

Over the course of the next six months, Parabon NanoLabs will continue working on the NIH SBIR Phase I project to complete the tests outlined in the research work plan; supply NCL with nanostructures for testing; participate in a media campaign with National Science Foundation (NSF), Johnson & Johnson, and Janssen Pharmaceuticals; identify and retain an NIH proposal consultant and begin writing a Phase II proposal; and continue to work towards a Series A raise.

Phthisis Diagnostics, Inc. (SBIR-002)

ORGANIZATION: Phthisis Diagnostics, Inc.
LOCATION: Charlottesville
PROJECT TITLE: *Molecular Diagnostic for Microsporidia*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$49,400
AMOUNT SPENT: \$28,930
PARTNERS: N/A

The purpose of this SBIR Matching Funds award is to develop a new clinical diagnostic using the precision of DNA testing – a faster, more sensitive, and less costly diagnostic – to diagnose intestinal infections caused by microsporidia, as currently no other polymerase chain reaction (PCR)-based diagnostic tests of these pathogens exist. Microsporidia are fungi that cause chronic diarrhea and can cause death in people with impaired immune systems; at present, microsporidiosis is under-reported due to inadequate diagnostic tools, and the routine diagnosis of microsporidial infection is through microscopic examination, a process that is labor intensive, time consuming, and subjective.

Phthisis has developed *R-Sphere® Microsporidia Detect* to improve diagnosis and reduce diagnostic complexity of microsporidia, improve reimbursement of clinical microsporidial testing, and increase the demand for microsporidia diagnosis. Thus far, Phthisis has completed several important milestones, such as additional market research and refined design plan to ensure technology meets market needs, including outreach to potential customers; refined DNA extraction methodology required for diagnostic; developed initial diagnostic pilot assays; and presented both DNA extraction methodology and

diagnostic prototype at two scientific conferences. Next, Phthisis team members will begin validation testing on the *R-Sphere® Microsporidia Detect*.

Phthisis is awaiting award of an NIH National Institute of Allergy and Infectious Diseases (NIAID) Phase II grant to complete research on this diagnostic, and private angel investors have been recruited by the team to fund commercialization efforts of this diagnostic once it is ready to progress. Direct commercialization activities are expected to begin immediately after the completion of this award.

Synthonics Inc. (SBIR-015) (Final)

ORGANIZATION: Synthonics Inc.
LOCATION: Roanoke-Blacksburg
PROJECT TITLE: *Levodopa Pharmacokinetic Optimization by Metal Coordination*
TECHNOLOGY SECTOR: Life Sciences
AWARD AMOUNT: \$50,000
AMOUNT SPENT: \$50,000
PARTNERS: N/A

In this SBIR Matching Funds award, Synthonics Inc. furthered the development of a metal coordinated levodopa compound for the management of the symptoms of Parkinson’s disease (PD). PD is a degenerative neurological disorder that affects a large and growing portion of America’s population; experts believe that between 500,000 and 1.2 million Americans suffer from it. Because the disease occurs primarily in older persons and is both chronic and incurable, the financial and public health impacts of PD on our society are likely to increase as our population ages.

Although PD cannot be cured, it can often be managed through medication and surgery. The global market for drugs intended to treat PD is large and growing and is expected to increase. Despite efforts to introduce new treatments, levodopa remains the standard care of PD therapy, as it appears uniquely capable of facilitating motor control among PD patients. Levodopa’s long-term use, however, can present serious issues. As a result of the issues associated with delivering too little or too much of the drug, maintaining consistent dopaminergic effects from oral levodopa has been one of the most challenging problems in managing advanced PD.

Synthonics’ metal coordination chemistry provides a simple and elegant way to deliver levodopa in the desired manner. Synthonics covalently binds levodopa to bismuth to create MCP-311. MCP-311 attaches to the lining of the gut, where levodopa molecules gradually detach from the complex and enter the bloodstream through the active transporters in the small intestine – a significant advance in PD treatment that offers meaningful clinical benefits to PD patients. Reports of dramatically fewer periods of dyskinesia and “off” time from patients receiving continuous infusions of levodopa than from patients taking currently available oral treatments and would substantially reduce the risks associated with long-term levodopa use.

