Ohio | Department of Development

Final Proposal Evaluation

2010

Third Frontier Biomedical Program
Third Frontier Medical Imaging Program

June 2010

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This Report written by:

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PROPOSAL REVIEW TEAM

❖ TARATEC CORPORATION

- Edward Ungar, President
- Paula Dunnigan, Project Leader
- Chuck Meadows
- Bill Munk
- Reed Slevin

❖ Ten (10) EXTERNAL REVIEWERS

Imaging Experts

- **Tracy Lynn Faber**[2] — B.S.E. (Case), Ph.D. in Biomedical Engineering (UTHSCD); Professor of Radiology, Emory University; (specializes in methodology for quantifying information in medical images); American Society of Nuclear Cardiology; Editorial Board, Journal of Nuclear Cardiology
- **John C. Gore**[2] — Ph.D. in Physics, University of London, Bedford College; Chancellor's University Professor; Director, Vanderbilt University Institute of Imaging Science; Professor of Radiology Radiological Sciences, Biomedical Engineering, Physics and Astronomy, and Molecular Physiology and Bio-Physics; Vice-Chair for Research, Department of Radiology and Radiological Sciences
- **Xiaoping Hu**[2] — Ph.D. in Medical Physics (specialized in MRI), University of Chicago; Professor and Georgia Research Alliance (Endowed) Eminent Scholar in Imaging, Department of Biomedical Engineering, Georgia Tech/Emory University; Founding Director, Biomedical Imaging Technology Center Georgia Tech/Emory University; Deputy Editor, Magnetic Resonance in Medicine
- **John Oshinski**[2] — Ph.D. in Mechanical Engineering, Georgia Institute of Technology; Associate Professor, Division of Radiology, Emory University; Director, MR Research Center, Emory School of Medicine; Co-Chair, NIH Workshop on High Field Cardiac MRI; Founding Member, Society of Cardiac Magnetic Resonance

Commercialization Specialists

- **Lluis Lagarda**[1,2] — B.S. Industrial Engineering, M.B.A. ESMT European School of Management and Technology (Berlin); Business Development Manager (technology licensing in pharmaceutical and biotechnology industry), Bioiberia, SA, Barcelona Spain
- **Donald S. Lucas**[1] — Ph.D. in Microbiology/Biochemistry (University of Arizona); Associate Director, Global Licensing, Alliances, and Acquisitions, Proctor & Gamble Pharmaceuticals (ret.), AUTM, Licensing Executive Society

Clinical Experience and Business Background (End-User Perspective)

- **Gordon Butler**[1,2] — M.D. (Northwestern); Residency in Radiology (UTSMC); Technology Analyst, Accenture, LLC
- **Brian Cox**[1,2] — M.D. (UTHSC), M.E. Biomedical Engineering (Vanderbilt); Residency in Radiology (UTSMC); Medical device licensing associate, Vanderbilt University
- **Erin Dunnigan**[1] — M.D. (OSU), M.B.A. (University of Notre Dame); Residency in Internal Medicine (Duke); Fellow in Endocrinology (UTSMC); Various positions with OSU, Children's, and predecessor organizations to Tech Columbus and BioOhio; National Chair-Council of Residents and Fellows, American College of Physicians
- **Erin Moody**[1,2] — M.D.(UTSMC), M.B.A. (UTD); Residency in Diagnostic Radiology (UTSMC); Project Manger for MRI device company with responsibility for device modifications, FDA and CE approvals, and beta testing.

[1]Reviewer for Biomedical proposals
[2]Reviewer for Medical Imaging proposals

PROPOSAL REVIEW PROCESS

❖ FIRST ROUND

- Conflict of Interest evaluation for all reviewers
- Each proposal read by 3 reviewers
- Scored 3 times using instrument based on RFP criteria
- All scores entered into database in duplicate
- Reviewers comment on areas requiring clarification
- Database produces list of proposals ranked by average score
- Top scoring proposals make Competitive Range and advance to Round 2

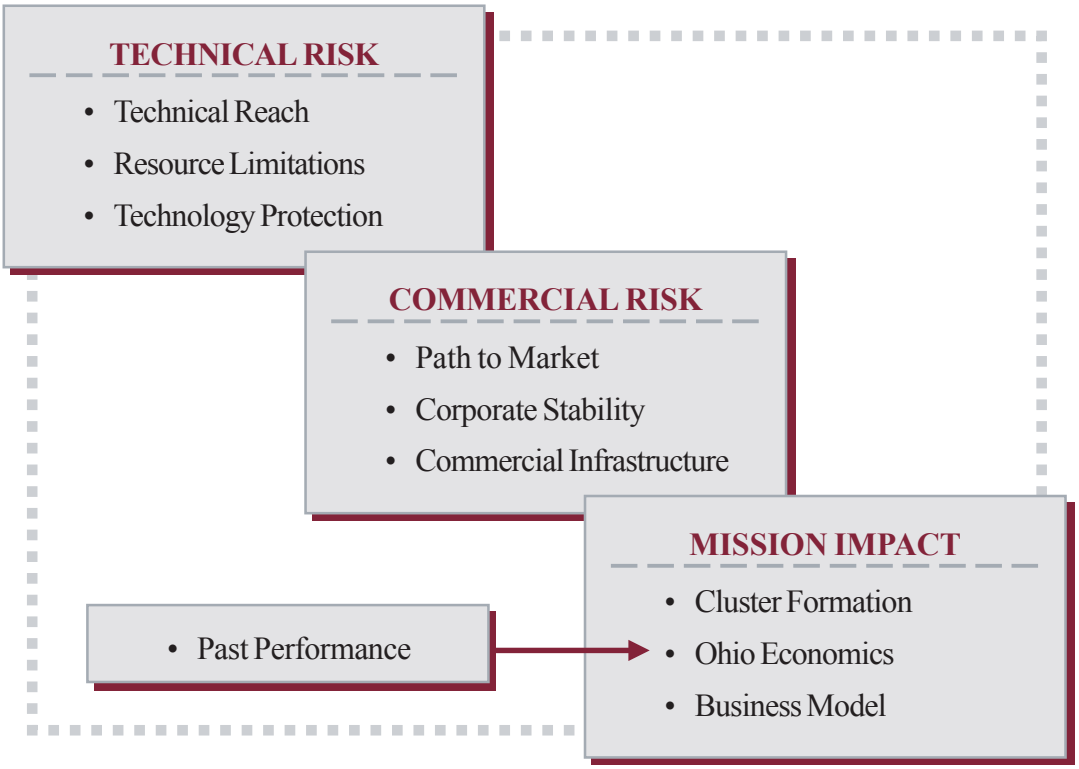
❖ SECOND ROUND

- Set of customized questions prepared for each proposal
- Applicant submits responses
- Face-to-face meeting (90 min.) of reviewers and applicants to discuss issues
- Preparation of detailed project write-up
- Final risk-benefit scoring by entire review team
- Scores entered into database
- Final recommendations developed
- Preparation of materials for Third Frontier Commission

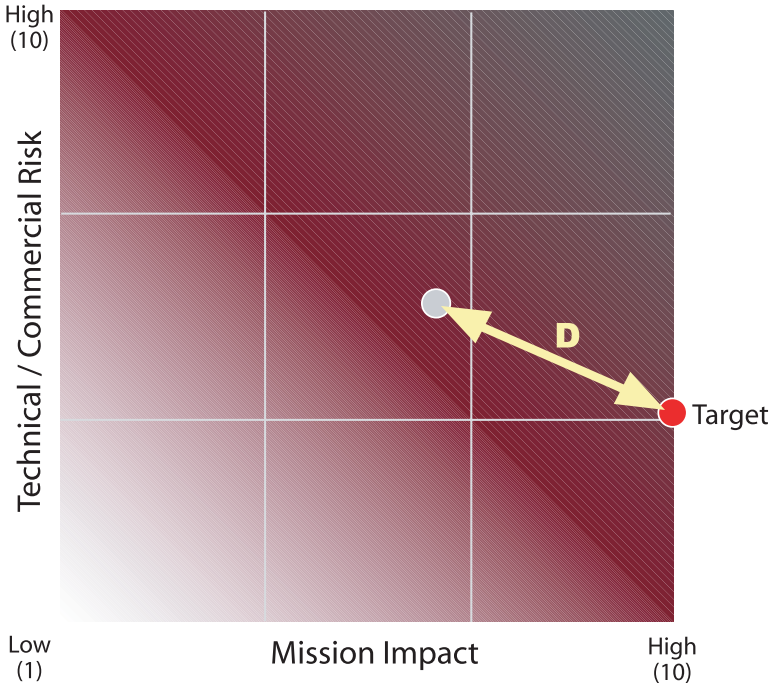
SUMMARY OF FIRST ROUND EVALUATIONS

	TFBP	TFMIP
Proposals Received	25	16
Recommended for 2nd Round	10	11
Lowest Score Recommended	61.7	56.0
Highest Score Not Recommended	58.0	50.7
TFRDF Available	$5M	$8M
TFWCF Available	$2M	$2M
Cumulative TFRDF Requested	$9.9M	$10.8M
Cumulative TFWCF Requested	None	$1.2M

SECOND ROUND EVALUATION FACTORS



SCORING METHODOLOGY



2010 TARGETS

Cluster	Technical Risk	Commercial Risk	Mission Impact
Biomedical	3.5	2.67	10
Medical Imaging	3.5	1.66	10

RECOMMENDATIONS FOR FUNDING
2010 Third Frontier Biomedical Program (TFBP)

	APPLICANT	PROPOSAL TITLE	TFRDF REQUESTED	TFRDF CUMULATIVE	TFWCF REQUESTED	TFWCF CUMULATIVE	RECOMMENDED CONTINGENCY
1.	OrthoHelix Surgical Designs, Inc.	Mini/Mega MaxLock Extreme Orthopedic Implants	$1,000,000	$1,000,000	$0	$0	
2.	Cardiox Corporation	Validation and Commercialization for Non-Invasive Detection of Cardiox Shunts	$ 986,373	$1,986,373	$0	$0	
3.	CWRU, School of Medicine	Clinical Development of MultiStem® for Treatment of Spinal Cord Injury	$1,000,000	$2,986,373	$0	$0	
4.	SpineForm LLC	Clinical Study and Commercialization of an Idiopathic Scoliosis Growth Modulation System	$ 999,250	$3,985,623	$0	$0	
5.	Lanx, Inc.	Lumbar Motion Monitor Commercialization in Ohio	$1,000,000	$4,985,623	$0	$0	

RECOMMENDATIONS FOR FUNDING
2010 Third Frontier Medical Imaging Program (TFMIP)

APPLICANT	PROPOSAL TITLE	TFRDF REQUESTED	TFRDF CUMULATIVE	TFWCF REQUESTED	TFWCF CUMULATIVE	RECOMMENDED CONTINGENCY
1. The Ohio State University	Multi-transmit Platform Technology for High and Ultra-high Field MR Imaging	$1,000,000	$1,000,000	$ 740,000	$ 740,000	
2. Neoprobe Corporation	Phase III Clinical Study Supporting Expanded FDA Claims for Lymphoseek™, A Medical Imaging Agent for Sentinel Lymph Node Mapping in Breast Cancer, Melanoma, and Head and Neck Cancer	$1,000,000	$2,000,000	$0	$ 740,000	
3. Philips Healthcare	PET/CT Scanner Optimized for Quantitative Myocardial Blood Flow Assessment	$ 999,175	$2,999,175	$0	$ 740,000	
4. InfraRed Imaging Systems, Inc.	Completion of Commercialization and Relocation of Manufacturing to Ohio of the INRIS VascularViewer Product Portfolio	$ 812,000	$3,811,175	$0	$ 740,000	
5. Quality Electrodynamics LLC	7-Tesla High Density MRI RF Coil Development & Commercialization	$1,000,000	$4,811,175	$0	$ 740,000	
6. GE Healthcare Technologies	MRI Imaging and Devices for Pediatric Populations	$1,000,000	$5,811,175	$0	$ 740,000	
7. EXCMR, Ltd.	An In-State Multi-Center Evaluation of Treadmill Exercise Stress Cardiac Magnetic Resonance	$ 999,694	$6,810,869	$ 425,000	$1,165,000	
8. CardioInsight Technologies, Inc.	The Atlas Electrocardiographic Mapping System	$1,000,000	$7,810,869	$0	$1,165,000	

2010 TFBP
Third Frontier Biomedical Program

Summaries of Proposals in Competitive Range

Third Frontier Biomedical Program
FY 2010 Review Summary and Rankings

Legend: **Strength** (S) - **Met Requirements** (M) - **Weakness** (W)

Rank	TF ID	Applicant	Project Title	Collaborators	TFRDF $	WCF $	Total Funding Requested	Match	2nd Rnd Score	Technical Risk: Technical Reach	Technical Risk: Resource Limitations	Technical Risk: Technology Protection	Commercialization Risk: Path to Market	Commercialization Risk: Corporate Stability	Commercialization Risk: Commercial Infracture	Mission Impact: Cluster Formation	Mission Impact: Ohio Economics	Mission Impact: Business Model	Proposal Review Summary
RECOMMENDED FOR FUNDING																			
1	10-837	OrthoHelix Surgical Designs, Inc.	Mini/Mega MaxLock Extreme Orthopedic Implants	· Hudak, Shunk & Farine Co. LPA · Orthopaedic Research Laboratories, Inc.	$1,000,000	$0	$1,000,000	$1,224,708	86.1	S 3.00	S 3.00	S 3.30	S 2.70	S 2.70	S 2.70	S 6.70	S 9.00	S 8.70	· 2-year project to continue the development program for an improved performance, patentable, fixation product for orthopedic repair · Remaining technical work is associated with preparing test samples for 510(k) demonstration trials - rapid 510(k) approval is projected · Forecasts annual sales of the new products at $3.8M in 2011, growing to $20M in 2013, and the addition of 42 new jobs. · The proposed improved products are extensions of current technology and will be sold through the existing sales network already in contact with the end-user market
2	10-866	Cardiox Corp.	Validation and Commercialization for Non-Invasive Detection of Cardiox Shunts	· Nottingham-Spirk Design Associates · QTest Lab	$986,373	$0	$986,373	$1,538,889	83.3	S 3.70	S 3.30	S 3.00	S 3.70	M 5.00	M 4.70	S 7.30	S 8.70	S 8.70	· Develop a simple, inexpensive, non-invasive device and method to detect the presence of a Patent Foramen Ovale (PFO - a shunt, or small hole in the heart wall between chambers) · Nottingham-Spirk will develop the final design, and QTest Lab will perform critical animal trials · Annual sales are forecasted to begin in 2012 at $11 million, and will increase to $46 million by 2015 - will move manufacturing to its Ohio facility - predicts 22 new jobs in 2013 and 60 new jobs in five years after product launch · Strong and experienced management team in medical devices, plans to be vertically integrated and stay in Ohio
3	10-833	Case Western Reserve University - School of Medicine	Clinical Development of MultiStem for Treatment of Spinal Cord Injury	· Athersys Inc.	$1,000,000	$0	$1,000,000	$1,000,000	70.9	M 5.30	S 3.30	S 2.30	S 4.30	S 3.00	M 5.00	S 8.00	M 6.00	M 6.30	· MultiStem, a stem cell based product from Athersys, promotes healing and re-growth for spinal cord injuries · Case Western will perform a series of clinical experiments using MultiStem on rats with spinal cord injuries –Athersys will be the commercializer · Athersys expects that successful completion of this project will enable it to raise $20-50 million from a partner to fund the human clinical testing program · MultiStem has already received FDA approval for the treatment of ischemic stroke, and other conditions
4	10-810	SpineForm LLC	Clinical Study and Commercialization of an Idiopathic Scoliosis Growth Modulation System	· Cincinnati Children's Hospital Medical Center · University Hospital Case Medical Center · Reynolds Consulting, Inc · E-Prime Group	$999,250	$0	$999,250	$999,250	70.6	S 4.00	S 5.00	S 3.30	W 7.00	M 5.30	M 6.00	S 7.30	S 7.70	S 6.70	· SpineForm LLC plans to develop, commercialize, manufacture, and sell surgical implant products intended to arrest spine curve progression in patients with scoliosis (curvature of the spine) · Cincinnati Children's Hospital Medical Center and University Hospital Case Medical Center will perform clinical trials in humans; Reynolds Consulting, Inc. is contributing funds to this project; E-Prime Group will provide product development/engineering, FDA, ISO, product testing, and business management services · SpineForm expects sales of $12.5 million in 2013 and $44 million in 2015, and plans to hire 5-10 FTE's by 2013 · This project is in an advanced stage of development, is ready for human trials, and is expected to generate positive economic impacts to Ohio in a relatively short time
5	10-825	Lanx, Inc.	Lumbar Motion Monitor Commercialization in Ohio	· The Ohio State University – Biodynamic Laboratory · OrthoNeuro · Cleveland Clinic Center for Spine Health · Ohio Spine Network · American Medical Management LLC · KB Medical · RBK Spine LLC	$1,000,000	$0	$1,000,000	$1,000,000	70.3	M 6.30	S 3.70	S 3.70	S 4.00	S 2.30	S 2.00	S 8.70	M 5.30	S 6.70	· Lanx Inc. will develop and commercialize the Lumbar Motion Monitor, a system developed at OSU, that monitors the motion characteristics of lower back injuries · The Cleveland Clinic will host the alpha test; OrthoNeuro will host the Beta prototype field tests; and Ohio Spine Network, American Medical Management LLC, KB Medical , and RBK Spine LLC will handle regional sales and marketing · The new company will create 20 jobs during the project period – sales are forecasted at $5 million by 2013 and over $11 million by 2015 · Lanx, a Colorado-based company, will establish a division in Columbus, OH that will direct the proposed product manufacturing and commercialization
			TOTALS		**$4,985,623**	**$0**	**$4,985,623**												

Third Frontier Biomedical Program
FY 2010 Review Summary and Rankings

Legend: **Strength** (S) - Met Requirements (M) - **Weakness** (W)

Rank	TF ID	Applicant	Project Title	Collaborators	TFRDF $	WCF $	Total Funding Requested	Match	2nd Rnd Score	Technical Risk			Commercialization Risk			Mission Impact			Proposal Review Summary
										Technical Reach	Resource Limitations	Technology Protection	Path to Market	Corporate Stability	Commercial Infracture	Cluster Formation	Ohio Economics	Business Model	
NOT RECOMMENDED FOR FUNDING																			
6	10-828	Leadscope, Inc.	Predicting Cardiac Toxicity in Humans	ChanTest Corp.	$983,308	$0	$983,308	$983,308	63.3	M 5.30	S 4.70	S 3.70	M 4.70	S 4.30	M 4.70	S 7.70	M 4.80	M 6.00	· The project will develop a new series of database products and services based upon high quality cardiac toxicity databases and methods for predicting cardiac toxicity · Leadscope and ChanTest will collect currently fragmented data of human cardiac toxic effects and cardiac toxicity – Leadscope will compile the information into a structured database, develop the databases and computer models, and market the resulting products · Leadscope's products are software applications, and job creation involves software support and internal sales positions - the number of new jobs projected appears somewhat aggressive, and the sales revenues appear minimal · Continued growth of Leadscope will require development of products beyond the cardiac toxicity model proposed, and the resources to support commercialization of future products have not been established
7	10-801	Syncro Medical Innovations, Inc.	Development of Tracheal Avoidance Feeding Tube System with a Hand Held Electromagnet	· Youngstown State University – Electrical Engineering & Computing · Forum Health - North Side Hospital – John J Turner Research Foundation	$950,000	$0	$950,000	$1,249,873	63.1	M 6.30	M 5.70	S 3.00	S 3.00	M 5.00	S 2.70	M 5.70	M 5.40	S 6.70	· Syncro will develop a new electro-magnet for use with a modified enteral feeding tube that will avoid tracheal entry and assist in lower intestine placement, and sell the system under the name TrueTube · A functional prototype of the critical, electromagnet filled with liquid nitrogen and hand-held immediately over the patient, has not yet been built · TrueTube sales are forecasted at $24 million in 2015 with approximately 50 new jobs · Syncro is a small and young company that will need to attract additional grant and investment support for several more years to be successful
8	10-836	VasoStar Inc.	Miniaturized Distal Vibration System for Penetrating Vascular Occlusions	· Frantz Medical Development, Ltd. · Cleveland Clinic · Interplex Medical, LLC	$950,000	$0	$950,000	$997,730	58.6	M 6.00	S 3.70	S 3.30	M 6.30	M 6.30	W 7.00	S 6.70	M 5.30	M 5.70	· VasoStar will develop and commercialize a Vibrating Tip Guidewire, a small longitudinally oscillating impact device used by interventional cardiologists to penetrate vascular occlusions in coronary arteries · The Cleveland Clinic will perform the animal safety studies, Interplex will provide engineering, design and prototyping support, and will manufacture the final device · Forecasted sales revenues are $2 million by 2013 and $9 million by 2015, and will increase VasoStar's employment from 4 to 30 over that time period · VasoStar is a start-up company that will rely on grant income and investments to sustain itself through the product development and commercialization stages - a potential exit strategy for VasoStar is a buyout from a potential strategic partner
9	10-830	Juventas Therapeutics, Inc.	Novel Epidermal Wound healing: SDF-1 Treatment for Advanced Regenerative Therapy (NEW START)	· Cleveland Clinic - Departments of Cardiovascular Medicine and Stem Cell and Regenerative Therapy, and Department of Thoracic and Cardiovascular Surgery · Ricerca Biosciences	$999,483	$0	$999,483	$1,002,634	56.6	S 5.00	S 5.00	S 3.00	W 8.00	M 6.00	W 7.70	S 6.70	M 6.00	M 4.30	· Juventas will continue development of a stem cell based product that accelerates the rate of wound repair and heals wounds with no evidence of scarring · Cleveland Clinic will treat stab wounds on pigs, and Ricerca will treat wounds on rabbits · Near term economic benefits to Ohio will be related to the investments attracted and the R&D and clinical work from product development efforts · Juventas plans to generate revenues via licensing to companies with established commercial infrastructures, and has no short term plans for manufacturing – Juventas must acquire investments of about $35 million by 2015 to perform the clinical trials prior to product launch
10	10-847	Cleveland Clinic	Development and Commercialization of a Cellular Imaging, Analysis and Processing Tool for Application in Regenerative Medicine	· Parker Hannifin Corp. – Automation Group · Athersys Inc. · University of Cincinnati Medical School of Surgery	$981,715	$0	$981,715	$993,943	52.8	M 6.70	S 4.70	S 4.70	W 8.00	W 8.00	W 8.70	S 8.70	M 6.30	W 2.00	· Project will combine two stand-alone biotechnology systems, Cleveland Clinic's Colonyze System and Parker Hannifin's Smart Syringe/Autosampler System, into one automated system named Smart Cellector · An alpha prototype will be created, and will be evaluated at Athersys, the Cleveland Clinic, and the University of Cincinnati Medical School · Six new jobs will be created by 2011 and will grow to 35 - sales are forecasted at $40 million by 2013 and ramping to $400 million in 2015 · The new company that will market the proposed system has not yet been established and the details of its structure and its market and business plans will not be developed until later in the project - revenue projections appear overly aggressive

2010 Third Frontier Biomedical Program Final Round Scores

Score (Round 1)			City	County	OTFRD $ Requested	OTFRD Cumulative $	WRIGHT $ Requested	WRIGHT Cumulative $
Targets - Mission Impact: 10 Commercial Risk: 2.67 Technical Risk: 3.5								
86.1 (81.3)	**TFBP 10-837**	OrthoHelix Surgical Designs, Inc. Mini/Mega MaxLock Extreme Orthopedic Implants	Medina	Medina	$1,000,000	**$1,000,000**	$0	**$0**
		Mission Impact: **8.34** (E: 9.0 M: 8.7 C: 6.7)	Technical Risk: **3.07** (T: 3.0 R: 3.0 P: 3.3)	Commercial Risk: **2.67** (P: 2.7 S: 2.7 I: 2.7)				
83.3 (62.3)	**TFBP 10-866**	Cardiox Corporation Validation and Commercialization for Non-Invasive Detection of Cardiox Shunts	Dublin	Franklin	$986,373	**$1,986,373**	$0	**$0**
		Mission Impact: **8.34** (E: 8.7 M: 8.7 C: 7.3)	Technical Risk: **3.40** (T: 3.7 R: 3.3 P: 3.0)	Commercial Risk: **4.40** (P: 3.7 S: 5.0 I: 4.7)				
70.9 (67.3)	**TFBP 10-833**	Case School of Medicine Clinical Development of MultiStem® for Treatment of Spinal Cord Injury	Cleveland	Cuyahoga	$1,000,000	**$2,986,373**	$0	**$0**
		Mission Impact: **6.58** (E: 6.0 M: 6.3 C: 8.0)	Technical Risk: **3.93** (T: 5.3 R: 3.3 P: 2.3)	Commercial Risk: **3.93** (P: 4.3 S: 3.0 I: 5.0)				
70.6 (79.3)	**TFBP 10-810**	SpineForm LLC Clinical Study and Commercialization of an Idiopathic Scoliosis Growth Modulation System	Cincinnati	Hamilton	$999,250	**$3,985,623**	$0	**$0**
		Mission Impact: **7.34** (E: 7.7 M: 6.7 C: 7.3)	Technical Risk: **4.27** (T: 4.0 R: 5.0 P: 3.3)	Commercial Risk: **6.13** (P: 7.0 S: 5.3 I: 6.0)				
70.3 (69.7)	**TFBP 10-825**	Lanx, Inc. Lumbar Motion Monitor Commercialization in Ohio	Broomfield	N/A	$1,000,000	**$4,985,623**	$0	**$0**
		Mission Impact: **6.50** (E: 5.3 M: 6.7 C: 8.7)	Technical Risk: **4.73** (T: 6.3 R: 3.7 P: 3.7)	Commercial Risk: **2.93** (P: 4.0 S: 2.3 I: 2.0)				
63.3 (61.7)	**TFBP 10-828**	Leadscope, Inc. Predicting cardiac toxicity in humans	Columbus	Franklin	$983,308	**$5,968,931**	$0	**$0**
		Mission Impact: **5.83** (E: 4.8 M: 6.0 C: 7.7)	Technical Risk: **4.73** (T: 5.3 R: 4.7 P: 3.7)	Commercial Risk: **4.53** (P: 4.7 S: 4.3 I: 4.7)				

2010 Third Frontier Biomedical Program Final Round Scores

Score (Round 1)			City	County	OTFRD $ Requested	OTFRD Cumulative $	WRIGHT $ Requested	WRIGHT Cumulative $
Targets - Mission Impact: 10 Commercial Risk: 2.67 Technical Risk: 3.5								
63.1	**(76.0)**	**TFBP 10-801** Syncro Medical Innovations Development of the Tracheal Avoidance Feeding Tube System with a Hand Held Electromagnet Mission Impact: **5.79** (E: 5.4 M: 6.7 C: 5.7) Technical Risk: **5.40** (T: 6.3 R: 5.7 P: 3.0) Commercial Risk: **3.73** (P: 3.0 S: 5.0 I: 2.7)	Youngstown	Mahoning	$950,000	**$6,918,931**	$0	**$0**
58.6	**(71.7)**	**TFBP 10-836** VasoStar Inc Miniaturized Distal Vibration System for Penetrating Vascular Occlusions Mission Impact: **5.75** (E: 5.3 M: 5.7 C: 6.7) Technical Risk: **4.53** (T: 6.0 R: 3.7 P: 3.3) Commercial Risk: **6.46** (P: 6.3 S: 6.3 I: 7.0)	Mentor	Lake	$950,000	**$7,868,931**	$0	**$0**
56.6	**(77.0)**	**TFBP 10-830** Juventas Therapeutics, Inc Novel Epidermal Wound healing: SDF-1 Treatment for Advanced Regenerative Therapy (NEW START) Mission Impact: **5.75** (E: 6.0 M: 4.3 C: 6.7) Technical Risk: **4.60** (T: 5.0 R: 5.0 P: 3.0) Commercial Risk: **7.13** (P: 8.0 S: 6.0 I: 7.7)	Cleveland	Cuyahoga	$999,483	**$8,868,414**	$0	**$0**
52.8	**(69.3)**	**TFBP 10-847** Cleveland Clinic Development and Commercialization of a Cellular Imaging, Analysis and Processing Tool for Application in Regenerative Medicine Mission Impact: **5.83** (E: 6.3 M: 2.0 C: 8.7) Technical Risk: **5.47** (T: 6.7 R: 4.7 P: 4.7) Commercial Risk: **8.13** (P: 8.0 S: 8.0 I: 8.7)	Cleveland	Cuyahoga	$981,715	**$9,850,129**	$0	**$0**

Ohio Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Mini/Mega MaxLock Extreme Orthopedic Implants

OrthoHelix Surgical Designs, Inc.

TFBP 10-837 1st Round Score: 81.3 2nd Round Score: 86.1 Rank: 1

Previous Ohio Investment

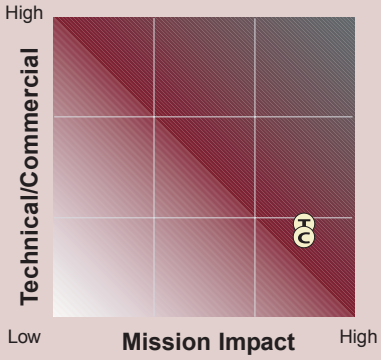
In November 2007, OrthoHelix entered into a loan agreement through the Innovation Ohio Loan Fund. Loan proceeds were used to expand the availability of its four original product lines to its field sales organization. This expansion provided the resources to generate an 88% increase in sales in 2008. This sales growth laid the groundwork for launching follow-up products and improvements and led to a $9 million financing round in 2008.

Project Description

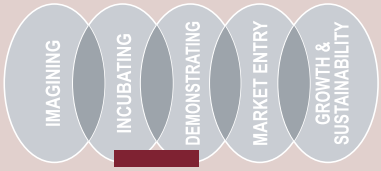
OrthoHelix develops, commercializes, and sells fixation implant products (special metal plates and screws) for repairing trauma to foot and hand bones. This 2-year project will continue the development program for expanding its current product line, MaxLock Extreme to include MaxLock Extreme Trauma products, and for continuing the development program of a new product line, Mini MaxLock Extreme. Mini MaxLock Extreme is a scaled-down version of the MaxLock Extreme that is designed for areas of the foot, ankle, and hand where traditional, larger plates do not fit. In both product lines, the proposed design improvement enables the surgeon to vary the angle of the securing screws allowing better fixation of the plate to the irregular shapes of the foot, ankle, hand and wrist bones. TFP funding will cover OrthoHelix project activities and the collaborators' efforts related to legal fees for the IP protection and to materials research and testing.

Key Issues

- OrthoHelix is currently growing but will not reach profitability until the end of 2010 at the soonest. Growth to profitability has been hampered by limited capital, and the TFP grant will allow OrthoHelix to invest in product inventory that is expected to accelerate the rate of sales growth and profitability.
- The products proposed are extensions of current technology, and normally debt capital funding would be expected to provide the funding resources needed. However, because the funding supports inventory that is placed in hospitals, loan support has not been available.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$0
TOTAL Request:	$1,000,000
Cost Share:	$1,224,708

Collaborators

- Hudak, Shunk & Farine Co. LPA
- Orthopaedic Research Laboratories, Inc.

Prior Ohio Investments

- Innovation Ohio Loan Fund, 2007, $1,177,000

Technical Risk

Overall Score = 3.07

Technical Reach

In most fixation plates, the attaching screw is positioned and locked perpendicularly or at a fixed angle to the plane of the plate. The OrthoHelix design places a special polymer O-ring at the underside of the screw head (modified) so that the surgeon has flexibility to insert the screw at the best angle to secure the plate to the irregularly shaped portions of hand and foot bones. OrthoHelix indicates that the significant technical hurdles have already been resolved and the remaining technical work is associated with preparing test samples for 510(k) demonstration trials. Rapid 510(k) approval is projected.

Resource Limitations

OrthoHelix claims to have all of the technical experience resources needed to complete the product expansions proposed and projects that the TFP project funds are sufficient to support the working capital will be needed to deploy surgical trays of the fixation products (inventory) and the development costs.

Technology Protection

OrthoHelix has filed 3 patent applications related to the variable angle locking technology and intends to file at least two more related to driver and plate concept technologies. Design and utility patents are filed for each family of plate designs it produces. Subcontracted legal assistance has indicated it is confident in the IP protection for the existing and proposed products.

Commercialization Risk

Overall Score = 2.67

Path to Market

OrthoHelix has an established sales network (6 internal sales managers and approximately 125 sales representatives) in the USA and it is generating revenues for the existing product line from approximately 400 orthopedic hospitals. The foot, ankle, and hand market is a niche market driven by surgeon preference, and OrthoHelix has been successful by providing customized designs per surgeon requests and will leverage that success for introducing its new products.

Corporate Stability

OrthoHelix Surgical Designs, Inc., founded in 2004 by Akron-based surgeon Dr. David Kay, is an orthopedic device company located in Medina, Ohio. OrthoHelix's annual sales in 2009 exceeded $10 million, and it currently has approximately 32 employees. Since inception in 2004, OrthoHelix has raised over $20 million in equity financing and has a positive cash position. It has generated increasingly positive revenues each year and expects to reach a breakeven income position by the end of 2010. OrthoHelix recently hired a new CEO with previous, successful experience in a large spinal implant company.

Commercial Infrastructure

OrthoHelix is headquartered in Medina and currently leases a 12,000 SF facility for offices, warehouse, quality inspection area, lab, and is building a machining area for prototyping components. It will leverage its existing internal sales staff and external sales representatives to market the new product offerings.

Mission Impact

Overall Score = 8.34

Cluster Formation

OrthoHelix currently outsources the manufacturing of products to 2 Ohio companies (Norman Noble Inc., and Design Services) and 3 non-Ohio based vendors. OrthoHelix plans to bring manufacturing in-house when sufficient revenue is available and when economics justify the transition. The timing to initiate in-house production is undetermined.

Ohio Economics

OrthoHelix forecasts annual sales of the new products proposed will be approximately $3.8M in 2011, growing to $20M in 2013 and allowing OrthoHelix to grow to an 80 employee company. This represents the addition of 42 new jobs.

Business Model

Orthopedic implant suppliers place trays of implant products into hospitals and charge for only the products used by the surgeons. Surgeons specify which suppliers to use, and sales volumes are dependent upon the number of trays that are placed into hospitals. OrthoHelix uses this approach and maintains a close relationship with surgeons to assure they provide the products the surgeons want. OrthoHelix will continue as a product developer with its own sales force and will continue to use contract manufacturers until internal manufacturing becomes more cost effective. It also plans to move into other anatomical areas with its novel product platform.

Ohio Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Validation and Commercialization for Non-Invasive Detection of Cardiox Shunts

Cardiox Corporation

TFBP 10-866 1st Round Score: 62.3 2nd Round Score: 83.3 Rank: 2

Previous Ohio Investment

Cardiox has not received any prior TFRDF awards. The company recently received an investment of up to $500,000 from the TechColumbus Regional Commercialization Fund (RCF).

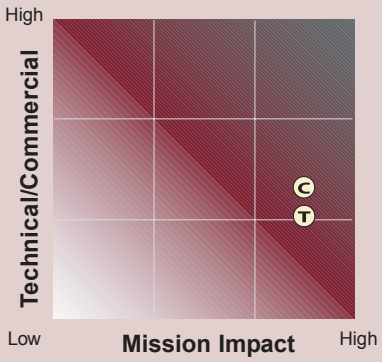
Project Description

One third of all strokes are attributed to the presence of a Patent Foramen Ovale (PFO—a shunt, or small hole in the heart wall between chambers) that is present at birth, but normally closes. Under ordinary circumstances, the presence of a PFO (in greater than 20% of adults) is not realized until after a cardiac event. Current methods of detecting the presence of a PFO are invasive, expensive, and uncomfortable. Cardiox has developed a simple, inexpensive, non-invasive method and device to detect the presence of a PFO and estimate its size. Minimally invasive methods to close PFO's have become widely available in the EU (10 companies with approved products), and are expected to be approved in the U.S. by 1Q 2011 (3 companies). The availability of appropriate treatments makes the timely introduction of a PFO detection device particularly important in patients with transient ischemic attacks for pro-actively preventing strokes. Patients with PFOs who have had an initial stroke have a 30% recurrence if the PFO is not closed and a 3% recurrence if the PFO is closed.

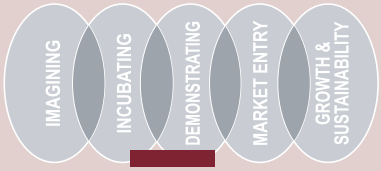
The CardiOx product is at the beginning of human trials. Preclinical work was done in over 700 in vivo tests including tests in adult pigs. First clinical trial was initiated at Columbia University in March 2010. In this 2-year project, Cardiox will continue human trials, validate the device's ability to estimate shunt size, determine the appropriate range for a critical parameter in the test protocol, and finalize the designs of the components for the production system. QTest Lab will conduct the animal studies to confirm the ability to estimate shunt size. Nottingham-Spirk Design Associates will finalize the design of the system components. Cardiox will also prepare patents, secure FDA allowance of 510(k) application, and be in a position to raise $6 million financing for product launch.

Key Issues

- The CardiOx device, after 4 years of work, can test for PFOs in an office setting in 10 minutes. It is a non-invasive procedure that costs 5x to 10x less than existing shunt detection systems. It has demonstrated a sensitivity of >95% for even the smallest shunts. The device is expected to be used to screen stroke patient for the presence of a shunt, to follow-up after shunt closure, and to screen patients with migraine, pacemakers, venous reflux, obstructive sleep apnea, or joint surgery.
- An independent market study showed that 90% of cardiologists surveyed confirmed the product would be useful in their practice. Adoption by cardiologists is expected to be rapid. Many cardiologists surveyed indicated they would like to conduct a clinical trial using the CardiOx product.
- As a diagnostic device, the success or failure of the device will be confirmed immediately upon completion of the tests. New product launch is projected in 2012.
- Cardiox is a start-up company and is not yet revenue producing. It plans to be vertically integrated and plans to stay in Ohio. Cardiox will need to establish a sales/marketing organization, and will transition from an initial contract manufacturing approach to internal production when sales volumes make such a transition feasible.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$986,373
WCF Request:	$0
TOTAL Request:	$986,373
Cost Share:	$1,538,889

Collaborators

- Nottingham-Spirk Design Associates
- QTest Lab

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 3.40

Technical Reach

The dye to be used with the system has been approved for use by the FDA, and initial trials have been successful. The FDA approved the next series of human tests (75 to 100 patients) at four clinical locations (Cleveland Clinic, Columbia University, UCLA, and University College—London, UK) to demonstrate the sensitivity and specificity of the proposed system to detect PFO's in patients with and without PFO's. Since the product is a diagnostic device and will be used on patients with a known PFO status, success of the system will be confirmed immediately upon test completion. Concurrent to these human clinical tests, animal tests will be conducted to demonstrate the ability of the system to predict the size of the PFO's. During the series of tests, the design of the system will be finalized, which will enable the initiation of the production of the commercial version.

Resource Limitations

Cardiox has previously obtained series A and B financing of $ 2.8 million. Cardiox has assembled a strong management team with proven capabilities in their respective areas. Upon successful completion of the animal and clinical trials proposed, Cardiox expects FDA and CE Mark clearance. The 510(k) allowance will trigger an additional $ 6 million in financing that will support the preparation for product launch in 2012.

Technology Protection

Cardiox and its founder (P. Eggers) own four U.S. patents related to the proposed device, and have filed three additional applications for the proposed device. Additional patents will be filed, if deemed appropriate, during the clinical tests. The team has broad experience in patent application, prosecution and defense.

Commercialization Risk

Overall Score = 4.40

Path to Market

Cardiox has hired a new CEO who relocated from the Bay area and brings many years of successful experience with start-up medical device companies. He has had direct experience setting-up domestic and international sales and marketing organizations. Cardiox plans to set-up a direct sales force in the U.S., and a distributor network for the EU. The sales and marketing focus will start with the clinical locations, then progress to PFO closure specialists for use in hospitals and physician offices.

Corporate Stability

Cardiox was founded in 1996, but is still relying on investor funding for support. Eggers & Associates have successfully started up and commercialized five prior companies and Cardiox, is the sixth start-up by Eggers and was established specifically to commercialize the proposed product. The plan is for Cardiox to remain in the Columbus area, and the majority of the funding to date has been provided by Ohio-based sources. A CEO and a CFO with proven, successful experience with start-up medical device companies have been hired to manage Cardiox. Eggers will assume the role of CTO.

Commercial Infrastructure

Cardiox headquarters will remain in the current Ohio location. The system is currently produced by contract manufacturers, and initially that approach will be continued. At the appropriate time, when Cardiox profits justify it, Cardiox will consolidate its operations and set up in-house product manufacturing at its current Ohio location. Sales, sales support, marketing, distribution, etc. will be based out of that location.

Mission Impact

Overall Score = 8.34

Cluster Formation

Cardiox has been supporting the Ohio cluster with its use of Ohio companies, such as a law firm, product design firm, animal study firm, and other supply chain companies. Cardiox will use Ohio contract manufacturing to produce initial product. It plans to expand the cluster by setting up an Ohio manufacturing facility and will expand its local supply chain for product support.

Ohio Economics

Annual sales are forecasted to begin in 2012 at $11 million, and will increase to $46 million by 2015.Within 3 years after the project begins, Cardiox will begin to move contracted manufacturing to its Ohio facility. One year after product launch, Cardiox predicts 22 new jobs (2013), and 60 new jobs in five years after product launch (2017).

Business Model

Cardiox plans to become a vertically integrated medical supply company with its own sales and in-house manufacturing departments. The installed base of monitor systems will generate demand for the disposables needed to run each test. Cardiox expects the majority of its revenues to come from the sales of disposables.

Ohio | Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Clinical Development of MultiStem® for Treatment of Spinal Cord Injury

Case Western Reserve University—School of Medicine

TFBP 10-833 1st Round Score: 67.3 2nd Round Score: 70.9 Rank: 3

Previous Ohio Investment

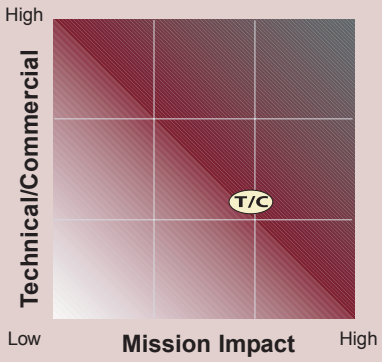
The multi-institutional Center for Stem Cell and Regenerative Medicine (CSCRM) was established in July 2003 as a Wright Center of Innovation (WCI) with a combined Biomedical Research and Technology Transfer (BRTT) award for three years totaling $19.4 M to the five partner institutions: Case Western Reserve University (CWRU), the Cleveland Clinic (CC), University Hospitals Case Medical Center (UHCMC), Athersys, Inc and the Ohio State University (OSU). In 2006, CSCRM was awarded an additional $8M award through the Biomedical Research and Commercialization Program (BRCP). In 2009, $5M was awarded CSCRM through the Research Commercialization Program (RCP). To date the CSCRM reports that its activities have led to over 125 Ohio jobs and revenues (investments, follow-on awards and sales) approaching $300 million.

Project Description

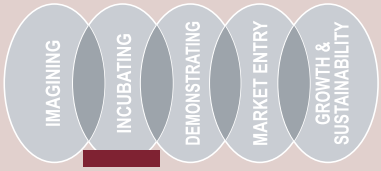
In a series of pilot animal trials, MultiStem®, an adult stem cell product developed by Athersys, was applied to rats with spinal cord injuries (SCI). The results indicated MultiStem® suppressed the progression of neuroinflammation, suppressed axonal (nerve cell) retraction (nerve die-back), and promoted re-growth of the axons. MultiStem® has already received approval for human clinical trials for bone marrow transplants, acute myocardial infarction, and ischemic stroke patients. In this 3-year project, Case Western will perform a larger and more definitive series of clinical experiments with rats using the MultiStem® to treat SCI's. By the end of the 3-year project, the data from the expanded rat studies will be used to submit an FDA application to gain approval for a Phase I IND clinical study for use of MultiStem® for the treatment of human patients suffering from spinal cord injuries.

Key Issues

- The preliminary animal tests indicate spinal cord damage may be reversible. The potential economic and social benefits are significant, but the clinical trials required to gain regulatory approval for treatment will place the economic benefits outside the TFP-targeted timeframe.
- Athersys has demonstrated the ability to attract multi-million dollar investments in its technology through co-development partnerships and will need to do the same for the SCI application.
- The project leverages Ohio's strong position in stem cell research and product development, but the short-term economic benefit to Ohio will be a limited number of jobs for product development and clinical trial efforts. Revenues through 2017 will be mainly from new investments and grants.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$0
TOTAL Request:	$1,000,000
Cost Share:	$1,000,000

Collaborators

- Athersys Inc.

Prior Ohio Investments

- Center for Stem Cell and Regenerative Medicine, 2003, 2006, 2009, $32,500,000

Technical Risk

Overall Score = 3.93

Technical Reach

Case proposes five clinical experiments in rats to determine dosing related parameters. A contract research organization in Ohio will conduct a pivotal safety study using another series of rats to confirm product safety. Post mortem examinations of the rats will be outsourced to CSCRM at the Cleveland Clinic. After completion of all studies and receipt of the final safety study reports, Athersys will compile and submit a Phase I IND application to demonstrate safety of MultiStem® in treatment of SCI in humans. The end objective of the 3-year project is to receive the approval from the FDA for this Phase I study. Phase II and Phase III studies, that are beyond the scope of this project, will be necessary to receive full FDA approval for use in humans.

Resource Limitations

Athersys has two multi-million dollar co-development partnerships with major pharmaceutical companies for other applications of MultiStem®. Athersys plans to bear costs of product manufacturing for clinical trials and the sponsorship of the trials through Phase II evaluation process. Athersys intends to partner with an appropriate healthcare organization with marketing experience in the central nervous system market area prior to initiation of Phase III studies. Athersys projects it will need at least $20 million from an outside source to fund Phase III clinical studies. TFP funding will help generate the key data necessary to attract a future partner.

Technology Protection

Athersys has a track record of successfully developing intellectual property (e.g., more than 25 patents and multiple technology-based partnerships) focused on stem cell products. Athersys has an extensive patent portfolio for the MultiStem® platform, and anticipates that work under this project may lead to additional intellectual property with commercialization potential. New intellectual property from this project would be covered under existing collaborative research agreements between Athersys and Case. The party that generates IP will own that IP, and both parties have the right to negotiate license rights.