This award allowed Synthonics to fund work intended to demonstrate the effect of varying particle size on the pharmacokinetics of MCP-311. Studies underwritten by this CRCF award sought to show the relationship between particle size and plasma profile. Specifically, Synthonics was primarily trying to determine if particle size had a significant impact on the length of time the levodopa blood concentration stayed above a certain value that was theoretically deemed to be the minimum therapeutic level. Synthonics' theory was that smaller particle size would result in better dispersion in the stomach, leading to strong mucoadhesion, greater retention time in the stomach, and slower and more constant release of levodopa from the bismuth-levodopa copolymer. Synthonics determined that changes in particle size cause changes in the drug's absorption, but has not yet identified the ideal particle size for MCP-311. Synthonics will continue to experiment with various particle sizes as it refines its lead compound.

Synthonics will continue to advance MCP-311 towards commercialization. Synthonics has received \$2.2 million in funding from NINDS to complete the formulation with the other components necessary to the filing of an investigational new drug (IND) application. The researchers have strengthened their relationship with a large pharmaceutical company – the marketer of a leading branded levodopa product – and seek to partner with another company on the product's commercialization while Synthonics pursues development and approval.

The short-term impact of the work completed pursuant to the CRCF award and to be undertaken pursuant to the NIH grant is the creation of one full- and one part-time position at Synthonics' Blacksburg, Virginia offices. Synthonics expects to add additional personnel and specialized machinery for this and other projects as work advances.

Fall 2011 Declined Awards

The following organizations recommended for funding declined these fall 2011 awards:

- Jericho Sciences, LLC, *A Novel CNS-Penetrable Antiretroviral* (SBIR-021)
- Old Dominion University, *Frank Reidy Center for Bioelectrics Facility Expansion* (FE-001)
- Virginia Tech, *Chemical Synthesis of Square Quantum Dots* (MF-003)
- Xyken, LLC, *An Intelligent Capsule Endoscopy Video Analysis Software Platform* (SBIR-005)

Winter 2012 Solicitation

The following organizations received CRCF awards in July 2012 as part of the second FY2012 solicitation. As of this writing, awards are being disbursed, and many projects are underway. CIT will discuss the progress of these projects in the FY2013 Annual Report, and an overview is included in Appendix A.

Commercialization Fund

- Dr. Kevin McElfresh, BrinkID, *Defining Backward Compatibility Algorithms of Ultra-High-Density Single Nucleotide Polymorphism Forensic Results with Forensic STR DNA Results*, \$125,000, Northern Virginia (CP-044-W)
- Mr. Kevin Williams, ClearEdge3D, Inc., *3D Modeling and Simulation Software for Defense and Security Operational Planning*, \$145,717, Northern Virginia (CP-022-W)
- Mr. Geoffrey Miller, Eastern Virginia Medical School, *Automated Intelligent Mentoring System (AIMS)*, \$244,441, Hampton Roads (CP-018-W)
- Mr. Guy Davis, ElectraWatch, Inc., *Aluminum Sensitization Probe and Portable Potentiostat*, \$250,000, Charlottesville (CP-014-W)
- Dr. Francesco Viola, HemoSonics, LLC, *Design for Manufacture of the Sensor Interface for a Novel In-Vitro Diagnostic Instrument*, \$100,000, Charlottesville (CP-008-W)
- Dr. Donna Marie Bilkovic, Innovative Marine Products and Solutions, *Biodegradable Panels for Crab and Lobster Pots*, \$108,500, Hampton Roads (CP-011-W)
- Dr. Christopher Detzel, NanoSafe Inc., *NanoSafe Tested™ - A Commercial Testing Platform for Safe Nanomanufacturing and Nano-Enabled Consumer Products*, \$65,915, Roanoke-Blacksburg (CP-061-W)
- Dr. Karen Morgan, PocketSonics, Inc., *SonicWindow Low-Cost Ultrasound Vascular Access Device*, \$53,769, Charlottesville (CP-020-W)
- Mr. David Kenealy, Southern Virginia Higher Education Center, *Use of Southern Yellow Pine as an Alternative Material for the Manufacture of Cross-Laminated Timbers for Use in Commercial Construction*, \$250,000, Southern Piedmont (CP-069-W)
- Mr. Kevin Sapp, SpydrSafe Mobile Security, Inc., *Data Loss Prevention for Mobile Applications*, \$100,000, Northern Virginia (CP-005-W)
- Dr. Lloyd Gray, Tau Therapeutics LLC, *Commercialization of Mibefradil, A Novel Cancer Therapy*, \$200,000, Charlottesville (CP-072-W)
- Dr. Thomas Campbell, Virginia Tech, *Additive Manufacturing System for Nanocomposites*, \$200,000, Roanoke-Blacksburg (CP-076-W)
- Mr. Jay Titlow, WeatherFlow Inc., *Development of an Operational Tuned Forecast System for Use in Offshore Wind Energy*, \$242,000, Hampton Roads (CP-078-W)