Commercialization Risk

Overall Score = 3.93

Path to Market

Athersys is the commercializing organization for this project, and will either team up with and /or license the product to a large pharmaceutical company with an existing sales and marketing force in the central nervous system market. Product launch and product sales revenues are not expected until after FDA approval for use in humans, which is anticipated about 8 years from the beginning of the proposed project.

Corporate Stability

Athersys has raised over $180 million since its inception. Athersys is a publically owned R&D commercializing company with approximately 40 employees and $ 2M in contract and grant revenues in 2009. The recent co-development partnerships for MultiStem® for other applications have placed Athersys in a solid financial position. Athersys claims that it will be cash neutral by the end of the project. For the SCI application, Athersys will need to attract $20 million or more from outside sources to support future clinical testing.

Commercial Infrastructure

Athersys is an R&D commercialization company that outsources its product to a contract manufacturing organization (outside Ohio), and partners with large pharmaceutical companies for sales and distribution. Current corporate partners and licensees for other application areas are Angiotech, Bristol-Meyers Squibb, Johnson & Johnson, Pfizer, Wyeth, and others. For this project Athersys will partner with a leading pharmaceutical company in the central nervous system market for the sales and distribution of the product.

Mission Impact

Overall Score = 6.58

Cluster Formation

Athersys is a founding member of CSCRM (Center for Stem Cell & Regenerative Medicine) and has conducted many collaborative projects with other members of the Ohio regenerative medicine cluster. Athersys' near-term business plan is to initiate its own pilot manufacturing facility in Ohio and in the long-term, it will investigate the potential for a Good Manufacturing Practice (GMP) facility for cell-based products in Ohio.

Ohio Economics

Athersys will hire 2–4 FTE's by the end of the 3-year project (2013) and will hire another 3 in 2014. It projects an additional 20 to 25 new jobs for product manufacturing and development by 2018. Revenues from product sales will not occur until after FDA approval, anticipated to occur after 2017. However, Athersys expects that successful completion of this project will enable it to raise $20-50 million from a partner to fund the clinical testing program.

Business Model

Athersys is headquartered in Ohio and will continue to be an R&D and product commercialization company that partners with leading companies in the appropriate market area for sales and distribution. Currently, production is outsourced to a contract manufacturing organization, but Athersys plans to establish its own internal pilot production facility by 2012 and will support efforts to establish a GMP cell-based production facility in Ohio, although this is not likely to occur before 2018.

Ohio Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Clinical Study and Commercialization of an Idiopathic Scoliosis Growth Modulation System

SpineForm LLC

TFBP 10-810 1st Round Score: 79.3 2nd Round Score: 70.6 Rank: 4

Previous Ohio Investment

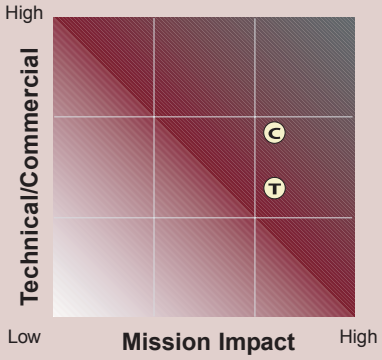
Applicant has not received any prior Ohio investment.

Project Description

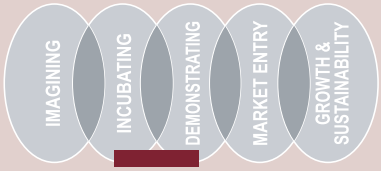
SpineForm LLC plans to develop, commercialize, manufacture, and sell surgical implant products for spine repair. In November 2009 SpineForm received an Investigational Device Exemption (IDE) to proceed with human trials of its HemiBridge™ System, a less invasive, non-fusion, thoracoscopic surgical procedure intended to arrest spine curve progression in patients with scoliosis (curvature of the spine). The device arrests the "vicious cycle" by applying pressure on the convex side of the deformity and relieving compression on the concave side to allow for more normal growth (i.e. employing growth modulation principles termed "hemiepiphysiodesis"). In this 2-year project, Cincinnati Children's Hospital Medical Center and University Hospital Case Medical Center will perform clinical trials in humans. Reynolds Consulting, Inc., an investor, is contributing funds to this project. E-Prime Group, founder and investor, will provide product development/engineering, FDA, ISO, product testing, and business management services. The commercial outcome from this funded project is product launch and market entry outside of the United States starting in Europe, and then followed by Asia, South and Central America.

Key Issues

- This project is in an advanced stage of development, is ready for human trials, and is expected to generate positive economic impact to Ohio in a relatively short time.
- The surgical procedure related to the proposed product offers significant advantages over the current, maximally invasive procedure for arresting the progression of scoliosis.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$999,250
WCF Request:	$0
TOTAL Request:	$999,250
Cost Share:	$999,250

Collaborators

- Cincinnati Children's Hospital Medical Center
- University Hospital Case Medical Center
- Reynolds Consulting, Inc.
- E-Prime Group

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 4.27

Technical Reach

The current treatment to correct progressive scoliosis is the deformity fusion procedure, which is the most invasive of all orthopaedic surgeries. This extremely invasive procedure makes large front and back incisions, destroys a rib, removes several discs, and fuses several vertebra together during a 5 to 12 hour surgery. The procedure with the HemiBridge™ system requires 3 to 4 small incisions in the chest, no loss of a rib, no loss of spinal discs, no fusion of vertebra, and requires approximately 90 minutes. The procedure encourages the spine's ability to correct itself without permanent loss of mobility. Recovery time is faster, requires less rehabilitation, and results in less risk of life-long complications. Having received an Investigational Device Exemption (IDE) from the FDA, SpineForm will conduct the first human trials in a 6 patient pilot study at Cincinnati Children's Hospital and University Hospital Case Medical Center within the first year of the project. With successful results, SpineForm will initiate application for the European CE marking, apply to the FDA for a 20–30 patient, multi-center clinical study, and initiate clinical studies in the UK and France.

Resource Limitations

SpineForm has already raised $2.5 million. With the OTF grant, SpineForm will be able to leverage $1M series A2 equity from current investors (including Spine Form executives) to fund the initial pilot clinical study. After successful conclusion of the first clinical trials, SpineForm will obtain another $4M in series B financing which will enable the company to hire key personnel, expand sales outside of the US, achieve a break-even cash flow, self-fund the remainder of the clinical studies and achieve regulatory marketing approval in Europe, Canada, and USA.

Technology Protection

SpineForm has an exclusive licensing agreement for the 5 patents held by the Children's Hospital Medical Center for all aspects of the technology including the implants, key functional and safety features, and surgical methods.

Commercialization Risk

Overall Score = 6.13

Path to Market

Due to the significantly reduced degree of invasiveness of the surgical procedure, SpineForm expects very strong market pull from pediatric spine surgeons. SpineForm will hire a marketing consultant, and will develop a domestic and international sales force, customer service, and distribution center in the Cincinnati area.

Corporate Stability

SpineForm LLC is a virtual company spun off from E-Prime Group in 2004. E-Prime is an 8-person medical product incubator established 10 years ago, and has successfully spun off Ortheon Medical in Columbus, OH. SpineForm executives (from E-Prime, and formerly from Ethicon) have many years of successful medical device business development experience, plus successful experience in raising capital.

Commercial Infrastructure

SpineForm has leased facilities in Blue Ash for inventory, distribution, customer service, and sales. SpineForm will set up a direct domestic and international sales network, with VP Sales (to be hired) based in Ohio. Two Ohio contract medical device manufacturing companies (RAM Medical and Interplex Medical) will produce the implants and surgical trays.

Mission Impact

Overall Score = 7.34

Cluster Formation

SpineForm has utilized the Ohio supply chain involving companies such as RAM Medical Precision, Interplex Medical, NAMSA, Accutec Testing Laboratory, and others. Clinical testing will take place at Cincinnati Children's Hospital Medical Center and the University Hospital Case Medical Center. By remaining in Ohio, SpineForm will continue supporting the cluster and use the Ohio supply chain for normal business supplies.

Ohio Economics

SpineForm expects sales to begin in Europe in mid 2012, with $12.5 million in 2013 and $44 million in 2015. After FDA approval in 2013, SpineForm expects additional sales in the USA to be $2.5 in 2013 and $25million in 2015. Total annual sales of $100 million are forecasted by 2016/2017. SpineForm plans to hire 5–10 FTE's by 2013. By 2016 SpineForm projects Ohio payroll would exceed $11million (based on medical device industry ratios to sales) and Ohio purchased cost of goods would exceed $5million annually. The venture money is coming from Ohio sources, so the company is most likely going to remain in Ohio.

Business Model

SpineForm plans to be a commercializing company for medical products, will have its own sales and marketing force, and will use contract manufacturing organizations. SpineForm will use product revenues to self-fund development efforts for future products.

Ohio Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Lumbar Motion Monitor Commercialization in Ohio

Lanx, Inc.

TFBP 10-825 1st Round Score: 69.7 2nd Round Score: 70.3 Rank: 5

Previous Ohio Investment

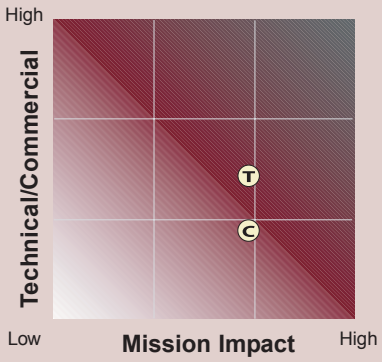
Applicant has not received any prior Ohio investment.

Project Description

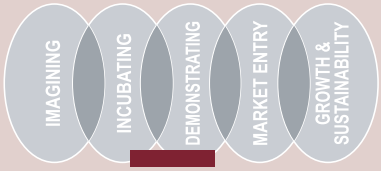
In this 3-year project Lanx Inc. will develop and commercialize an electronically based version of the Lumbar Motion Monitor (LMM). The LMM is a system that monitors the motion function characteristics (kinematic signature) of a patient's lower back to determine if the source of the pain is structural or muscular, to monitor lower back post treatment progress, and to indicate the patient's sincerity of effort (whether the patient is exaggerating symptoms). The system is comprised of a vest with motion and position sensitive sensors, a wiring harness, control/display electronics, and proprietary software. The original mechanical device was developed at The Ohio State University over a decade ago. Lanx will use a local engineering firm to improve the design, and use a local contract manufacturer to produce the system. The Cleveland Clinic Center for Spine Health will host the alpha test. OrthoNeuro will host the Beta prototype field tests. Ohio Spine Network (Brecksville, OH), American Medical Management LLC (Northbrook, IL), KB Medical (Indianapolis, IN), and RBK Spine LLC (Wixom, MI) have agreed to handle regional sales and marketing of the final product. Lanx, a Colorado-based company, will establish a division in Columbus, OH that will direct the proposed product manufacturing and commercialization.

Key Issues

- The regulatory path assumes 510(k) approval will be straightforward since the LMM is considered a Class I device (minimal potential for harm to the user). However, any delays in this approval will delay the conduct of the proposed clinical trials and ultimate product commercialization that is already on a very aggressive schedule.
- The Beta testing of the LMM will be done on the mechanical version of the device and this is expected to make the transition to the electronic version smoother. While the bench-scale testing of the electronic version should prove performance equivalence, the transition may uncover issues not currently anticipated.
- Although Lanx appears to have the resources needed and is committed to creating an Ohio start-up, the entity is currently only a concept, and the operation and its management will be built as the project progresses.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$0
TOTAL Request:	$1,000,000
Cost Share:	$1,000,000

Collaborators

- The Ohio State University–Biodynamic Laboratory
- OrthoNeuro
- Cleveland Clinic Center for Spine Health
- Ohio Spine Network
- American Medical Management LLC (Northbrook, IL)
- KB Medical (Indianapolis, IN)
- RBK Spine LLC (Wixom, MI)

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 4.73

Technical Reach

The mechanical version of the LMM is a commercial product that monitors lumbar motion for protecting workers during industrial activities. While the basic monitoring approach is identical in the proposed version, the mechanical hardware will be replaced with a lighter, easier to use and more accurate electronic system, and new data handling algorithms that allow diagnostic capability. The project will produce alpha, beta and production prototypes of the new version of the device. To be used as a diagnostic tool, 510(k) regulatory approval must be obtained and clinical trials performed.

Resource Limitations

The project funding is expected to be sufficient to support the proposed product through the alpha site clinical trials. The project team includes the technical (OSU), clinician (Cleveland Clinic and others), end user (OrthoNeuro), sales network (4 regional distributors), and commercialization (Lanx) resources needed to complete the proposed project. Lanx is an established orthopedic medical device company with resources committed for establishing Lanx Diagnostic in Ohio and commercializing the LMM diagnostic device.

Technology Protection

The mechanical LMM is a patented device, but its patent coverage is nearing the end of its protected life. The key IP involved in the LMM are the algorithms that interpret the data collected from the device's sensors and that technology is held as trade secret. OSU's 20 years plus of research on and understanding of the relationships between lumbar motion and source cause also provide IP protection.

Commercialization Risk

Overall Score = 2.93

Path to Market

Lanx believes the LMM device developed and evaluated in the proposed project is unique and provides features not available from potential competing technologies. Lanx will market the new LMM device through its current direct and indirect sales channels in the US and abroad. Lanx specializes in spine-related products and has experience in introducing new spine-related technologies to clinicians.

Corporate Stability

Founded in 2003, Lanx is based in Bloomfield, CO and has created a robust product portfolio with a line of quality spine related products. It claims to be one of the fastest growing spinal implant companies in the US. It is a financially sound and profitable company with over 100 employees and it has committed to supporting a new Ohio start-up, Lanx Diagnostic, to develop, assemble, sell and support the device proposed.

Commercial Infrastructure

Lanx's sales and distribution channels include about 200 direct and distributor sales professionals throughout the world. It plans to co-market the LMM with its other spine-related products.

Mission Impact

Overall Score = 6.50

Cluster Formation

Lanx indicates that one driver for locating a new division in Ohio is the biomedical cluster, particularly the orthopedic cluster in NE and Central Ohio. The LMM technology is from OSU and several Ohio entities are involved in the project conduct. Lanx is working with Ohio manufacturing contractors and other Ohio service providers and will add a new company to the cluster.

Ohio Economics

Lanx has committed to establishing a new division within 6 months of project award to oversee the LMM device development, regulatory trials and ultimate product commercialization. The new company will create 20 jobs during the project period. Product revenues are expected to approach $5 million by 2013 and over $11 million by 2015. Ohio distribution and clinical trial collaborators are also expected to create new jobs due the LMM project and its commercialization.

Business Model

Lanx plans to leverage the interest of the spine centers that have agreed to participate in the clinical trials to gain access to the surgeons and physicians who will be the first adopters of the LMM product. The regulatory path has been established and an attractive pricing strategy has been developed for introducing the product. This strategy is designed to permit larger and smaller clinics and private practices to acquire the technology.

Predicting Cardiac Toxicity in Humans

Leadscope, Inc.

TFBP 10-828 1st Round Score: 61.7 2nd Round Score: 63.3 Rank: 6

Previous Ohio Investment

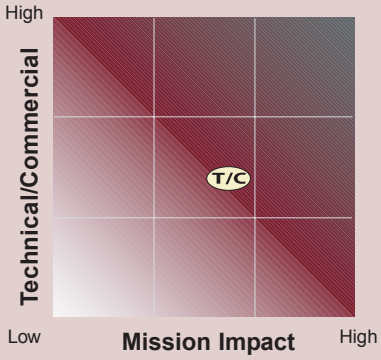
Leadscope received a 2002 Technology Action Fund (TAF) award to generate software applications in the area of chemical genomics. Leadscope indicates that all technical milestones were successfully reached and the software applications were developed, have been commercialized, and are generating revenue. One such software/database application is the NIH Chemical Genomics Center (NCGC) that currently has 53 users working in the area of cures for rare diseases. These researchers have produced over 60 publications, of which, 40 reference the use of the technology developed under the TAF grant. While the 2002 TFAF proposal indicated that the company projected annual revenues of $70 million and employment of 200 by 2007, information provided by the company showed revenues of slightly more than $1 million with 13 employees.

Project Description

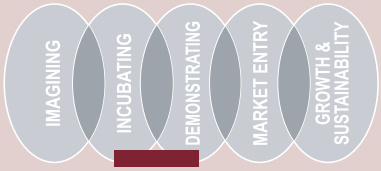
In this 2-year project, Leadscope and ChanTest will collect fragmented data of human cardiac toxic effects, and fragmented cardiac toxicity information from *in vivo* and *in vitro* testing, and compile the information into a structured database. Leadscope will work in collaboration with the US Food and Drug Administration to develop the toxicology databases and computer models and will market the resulting products. ChanTest will provide pre-clinical cardiac risk assessment services, including ion channel and G protein-coupled receptor (GPCR) services, cell lines, membranes, and reagents. The goal is to develop a new series of database products and services based upon high quality cardiac toxicity databases and methods for predicting cardiac toxicity.

Key Issues

- Leadscope's products are software applications that offer improved database and read-across features. As such, the job creation involves software application, support and internal sales positions rather than manufacturing jobs. The number of jobs projected by Leadscope appears somewhat aggressive for developing and supporting the applications proposed.
- The value proposition presented, a cardiac toxicity model mirroring that used by the US FDA, would have strong user incentive, but there are no users involved in the project who will provide feedback on the model's use and efficacy. Such feedback may be important to the timing on the commercial release of the models.
- Continued growth of Leadscope will require development of products beyond the cardiac toxicity model proposed, and the resources to support commercialization of future products have not been established.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$983,308
WCF Request:	$0
TOTAL Request:	$983,308
Cost Share:	$983,308

Collaborators

- ChanTest Corporation

Prior Ohio Investments

- Chemical Genomics Discovery Platform with Novel Informatics Methods to Link Genes to Drugs, 2002, $721,411

Technical Risk

Overall Score = 4.73

Technical Reach

Leadscope will follow an established methodology for collecting cardiac toxicity data from existing *in vivo*, *in vitro* and human adverse event databases. It will extend the current ChanTest internal *in vitro* data as necessary and create a relationship base between these data. The end product will result in predictive models and will provide a comprehensive resource for compound look-up and read-across that will cover approximately 1,500 compounds.

Resource Limitations

The technical team has experience in creating similar software applications and databases and currently has such products in the market. Leadscope believes the proposed TFBP project funding is sufficient to complete the work proposed and introduce the resultant applications within one year of the end of the project.

Technology Protection

The base source code platform for the proposed cardiac toxicity application and database is protected through licensing arrangements and copyright, and is based on over ten years of development. The user interface is patent- and copyright-protected. The new code to be created in the project will be held as trade secret and will be reside behind Leadscope's current firewall.

Commercialization Risk

Overall Score = 4.53

Path to Market

Leadscope has a working relationship with the US FDA that uses its current chemical toxicity models. It has established customer relationships with at least half of the major pharmaceutical companies and while it will extend the cardiac application to them, it will target smaller pharmaceutical companies that it believes offer a larger market potential. Within one year of project completion, Leadscope will engage three early adopters from its or ChanTest's existing customer base. Several Ohio-based candidates are included as potential candidates.

Corporate Stability

Leadscope has 13 employees and has been in business since 1997. It is venture capital-based, generates over $1 million in revenues annually, and expects to be cash flow positive in 2010. It is applying for additional R&D funding from U.S. and foreign federal agencies to enhance current products and support new initiatives, but current investment and revenues are sufficient to support the company.

Commercial Infrastructure

Leadscope plans to sell its products ("FDA models") directly via conferences/exhibitions, publications and online tools. It will leverage its and ChanTest's current customer bases, with ChanTest providing an existing global sales network.

Mission Impact

Overall Score = 5.83

Cluster Formation

Both Leadscope and ChanTest are established Ohio-based biomedical companies. The project directly supports the TFBP's cardiovascular medicine technology target. ChanTest's involvement in the project represents the only direct supply chain relationship in the project, although several Ohio-based end-users are potential early adopter candidates for the software/database application. No end-users are actively involved in the project.

Ohio Economics

Both Leadscope and ChanTest will generate the Ohio economic impacts from the proposed project. The project will create 2 new jobs at Leadscope and 1 new job at ChanTest. One year after project completion (2013), Leadscope and ChanTest project new revenues of $3.5 million and $2 million, creating 10 and 2 additional jobs respectively. By 2015, revenues of about $6.5 million by each company are projected and a total of 38 new jobs created.

Business Model

Leadscope plans to continue its existing business approach that involves an annual licensing fee for use of the cardiac toxicity models. It will target smaller pharmaceutical companies offering these companies *in silco* compound toxicity results that are generated by the same models that the US FDA uses. Product sales and support will be provided directly by Leadscope in the U.S. and via distribution partners outside the U.S.

Ohio Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Development of Tracheal Avoidance Feeding Tube System with a Hand Held Electromagnet

Syncro Medical Innovations, Inc.

TFBP 10-801 1st Round Score: 76.0 2nd Round Score: 63.1 Rank: 7

Previous Ohio Investment

Syncro received an ORCGP grant in 2008 to build inventory of the Gabriel feeding tube (the predecessor to the current BlueTube™), conduct additional clinical studies at St. Elizabeth's Hospital in Youngstown, and to hire 3 employees (clinical educator, staff engineer, and director of marketing) to support the product commercialization. The product manufacturing, done in Germany at that time, was to be transferred to Ohio. The clinical studies were successful and the staff hired, and while some initial sales were made, based on feedback from users, Syncro determined modifications to the feeding tube design were needed. These changes have been made and the newly named BlueTube™ was put back on the market and is generating revenue.

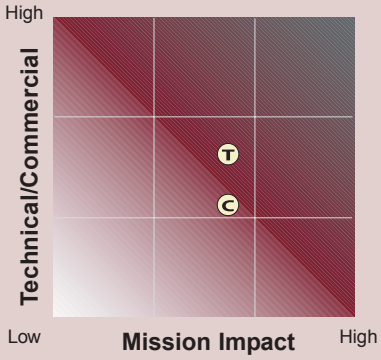
Syncro has been successful in moving production from Germany to Ohio. Interplex Medical (Ohio) has signed a contract to produce the BlueTube, ™ and its manufacturing capability will be fully operational by Labor Day 2010. Syncro has also been successful in moving its headquarters from Macon, GA to Youngstown, OH. While the 2008 ORCGP proposal implied that Syncro would create 20 jobs with $50 million in annual revenues by 2013, the most recent entry in the ODOD database indicates that the company has created 4 jobs, obtained $2.1 million in federal grants, and made $74,400 of product sales.

Project Description

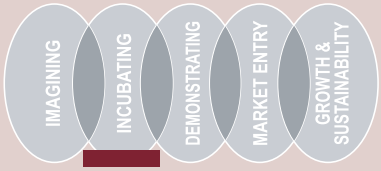
During clinical trials of the BlueTube™, users reported the magnetic guiding feature of the system helped avoid feeding tube insertion into the trachea and lungs. The proposed 2-year project is aimed at replacing the Syncro BlueTube™ permanent magnet with an electromagnet and qualifying the product as a tracheal avoidance device. The project objectives are to conduct clinical studies to obtain an FDA 510(k) clearance to market the tracheal avoidance capability of system, develop a new product with an electromagnetic guidance system (Syncro TrueTube™), to introduce the new product into the enteral feeding tube (EFT) market and to complete the transfer of EFT manufacturing capabilities to Ohio. Forum Health Care—North Side Hospital in Youngstown will perform the clinical trials. Syncro will manage the development efforts at YSU and the efforts of contractors from American Superconductor, the University of Pittsburgh Medical Center, and MIT. Syncro will supervise the interactions with Interplex Medical, the Ohio contract manufacturer that will produce the device.

Key Issues

- A functional prototype of the new electromagnet-based guidance unit has not yet been built, so the performance of the unit has not been validated. A prototype is expected before the TFBP award date, but it will not be in its final design form.
- Syncro is a small and young company that will need to attract additional grant and investment support for several more years to be successful. While initial sales of its introductory product appear to be gaining a foothold, the revenue levels being generated are well below those projected for the end of the project.
- While not required for product success and not part of the proposed effort, visualization capability will be added to the product in the future. This feature will strengthen the device's competitive advantage.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$950,000
WCF Request:	$0
TOTAL Request:	$950,000
Cost Share:	$1,249,873

Collaborators

- Youngstown State University, Electrical Engineering & Computing
- Forum Health, North Side Hospital

Prior Ohio Investments

- Commercialization of the Gabriel Magnetically Guided Feeding Tube, 2008, $350,000

Technical Risk

Overall Score = 5.40

Technical Reach

The BlueTube™ EFT device is currently in the marketplace and is being successfully used for severe patient cases where small bowel feeding is needed. However, to reach the larger, gastric feeding tube market, the device cost must be reduced and the ability to turn the guidance system on and off would be an attractive feature. YSU, American Superconductor (AMSC) and MIT are collaborating to design an electromagnet guidance device to replace the current permanent magnet. A preliminary design has been developed, but functional prototype hardware has not yet been built. Preparation for and 510(k) approval for the new device (TrueTube™) as a tracheal avoidance device will also be required to access this market.

Resource Limitations

YSU has experience in electromagnet coil design and AMSC and MIT have strong superconductor background, however, it is not clear the team has produced a device with the cost, size and performance characteristics required for the TrueTube™. Syncro believes the project funding is sufficient to bring the TrueTube™ to market. It is leveraging USDOD support, funding from its current investor, and debt financing to support product commercialization.

Technology Protection

Syncro has a strong patent portfolio (worldwide coverage) that covers the core magnetically guided feeding tube technology, Syncro also has 2 PCT applications pending, one filed jointly with the University of Pittsburgh. Syncro has exclusive manufacturing and marketing rights for devices based on this patent. Syncro indicates it has a cost advantage over its main guided feeding tubes competitor and that the success of the BlueTube™ places it ahead of others developing technologies.

Commercialization Risk

Overall Score = 3.73

Path to Market

The ability to guide a feeding tube to the stomach and small bowel is a unique feature of Syncro's technology. Successful use of the BlueTube™ by hospitals and the US Army will be leveraged to accelerate adoption of the TrueTube™. Syncro expects that ultimately the 2 products will become a single multi-use product that will also include visualization of the tube placement.

Corporate Stability

Syncro Medical Innovations was incorporated in December of 2005 specifically to commercialize the original Gabriel Feeding Tube. It is located in the Youngstown Business Incubator and has 6 full-time employees. The majority of revenues for the company are from grants and investments. Its BlueTube™ product is just beginning to produce meaningful revenue. Additional investment and/or grant funding will be needed to support TrueTube™ and future product commercialization.

Commercial Infrastructure

Syncro markets its product through distributors throughout the US. Currently it has 25 representatives in its distributor network. After successfully achieving 510(k) status, Syncro will expand into the global market. An additional investment of several million will be needed to support this market expansion.

Mission Impact

Overall Score = 5.79

Cluster Formation

Syncro has contracted with Interplex Medical (Milford, OH) to transfer Syncro's primary manufacturing capability from Dresden, Germany to Ohio. Interplex, in turn, utilizes Ohio subcomponent suppliers as much as possible. Syncro uses the resources available at YSU, and the initial TrueTube™ clinical trial proposed will be done at the Youngstown North Side Hospital, as was the BlueTube™ clinical. The multi-center clinical study will be led by the University of Pittsburgh Medical Center.

Ohio Economics

Approval as a tracheal avoidance device will benefit both Syncro products and therefore economic impacts from both are projected. By the end of the project, BlueTube™ sales of $3.2 million and TrueTube™ sales of $1.6 million are expected. These are projected to grow to $7 million and $6 million respectively in 2013 and to $24 million each in 2015. Syncro will grow to 22 employees by 2013 and about 50 by 2015. The contract manufacturing is expected to add 27 jobs over that time period.

Business Model

Syncro will remain headquartered in Ohio and has contracted with Interplex to produce its guided feeding tube products. It will remain at the Youngstown incubator until its business can support a company owned facility. A timetable for establishing such a facility has not yet been determined. Syncro will market the products in the US through its current distributor and sales representative network.

Ohio Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Miniaturized Distal Vibration System for Penetrating Vascular Occlusions

VasoStar Inc.

TFBP 10-836 1st Round Score: 71.7 2nd Round Score: 58.6 Rank: 8

Previous Ohio Investment

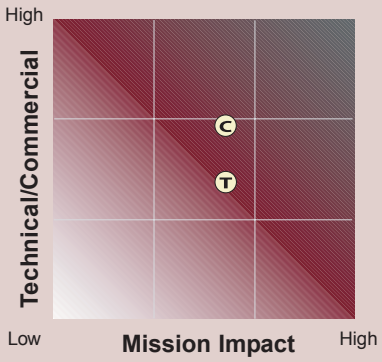
VasoStar was the recipient of funds from the Cleveland Clinic Global Cardiovascular Innovation Center (GCIC) Initiative, which were used to support the design optimization of the proposed system. To date the specific aims of that project have been successfully completed on schedule and within budget. The final aim, an animal study, is scheduled to complete by mid-May 2010. As a result of the project, VasoStar created a total of 4 new jobs, meeting its projected economic growth objective.

Project Description

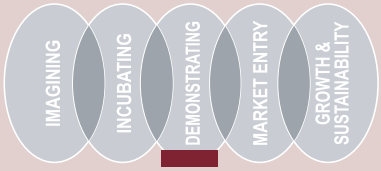
VasoStar is a joint venture of Frantz Medical and the Cleveland Clinic that was formed to develop and commercialize the Vibrating Tip Guidewire (VTG), a small longitudinally oscillating impact device used by interventional cardiologists to penetrate vascular occlusions in coronary arteries safely and reliably. In this 2-year effort, the project team will finalize the design of the device, manufacture pre-production units, test the units, and perform additional animal safety studies. The goal of the project is to develop the data and information necessary for an FDA 510(k) submission that will allow the first human use of the VTG. The Cleveland Clinic will perform the animal safety studies proposed. Interplex Medical, a contract medical device manufacturer, will provide engineering, design and prototyping support. Interplex will also support the manufacturing development effort and produce the final device.

Key Issues

- VasoStar's planned role will be sales and sales support to the strategic partners that will market the technology. It will also be the innovative arm of the team and develop new product opportunities. Frantz will manufacture the key product component while other components will be purchased from suppliers meeting system specifications. Other than the interest and investment of Frantz, the tie to the Ohio biomedical cluster appears uncertain.
- A potential exit strategy for VasoStar is a buyout from a potential strategic partner. If this were to occur there is no guarantee that manufacturing would remain in Ohio.
- VasoStar is a start-up company that will rely on grant income and investments to sustain itself through the product development and commercialization stages. Frantz has a history of supporting such start-up companies, but delays in the product's progress could threaten the successful completion of the product's introduction.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$950,565
WCF Request:	$0
TOTAL Request:	$950,565
Cost Share:	$997,730

Collaborators

- Frantz Medical Development, Ltd.
- Cleveland Clinic
- Interplex Medical, LLC

Prior Ohio Investments

- Global Cardiovascular Innovation Center sub-award, 2007, $350,000

Technical Risk

Overall Score = 4.53

Technical Reach

VasoStar has built and bench tested a series of prototype devices that have demonstrated that the vibrating engine and wire can be delivered through a standard catheter and provide sufficient impact force to the wire tip to allow penetration through simulated chronic total occlusions (CTOs). Animal safety studies are currently ongoing at the Cleveland Clinic and will be completed in May of this year. Within the first few months of the project, the instrument design will be finalized, and functional prototypes for market release will be produced.

Resource Limitations

VasoStar's chief technical officer is also one of principals of the company that developed the proposed CTO-penetrating device. It is backed by Frantz Medical Group, an Ohio consortium of companies specializing in the development and manufacturing of medical devices and diagnostics with about 30 products to its credit. Project funding is projected to be sufficient to gain FDA product clearance, complete the manufacturing transfer and, with assistance from Frantz, secure a strategic partner.

Technology Protection

The original technology was developed and patented by an Israeli medical device company, EyoCa and VasoStar has worldwide exclusive rights to the technology and IP. Three additional PCT applications have been filed by EyoCa and these are also licensed to VasoStar. Frantz performed a freedom to operate search that returned a positive assessment.

Commercialization Risk

Overall Score = 6.46

Path to Market

Frantz Medical will use its current relationships with both major and smaller medical device manufacturers to develop a partnership arrangement with a market leader in the U.S. and internationally that will provide access to an established sales and marketing force. Frantz has previously established similar partnerships with Abbott Nutrition and Medtronics.

Corporate Stability

VasoStar was established specifically to develop and commercialize the CTO crossing technology proposed. It is a Joint Venture of Frantz and EyoCa with Frantz having the majority ownership. As such, VasoStar is not revenue-producing at this time and will rely on the joint venture partners and grants for financial support for the development and commercialization activities. Frantz has an SBIR related to the technology that is currently pending.

Commercial Infrastructure

Frantz will use its established approach to acquiring strategic partnerships to create the commercial infrastructure needed to take the product to the market.

Mission Impact

Overall Score = 5.75

Cluster Formation

Frantz Medical Group provides an incubator resource for start-up medical device companies. VasoStar, CardioStar, and Merlot Orthopedix are a few of the examples of companies residing within its facilities. Frantz will perform the assembly of the finished medical device, and Interplex will modify and supply the catheter. Opportunities for Ohio suppliers to provide the guide wire and electromagnetic coils may exist, but this has not been investigated to date.

Ohio Economics

Ohio impacts from the successful completion of the proposed project will come from sales of both vibration drivers and consumables (catheters and guide wires). Frantz projects sales revenues of slightly over $2 million by 2013 and about $9 million by 2015. This will increase VasoStar's employment from its current 4 to 30 over that time period.

Business Model

VasoStar will follow the business model Frantz has used to incubate a series of new companies and products. VasoStar will serve as a product and business development unit with Frantz providing the development and manufacture of the vibration driver. Interplex will provide the catheter. Frantz will engage strategic business partners to provide sales and marketing structure and set up any needed clinical trials.

Ohio Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Novel Epidermal Wound Healing: SDF-1 Treatment for Advanced Regenerative Therapy (NEW START)

Juventas Therapeutics, Inc.

TFBP 10-830 1st Round Score: 77.0 2nd Round Score: 56.6 Rank: 9

Previous Ohio Investment

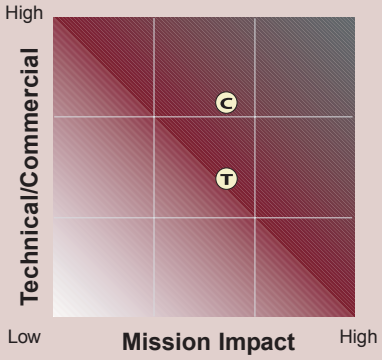
Juventas has received support from the Center for Stem Cell and Regenerative Medicine (CSCRM), the Global Cardiovascular Innovation Center (GCIC) and the Cleveland Clinic Innovations Biovalidation Fund. These programs have supported the SDF-1 cardiovascular platform and enabled the technology to move from the Imagining Phase efforts at Cleveland Clinic through to "A" & "B" metrics such as IP development, initial venture funding, formal company formation, execution of strategic alliances, management placement, and filing of an IND. Through the evolution of this platform, the State funding has been complemented by more than $17.5 million in non-State grant funding, private investment and license income, and 11 jobs have been created.

Project Description

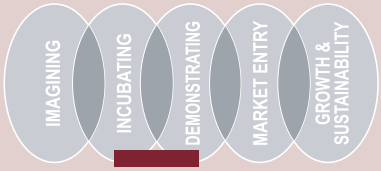
The Juventas-led SDF-1 product, ACRX-100, has received FDA approval for clinical use in the treatment of heart failure and for the treatment of peripheral vascular disease (PVD). Juventas found that surgical wounds treated with ACRX-100 demonstrated significantly accelerated rates of wound repair and healed fully with no evidence of scarring. During the 2-year project, collaborator, Cleveland Clinic, will treat stab wounds on pigs and collaborator, Ricerca Biosciences, will treat sternotomy wounds (removing and replacing the breastbone during open heart surgery) on rabbits. If animal trials are successful, human trials will be performed. The project will culminate in completion of a human clinical trial demonstrating the safety and efficacy of ACRX-100 for treatment of wound closure and scar prevention in patients undergoing median sternotomies during cardiac surgery.

Key Issues

- Juventas' planned business model is to be a product development company focused on regenerative medicine products. It does not plan to become a manufacturing operation or to establish product sales and service operations, but will generate revenues via licensing its products to companies with established commercial infrastructures. Opportunities for product manufacturing in Ohio will result if product demand justifies the creation of an FDA-approved facility here. In the near term, economic benefits to Ohio will be related to the investments attracted and the R&D and clinical jobs created from product developments.
- The market potential for a wound treatment capable of delivering the benefits indicated in the trials to date makes a compelling case for supporting the project. Juventas makes a case that the Ohio funding is critical to advancing the technology to a stage where more investors and/or strategic partners are attracted. However, the Ohio funding is a very small percentage of the investment needed to advance the technology through the regulatory channels.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$999,483
WCF Request:	$0
TOTAL Request:	$999,483
Cost Share:	$1,002,634

Collaborators

- Cleveland Clinic: Departments of Cardiovascular Medicine and Stem Cell and Regenerative Therapy, and Department of Thoracic and Cardiovascular Surgery
- Ricerca Biosciences

Prior Ohio Investments

- Cell-based SDF-1 Therapy for Cardiovascular Disease, 2004 & 2005 sub-awards from CSCRM, $1,900,000
- SDF-1 Plasmid-based Therapy for Chronic Heart Failure and PVD, 2007 & 2009 sub-awards from GCIC and CSCRM, $1,800,000

Technical Risk

Overall Score = 4.60

Technical Reach

Having received completed similar studies for use of ACRX-100 in heart failure and PVD should facilitate rapid approval of ACRX-100 for clinical use for wound treatment. Over 30 publications have shown SDF-1 yields functional improvement in a range of post-injury animal models. In this project additional large animal testing will be performed to determine the efficacy of dermal repair and produce all data needed for submission to support an IND for clinical use of ACRX-100 for wound closure and scar prevention. This will be followed by the first human clinical trial for treating patients undergoing sternotomies.

Resource Limitations

Juventas was founded in 2007 and is operating on cash assets from its initial investments. Its team has substantial experience in regenerative medicine, commercial product development and clinical trial management. It is supported by a Board of Directors that have raised over $1 billion for medical startups and a Board of Medical Advisors responsible for treating thousands of patients. Resource needs for completing the regulatory requirements and introducing the new product have been established, and plans to acquire the next level of financial investment are in place.

Technology Protection

Juventas has secured exclusive rights to the fundamental patents for application of SDF-1 for treating ischemic disease. These rights include IP related to SDF-1 developed through collaborators in the project proposed. Juventas' current investors have performed a freedom to operate search and verified the IP position is strong.

Commercialization Risk

Overall Score = 7.13

Path to Market

ACRX-100 is the only product that has shown the ability to both accelerate wound closure and reduce scarring. Juventas plans to establish partnership relations to access the very large wound treatment market available to ACRX-100. Juventas has not yet engaged any partners at this point and will rely on its Board of Directors to handle these discussions and negotiations.

Corporate Stability

Juventas is currently located in the Cleveland Clinic Innovation Center (CCIC). Juventas' Board has successfully transitioned technologies from concept to clinic, structured multi-million dollar strategic partnerships with top-10 pharmaceutical companies, and secured private investment from venture capital for over 100 products. Juventas will be relocating to the newly constructed Global Cardiovascular Innovation Center (GCIC) in May 2010. The CCIC companies are supported by CCF Innovations, the exclusive commercialization arm for the Cleveland Clinic.

Commercial Infrastructure

Juventas will develop the commercialization relationships needed to market ACRX-100 for wound healing as the platform demonstrates its efficacy through the clinical trials. Current investors have reserved the next level of follow-on investment and will assist Juventas in developing the partnerships that will provide the commercialization infrastructure.

Mission Impact

Overall Score = 5.75

Cluster Formation

The Juventas technology is a direct outcome of activities in regenerative medicine conducted by researchers at the Cleveland Clinic. The Clinic and Ricerca (Ohio) will conduct the clinical trials proposed in the project. Currently, acompany located outside Ohio is producing ACRX-100 for Juventas and will continue to do so until enough demand is generated to justify an operation in Ohio. This would likely be a contract manufacturing operation, and no timetable for this has been established.

Ohio Economics

Juventas projects that product sales/licensing for ACRX-100 for wound closure will begin in the 2016/2017 timeframe. In the interim, Juventas will acquire the investments needed to perform the clinical trials needed and prepare for product launch. These investments are expected to about $15 million by 2013 and $35 million by 2015. Job creation including R&D, clinical trial support, product management and administrative positions are projected to grow to 22 by 2015.

Business Model

Juventas plans to become a platform company based on several applications of the ACRX-100 product. A multiple platform will better position Juventas for obtaining the funding for translating indications from concept to initial human trials. The funding will come from new investors and partnering relationships. Basically, Juventas' business model is to become a product development company.

Ohio Department of Development

2010 TFBP Evaluation Summary

Third Frontier Biomedical Program

Development and Commercialization of a Cellular Imaging, Analysis and Processing Tool for Application in Regenerative Medicine

Cleveland Clinic

TFBP 10-847 1st Round Score: 69.3 2nd Round Score: 52.8 Rank: 10

Previous Ohio Investment

The Cleveland Clinic has received several OTFRDF awards, including a BRCP award for creating the Clinical Tissue Engineering Center (CTEC) in 2005. This Center supported the initial Colonyze™ system with a $230K grant and overall has leveraged $35 million in sponsored research and technical service revenues and created 21 R&D jobs and 5 new jobs at partnering start-up companies.

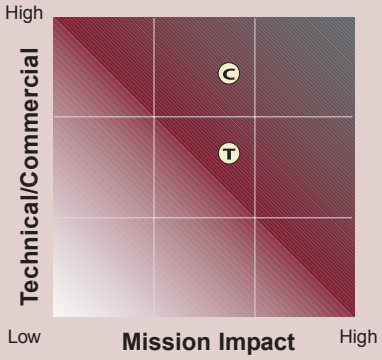
Project Description

The Cleveland Clinic proposes a 2-year project to combine two stand-alone biotechnology systems, Cleveland Clinic's Colonyze™ System and Parker Hannifin's Smart Syringe™/Autosampler™ System, into one automated system named Smart Cellector™. In this system, the operator will place a container (tray) of cells under the Colonyze™ camera and the Colonyze™ software will identify and classify each cell and remembering its location. The tray will then be moved into the Autosampler™ where the the software will direct the Smart Syringe™ to each location of the desired cell type. The Smart Syringe™ will select and remove the targeted cells, and place them into another tray for further growth and processing. This automated system is designed to select the desired cells faster and more accurately than manual cell selection.

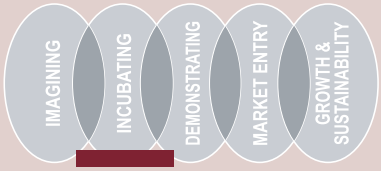
In this project, an Alpha prototype of the combined technologies will be created and evaluated. The Cleveland Clinic and Parker Hannifin intend to forma company to commercialize the new Smart Cellector™ system after the system has been tested successfully at Athersys, the Cleveland Clinic, and the University of Cincinnati Medical School. The Smart Cellector platform is intended to enable small- to medium-sized companies to manufacture autologous and allogeneic cell products more easily.

Key Issues

- A fully functioning prototype has not yet been assembled although it appears there are only engineering level issues to be resolved.
- The new company that will market the proposed system has not yet been established, and the details of its structure and its market and business plans will not be developed until later in the project. The revenue projections, while based on only capturing only a relatively small part of the total potential market, appear to be overly aggressive considering the status of the new company's development.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$981,715
WCF Request:	$0
TOTAL Request:	$981,715
Cost Share:	$993,943

Collaborators

- Parker Hannifin Corporation, Automation Group
- Athersys Inc.
- University of Cincinnati Medical School of Surgery

Prior Ohio Investments

- Clinical Tissue Engineering Center, 2005, $4,000,000

Technical Risk

Overall Score = 5.47

Technical Reach

The two systems, Colonyze™ and Smart Syringe™/Autosampler™, have progressed to the point where commercialization as complete, independent, stand-alone systems can begin. The software library for Colonyze already includes information for the Cleveland Clinic efforts on human bone marrow derived osteoblastic connective tissue progenitor cells (CTP-Os), an engineered skin substitute (ESS) for the University of Cincinnati efforts; and multipotent adult progenitor cell (MAPC) derived therapy (MultiStem®) for Athersys. Even though no complete prototype assembly has been generated, the Parker Hannifin group has extensive experience with designing and building complex automatic handling systems, so Parker Hannifin describes the process of integrating the Colonyze™ and Autosampler™ as "not sophisticated". Current agreement rate between the Colonyze™ system and the findings of multiple independent observers is 87.5% and needs to be improved.

Resource Limitations

The technical team has the skills to conduct the proposed project, and the TFBP support is expected to be sufficient to complete the project goals. However, commitments for financial support have not been provided in the event that additional development work is required to optimize the system beyond what is proposed in this project. It is projected that another $8 million in investment by the end of 2014 will needed to fully commercialize the proposed system, and third party sources and internal funding from Parker Hannifin will be sought.

Technology Protection

Device IP protection currently exists on the two stand-alone systems in the form of patent applications, and IP on the new integrated system is expected. The team has standing policies on any IP developed during the project. IP related to manufacturing will be primarily developed by Parker Hannifin, and cell-related IP will be developed by the Clinic, UC, and Athersys. Project IP will be licensed to the new company after it is formed.

Commercialization Risk

Overall Score = 8.13

Path to Market

The Smart Cellector™ platform, which will be one system of many used in stem cell research and production, is intended to assist small- to medium-sized companies to manufacture stem cell products more easily, instead of relying on contract manufacturing organizations. Potential customer segments have been identified and are expected to be immediately receptive to the new products once the proposed platform has been accepted. The collaborators will be its initial customers, and they will provide market access to their existing clients.

Corporate Stability

The new company that will take the integrated product to market has not yet been established. The new company may be a joint venture of the Clinic and Parker Hannifin, and it will rely on their experience in forming start-up companies. Staffing and funding of the company will take place at a later time. Financial support from the Clinic, Parker Hannifin and/or other investors will be needed to sustain the new company until it becomes revenue positive. No commitments regarding company formation have been made.

Commercial Infrastructure

The Cleveland Clinic does not directly commercialize new products, and Parker Hannifin 's business model is as a seller of systems and sub-systems to other companies for sales to the end users. The new company to be formed will handle the integrated product that will be developed in this project. The sales and marketing plan details for the new company have yet to be fully developed, and it is not clear what will happen if proof of a compelling value proposition does not result from this project.

Mission Impact

Overall Score = 5.83

Cluster Formation

Four Ohio organizations, plus supply chain companies, are collaborating in this project, and each will benefit from the resulting product. The new commercialization company to be formed is intended to be located in Ohio, expanding the regenerative medicine cluster here. The drug manufacturers using the platform technology proposed are expected to sponsor any clinical trial activities needed.