Eminent Researcher Recruitment Program

- Dr. Richard Heller, Old Dominion University, *Recruitment of Dr. Igor Efimov*, \$250,000, Hampton Roads (ER-001-W)

Matching Funds Program

- Dr. Sylvain Marsillac, Old Dominion University Research Foundation, *Embedded Health Monitoring for Large-Scale Solar Power Systems*, \$150,000, Hampton Roads (MF-003-W)
- Mr. Bob Bailey, Region 2000 Research Institute dba CAER, *A Regional Cognitive Radio Testbed*, \$150,000, Region 2000 (MF-002-W)
- Dr. Eric Loth, University of Virginia, *Innovative Nano-Textured Protective Coatings for Structurally Integrated Panels*, \$150,000, Charlottesville (MF-016-W)
- Dr. Louis J. Guido, Virginia Tech, *Bottomless GaN Power Devices*, \$150,000, Roanoke-Blacksburg (MF-018-W)

SBIR Matching Funds Program

- Dr. Amy Papadopoulos, AFrame Digital, Inc., *Non-Intrusive Automated Portable Data Collection System for Aging Surveys*, \$50,000, Northern Virginia (SBIR-008-W)
- Dr. Johanna Craig, GATACA LLC, *Integrated Desktop Software for Management of Hepatitis C Data*, \$50,000, Roanoke-Blacksburg (SBIR-005-W)
- Dr. Vladimir Karginov, Innovative Biologics, Inc., *Synthesis and Testing of Potential Anti-MRSA Therapeutics*, \$49,990, Northern Virginia (SBIR-004-W)
- Dr. Steven Yi, Xyken, LLC, *Next Generation Capsule Endoscopy Video Data Acquisition and Visualization Platform*, \$50,000, Northern Virginia (SBIR-002-W)

Preparations for FY2013

The General Assembly and Administration appropriated \$4.8 million to CRCF for FY2013, and CIT will develop and announce FY2013 opportunities in early fall.

Administration

Administrative activities in FY2012 included managing the two solicitations and establishing the Research and Technology Investment Advisory Committee (RTIAC). Planning steps included developing guidelines for each of the five programs in consultation with the technology community and the Administration. Of the total appropriated funding for FY2012, \$150,000 went to CIT for administrative expenses related to implementing the guidelines and the review process. Such organizations as Virginia's regional technology councils and the Virginia Biotechnology Association (VABio) assisted with establishment of the RTIAC and CRCF and its outreach; the Administration, including the Secretariats of Commerce & Trade, Education, and Technology supported establishment of the RTIAC, development of the guidelines, and community outreach. The State Council of Higher Education for Virginia (SCHEV) and the Virginia Economic Development Partnership (VEDP) were among agencies that assisted with these processes.

CIT used an online grants management system, CyberGrants, to facilitate application submissions and reporting; the tool became an integral part of the CRCF process. As Fund Administrator, CIT established a multi-step proposal reviewing process. CIT performed an internal compliance review to determine which applications advanced to a review by subject matter experts. These subject matter experts – comprised of individuals from industry, academia, and government – evaluated and rated proposals. Those that advanced were reviewed by the RTIAC. The RTIAC assessed projects and recommended to the IEIA which should be funded. The IEIA makes final award decisions, after which announcements are made.

CIT maintained information on the Fund, including solicitations and award announcements, on the CIT website. As appropriate, press releases described the request for proposals, solicitations, and, subsequently, award recipients. Outreach and communications also included email announcements and speaking engagements.

Also as Fund Administrator, CIT collected, reviewed, and assessed the final reports from CTRF award recipients and prepared the FY2011 Annual Report. Additionally, CIT received and revised annual and final reports from fall FY2012 awardees, included herein. CIT provided support to external organizations, state agencies, and researchers from academia, industry, and other members of the technology community that desired information about the Fund and future solicitations. Lastly, throughout the year, CIT provided oversight to ensure compliance with the CRCF guidelines and other requirements.