Ohio Economics

Six new jobs will be created, three each at Parker Hannifin and the new company, by 2011 as part of the project. Sales of the new system are forecasted to begin in 2013 with approximately $40 million, ramping to approximately $400 million in 2015. Direct employment over that period is projected to grow to about 35. These projections appear overly aggressive for a company that has yet to be formed.

Business Model

This project will develop an integrated and automated platform system. However, the plans for production of its components and the integrated system have not been described, and there is no indication of where they will be produced. CCF and Parker Hannifin have indicted an intent to form a joint venture located in Ohio, but information about the functions the company will perform and commitments for its financial support have not been provided. CCF has indicated that it intends to provide scientific and clinical support, and Parker Hannifin will continue development, manufacturing and marketing support

2010 TFMIP

Third Frontier Medical Imaging Program

Summaries of Proposals in Competitive Range

Third Frontier Medical Imaging Program
FY 2010 Review Summary and Rankings

Legend: **Strength** (S) - **Met Requirements** (M) - **Weakness** (W)

										Technical Risk			Commercialization Risk			Mission Impact			
Rank	TF ID	Applicant	Project Title	Collaborators	TFRDF $	WCF $	Total Funding Requested	Match	2nd Rnd Score	Technical Reach	Resource Limitations	Technology Protection	Path to Market	Corporate Stability	Commercial Infracture	Cluster Formation	Ohio Economics	Business Model	Proposal Review Summary
RECOMMENDED FOR FUNDING																			
1	10-936	The Ohio State University Office of Sponsored Programs	Multi-transmit Platform Technology for High and Ultra-High Field MR Imaging	· Philips Healthcare Cleveland	$1,000,000	$740,000	$1,740,000	$1,740,000	83.2	M	S	S	S	S	S	S	S	S	· Philips will apply its "multi-channel" imaging technology to its 7T MRI to reduce scan time and improve the image quality by eliminating ghosting and shading. · Philips will develop a step-up unit, modify the amplification, optimize the switches and coils, and create a new algorithm. OSU will demonstrate the value of the 2-channel system for patient care imaging. · Validation of improved performance may speed clinical approval for the 7T MRI that Philips produces in Ohio. · Annual sales from products directly related to this project are projected to be $2.5 million in 2013 and $10 million in 2015.
2	10-904	Neoprobe Corporation	Phase III Clinical Study Supporting Expanded FDA Claims for Lymphoseek, a Medical Imaging Agent for Sentinel Lymph N ode Mapping in Breast Cancer, Melanoma, and Head and Neck Cancer	· Cardinal Health · STATKING Consulting, Inc · Phylogeny, Inc. · Integrated BioScience Solutions, LLC	$1,000,000	$0	$1,000,000	$1,140,252	81.6	S	S	S	M	S	M	S	S	S	· Neoprobe expects Lymphoseek to enter the market in 2011 as a biomarker for anatomic delineation of lymphatic vessels to allow surgeons to identify lymph nodes during surgery. · Neoprobe's product revenues will govern the funding for expansion of its Phase III clinical trials. TFP funding would allow submission of an amended NDA for detection of sentinel lymph nodes in 2011. · Out-of-state companies will produce Lymphoseek, but Cardinal Health will do the distribution. · Accelerating the filing for expanded claims by 18-24 months could increase revenues to Neoprobe and Cardinal by $15-25 million annually for each company.
3	10-918	Philips Healthcare	PET/CT Scanner Optimized for Quantative Myocardial Blood Flow Assessment	· Case Western Reserve University · University Hospitals Case Medical Center	$999,175	$0	$999,175	$999,175	79.6	W	S	M	S	S	S	S	S	S	· Project will result in an upgrade to Philips' PET/CT scanner that will quantitatively measure myocardial blood flow to evaluate disease severity and response to treatment. · Philips and Case will perform hardware and software modifications. Clinical validation will be done at the University Hospitals Health System. Philips will be responsible for obtaining 510 (k) approval, and manufacturing will be done at the Philips' facility in Cleveland. · Enhancement of the Philips' PET/CT scanner is expected to occur by 2013 and is projected to result in additional sales of nearly $50 million in 2013 and $100 million in 2015. · Technical challenges include higher speed data acquisition, improved image reconstruction software, new software algorithm, and hardware and software integration.
4	10-926	InfraRed Imaging Systems, Inc.	Completion of Commercialization and Relocation of Manufacturing to Ohio of the INRIS VascularViewer Product Portfolio	· Astro Manufacturing & Design, Inc. · United Medical Products, LLC · entrotech	$812,000	$0	$812,000	$941,000	77.0	S	M	S	M	M	M	S	S	S	· INRIS has developed a medical imaging device based on infrared technology that enables doctors and nurses to locate veins and arteries to more accurately insert needles and catheters. · Astro Manufacturing will move manufacturing from CA to OH and assist with the development of the next 2 products. Enrotech will develop a single-use near-infrared light source. United Medical Products will refine and expand the U.S. marketing efforts. · INRIS projects that its initial product will enter the market in 2010 followed by a digital version in 2011 and a new product to visualize thicker portions of the body in 2013 creating revenues of $20 million by 2013 and $50 million by 2015. · Financial position of INRIS is weak. To ensure survival, company will need to achieve sales quickly to attract additional investment.
5	10-910	Quality Electrodynamics LLC	7 Tesla High-Density MRI RF Coil Development & Commercialization	· Case Western Reserve University – Dept. of Physics · Case Center for Imaging Research · Siemens Healthcare	$1,000,000	$0	$1,000,000	$1,002,806	76.3	M	S	S	S	S	S	S	M	S	· QED will design and commercialize knee and breast coils initially for Siemens' 7T MRI but later for the 7T MRI scanners of other manufacturers. · Siemens will provide electronic interface specifications, and Case will use software to simulate the electromagnetic interaction between the patient and imaging equipment. Testing and validation will be done at New York University Medical School, University of Pittsburgh Medical Center, and the University of Vienna Medical School. · Anatomically specific RF coils are expected to be available by 2012 with sales of $3 million by 2013 and $8.5 million by 2015. · 7T MRI systems are currently used for research, but FDA has not approved their use in clinical applications.

Third Frontier Medical Imaging Program
FY 2010 Review Summary and Rankings

Legend: **Strength** (S) - **Met Requirements** (M) - **Weakness** (W)

										Technical Risk			Commercialization Risk			Mission Impact			
Rank	TF ID	Applicant	Project Title	Collaborators	TFRDF $	WCF $	Total Funding Requested	Match	2nd Rnd Score	Technical Reach	Resource Limitations	Technology Protection	Path to Market	Corporate Stability	Commercial Infracture	Cluster Formation	Ohio Economics	Business Model	Proposal Review Summary
RECOMMENDED FOR FUNDING																			
6	10-930	USA Instruments/GE Healthcare Coils, Inc.	MR Imaging and Devices for Pediatric Populations	· Cincinnati Children's Hospital Medical Center · Davis Heart & Lung Research Institute	$1,000,000	$0	$1,000,000	$1,614,140	74.9	W	S	M	M	S	S	M	S	S	· USAI/GE will design, build, and validate a new pediatric torso coil and head fixation coil for MR imaging of children. · Coil development work will be done in USAI/GE's Ohio facility; Cincinnati Children's Hospital and OSU will conduct clinical trials; and USAI/GE will submit 510 (k) to FDA. · Products are projected for introduction by 2013 and are likely to generate $70 million in sales by 2015, but detailed job and revenue projections are proprietary. · Products are still at the conceptual stage, and their competitive advantage over similar products is unclear.
7	10-922	EXCMR, Ltd.	An In-state Multi-center Evaluation of Treadmill Exercise Stress Cardiac Magnetic Resonance	· Cleveland Clinic Heart and Vascular Institute · University Hospitals Case Medical Center · The Heart and Vascular Center, The Christ Hospital · The Ohio State University · Quality Electrodynamics · Siemens Medical Solutions, Inc. (Malvern, PA) · Heart Imaging Technologies (Durham, NC) · Zukun Plan	$999,694	$425,000	$1,424,694	$1,497,827	74.3	S	M	S	M	M	M	S	S	S	· Applicant has developed an MRI-compatible (containing no ferromagnetic materials) treadmill that can be placed in close proximity to an MRI machine to image the heart immediately after exercise. · EXCMR will assemble demonstration prototypes with assistance from Zukun Plan; clinical demonstration trials will be conducted at Cleveland Clinic Heart and Vascular Institute, Case Medical Center University Hospital, The Heart and Vascular Center-The Christ Hospital, and OSU; and Heart Imaging Technologies will manage the data from the clinical trials. · Siemens has an exclusive 3-year agreement to sell the treadmill through its MRI catalogue. EXCMR sales are projected to be $5 million by 2013 and $14 million by 2015. · Cardiologists must be convinced to change cardiac imaging after exercise from SPECT to MRI to improve image quality and reduce radiation exposure.
8	10-944	CardioInsight Technologies, Inc.	The Atlas Electrocardiographic Mapping System	· Case Medical School – University Hospital of Cleveland · Cleveland Clinic Foundation · Le Centre Hospitalier Universitaire de Bordeaux (Cedex, France) · Battelle Memorial Institute · Michel Haissaguerre, MD (Bordeaux, France) · Draper Triangle Ventures	$1,000,000	$0	$1,000,000	$2,491,990	72.0	S	S	S	M	M	M	S	S	S	· The Atlas Electrocardiographic Mapping System will allow physicians to measure the electric field of the heart instantaneously and non-invasively and will produce a 3-D map of electrical activity for all four heart chambers for diagnosis and treatment of cardiac arrhythmias and congestive heart failure. · CIT will complete product development and testing and secure FDA approval. Case Medical School University Hospital, Cleveland Clinic Foundation, and Le Centre Hospitalier Universitaire de Bordeaux will conduct additional clinical trials. Battelle will provide hardware/software enhancements and optimization. · Commercial introduction is scheduled for 2013 with sales of over $25 million growing to $100 million by 2015. · CIT plans to become a sales and product development organization and will rely on Astro Instrumentation for production. Its sales infrastructure is still in the early planning stage.
			TOTALS		**$7,810,869**	**$1,165,000**	**$8,975,869**												

Third Frontier Medical Imaging Program
FY 2010 Review Summary and Rankings

Legend: **Strength** (S) - **Met Requirements** (M) - **Weakness** (W)

										Technical Risk			Commercialization Risk			Mission Impact			
Rank	TF ID	Applicant	Project Title	Collaborators	TFRDF $	WCF $	Total Funding Requested	Match	2nd Rnd Score	Technical Reach	Resource Limitations	Technology Protection	Path to Market	Corporate Stability	Commercial Infracture	Cluster Formation	Ohio Economics	Business Model	Proposal Review Summary
NOT RECOMMENDED FOR FUNDING																			
9	10-925	FMI Technologies, Inc.	Commercialization of Organ/Disease Specific Cardiac and Neurologic PET/CT/SPECT Molecular Imaging Systems for Global Markets: A value Proposition Demonstration	· Lantheus Medical Imaging (N. Billerica, MA) · Kettering Medical Center · Image Registration and Fusion Systems · Akron General Medical Center · The Ohio State University - Wright Center of Innovation in Biomedical Imaging · Summa Health System · Akron G	$1,000,000	$0	$1,000,000	$2,347,929	57.3	M	M	M	M	W	M	M	S	M	· Product is intended to be a low-cost, high-resolution diagnostic imaging system for cardiac and neurological applications that combines PET, CT, and SPECT and can be installed in an office environment. · FMI will complete developmental work on the device and obtain 510(k) approval from FDA; Lantheus Medical Imaging will provide the perfusion agent; and clinical evaluations will be done at Kettering, Akron, OSU, and Summa Heath System. · FMI will rely on Lantheus to provide the sales and marketing to bring this product to market by 2013, but projected 2013 revenues of $47 million appear optimistic. · The ability of the device to meet its cost and performance targets has not been demonstrated.
10	10-902	Imalux Corporation	Fourier Domain (FD) Optical Coherence Tomography (OCT) Imaging System for Real-Time 3D Imaging of Epithelium for Pre-Invasive and Invasive Cancer	· GVI Medical · Preventive Oncology International - Cleveland Clinic · Case Western Reserve University - Department of Oral & Maxillofacial Surgery	$999,000	$0	$999,000	$1,110,000	54.9	M	M	S	M	M	M	S	M	M	· Third-generation device for detecting cancer in tissues of cervix and mouth using 3-D optical coherence tomography. · Optiphase will develop the interferometer; George Washington University, the algorithms for image reconstruction; GVI Medical Devices, the electronics and software; NPI, product design and manufacturing sourcing; and Imalux, the probes. · Second generation product will be commercialized later this year. Sales of third-generation product are projected to begin in 2013 with creation of 23 jobs, rising to 38 jobs by 2015. · Diagnostic capabilities and market validation of the pricing model remain to be demonstrated.
11	10-914	Interventional Imaging Inc.	Manufacturing and Development, MRI Guided Treatment of Atrial Fibrillation	· Case Western Reserve University – Case Center for Imaging Research · Case Western Reserve University – School of Medicine · Case Western Reserve University and University Hospitals	$997,010	$0	$997,010	$1,007,503	45.5	M	M	S	W	M	W	M	M	M	· RF ablation catheter that can be viewed real-time by MRI for treatment of atrial fibrillation · Project includes completion of product development and animal work required prior to clinical tests, relocation of prototype manufacturing to OH from MN, establishment of an Ohio supply chain · Commercialization of product projected in 2015 with sales of $3.6 million and creation of 11-14 jobs · Manufacturing will be outsourced; corporate partner needed to fund clinical trials and bring product to market.

2010 Third Frontier Medical Imaging Program Final Round Scores

Score (Round 1)			City	County	OTFRD $ Requested	OTFRD Cumulative $	WRIGHT $ Requested	WRIGHT Cumulative $
Targets - Mission Impact: 10 Commercial Risk: 1.66 Technical Risk: 3.5								
83.2	**(79.3)**	**TFMIP 10-936** The Ohio State University Multi-transmit Platform Technology for High and Ultra-high Field MR Imaging Mission Impact: **8.00** (E: 6.7 M: 9.0 C: 9.7) Technical Risk: **4.40** (T: 6.3 R: 3.0 P: 3.3) Commercial Risk: **1.66** (P: 2.3 S: 1.3 I: 1.0)	Columbus	Franklin	$1,000,000	**$1,000,000**	$740,000	**$740,000**
81.6	**(63.3)**	**TFMIP 10-904** Neoprobe Corporation Phase III Clinical Study Supporting Expanded FDA Claims for Lymphoseek™, A Medical Imaging Agent for Sentinel Lymph Node Mapping in Breast Cancer, Melanoma, and Head and Neck Cancer Mission Impact: **8.00** (E: 8.7 M: 7.7 C: 7.0) Technical Risk: **2.80** (T: 2.3 R: 3.3 P: 2.7) Commercial Risk: **3.13** (P: 4.0 S: 2.0 I: 3.7)	Dublin	Franklin	$1,000,000	**$2,000,000**	$0	**$740,000**
79.6	**(68.7)**	**TFMIP 10-918** Philips Healthcare PET/CT scanner optimized for quantitative myocardial blood flow assessment. Mission Impact: **7.92** (E: 8.0 M: 8.3 C: 7.3) Technical Risk: **5.60** (T: 7.0 R: 3.7 P: 6.7) Commercial Risk: **2.13** (P: 3.0 S: 1.7 I: 1.3)	Highland Heights	Cuyahoga	$999,175	**$2,999,175**	$0	**$740,000**
77.0	**(71.0)**	**TFMIP 10-926** InfraRed Imaging Systems, Inc Completion of Commercialization and Relocation of Manufacturing to Ohio of the INRIS VascularViewer Product Portfolio Mission Impact: **8.17** (E: 8.7 M: 6.7 C: 8.7) Technical Risk: **4.40** (T: 3.3 R: 6.0 P: 3.3) Commercial Risk: **4.87** (P: 3.7 S: 6.0 I: 5.0)	Eastlake	Lake	$812,000	**$3,811,175**	$0	**$740,000**
76.3	**(77.7)**	**TFMIP 10-910** Quality Electrodynamics, LLC 7-Tesla High Denisty MRI RF Coil Development & Commercialization Mission Impact: **7.25** (E: 6.3 M: 8.7 C: 7.7) Technical Risk: **4.86** (T: 6.3 R: 3.3 P: 5.0) Commercial Risk: **2.40** (P: 2.3 S: 2.3 I: 2.7)	Mayfield Village	Cuyahoga	$1,000,000	**$4,811,175**	$0	**$740,000**
74.9	**(65.3)**	**TFMIP 10-930** GE Healthcare Technologies MRI Imaging and Devices for Pediatric Populations Mission Impact: **7.33** (E: 8.3 M: 7.0 C: 5.7) Technical Risk: **5.47** (T: 7.0 R: 3.3 P: 6.7) Commercial Risk: **2.93** (P: 5.3 S: 1.3 I: 1.3)	Aurora	Portage	$1,000,000	**$5,811,175**	$0	**$740,000**

2010 Third Frontier Medical Imaging Program Final Round Scores

Score (Round 1)			City	County	OTFRD $ Requested	OTFRD Cumulative $	WRIGHT $ Requested	WRIGHT Cumulative $
Targets - Mission Impact: 10 Commercial Risk: 1.66 Technical Risk: 3.5								
74.3	**(70.3)**	**TFMIP 10-922** EXCMR, Ltd. An In-State Multi-Center Evaluation of Treadmill Exercise Stress Cardiac Magnetic Resonance Mission Impact: **7.58** (E: 7.0 M: 7.3 C: 9.0) Technical Risk: **4.20** (T: 2.3 R: 6.0 P: 4.3) Commercial Risk: **4.73** (P: 3.3 S: 6.3 I: 4.3)	Columbus	Franklin	$999,694	**$6,810,869**	$425,000	**$1,165,000**
72.0	**(69.0)**	**TFMIP 10-944** CardioInsight Technologies, Inc. The Atlas Electrocardiographic Mapping System Mission Impact: **7.58** (E: 8.3 M: 6.7 C: 7.0) Technical Risk: **4.27** (T: 4.7 R: 4.3 P: 3.3) Commercial Risk: **5.40** (P: 5.3 S: 5.3 I: 5.7)	Cleveland	Cuyahoga	$1,000,000	**$7,810,869**	$0	**$1,165,000**
57.3	**(60.0)**	**TFMIP 10-925** FMI Technologies Inc. Commercialization of Organ/Disease Specific Cardiac and Neurologic PET/CT/SPECT Molecular Imaging Systems for Global Markets: A Value Proposition Demonstration Mission Impact: **6.50** (E: 7.3 M: 5.7 C: 5.7) Technical Risk: **6.33** (T: 6.3 R: 6.7 P: 5.7) Commercial Risk: **6.73** (P: 6.3 S: 7.3 I: 6.3)	Akron	Summit	$1,000,000	**$8,810,869**	$0	**$1,165,000**
54.9	**(56.0)**	**TFMIP 10-902** Imalux Corporation Fourier Domain Optical Coherence Tomography Imaging System for Real-Time 3D Imaging of Epithelium for Pre-Invasive and Invasive Cancer Mission Impact: **5.53** (E: 5.1 M: 5.3 C: 6.7) Technical Risk: **5.33** (T: 6.0 R: 5.7 P: 3.3) Commercial Risk: **6.27** (P: 6.7 S: 6.0 I: 6.0)	Cleveland	Cuyahoga	$999,000	**$9,809,869**	$0	**$1,165,000**
45.5	**(65.0)**	**TFMIP 10-914** Interventional Imaging, Inc. Manufacturing and Development, MRI Guided Treatment of Atrial Fibrillation Mission Impact: **4.67** (E: 4.3 M: 5.3 C: 4.7) Technical Risk: **5.53** (T: 5.3 R: 6.3 P: 4.3) Commercial Risk: **7.47** (P: 8.0 S: 6.3 I: 8.7)	Cleveland	Cuyahoga	$997,010	**$10,806,879**	$0	**$1,165,000**

Ohio | Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Multi-transmit Platform Technology for High and Ultra-High Field MR Imaging

The Ohio State University Office of Sponsored Programs

TFBP 10-936 1st Round Score: 79.3 2nd Round Score: 83.2 Rank: 1

Previous Ohio Investment

In 2003, The Ohio State University was awarded $17 million to create the Wright Center of Innovation in Biomedical Imaging (WCI-BMI), and funding was continued through 2010. The Philips 7T Achieva system has been introduced, and the initial production goal of ten units at about $7 M each was achieved within three instead of five years. Philips Healthcare has decided to develop and build a Cleveland-based Ultra-High Field Research Center that supports the Cleveland factory facility. OSU and its partners have been awarded approximately $24.8 million in additional public/private-funded research to be conducted in Ohio. The WCI-BMI commercialization efforts within the state have resulted in $78.5 million of documented revenue with pending revenue of $464 million, the creation of 378 FTEs, and the start-up/attraction of 7 companies now operating in Ohio.

Project Description

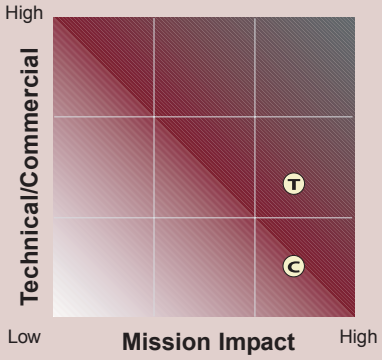
Philips Healthcare developed and recently commercialized a "multi-channel" imaging technology for its 3T MRI systems which significantly reduces the scan time and improves the images produced by these systems. The multi-channel technology allows the simultaneous transmission of magnetic resonance radio-frequency waves into the body and volume of interest from different antenna systems, thereby overcoming biophysical challenges of dielectric (signal shading or ghosting) effects of radio-frequency waves at high and ultra-high field MR. The 2-channel option on the 3T system works well for imaging of the head, but not the body. The 8-channel option for the 3T system has been transferred from R&D to the field where the first clinical studies are now underway.

The goal of this 2-year project is to expand the application of this multi-channel technology for use in the new 7T systems. The team will develop a functional 2-channel system for the 7T system requiring a step-up unit, an additional component that is not part of the 3T system. The radio-frequency amplification needed will be different for the 7T system. The switches and coils will also be specific to the 7T system. Finally, the system will require a different algorithm since the fields are distributed differently.

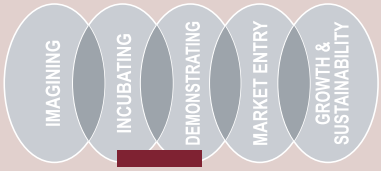
The Philips Cleveland team will focus on the technology development of the equipment and commercialization, and the OSU team will develop the appropriate medical imaging applications, demonstrate its capabilities for patient care imaging and validate its benefit. The clinical work will include studies in the areas of neuroanatomy/neurofunctional (implantation of brain pacemakers), neuro-oncology, vascular, and musculo-skeletal. It is anticipated that the 2-channel 7T system compatible with the current coil will be available by 1Q 2011 and the 8-channel 7T system by 2012 as a research platform.

Key Issues

- Philips recently announced that it was shifting the 7T system to active shielding which will reduce the amount of shielding that must be installed at the clinical site allowing the 7T units to be installed at any site and greatly expanding their potential market.
- Competitors are currently offering 7T systems and have announced intent to develop multi-transmit capabilities. However, Philips believes that it has the lead in multi-transmit technology, and it will be important for Philips to capitalize on this know-how in a timely manner. If this project is successful, Philips has committed to support the development of the 8-channel technology for the 7T system within 3 years and to have that work done in Cleveland.
- The improved target definition afforded by a multi-channel 7T system is likely to lead to a number of clinical advances in the areas of brain modulation, treatment of prostate cancer, and location of biomarkers.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$740,000
TOTAL Request:	$1,740,000
Cost Share:	$1,740,000

Collaborators

- Philips Healthcare Cleveland

Prior Ohio Investments

- Biomedical Structural Functional and Molecular Imaging (WCI), 2003, $17,114,362
- Biomedical Structural Functional and Molecular Imaging (BRCP), 2006, $7,878,957
- Molecular Imaging SPECT Technology Center (WP), 2009, $2,999, 924

Technical Risk

Overall Score = 4.40

Technical Reach

The project team understands the engineering and technical challenges that it will encounter as it tries to transfer the multi-channel technology from the 3T MR platform to the 7T MR platform. While some of the experience base gained with the 3T unit will be transferrable, both hardware and software changes will be needed to adapt the technology to the 7T unit. Current 7T owners are expected to be eager to upgrade the imaging capability of their equipment since the upgrade is estimated to cost about 10% of the purchase price of the original equipment.

Resource Limitations

This is a strong technical team that has demonstrated competence in the development of multi-channel imaging systems for the 3T system. The initial multi-channel development work for the 7T system that will be done in this project will be supplemented by additional resources of $4–8 million from Philips to move the technology to commercialization. Philips already has more than 30 7T systems operational and will not require any additional external funding for further up-scaling of this technology. OSU plans to seek NIH funding to fund cancer imaging quick trials and an academia-industry development partnership grant for quantitative MRI cancer imaging to monitor therapies using preliminary data from this project.

Technology Protection

OSU has already established IP management procedures with Philips Healthcare through the WCI-BMI center. The Philips corporate research team in Hamburg, Germany has developed a considerable technology portfolio in this area. As patents are typically cross-licensed in MR technology between the major vendors, multi-transmit technology will not be limited to Philips, but Philips is hoping to have clear first-to-market advantages.

Commercialization Risk

Overall Score = 1.66

Path to Market

Philips Healthcare is one of the world's largest manufacturers of imaging equipment including x-ray, ultrasound, CT, MRI, and PET systems. Product advances made in this project will be commercialized using Philip's existing path to market. Philips anticipates that current 7T equipment owners will be anxious to upgrade their equipment as soon as the 2-channel or 8-channel capabilities become available.

Corporate Stability

Philips has annual sales of $30 billion and Philips Healthcare makes up about 1/3 of the total. About 1,100 people in the Cleveland area are employed by Philips making it a major employer in Northeast Ohio. OSU employs more than 20,000 faculty and staff in the central Ohio area.

Commercial Infrastructure

Philips Healthcare has current sales of over $1 billion annually in MR systems. To support this business, Philips has existing sales, marketing, and product support staff located throughout the world. This existing infrastructure should be capable of handling product enhancements for the 7T systems.

Mission Impact

Overall Score = 8.00

Cluster Formation

Philips Healthcare subcontracts more than $50 million in goods and services to other Ohio vendors. This project will create substantial add-on opportunities for Ohio-based accessory and service providers. Philips intends to team with Rapid MR International in Columbus on an SBIR proposal for coil development. This project should also position researchers at OSU to compete for federal research funding from NIH, NCRR, NSF, DOD, and NIST because they will have early access to enhanced imaging capabilities.

Ohio Economics

Scaling-up of the multi-channel 7T technology is anticipated during the 2013–15 timeframe. Initial early adopter sales (as upgrades to current systems) are anticipated to begin during the course of this project. Current 7T owners are expected to be eager to upgrade the imaging capability of their equipment since the upgrade is estimated to cost about 10% of the purchase price of the original equipment. Annual sales revenues from products directly related to this project are projected to be $2.5 million in 2013 and $10 million in 2015. The multi-channel transmit technology for 7T systems is anticipated to create 26 jobs by 2013 increasing to 37 jobs by 2015.

Business Model

The Ultra-High Field Research Center in Cleveland will be responsible for developing the 8-channel 7T MR imaging system. Philips is planning to conduct engineering, manufacturing, and verification work for this system in Cleveland. Work on the software and system coils will also be done in Cleveland. Work on the electronics will be done in Ohio. Technology developed during this project is also expected to lead to additional enhancements in the 3T systems.

Ohio Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Phase III Clinical Study Supporting Expanded FDA Claims for Lymphoseek®, a Medical Imaging Agent for Sentinel Lymph Node Mapping in Breast Cancer, Melanoma, and Head and Neck Cancer

Neoprobe Corporation

TFBP 10-904 1st Round Score: 63.3 2nd Round Score: 81.6 Rank: 2

Previous Ohio Investment

Neoprobe has not received previous Third Frontier funding. One of the collaborators on this project, Phylogeny, received a 2004 TFAF award of $1 million to commercialize human Tissue Microarray products for drug discovery.

Project Description

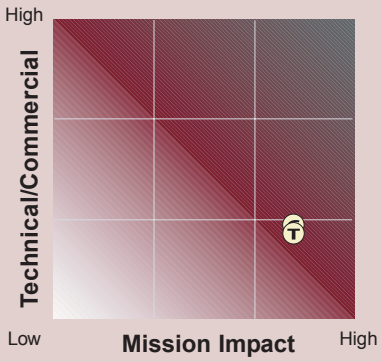
Neoprobe is developing a radiopharmaceutical diagnostic drug that can be used for the anatomic delineation of the lymphatic vessels in the lymphatic pathway draining the primary site of a malignant tumor. The product is known as Lymphoseek®, and it consists of a custom designed molecule that has specific functionality that will bind both to a radioactive tracer and to the macrophages that can be found on the surface of lymph nodes. This allows the surgeon to identify the location of lymph nodes using a Geiger counter-like device during surgery. The product has a good safety profile and has completed Phase I, II, and III clinical trials to support this label claim. Neoprobe has reviewed its data with the FDA and has been given the green light to submit an NDA (new drug application) covering the use of Lymphoseek® for anatomic delineation. Neoprobe is currently preparing the NDA submittal for the FDA, and anticipates receiving approval and beginning marketing in 2011.

Neoprobe would like to expand its label claims for Lymphoseek® to include identification of sentinel lymph nodes. Among the biomarkers, Lymphoseek® is unique in that it contains a specific functionality that binds to lymphatic immune cells and provides an indication of which lymph nodes contain metastases. This claim would allow surgeons to limit their work to only the affected lymph nodes; it would reduce their liability since there is no biomarker on the market that can make this claim; and it would improve the surgical outcomes for the patient.

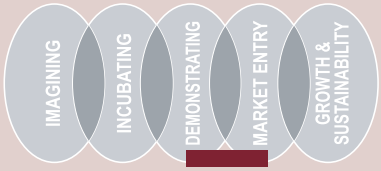
Such an amendment to Neoprobe's NDA submission will require the successful completion of an additional Phase III clinical study in patients undergoing therapeutic surgeries for head and neck squamous cell carcinoma where the performance of Lymphseek® can be compared with pathology results. Neoprobe has begun this Phase III study on an initial cohort of 60 patients, but FDA subsequently indicated that it would like to see the study expanded. Since Neoprobe must rely on current revenues to fund this expansion of the Phase III clinical trial, marketing of Lymphoseek® with the sentinel lymph node claim could be delayed by 18–24 months. With additional support from the TFP, the trial could be completed and the amended NDA filed during 2011.

Key Issues

- Current competitive products including Vital Blue Dye, Methylene Blue, and ^{99m}TC-S Colloid are being used "off-label" and without FDA approval to identify sentinel lymph nodes. If Lymphoseek is successful in gaining approval of its expanded claim, it would be would be the only drug with such an efficacy claim and that claim would not be disease- or tumor-specific.
- Each 12-month delay in reaching the market with the expanded claims for Lymphoseek® is projected to result in the loss of incremental sales of $15–25 million annually for Neoprobe. A similar amount of revenue will also be lost by Cardinal Health.
- Delays in bringing Lymphoseek® to market with its expanded claims will also slow down the development and commercialization of subsequent products such as a monoclonal antibody that Neoprobe has licensed for detecting protein products of colon cancer cells that have metastasized to other parts of the body.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$0
TOTAL Request:	$1,000,000
Cost Share:	$1,140,252

Collaborators

- Cardinal Health
- STATKING Consulting, Inc.
- Phylogeny, Inc.
- Integrated BioScience Solutions, LLC

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 2.80

Technical Reach

Neoprobe has completed the clinical work to support a general "anatomic delineation' claim and expects to file its NDA for Lymphoseek® with FDA in 2Q2010. The product has shown no serious adverse effects or safety issues. In a March 2010 meeting with FDA, the FDA requested that the Phase III protocol for studying the effectiveness of Lymphoseek® in sentinel lymph node mapping of head and neck cancers be expanded from 60 patients (at a cost of $1.5 million) to 180 patients (at a cost of $4–5 million). Initial results from the first 60 patients indicate that Lymphoseek® is demonstrating the desired sensitivity and selectivity.

Resource Limitations

Neoprobe views the proposed Phase III clinical trial in head and neck cancer as essential and will self-fund to the extent that it is able. If this clinical study has to be supported solely from Neoprobe's earnings, the time to complete the study will increase by 18–24 months.

Technology Protection

The chemical compound known as Lymphoseek® was invented by Dr. David R. Vera at the University of California, San Diego. The molecular structure of Lymphoseek® and its application to map and identify sentinel lymph nodes is protected by US patent 6,409,990 issued on June 25, 2002 for which Neoprobe has an exclusive license. Lymphoseek® is also covered under an EU patent that was issued in November 2005 and a Japanese patent that was issued in December 2007, both of which have been licensed to Neoprobe.

Commercialization Risk

Overall Score = 3.13

Path to Market

The clinical trials from this project will make Lymphoseek® the first targeted mapping agent with FDA approval that doctors can use for locating cancerous lymph nodes during surgery. Neoprobe plans to have Lymphoseek® synthesized at Reliable Biopharmaceutical Corporation (St. Louis) and formulated at OSO BioPharmacueticals Manufacturing, LLC (Alburquerque). Lymphoseek® will be distributed by Catalent, the nuclear pharmacy division of Cardinal Health, since it has to be used with a radionucleotide.

Corporate Stability

Neoprobe has been in business for 27 years and has annual sales of approximately $10 million and a staff of nearly 30 employees. Its main product is Neoprobe® GDS, an intraoperative gamma detection device that is sold and marketed by its partner, J&J/Endo-Ethicon Surgery, Cincinnati, Ohio. Revenue from this product line covers all corporate overhead and is used to fund development of future products.

Commercial Infrastructure

Neoprobe signed an exclusive sales, marketing, and distribution agreement in the U.S. with Cardinal Health that extends for 5 years from NDA clearance. Cardinal Health, located in Dublin Ohio, is the U.S. market leader in radiopharmaceutical distribution, and its pharmacies can deliver to 90% of U.S. hospitals within 3 hours. Cardinal will provide the Tc-99m that is needed to radiolabel Lymphoseek® just prior to use in the operating room. Neoprobe is in late stage negotiation with an international medical device and supply company to act as its marketing partner and distribution channel to the international market.

Mission Impact

Overall Score = 8.00

Cluster Formation

Neoprobe has demonstrated its ability to team with another Ohio company (J&J's Endo-Ethicon Surgery in Cincinnati) to bring a product to market, so it has a history of success with this business model. In this project, Neoprobe will team with the nuclear pharmacy division of Cardinal Health located in Dublin, Ohio. Revenues will be shared between the two companies producing a double impact for Ohio in this value chain.

Ohio Economics

Neoprobe expects Lymphoseek® to enter the market in 2011 with the general "Anatomic Delineation" claim and projects that it will generate annual sales of $50–75 million by 2013. Annual sales are projected to increase by another $20 million by 2015. If Neoprobe is successful in completing the expanded head and neck cancer trial and obtaining FDA approval for the "Sentinel Lymph Node Mapping" claim by the end of 2011, these numbers are projected to increase by $15–25 million respectively. Supporting this business is projected to create 27 new jobs at Neoprobe by 2013, increasing to 31 by 2015. Additional job creation can be expected at Cardinal Health.

Business Model

Neoprobe intends to use gross profits from Lymphoseek®, especially following acquisition of sentinel node claims, to evaluate Lymphoseek®'s performance in pediatric cancers. Both Cincinnati Children's Hospital and Nationwide Children's Hospital (Columbus, OH) are considering participation in this study. With a long history in Ohio and primary distribution relationships with other Ohio companies, Neoprobe expects to keep its company headquarters in Ohio where product development, management of clinical trials, and regulatory interactions will take place. Production, formulation, and packaging will take place at FDA-approved facilities located out-of-state.

Ohio Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Absolute Myocardial Blood Flow

Philips Healthcare

TFBP 10-918 1st Round Score: 68.7 2nd Round Score: 79.6 Rank: 3

Previous Ohio Investment

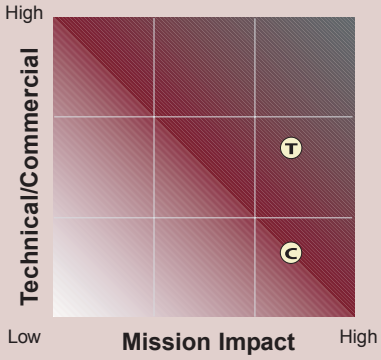
Although Philips has collaborated with the Ohio State University Research Center on three prior OTF projects in medical imaging, they are not related to this proposal and therefore not included in the discussion.

Project Description

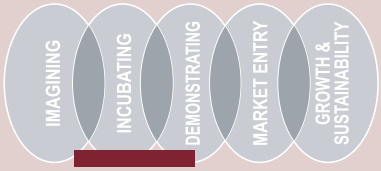
PET/CT (positron emission tomography / computed tomography) scanners combine the physiologic information from PET with anatomic information from CT to enable doctors to identify qualitatively specific areas within the heart that are not receiving nutrients from blood. The amount of myocardial blood flow influences the heart's ability to pump blood. To advance clinical care of coronary artery disease, physicians increasingly demand quantitative information on blood flow rates to evaluate disease severity and response to treatment. The purpose of the proposed 2-year project is to develop an upgrade to the Philips PET/CT scanner so that it can measure quantitatively the myocardial blood flow. The proposed scanner hardware/software modification will be co-developed by Philips Healthcare and Case Western Reserve University. Clinical validation will be performed at the University Hospitals Health System and manufacturing would be in the Philips Healthcare factory in Cleveland, Ohio. The end goal of the project is to generate and test an upgraded system, and receive 510(k) Premarket Notification.

Key Issues

- The proposed project will expand the capabilities of the PET/CT system to provide critical data desired by cardiac practitioners.
- Upon successful completion of the 2-year project, Philips has committed to provide the substantial funds for commercialization and market entry.
- Upon project completion and market entry, Philips predicts immediate and substantial additional sales revenue generation in Ohio.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$999,175
WCF Request:	$0
TOTAL Request:	$999,175
Cost Share:	$999,175

Collaborators

- Case Western Reserve University
- University Hospitals Case Medical Center

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 5.60

Technical Reach

The project has four, technically challenging key elements: upgrade system electronics and software for higher speed data acquisition; upgrade the image reconstruction software to accommodate the increased data stream and generate the required images within 10 minutes of test completion; develop, add, and test a new software algorithm that calculates blood flow rates from the data; and integrate the hardware and software into an upgraded system for commercialization. The system will be tested on phantoms with known flow rates, and validation will be performed at the University Hospitals Health System.

Resource Limitations

Philips predicts the OTF award along with cost share will provide sufficient funding to meet project goals. Philips will use its substantial internal experience in designing and manufacturing PET/CT systems to design the upgraded hardware and software. CWRU will provide its technical expertise in the development and testing of new technologies, and clinical validations will be performed at the University Hospitals Health System. Subject to the success of the project, Philips has committed to providing the significant amount of funds to bring the product to market.

Technology Protection

Due to the highly collaborative nature of this development effort, intellectual property will be managed through legal agreements executed by the participating institutions and through an ongoing process of invention disclosure, review for possible patent protection, and licensing. Every effort will be made to accommodate the needs and obligations of the participating institutions. Each institution will execute one or more agreements depending upon the extent of their participation, the nature of the specific projects in which they participate, and their involvement in the commercialization of IP.

Commercialization Risk

Overall Score = 2.13

Path to Market

Philips will produce a product that will meet an unmet need for cardiac diagnosis, and has strong encouragement from a respected nuclear radiologist. Philips currently manufactures and sells PET/CT and SPECT systems through its existing sales network. Philips will include the proposed system upgrade on future PET/CT systems and expects sales of PET/CT systems through its existing sales/marketing network to increase significantly. While the increased capability of the enhanced PET/CT system will replace a small percentage of its SPECT business, Philips does not view this as competition, but rather as an extension and appropriate use of these technologies.

Corporate Stability

Philips Healthcare Imaging Systems is a billion dollar, well respected and financially stable organization serving the international nuclear medical imaging market.

Commercial Infrastructure

The headquarters for the imaging systems business unit, sales, and manufacturing are located in Highland Heights, Ohio. The proposed PET/CT systems will be assembled in the Highland Heights facility currently making Philips' nuclear imaging systems, and sales will be handled through its existing, extensive sales/marketing organization.

Mission Impact

Overall Score = 7.92

Cluster Formation

Philips is a significant member of the Ohio medical imaging cluster, and this project further strengthens that cluster with its collaboration with CWRU and the UHCMC. Philips utilizes Ohio employees and purchases about $40 million per year of goods from the Ohio supply chain.

Ohio Economics

Due to the anticipated expanded use of the PET/CT system, Philips expects the sales of the upgraded PET/CT system to increase PET/CT sales by approximately $49 million in the first year of product launch, 2013, and another $49 million in 2015. Philips believes this quick and significant sales level increase is realistic. Philips expects to add 5 to 7 new production jobs at the Philips facility in Cleveland as a result of this project.

Business Model

With lower reimbursements for SPECT procedures and the expanded capability of the proposed enhanced PET/CT system, Philips expects an increase in the use of PET/CT systems with the proposed enhancements. This enhanced system will easily transition into the current product line and is compatible with Philips' current business model as a designer, manufacturer and seller of nuclear imaging systems.

Ohio Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Completion of Commercialization and Relocation of Manufacturing to Ohio for the INRIS VascularViewer Product Portfolio

InfraRed Imaging Systems, Inc.

TFBP 10-926 1st Round Score: 71.0 2nd Round Score: 77.0 Rank: 4

Previous Ohio Investment

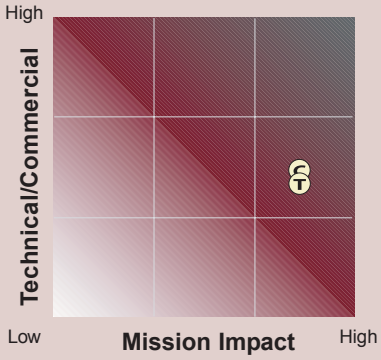
InfraRed Imaging Systems has not received any prior TFRDF awards.

Project Description

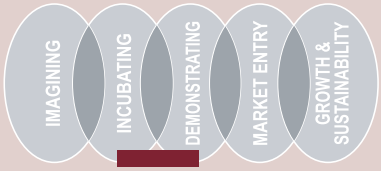
InfraRed Imaging Systems, Inc. (INRIS) is developing and preparing to enter the market with VascularViewer I, a medical imaging device based on infrared technology (developed and patented by the US Air Force at Wright Paterson AFB in Dayton, OH) that enables doctors and nurses to locate veins and arteries to more efficiently and accurately insert needles and catheters thereby reducing the number of "sticks" and peripheral vascular access failures. In this 2-year project, INRIS expects to contract with Astro Manufacturing to move its manufacturing and engineering from California to Ohio. Astro will assemble INRIS's first product VascularViewer® I, assist with various engineering improvements, and help in the development and manufacture of INRIS' next two follow-on products: VascularViewer I Digital and VascularViewer II. Collaborator entrotech will participate in the development of INRIS' companion disposable product, a single-use disposable near infrared (nIR) light source. INRIS will also work with its Ohio distributor, United Medical Products, to refine and expand its marketing efforts in OH and around the US.

Key Issues

- INRIS is not profitable at this time and will rely on the TFMIP funding to support the proposed product developments and to attract the additional resources it requires to execute its commercialization plans.
- The technology proposed is a new modality and while it offers cost, performance and ease of use advantages over existing technologies, it will require continued positive end-user feedback on its performance to support its introduction to new customers.
- The proposed device is Class 1 with 510(k) certification. The newer versions do not change the basic function of the device, so additional regulatory approvals should not be needed or, at worst, be fast track approvals.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$812,000
WCF Request:	$0
TOTAL Request:	$812,000
Cost Share:	$941,000

Collaborators

- Astro Manufacturing & Design, Inc.
- United Medical Products, LLC
- entrotech

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 4.40

Technical Reach

INRIS has built and sold first generation commercial prototype Vascular Viewers (through the lens viewing) and these are being used at several Beta sites. INRIS has received strong positive feedback on the device's utility. The Vascular Viewer has obtained 510(k) and UL certifications. Improvements to the current design will involve straightforward engineering tasks while the digital version (LCD display) will require additional software development, prototype construction and testing. A manufacturing method capable of high production rates will be developed to produce the disposable nIR sources used by the device.

Resource Limitations

The technical team includes the technology inventor, and the management team has past experience introducing new medical products. INRIS itself is a virtual company, with only 5 employees (2 full-time), but it will use Ohio contract manufacturers and design/engineering services to produce its products. The company currently generates a small amount of revenue, but it intends to rely on the TFMIP funding for its support and will leverage that support to obtain additional investment during the project period. Current investors and project collaborators have indicated their interest in making further investments once the system demonstration phase has been successfully completed.

Technology Protection

INRIS has an exclusive license to a patent that covers nIR visualization of sub-dermal veins and arteries. This patent provides wide coverage of the technology and freedom to operate research has been positive. INRIS has additional 5 patents pending that it owns or has licensed. INRIS management has experience in patent defense and access to resources in this field.

Commercialization Risk

Overall Score = 4.87

Path to Market

INRIS' imaging modality is unique. It is a relatively inexpensive tool that satisfies an unmet for neonatal intensive care units and has applications for hand and foot arterial location for IVs and shunts. The product has received very positive feedback from Beta users such as the Mayo Clinic and St. Jude's Hospital. INRIS will use specialty distributors serving hospitals to reach the marketplace and has already contracted with 3 regional distributors serving Ohio and surrounding states.

Corporate Stability

INRIS is about 8 years old, but its revenue to date has been predominantly support from its initial angel investors. Additional venture capital investment support has been identified and will be available upon achieving proof of sales.

Commercial Infrastructure

INRIS will contract its manufacturing/assembly operations to an Ohio medical device producer, Astro Manufacturing. INRIS intends to establish a sales and marketing team that will create and conduct its marketing campaign working with the already contracted distributors and new ones. INRIS will sell imaging units outright, offer leasing arrangements and will sell the disposable nIR light sources.

Mission Impact

Overall Score = 8.17

Cluster Formation

INRIS will transfer its contract manufacturing now located in California to Ohio (Astro). It will also move its current office operations in Pennsylvania (at an incubator site) back to Ohio where its principals reside and where it is incorporated. Clinicians from UH Rainbow Babies & Children's Hospital are providing some of the end-user guidance for product development and an OSU ER doctor is also an end-use evaluator/advisor.