APPENDIX A: Award Details

Fall 2011 Solicitation

Lead Institution	Project Title	Period of Performance	Principal Investigator	Total CRCF Award	Match
COMMERCIALIZATION PROGRAM					
Black Laboratories, LLC	Processing and Testing of Hydroformed SRF Cavities	1/1/2012 – 12/31/2012	Roy Crooks	\$91,922	\$91,922
HemoShear	Interspecies Drug-Induced Vascular Injury (DIVI) Consortium	7/1/2012 – 3/31/2013	James Powers	\$250,000	\$761,043
Phthisis Diagnostics, Inc.	Commercialization of Cryptosporidium/Giardia Molecular Diagnostic	1/1/2012 – 6/30/2013	Crystal Icenhour	\$499,477	\$532,048
RetiVue	Bringing Affordable Retinal Screening Technology and Services to the Primary Care Physician	7/1/2012 – 6/30/2014	Paul Yates	\$250,000	\$250,000
TOTAL FALL COMMERCIALIZATION PROGRAM AWARD:				\$1,091,399	
EMINENT RESEARCHER RECRUITMENT PROGRAM					
Virginia Tech	Recruitment of Eminent Scholar in Heart Regenerative Medicine Research	1/1/2012 – 6/1/2013* *NCE extended date	Michael Friedlander	\$250,000	\$250,000
TOTAL FALL EMINENT RESEARCH RECRUITMENT PROGRAM AWARD:				\$250,000	
FACILITIES ENHANCEMENT LOAN PROGRAM					
Old Dominion University **	Frank Reidy Center for Bioelectrics Facility Expansion	1/1/2012 – 12/31/2012	Robert Fenning	(\$500,000)	(\$1,246,060)
TOTAL FALL FACILITIES ENHANCEMENT LOAN PROGRAM AWARD:				N/A	
MATCHING FUNDS PROGRAM					
Old Dominion University	A Nonchemical Approach for Creating Platelet Gel	1/1/2012 – 12/31/2012	Richard Heller	\$100,000	\$100,000
Old Dominion	Development and Commercialization of	1/1/2012 – 12/31/2012	Richard Heller	\$100,000	\$136,850

University	Pulse Power Technology				
Region 2000 Research Institute	Center for Safe and Secure Nuclear Energy	6/1/2012 – 8/31/2013	Bob Bailey	\$100,439	\$3,825,640
University of Virginia	Bone Imaging: Technology Development and Pilot Study	1/1/2012 – 12/31/2012	John Hossack	\$120,000	\$125,000
Virginia Institute of Marine Science	Near-Infrared Reflectance Spectrometry (NIRS) for Evaluation of Oyster Physiology in Selective Breeding	1/1/2012 – 12/31/2012	Standish Allen	\$97,435	\$100,306
Virginia Tech **	Chemical Synthesis of Square Quantum Dots	7/1/2012 – 6/30/2013	Thomas Campbell	(\$50,000)	(\$50,000)
Virginia Tech	Photovoltaic Inverter Development for Virginia Manufacturing Industries	1/1/2012 – 12/31/2012	Jih-Sheng Lai	\$148,998	\$150,608
TOTAL FALL MATCHING FUNDS PROGRAM AWARD:				\$666,872	
SBIR MATCHING FUNDS PROGRAM					
AFrame Digital, Inc.	Continuous Fall Risk Monitoring System: Walking vs. Activities of Daily Living	1/2/2012 – 7/2/2012	Amy Papadopoulos	\$49,997	N/A
Alexander BioDiscoveries, LLC	Novel Anti-Viral Agents to Treat Influenza	3/2/2012 – 9/1/2012	Dipanwita Basu	\$50,000	N/A
Biospherex LLC	Development of an LH-PCR Based Diagnostic for Inflammatory Bowel Disease	1/1/2012 – 6/30/2012	Thomas Kuehn	\$50,000	N/A
Gencia Corp.	Treatment of Sepsis Bioenergetics Using a Protein Biologic	2/1/2012 – 5/31/2012	Rafal Smigrodzki	\$50,000	N/A
HemoSonics, LLC	Development of Quality Control System for In-Vitro Assessment of Hemostasis	2/1/2012 – 9/30/2012* *NCE extended date	Francesco Viola	\$49,734	N/A
HemoSonics, LLC	Reagent Optimization for In-Vitro Assessment of Hemostasis	2/1/2012 – 8/31/2012* *NCE extended date	Elisa Ferrante	\$49,994	N/A
INCOGEN, Inc.	Commercialization Strategy for Cancer Biomarker Intellectual Property	1/1/2012 – 6/30/2012	Maciek Sasinowski	\$49,915	N/A
Indoor Biotechnologies Inc.	Multiplex Array for Mold Biomarkers	1/1/2012 – 6/30/2012	Martin Chapman	\$50,000	N/A
iTi Health, Inc.	Comparing Imaging Agent Modalities for Optimal Detection of Pancreatic Cancer	1/1/2012 – 12/31/2012*	Greg Fralish	\$50,000	N/A