Ohio Economics

The current Vascular Viewer is already commercially available and is projected to provide about $3 million in sales revenues during Year 1 of the project. INRIS will build its staff to 16 during this period. The digital display version is scheduled for introduction 6 months into the project and the Vascular Viewer II scheduled for introduction within a year of the project completion. These products are projected to produce over $20 million in 2013 with INRIS staff growing to 33 and over $50 million in 2015 with staff growing to 50.

Business Model

INRIS will establish its headquarters in Ohio and will continue to refine and develop new products based on its infrared imaging modality. It intends to establish a sales and marketing operation to support medical device distributors across the country. It will continue to contract product manufacturing and assembly with its primary contractor being Astro Manufacturing in Eastlake, Ohio.

Ohio Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

7 Tesla High-Density MRI RF Coil Development & Commercialization

Quality Electrodynamics LLC

TFBP 10-910 1st Round Score: 77.7 2nd Round Score: 76.3 Rank: 5

Previous Ohio Investment

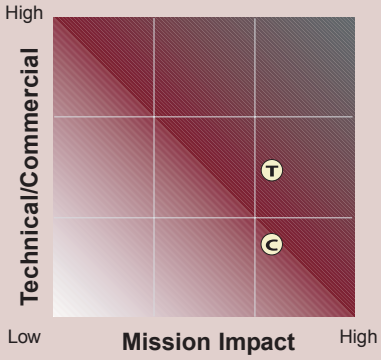
QED has received four grants since 2006, including an Ohio Rapid Outreach Grant and Training Grant, a New Energy and Industrial Technology Development Organization (NEDO) grant, and most recently a GCIC grant focusing on the commercialization of a 32-channel MRI cardiac array coil. Dr. Fujita, Founder, President & CEO of QED, was also involved as a collaborator and co-investigator with Ohio State University, Case Western Reserve University, and Philips Medical Systems in the Wright Center for Innovation in Biomedical Imaging (WCIB) Third Frontier Grant (2003) focused on the development and commercialization of Ultra High Field (UHF) MRI systems, and its phase II grant, the Biomedical Research and Commercialization Program (2006).

Project Description

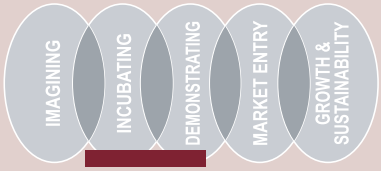
Quality Electrodynamics (QED) was spun out from CWRU Wright Center of Innovation in 2006 to manufacture anatomically specific RF coils for a variety of 1.5T and 3T MRI scanners. In this 2-year project, QED will design and commercialize anatomically specific (knee and breast) multi-channel, high density RF coils for the Siemens 7T MRI system. QED will be responsible for the overall success of this project, including financial oversight, overall project management, and technology and commercialization strategy development and implementation. CWRU will use software to simulate the electromagnetic interaction between patient and MRI. CCIR will provide critical expertise and testing in parallel excitation techniques for QED's RF coils. Siemens will arrange testing and evaluations of QED's RF coils at New York University Medical School, University of Pittsburgh Medical Center, and the University of Vienna (Austria) Medical School, thereby providing critical feedback regarding the capabilities and needed changes of QED's product. Upon successful project completion, Siemens will purchase RF coils from QED.

Key Issues

- Based upon past successes, QED presents a high likelihood of success on the proposed project, with positive short- and long-term benefits to Ohio.
- QED is on the leading edge of 7T MRI technology development and has existing relationships with the four major MRI manufacturers. While 7T systems are currently limited to research applications, the successful introduction of anatomically specific coils will help speed the transition of 7T systems from R&D to clinical use for certain applications.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$0
TOTAL Request:	$1,000,000
Cost Share:	$1,002,806

Collaborators

- Case Western Reserve University, Department of Physics
- Case Center for Imaging Research
- Siemens Healthcare (Erlanger, Germany)

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 4.86

Technical Reach

7T systems generate higher quality images than 1.5T and 3T systems. QED will expand its knowledge of designing and manufacturing 1.5T and 3T coils to overcome significant technical challenges (multi-channel local transmit/receive technology for parallel excitation, the ultra-compact preamplifier, and the RF coil mechanical package design for optimal patient comfort) to design novels coils and associated electronics and software that will effectively manage RF fields at ultra-high frequencies and magnetic strengths. At the higher frequencies and field strengths of 7T, QED must balance the safety aspects of localized tissue heating with the goal of improved image resolution of unique and specific anatomical features.

Resource Limitations

QED expects the OTF award with matching financial resources will be sufficient. In addition to its own extensive experiences in designing and manufacturing anatomically specific coils for MRI's, QED has access to Siemens' electronic interface specifications for its 7T system, and has access to the Case Western Reserve University Department of Physics and the Case Center for Imaging Research. Siemens will coordinate testing and validation at prestigious clinical locations: New York University Medical School, University of Pittsburgh Medical Center, and the University of Vienna (Austria) Medical School. QED has a well-qualified team with extensive experience to overcome the technical challenges of this project.

Technology Protection

Valuable intellectual property will be developed. The multichannel local transmit/receive technology for parallel excitation will be patented, while the remaining intellectual property will be protected by non-disclosure agreements and kept as trade secrets. The preference to keep IP as a trade secret is based on the fact that valuable knowledge can be better protected if it is not published in patent disclosure documents and is simply reserved for internal company use as institutional knowledge. QED will own all intellectual property created through this project.

Commercialization Risk

Overall Score = 2.40

Path to Market

Siemens is a collaborator and committed end-user for this project. QED will develop and manufacture 7T knee and breast coils for Siemens. Siemens will provide access to three end user sites for testing and validation, and Siemens will purchase the co-branded coils from QED for introduction to their current and future customer base. QED will sell these coils directly to Siemens.

Corporate Stability

QED, an internally funded and financially stable medical device manufacturer established in February 2006, has grown to a $10 to $20 million organization today that currently employs approximately 60 people. QED has strategic alliances with the four major MRI manufacturers, and in 2009 was ranked #11 in "America's Most Promising Companies" by Forbes Magazine.

Commercial Infrastructure

QED has a 27,000 square foot facility housing all operations, including engineering, manufacturing, quality assurance and regulatory affairs, human resources, accounting, and operations, located in Mayfield Village. QED is ISO-13485 certified, received 510(k) clearances on past products, and is registered with the Japanese Ministry of Health, Labour and Welfare (MHLW) as a foreign medical device manufacturer that is able to sell its products in Japan. QED sells its products directly to the four major MRI OEMs.

Mission Impact

Overall Score = 7.25

Cluster Formation

The proposed project builds upon the Wright Center of Innovation in Biomedical Imaging (WCIB) program for the 7T imaging cluster. Dr. Hiroyuki Fujita was appointed as the Director of MRI and Imaging Physics, and through his work he developed the foundations of what would become QED's core business innovations. Dr. Fujita has grown QED to become one of the premier MRI RF coil suppliers in the world. Now, through its work on the proposed project, QED will help assist in the further market proliferation of UHF MRI systems, and strengthen Ohio's position as a leader in medical imaging innovation.

Ohio Economics

QED forecasts sales of $ 6.3 million and $ 13.8 million in 2013 and 2015 for the proposed 7T coils to Siemens. QED forecasts the addition of approximately 8 new jobs in the first year, and ramping up to a cumulative total of approximately 39 new jobs by 2015.

Business Model

In close collaboration with Siemens, QED will develop and manufacture coils for Siemens and will sell the co-branded products directly to Siemens. QED has used this model in the past with other MRI manufacturers, and plans to continue this model in the future. QED expects similar efforts with 7T coil products with the other three MRI manufacturers in the future.

Ohio Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

MR Imaging and Devices for Pediatric Populations

USA Instruments/GE Healthcare Coils, Inc.

TFBP 10-930 1st Round Score: 65.3 2nd Round Score: 74.9 Rank: 6

Previous Ohio Investment

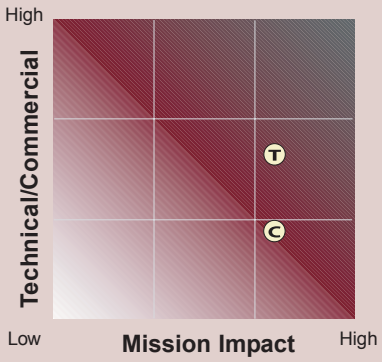
GE Healthcare, Inc has not directly received a TFP project award, but has been a collaborator in the BRTT Partnership Award with OSU on the Cardiovascular Bioengineering Enterprise. It is estimated that this initiative created or retained 184 jobs, attracted $46 million of external funding, and realized more than $2.5 million income from 3,000 patient treatments.

Project Description

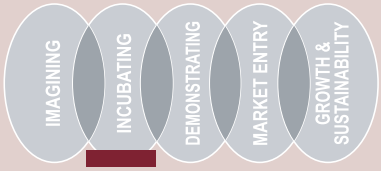
GE Healthcare Coils (GEHCC) will team with Cincinnati Children's Hospital and Ohio State University to design, build and validate a new pediatric torso array magnetic resonance (MR) coil for cardiac imaging of children. The team will also create new solutions pediatric head fixation with integrated imaging coils for MR assisted surgeries. During the two-year funding period, the team will identify optimal imaging approaches and mechanical designs. New coils and surgical MR devices will be constructed and validated on pediatric patients. The pediatric coils and fixation devices developed through the project will further the state-of-the-art of diagnostic imaging in children and are expected to facilitate increased use of MR imaging for interventional and surgical procedures by providing improved ways to stabilize young patients during imaging. By the end of the two-year collaboration, GEHCC will have developed several new products for 510(k) submission.

Key Issues

- By 2015, GEHCC projects significant revenue generation from the products proposed and that revenue is expected to result in new job creation and retention. However, GEHCC is not yet able to quantify the job projections due to GE standard policy.
- Design, engineering and production of the coils proposed will occur at GEHCC in Aurora, but it is not clear that the full system assembly will be done there. Opportunities for Ohio component suppliers will exist, but no commitments have yet been made.
- Since these products are still at the conceptual stage, the applicant is not able to make a strong case that they will offer a competitive advantage over similar MR products currently being used for pediatric patients.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$0
TOTAL Request:	$1,000,000
Cost Share:	$1,614,140

Collaborators

- Cincinnati Children's Hospital Medical Center
- Davis Heart & Lung Research Institute

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 5.47

Technical Reach

In both the pediatric torso array and head fixation projects, the initial steps involve simulation modeling of coils, field interactions and physical device layouts. Concept coils have been produced, but the first functional prototype equipment will be produced based upon the simulation efforts. GEHCC has successfully used this development path for producing the many coils it uses in its current MRI products. The proposed project will deliver the prototype equipment and data needed for regulatory submittals (510(k)) for both products. Connection between the pediatric products proposed and the adolescent/young adult clinical study at OSU is unclear.

Resource Limitations

GEHCC has successfully introduced over 150 products and has the experience and team to perform the project tasks proposed. Cincinnati Children's Hospital (CCH) is claimed to be among the top 3 children's hospitals in the U.S. and has the largest pediatric radiology faculty in the nation. GEHCC indicates it has the resources for and is fully committed to the commercialization of the proposed products.

Technology Protection

GEHCC has a strong portfolio of patents and trade secret know-how related to coil design, fabrication and application and will apply for new coverage as required. It has comprehensive research agreements covering IP rights with its collaborators on the project. Competitive advantages will be tied to performance and costs and GEHCC's reputation in the field.

Commercialization Risk

Overall Score = 2.93

Path to Market

GEHCC has an established design, review and approval process for its products to support market entry preparations. It has an established customer base and will leverage successful trials of the proposed devices at CCH to attract interest from other children's hospitals across the country and abroad. Competitive advantage of these products remains to be defined.

Corporate Stability

GEHCC is part of GE Healthcare that is under the Technology Infrastructure Segment of GE. GE Healthcare is a $17 billion business unit employing over 50,000 worldwide.

Commercial Infrastructure

GEHCC has access to GE Healthcare's worldwide sales and market force and existing manufacturing capabilities in Ohio. GEHC has an extensive supplier network that includes some Ohio suppliers.

Mission Impact

Overall Score = 7.33

Cluster Formation

GEHC is working with Ohio hospitals to validate the products proposed and with Lorain Community College to create and sustain a pipeline of MR and coil design-trained talent for GEHC to harvest. The project leverages the imaging research and product cluster in NE Ohio and extends GEHCC current line of products to pediatric devices.

Ohio Economics

GEHCC will create 7 new jobs over the course of the proposed project. It expects to introduce the new products by 2013 and by 2015 generate $70 million in sales. GEHCC currently has about 250 employees and projects this will grow significantly to support the product sales projected. However, GE policy is to keep job and revenue projections proprietary until an internally approved manufacturing and commercial release plan has been finalized

Business Model

GEHC's imaging research operations in the U.S. are conducted in New York, Wisconsin (complete MRI systems) and in Aurora, OH. Most of the surface coil development and production is done in Ohio and GEHCC indicates the coils for both proposed products would be made here. GEHCC uses a combination of internal and subcontracted manufacturing for its components and is expected to follow that same approach in producing the final end-use systems proposed.

Ohio Department of Development

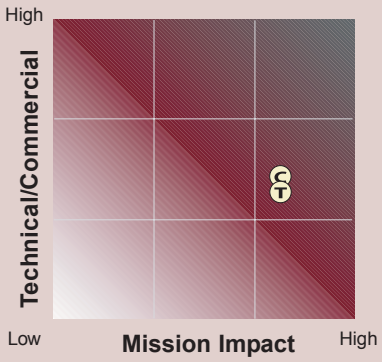
2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

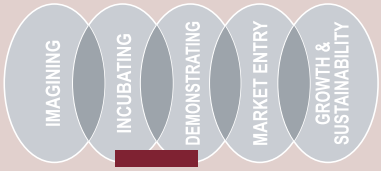
An In-state Multi-center Evaluation of Treadmill Exercise Stress Cardiac Magnetic Resonance

EXCMR, Ltd.

TFBP 10-922 1st Round Score: 70.3 2nd Round Score: 74.3 Rank: 7



Stage of Development



County Location

Funds Requested

TFRDF Request:	$999,694
WCF Request:	$425,000
TOTAL Request:	$1,424,694
Cost Share:	$1,497,827

Collaborators

- Cleveland Clinic Heart and Vascular Institute
- University Hospitals Case Medical Center
- The Heart and Vascular Center, The Christ Hospital
- The Ohio State University
- Quality Electrodynamics
- Siemens Medical Solutions, Inc. (Malvern, PA)
- Heart Imaging Technologies (Durham, NC)
- Zukun Plan

Previous Ohio Investment

EXCMR waspreviously awarded OTF funding through a $50,000 grant from the Entrepreneurial Signature Program (ESP) for market assessment and prototype design and a $156,000 subaward from the Global Cardiovascular Innovation Center for development of a working prototype and clinical feasibility testing of its MRI-compatible treadmill. Progress on the ESP award is proceeding according to the original plan. EXCMR has completed 2 out of 3 contracted phases of market assessment work, with the final phase underway and scheduled to be completed April 2010. Results have validated the market opportunity for EXCMR. Collaborator Zukun Plan has recently completed the contracted prototype design of the EXCMR treadmill system. Progress on the GCIC grant was completed ahead of schedule during the first 3 quarters of the project period. EXCMR was able to secure federal funding in the form of a $370,000 STTR Phase I award to accelerate the GCIC project.

This funding increased project cost share to 3:1, allowing the GCIC funds to support an expanded scope of work. The project period has been extended at no-cost until 7/31/2010, and the deliverables have been expanded to include the development of the pre-production prototype to be used in this proposed project, and enlargement of the clinical testing to incorporate 30% more patients.

Project Description

Cardiac imaging with a SPECT (single photon emission tomography) or an echocardiograph after exercise are widely used cardiac assessment methods. While MRI produces better cardiac images compared to SPECT and echocardiography, MRI's use after exercise is limited due to the excessive time needed to transfer the patient from the treadmill located outside the MRI room to the MRI. Conventional treadmills cannot be located in close proximity to MRI equipment because of the magnetic fields generated. EXCMR has developed an MRI-compatible treadmill system (made from non-ferromagnetic materials) that can be placed immediately adjacent to an MRI machine so that a patient can be easily and quickly transferred into the MRI tube within 60 seconds of exercise completion.

The goal of this 2-year project is to advance the proposed treadmill system to market entry. Clinical demonstration trials will occur at four locations: Cleveland Clinic Heart and Vascular Institute; University Hospitals Case Medical Center; The Heart and Vascular Center—The Christ Hospital; and The Ohio State University. Each clinical trial site will use the Wright Capital Funds to purchase a proposed treadmill from EXCMR and an RF coil from QED. Zukun will provide space to EXCMR for assembling the treadmills, will collect and analyze data regarding installation, operation, and ease-of-use, and will optimize the final product design. Heart Imaging Technologies will provide services to manage the clinical trial images, implement and manage secure data transfer procedures, and maintain image data. Siemens Medical Solutions, Inc. will support the integration and compatibility testing of EXCMR and QED equipment with the Siemens MRI systems.

Key Issues

- The treadmill developed by EXCMR will significantly improve the generation of cardiac images for assessment after excise. The availability of an MRI-compatible treadmill will expand the usage of MRI systems, improve the quality of cardiac assessment, and remove the patient and clinicians from radiation exposure associated with current stress testing procedures.
- The main obstacle to overcome in the sale of the treadmill is to convince practitioners to change their past imaging practices after exercise stress from using SPECTs and echocardiograms to using MRIs.

Prior Ohio Investments

- TechGenesis (ESP), 4/09/2009, $50,000
- GCIC (TECH-07 024), 2/18/2009, $156,183

Technical Risk

Overall Score = 4.20

Technical Reach

In more than 50 proof-of-concept demonstrations at OSU, a prototype treadmill (using non-magnetic alloys and a hydraulic drive system instead of electric motors) was placed next to an MRI for immediate cardiac imaging after exercise. The technical challenges involved in producing an MRI friendly treadmill have been overcome. Head-to-head comparisons of cardiac images from an MRI versus a SPECT/echocardiogram after exercise are planned for 227 patients at four clinics. The addition of the QED cardiac coil will provide improved MRI imaging capabilities at the four test site locations using Siemens MRI systems. The results from these clinical demonstrations will be used for sales/marketing purposes. The treadmill will likely be classified as a Class 1 device, which would exempt it from 501(k) regulation.

Resource Limitations

Since 2008, about $612K from grants has been raised. In addition to the OTF award, EXCMR plans to raise at least another $5 million from grants, private investments, and commercial funding needed to ramp up production, sales, and marketing resources to build and sustain and build a new medical device manufacturing business. EXCMR has access to adequate prototype production capabilities, and access to multiple sites for head-to head comparisons in a clinical setting.

Technology Protection

OSU has filed patent applications for the treadmill in 2006, 2007, and 2009. EXCMR has an option agreement for the exclusive right to evaluate the technology through April 2011, after which EXCMR can negotiate an exclusive license agreement to commercialize the technology. EXCMR will file additional patents if appropriate. Siemens has not indicated interest in the IP of the treadmill.

Commercialization Risk

Overall Score = 4.73

Path to Market

Results from the 227-patient demonstrations will be used to convince cardiac clinicians to change their imaging preferences to MRIs. In September 2009 Siemens signed a 3-year agreement for exclusive rights to sell the treadmill through its MRI catalog. Siemens claims to have systems in 50% of the large cardiac centers. The projected sales price for the treadmill is $100K. Following the 3-year agreement with Siemens, additional sales, service and distribution agreements will be sought with other major MRI equipment manufacturers (GE, Philips, Toshiba) and companies specializing in MRI accessories.

Corporate Stability

EXCMR is a spin-off company from OSU founded in 2008 to commercialize the MRI compatible treadmill. All revenues to date have been from grants. EXCMR will move into the Zuken facility for prototype assembly, and will later move to another facility to be determined by the end of the project.

Commercial Infrastructure

During the project EXCMR will move into the Zuken facility for prototype assembly. At the end of the project, EXCMR will set up full operational capacity in a Central Ohio facility (location to be determined) including sales, marketing, engineering, manufacturing, and administrative services. EXCMR plans to utilize contract suppliers until it becomes beneficial to bring manufacturing of major component systems in house.

Mission Impact

Overall Score = 7.58

Cluster Formation

The project supports the Ohio medical imaging cluster through the involvement of OSU treadmill technology, an Ohio MRI coil manufacturer, clinical demonstrations at 4 Ohio hospitals, the use of Ohio contract manufacturing organizations and the Ohio supply chain.

Ohio Economics

EXCMR forecasts annual sales of the MRI-compatible treadmill will begin in 2010, ramp up to $5 million in 2013, and further increase to $14 million in 2015. EXCMR forecasts 3 new jobs in 2010, 16 cumulative new jobs in 2013, and 50 cumulative new jobs in 2015.

Business Model

EXCMR plans to become a medical device manufacturer. At the end of the project, EXCMR will set up full operational capacity in a Central Ohio facility (location to be determined) including sales, marketing, engineering, manufacturing, and administrative services. EXCMR plans to utilize contract suppliers until it becomes beneficial to bring manufacturing of major component systems in house. Until 2015, sales will go through Siemens. After 2015 sales to end-users will be handled by MRI equipment manufacturers and companies specializing in MRI system accessories.

Ohio Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

The Atlas Electrocardiographic Mapping System

CardioInsight Technologies, Inc.

TFBP 10-944 1st Round Score: 69.0 2nd Round Score: 72.0 Rank: 8

Previous Ohio Investment

Cardio Insight Technologies (CIT) has not received a TFP grant directly. It has received funding through the Global Cardiovascular Innovation Center (GCIC). The goal of the GCIC project was to develop product-ready software in accordance with FDA mandated procedures and with an intuitive graphical user interface that would make it easy to operate for electrophysiologists and technicians, and would generate images in real time. The finalized software packages, graphic user interfaces, and hardware systems were completed and tested according to specifications. The final product was released with the Atlas Alpha 1 EC Mapping System on December 11, 2009, and CIT has completed a total of more than 50 clinical studies focused on atrial and ventricular arrhythmias as well as cardiac resynchronization therapy. GCIC funding supported a total of 8 full-time CIT employees and four of these employees became new CIT hires.

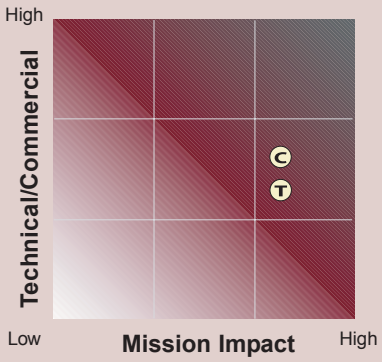
Project Description

CardioInsight Technologies was formed to develop and commercialize the Atlas Electrocardiographic Mapping (ECM) System based on licensed IP developed by Case Western Reserve University. The ECM system will measure the electric field of the heart using 252 sensors on the surface of the body to provide a non-invasive and instantaneous 3-D map of electrical activity for all four chambers of the heart enabling physicians to diagnose and treat cardiac arrhythmias and congestive heart failure more accurately, quickly, and effectively.