		*NCE extended date			
iTi Health, Inc.	Developing a SPECT Imaging Agent for Early Diagnosis of Pancreatic Cancer	1/1/2012 – 12/31/2012*	Greg Fralish	\$50,000	N/A
		*NCE extended date			
Jericho Sciences, LLC **	A Novel CNS-Penetrable Antiretroviral	1/1/2012 – 8/31/2012	Heidi Kay	(\$50,000)	N/A
LC Technologies, Inc.	Eyetracking Comprehension Assessment System (ECAS): Improving Validity of Comprehension Assessment for People with Brain Injury	3/15/2012 – 4/15/2013* *NCE extended date	Dixon Cleveland	\$49,922	N/A
Parabon NanoLabs, Inc.	Mixed-Ligand Targeting of a Nano-Pharmaceutical Against GBM Stem Cells	1/1/2012 – 12/31/2012	Steven Armentrout	\$50,000	N/A
Phthisis Diagnostics, Inc.	Molecular Diagnostic for Microsporidia	1/1/2012 – 12/31/2012	Crystal Icenhour	\$49,400	N/A
Synthonics Inc.	Levodopa Pharmacokinetic Optimization by Metal Coordination	1/21/2012 – 7/21/2012	Thomas Piccariello	\$50,000	N/A
Xyken, LLC **	An Intelligent Capsule Endoscopy Video Analysis Software Platform	1/1/2012 – 12/31/2012	Steven Yi	(\$50,000)	N/A
TOTAL SBIR MATCHING FUNDS PROGRAM AWARD:				\$698,962	
TOTAL CRCF FALL AWARD:				\$2,707,233	

** These fall FY2012 awards were declined; award amounts not included in totals

Winter 2012 Solicitation

Lead Institution	Project Title	Period of Performance	Principal Investigator	Total CRCF Award	Match
COMMERCIALIZATION PROGRAM					
BrinkID	Defining Backwards Compatibility Algorithms of Ultra-High-Density Single Nucleotide Polymorphism Forensic Results with Forensic STR DNA Results	7/16/2012 – 6/30/2013	Kevin McElfresh	\$125,000	\$282,850
ClearEdge3D, Inc.	3D Modeling and Simulation Software for	7/16/2012 – 7/15/2013	Kevin Williams	\$145,717	\$257,076

	Defense and Security Operational Planning				
ElectraWatch, Inc.	Aluminum Sensitization Probe and Portable Potentiostat	7/16/2012 – 1/31/2013	Guy Davis	\$250,000	\$500,000
Eastern Virginia Medical School	Automated Intelligent Mentoring System (AIMS)	7/16/2012 – 7/15/2013	Geoffrey Miller	\$244,441	\$244,483
HemoSonics, LLC	Design for Manufacture of the Sensor Interface for a Novel In-Vitro Diagnostic Instrument	7/16/2012 – 7/15/2013	Francesco Viola	\$100,000	\$401,588
Innovative Marine Products and Solutions	Biodegradable Panels for Crab and Lobster Pots	8/3/2012 – 7/30/2013	Donna Marie Bilkovic	\$108,500	\$189,002
NanoSafe Inc.	NanoSafe Tested™ - A Commercial Testing Platform for Safe Nanomanufacturing and Nano-enabled Consumer Products	7/16/2012 – 7/15/2013	Christopher Detzel	\$65,915	\$65,973
PocketSonics, Inc.	SonicWindow Low-Cost Ultrasound Vascular Access Device	7/16/2012 – 1/31/2013	Karen Morgan	\$53,769	\$546,915
SpydrSafe Mobile Security, Inc.	Data Loss Prevention and App Control for Mobile Devices	7/16/2012 – 7/16/2013	Kevin Sapp	\$100,000	\$100,000
Southern Virginia Higher Education Center	Use of Southern Yellow Pine as an Alternative Material for the Manufacture of Cross-Laminated Timbers for Use in Commercial Construction	7/16/2012 – 1/31/2014	David Kenealy	\$250,000	\$250,000
Tau Therapeutics LLC	Commercialization of Mibefradil, A Novel Cancer Therapy	7/16/2012 – 12/12/2012	Lloyd Gray	\$200,000	\$837,521
Virginia Tech	Additive Manufacturing System for Nanocomposites	8/1/2012 – 7/31/2014	Thomas Campbell	\$200,000	\$300,305
WeatherFlow Inc.	Development of an Anchored Wind Monitoring and Forecasting System for Offshore Wind Energy	8/1/2012 – 1/31/2014	Jay Titlow	\$242,000	\$634,000
TOTAL WINTER COMMERCIALIZATION PROGRAM AWARD:				\$2,085,342	
EMINENT RESEARCHER RECRUITMENT PROGRAM					
Old Dominion University	Recruitment of Eminent Scholar in Cardiac Bioelectricity Research ***	8/1/2012 – 7/31/2013	Richard Heller	\$250,000	\$305,250
TOTAL WINTER EMINENT RESEARCHER RECRUITMENT PROGRAM AWARD:				\$250,000	

MATCHING FUNDS PROGRAM					
Old Dominion University	Embedded Health Monitoring for Large-scale Solar Power Systems	7/16/2012 – 7/15/2013	Sylvain Marsillac	\$150,000	\$156,000
Region 2000 Research Institute dba CAER	A Regional Cognitive Radio Testbed	TBD (contingent upon federal award), 18-month PoP	Bob Bailey	\$150,000	\$1,001,108
University of Virginia	Innovative Nano-Textured Protective Coatings for Structurally Integrated Panels	7/16/2012 – 1/31/2014	Eric Loth	\$150,000	\$150,000
Virginia Tech	GaN-on-Metal Power Devices	8/1/2012 – 7/31/2013	Louis J. Guido	\$150,000	\$150,000
TOTAL WINTER MATCHING FUNDS AWARD:				\$600,000	
SBIR MATCHING FUNDS PROGRAM					
AFrame Digital, Inc.	Non-Intrusive Automated Portable Data Collection System for Aging Surveys	9/1/2012 – 2/28/2013	Amy Papadopoulos	\$50,000	N/A
GATACA LLC	Integrated Desktop Software for Management of Hepatitis C Data	7/16/2012 – 7/15/2013	Johanna Craig	\$50,000	N/A
Innovative Biologics, Inc.	Synthesis and Testing of Potential Anti-MRSA Therapeutics	7/16/2012 – 1/31/2013	Vladimir Karginov	\$49,990	N/A
Xyken, LLC	Next Generation Capsule Endoscopy Video Data Acquisition and Visualization Platform	7/16/2012 – 7/15/2013	Steven Yi	\$50,000	N/A
TOTAL WINTER SBIR MATCHING FUNDS AWARD:				\$199,990	
TOTAL CRCF WINTER AWARD:				\$3,135,332	

*** Modification: As of this writing, Dr. Michael Kong has been recruited to ODU in place of the original eminent researcher, Dr. Igor Efimov

FY2012 Funding Totals

PROGRAM	FALL AWARD TOTAL	WINTER AWARD TOTAL	FY2012 TOTAL
Commercialization	\$1,091,399	\$2,085,342	\$3,176,741
Eminent Research Recruitment	\$250,000	\$250,000	\$500,000
Facilities Enhancement Loan	N/A	N/A	N/A
Matching Funds	\$666,872	\$600,000	\$1,266,872
SBIR Matching Funds	\$698,962	\$199,990	\$898,952
ALL PROGRAMS	\$2,707,233	\$3,135,332	\$5,842,565

APPENDIX B: RTIAC Members

The following individuals were members of the Research and Technology Investment Advisory Committee (RTIAC) for FY2012, the group responsible for making award recommendations to the IEIA.

- **Martin Briley**, President and CEO, Virginia Economic Development Partnership (VEDP)
- **Daniel Gonzalez**, Principal, Avison Young
- **Robert Kahn**, Chairman, CEO & President, Corporation for National Research Initiatives (CNRI)
- **Mohammad Karim**, Vice President for Research, Old Dominion University (ODU)
- **Thomas Kirchmaier**, Division Senior Vice President and General Manager, Intelligence Solutions, General Dynamics Information Technology (GDIT)
- **Dennis Manos**, Vice Provost for Research and Graduate Professional Studies, College of William and Mary
- **Kenneth Newbold***, Vice Provost for Research and Public Service, James Madison University (JMU)
- **Bobby Ocampo**, Associate, Grotech Ventures
- **Robert Patzig**, Senior Managing Director and CIO, Third Security
- **Thomas Skalak**, Vice President for Research, University of Virginia (U.Va.)

* Dr. Newbold replaced Dr. John Noftsinger, JMU's original representative, following Dr. Noftsinger's passing in November 2011.