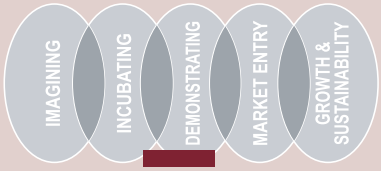
The primary goal of the proposed 1-year project is to complete clinical studies, develop and fully optimize the Atlas ECM System, secure FDA clearance, initiate pre-commercialization activities and influence follow-on investment that will be used for market entry and full-scale commercialization. Case Medical School University Hospital of Cleveland, Cleveland Clinic Foundation, and Le Centre Hospitalier Universitaire de Bordeaux will each conduct a study of 50 patients at their respective facilities. Battelle Memorial Institute will work on hardware/software enhancements and optimization for the proposed system.

Key Issues

- CIT appears to be well positioned to obtain the regulatory approvals and clinical data needed to introduce the Atlas ECM system within the next 2 years. However, it does not yet have sales and marketing infrastructure and will be creating this during the project period.
- CIT has leveraged the Ohio medical device cluster, and although its ties to Ohio are strong, it is possible that a small start-up company with a single unique product that has FDA clearance will become a candidate for acquisition.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$0
TOTAL Request:	$1,000,000
Cost Share:	$2,491,990

Collaborators

- Case Medical School, University Hospital of Cleveland
- Cleveland Clinic Foundation
- Battelle Memorial Institute
- Le Centre Hospitalier Universitaire de Bordeaux (Cedex, France)
- Michel Haissaguerre, MD (Bordeaux, France)
- Draper Triangle Ventures (Pittsburgh, PA)

Prior Ohio Investments

- Noninvasive Technology for Mapping Cardiac Electrical Activity, 2008 GCIC award, $282,000

Technical Risk

Overall Score = 4.27

Technical Reach

The CIT Alpha 1 ECM system has completed initial clinical trials and demonstrated functionality and performance. Pre-IDA meetings with the FDA are ongoing, and CIT expects a positive result for FDA clearance. The Beta system will require ruggedization of the sensor array (vest), single cable connection design, additional user interface optimization and aesthetic design. The Alpha 1 system data and the additional clinical trials proposed are expected to be sufficient for 501(k) approval and should allow commercial introduction by the end of the project.

Resource Limitations

CIT has completed a Series B financing round that will support its continued commercialization efforts. It is collaborating with Battelle for sensor array design, user-interface improvement and ergonomic design. CIT management has experience in cardiac EP product development and has acquired the technical expertise required for the software development. However, this will be CIT's first product offering.

Technology Protection

CIT has licensed four patents from Case and one from Case and the University of Washington that cover the ECM technology. Three provisional patents authored by CIT are in preparation. All IP generated during the TFMIP project will be owned by CIT.

Commercialization Risk

Overall Score = 5.40

Path to Market

CIT has taken a proactive approach to obtaining FDA approvals by conducting the pre-IDE meeting with the FDA. It appears this will permit a smooth and rapid FDA clearance path. The clinical sites have expressed interest in purchasing systems, and these initial first adopter sales will be leveraged to obtain sales at other hospitals and cardiac centers. Established reimbursement pathways are in place for advanced mapping systems such as the Atlas ECM system.

Corporate Stability

CIT was founded in 2006 with a Series A investment of $1.5 million and recently closed a Series B round for $6 million. It expects to produce revenue by 2013 and will be seeking a Series C investment starting in 2011 to support full system commercialization. Investors have indicted interest in participating in this next round of financing.

Commercial Infrastructure

CIT plans to contract with Astro Instrumentation (Strongville, OH) for product manufacturing. It will hire 11 new staff in early 2011, including a VP of Sales and Marketing, three sales representatives, a product manager, manufacturing manager and five clinical support technicians.

Mission Impact

Overall Score = 7.58

Cluster Formation

CIT's objective is to commercialize cardiovascular-related technology developed at Case with earlier TFP support. CIT is using Ohio collaborators for technical and design support and will use Ohio manufacturing resources for product production. The sensors utilized in the system are from an Ohio company and were developed with TFP funding. Ohio hospitals are included in the clinical trials, and investment resources include Ohio venture capital resources.

Ohio Economics

CIT projects that the proposed project will generate 11 new jobs and Beta system sales will produce $5 million in revenue by 2012. Commercial introduction is projected to grow product sales to over $25 million by 2013 and $100 million by 2015. CIT employment to for sales, product and clinical support will grow to 40 over that period. Manufacturing jobs at the Ohio suppliers involved will be in addition to these numbers.

Business Model

CIT will be a sales and product development organization using contract manufacturers for product production. In the near-term, CIT will sell directly to the end-user. After the product is established at the initial end-user sites, strategic partnerships with major medical device providers will be formed. Discussions are already underway with some the candidate companies. Revenues will be generated from the sales of both the capital equipment and the disposable sensor arrays.

Ohio Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

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

FMI Technologies, Inc.

TFBP 10-925 1st Round Score: 60.0 2nd Round Score: 57.3 Rank: 9

Previous Ohio Investment

FMI Technologies has not received any prior TFRDF awards.

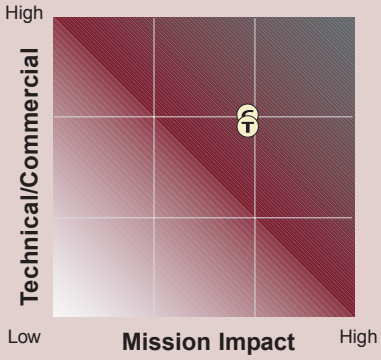
Project Description

FMI Technologies is seeking Third Frontier funding to produce pre-production prototypes of a ScintiStar™ Cardiac and a ScintiStar™ Neuro System. These systems are intended to be portable, ultra high resolution diagnostic imaging systems that combine Positron Emission Tomography (PET), Computed Tomography (CT), and Single Photon Emission Tomography (SPECT) into one system that will be 1/5 the cost and 1/5 the size of current whole body PET/CT systems. The systems are intended for use in the early detection and monitoring of neurodegenerative disorders, cardiovascular disease, breast cancer, and prostate cancer, and will enable the application of advanced therapies and the development of possible cures for Alzheimer's disease, vascular dementia, Parkinson's disease and other psychiatric diseases like schizophrenia and depression.

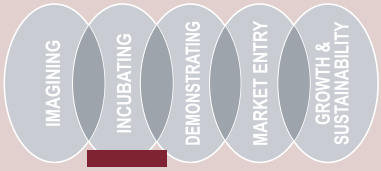
Clinical comparisons and evaluations will be conducted at Kettering Medical Center, Akron General Medical Center, The Ohio State University, and Summa Health System. Lantheus Medical imaging will provide the perfusion agents. Akron Global Business Accelerator will provide FMI space for its offices, imaging labs, production labs, and model shop for construction of the gantry and mechanical subassemblies. This 2-year program is designed to enable FMI to complete development work and obtain FDA 510k approvals for the systems.

Key Issues

- Both imaging agents intended for use with the ScintiStar™ Cardiac System and the ScintiStar™ Neuro System are currently in clinical trials. One manufacturer hopes to obtain FDA approval within the next 2 years, but the FDA approval timeline was not defined. It is therefore unclear if these agents can or will be used in the clinical trials proposed in this project.
- FMI makes reference to the "resolution potential" of the systems that will be developed, but it is unclear what resolution has been achieved to date. FMI claimed it has an operational neuro system, but did not provide a response to a specific request for information on the testing that has been completed.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$0
TOTAL Request:	$1,000,000
Cost Share:	$2,347,929

Collaborators

- Kettering Medical Center
- Image Reigstration and Fusion Systems
- Akron General Medical Center
- The Ohio State University, Wright Center of Innovation in Biomedical Imaging
- Summa Health System
- Akron Global Business Accelerator
- Lantheus Medical Imaging (N. Billerica, MA)

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 6.33

Technical Reach

These imaging systems appear to be at a very early stage of development. FMI claims to have built and operated the ScintiStar™Mammo R&D unit and ScintiStar™ Neuro R&D unit, but without data on the performance of this equipment, no assessment of the magnitude of the technical challenges remaining can be made. FMI claimed that it had performed a system validation that has yielded "encouraging results".

Resource Limitations

FMI has raised $3.3 million in angel investment but has a very weak balance sheet and no sales or revenues. Funding from the Third Frontier would be used to build pre-production units, to collect data, and to apply to the FDA for 510 (k) approval. FMI is working on a Series A financing of $8 million to build 6 additional units. The next stage of commercialization may require up to $16 million.

Technology Protection

FMI has filed 2 patent applications, one covering the fused SPECT, PET, X-ray CT, and Optical Surface Imaging of Breast Cancer, and a second covering "Modular Multi-Modal Tomographic Detector and System". The extent of the patent coverage for the cardiac and neuro systems is not specifically described.

Commercialization Risk

Overall Score = 6.73

Path to Market

FMI plans to collaborate with Lantheus Medical Imaging and AVID Radiopharmaceuticals to access cardiologists and neurologists worldwide. FMI indicates that it will use Lantheus's sales force of 100 people in the U.S. and distributors in Europe and Japan to sell cardiac imaging systems. While these two companies are major suppliers of imaging agents, it is not clear that their sales forces will be effective in promoting the purchase of high-capital imaging equipment.

Corporate Stability

FMI is located in the Akron Global Business Accelerator. Its predecessor company was founded in 2003. FMI did not respond to a direct question about the number of employees, but it appears that 7 individuals, each with extensive experience in medical imaging, are involved. FMI's financial status appears to be very fragile, and it does not yet have sales revenues. There was no evidence of grant income and the investor financing being sought appears to be critical to its stability.

Commercial Infrastructure

Although FMI has not yet reached the stage of having capabilities in the areas of marketing, sales, and product support, it plans to develop its own marketing group that will have experience selling capital equipment to hospitals, imaging centers, and clinicians in the U.S. The marketing group will be based in Ohio with additional branches on the east and west coasts.

Mission Impact

Overall Score = 6.50

Cluster Formation

FMI plans to build the ScintiStar™ systems in Akron, Ohio. The PET/SPECT detectors, CT detectors, PET/SPECT data acquisition, CT data acquisition, PET/SPECT/CT rapid GPU reconstruction and image processing, and system controls will be done at FMI labs. FMI will rely on Image Registration and Fusion Systems in Beavercreek, OH for image analysis and quantization. FMI intends to utilize the medical imaging supply chain for building, installing and servicing the systems, but no additional details are provided.

Ohio Economics

Initial revenues are projected to come from sales of the first units to clinical sites during the first year of the project. By 2013, FMI projects that it will generate $47 million in annual sales. Revenues are projected to increase to $139 million by 2015. FMI projects that it will create 80 jobs by 2013 and 120 jobs by 2015. By 2017, annual sales are projected to exceed $300 million. These business projections appear to overly aggressive based on the current status of the technology and company.

Business Model

FMI is currently located in Ohio and plans to do its product development work and initial clinical studies in Ohio. Its model for full-scale manufacturing has not yet been fully developed. It is also unclear how the sales and marketing functions will be divided between FMI, Lantheus, and AVID. The latter two companies are located in Massachusetts and Pennsylvania respectively.

Ohio Department of Development

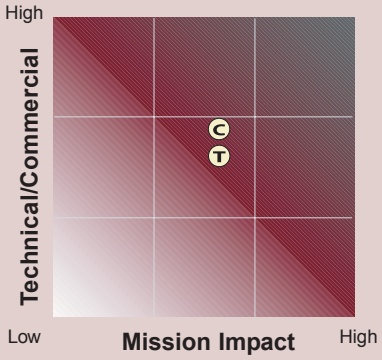
2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

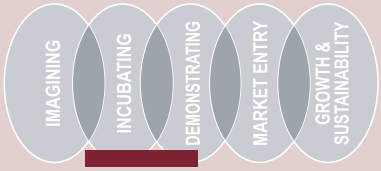
Fourier Domain (FD) Optical Coherence Tomography (OCT) Imaging System for Real-time 3D Imaging of Epithelium for Pre-Invasive and Invasive Cancer

Imalux Corporation

TFBP 10-902 1st Round Score: 56.0 2nd Round Score: 54.9 Rank: 10



Stage of Development



County Location

Funds Requested

TFRDF Request:	$999,000
WCF Request:	$0
TOTAL Request:	$999,000
Cost Share:	$1,110,000

Collaborators

- GVI Medical
- Preventive Oncology International, Cleveland Clinic
- Case Western Reserve University, Department of Oral & Maxillofacial Surgery

Previous Ohio Investment

At the time of its initial TFAF grant application in 2002, Imalux had developed a working prototype of its device for a new medical imaging technology known as OCT. This equipment was intended for use by clinicians in screening for cervical cancer. The device had been tested extensively and had produced results in agreement with pathology findings. Imalux received a TFAF grant of $542,000 to build additional prototypes and a probe protector and to conduct additional clinical testing of equipment. The company planned to purchase standard optical components and to build or have built proprietary imaging devices. Imalux was successful in obtaining 510 (k) approval from FDA for this equipment in 2004, and commercialized the device in mid-2005. To date, Imalux has manufactured and sold 50 units resulting in total sales of $560,000 creating 8 jobs. The company has been successful in raising total leverage of $18.4 million.

Project Description

Imalux' current first-generation product is 2-dimensional, and clinicians have reported a number of difficulties with its use. Clinicians also required further clinical validation for market acceptance. Imalux plans to introduce a second-generation product later in 2010 which will also be 2-dimensional and will address some of the problems. The funding from this request would be used to develop a third-generation product that would be targeted at screening for cervical cancer. Imalux claims that the transition to 3D-OCT is needed to increase the reliability of tissue identification and to simplify data analysis.

The proposed Imalux system is designed to optically scan a tissue area in 10 seconds producing a 3D-image of critical areas and providing valuable information regarding epithelial brightness and depth. It is expected to have the capability of distinguishing between normal, precancerous, and cancerous conditions.

The major tasks in this project are the responsibilities of the various service providers: Optiphase intends to develop the interferometer (the most critical component of the system); George Washington University intends to develop the algorithms for 3D image reconstruction; GVI Medical Devices intends to design the electronics, develop the software, and produce and assemble the electronics; NPI intends to provide product design and manufacturing sourcing for the disposable probe sheaths, submit application for 510 (k) clearance from FDA, conduct market evaluations; and introduce the product in China; and Preventive Oncology International will have the responsibility for clinical validation of the technology. Imalux plans to build the proposed anatomically specific probes.

Key Issues

- A first prototype of this third-generation device was produced as part of Imalux's SBIR project. It is unclear how significant the remaining hurdles are likely to be.
- Data presented on the performance of OCT equipment indicate that it is difficult to differentiate normal cervical response from mild dysplasia (CIN I).
- Since this device is targeted at replacing colposcopy in the diagnosis of cervical cancer, physicians are likely to have the same concerns about clinical validation that were expressed earlier.
- The pricing for the first-generation device was $35,000 which will increase to $65,000 for the second-generation device and $140,000 for the third-generation device. Market validation for this price structure remains to be demonstrated.
- Estimates of the time and cost required to bring this product to market appear optimistic based upon the results from the first-generation product. It is not clear if Imalux will have the resources to simultaneously support the second-generation device and develop the proposed, third-generation device.

Prior Ohio Investments

- Development of OCT in Management of Cervical and Vulvar Cancer, 2002, $542,000

Technical Risk

Overall Score = 5.33

Technical Reach

As a result of market feedback, Imalux developed a second-generation product, Niris II, which is planned for release to the market in 2010. Imalux plans to expand and improve the performance capabilities of Niris II with the addition of 3D mapping in a third-generation product, F3DNiris, the focus of this proposal. The major tasks in this project will be the responsibilities of the various service providers. Imalux plans to begin clinical trials for cervical examinations at the beginning of the second project year, receive FDA 510(k) approval by July 2012, begin production, and be ready for market entry by the end of the project at the end of 2012. The first-generation product received FDA 510(k) approval as a Class II device in 2004, and it is expected the proposed third-generation product will quickly receive Class II approval.

Resource Limitations

Imalux has raised $17 million in investments to date, and forecasts the need for $5 to $7 million (including the OTF grant) to achieve full commercialization. Imalux intends to rely upon the expertise of the suppliers for overcoming the challenges of their respective components, and the Cleveland Clinic and CWRU for the clinical trials and evaluations. Imalux plans to develop a new sales force and partner with distribution partners (not yet established) to promote and sell the new system.

Technology Protection

Imalux owns 11 issued US patents and has several patents pending. The Imalux OCT technology platform is based upon technology from the Institute of Applied Physics (IAP) of the National Academy of Sciences, Russia. This patent portfolio covers a variety of proprietary technologies that enable Imalux to deploy devices with high image quality at an affordable cost. Imalux has an open contract with IAP for developing additional IP. Imalux has received FDA clearance and ISO and CE Mark certification for the current product.

Commercialization Risk

Overall Score = 6.27

Path to Market

Imalux previously hired a sales force to promote the first-generation product, but due to performance limitations and lack of sufficient clinical data to generate sales, the sales force was eliminated, and a second generation product was developed. Existing personnel intend to sell the second-generation product. Once the proposed improved third-generation version, F3DNiris, is ready for product launch, Imalux plans to hire a new sales force and plans to generate new partnership sales agreements with suppliers in the appropriate industry segments. The F3DNiris system has three major components with the corresponding estimated sales prices: the base electronic system ($140K), a series of multiple-use anatomically specific probes ($3.4K each), and single-use disposable sheaths ($12 each) for the probes.

Corporate Stability

The predecessor to Imalux was formed as a medical device developer and manufacturer in 1996 in Cleveland, Ohio by a team that included the Russian inventors and a Cleveland law firm. Over the next several years, the group received seed funding to conduct investigational studies at The Cleveland Clinic Foundation, file a series of U.S. patents, and commercialize the Niris OCT Imaging System. Imalux currently has an 850 square foot lab area in the BioEnterprise Facilty, has 9 employees, and has generated revenues less than $1 million (mostly from grants) for the last 3 years. Product sales so far this fiscal year are approximately $50K.

Commercial Infrastructure

Imalux outsources most component manufacturing. Imalux currently manufactures the probes for the second-generation system in house, and plans to distribute them from its Cleveland facility. Imalux intends to sell second-generation systems using internal personnel while third-generation product will be handled by other partnership organizations, yet to be determined.

Mission Impact

Overall Score = 5.53

Cluster Formation

Imalux is working with Ohio hospitals for conducting clinical trials (Cleveland Clinic, Case), utilizes Ohio contract manufacturers (Robins Industries, GVI), and purchases products and services from over 150 Ohio based supply chain companies.

Ohio Economics

Imalux plans to continue generating revenues from sales of its existing second-generation system. Sales for the proposed third-generation system only are forecasted at $6.2 million in 2013, and $31 million in 2015. Imalux predicts 23 new jobs will be generated by 2013, and a cumulative total of 38 new jobs by 2015 as a result of the proposed third-generation product.

Business Model

Imalux plans to become a developer of medical imaging devices, will outsource device manufacturing, and will partner with organizations that have sales and marketing networks in the appropriate markets (to be determined). Partnerships can include joint ventures, exclusive distribution rights, and licensing. Most component production is planned at contract manufacturing organizations, while the production of the anatomically specific probes will be done in-house.

Ohio Department of Development

2010 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Manufacturing and Development, MRI Guided Treatment of Atrial Fibrillation

Interventional Imaging Inc.

TFBP 10-914 1st Round Score: 65.0 2nd Round Score: 45.5 Rank: 11

Previous Ohio Investment

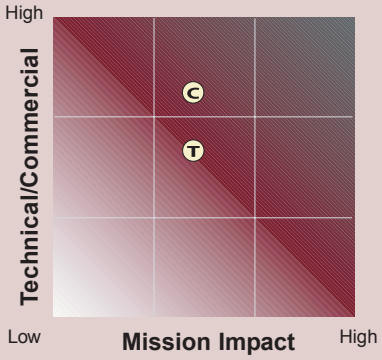
Interventional Imaging received funding from the Global Cardiovascular Innovation Center's commercialization fund program. With this funding, Interventional Imaging constructed an MRI prototype and is doing imaging validation studies.

Project Description

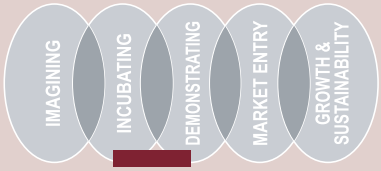
Interventional Imaging licensed technology from Case Western Reserve University for a radio-frequency (RF) ablation catheter that can be viewed real-time inside the patient with an MRI, thereby aiding the guidance of the catheter to the desired position inside the heart during treatment for atrial fibrillation. In addition, the catheter tip contains components that aid in providing MR images from its location inside the heart. The proposed device eliminates x-ray radiation exposure while providing accurate information on the placement of the catheter tip for treatment. The 2-year project will fund the continuing development which includes: completion of the development work required for clinical tests; relocation of the manufacturing from Minnesota to Ohio; and establishment of a supply chain for product components in NE Ohio. This project will establish Interventional Imaging as an Ohio-based medical device manufacturing company that will provide a high-volume source of MR-compatible RF ablation catheters for the treatment of atrial fibrillation.

Key Issues

- The proposed product is a promising improvement in the treatment of cardiac arrhythmias.
- This project is in an early stage of development. Clinical trials in humans are not expected to begin until after the end of the 2-year project, and if successful, sales revenues and job creation will not begin until at least 2015.
- The project contains significant technical obstacles, such as interfacing the catheter to various MRI's, conducting human clinical trials, and establishing an Ohio-based production infrastructure. The project also contains commercial uncertainties such as financial resource acquisition and development of business plan details.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$997,010
WCF Request:	$0
TOTAL Request:	$997,010
Cost Share:	$1,007,503

Collaborators

- Case Western Reserve University, Case Center for Imaging Research
- Case Western Reserve University, School of Medicine
- Case Western Reserve University and University Hospitals

Prior Ohio Investments

- *None*

Technical Risk

Overall Score = 5.53

Technical Reach

Over the last 6 years, Interventional Imaging has designed and built more than 50 imaging catheters and 10 ablation catheters, and evaluated the device in 50 pigs and human cadavers with promising results. The proposed catheter is designed so that it can be used on any MRI, but an interface kit specific for each MRI manufacturer is required. The project has developed the interface kit for only the Siemens system. The technical and commercial specifications for the beta prototype are currently approximately 60% complete, and are expected to be fully complete by the end of the project. After manufacturing and testing the beta prototypes, the design specifications will be subject to revisions. The work plan to address the technical obstacles, including moving production to contract manufacturing organizations in Ohio, is not fully developed.

Resource Limitations

Interventional Imaging has raised $2.8 million from Ohio investors, Ohio grants, and NIH grants. The OTF funds are required to continue development work. Interventional Imaging anticipates the need for FDA PMA and plans to develop a partnership with an appropriate company to provide funds for the clinical trials, plus other costs to bring the product to market. Sources of additional funding are not clear. Interventional Imaging has access to qualified clinical cardiologists for evaluating the product and access to technical resources for product development.

Technology Protection

There are several ablation catheter products in the market, but none have the ability to generate MR images from inside the body. Interventional Imaging licensed the technology for hardware and software from the Case Western Reserve University which provides world-wide rights to make, have made and use the technology. The rights are exclusive except for certain rights granted to Siemens Medical Solutions that do not restrict Interventional Imaging's opportunities. The field of use for the licensed technologies includes the vascular and esophageal systems.

Commercialization Risk

Overall Score = 7.47

Path to Market

Interventional Imaging intends to partner with an existing organization with an appropriate industry leader with a current sales network in the cardiac ablation market. Plans to sell the product at a potential pricing level, plans to secure several customers who use the product in a commercial environment, and plans to establish the reliability of the technology are not complete.

Corporate Stability

Interventional Imaging is a spin-off organization from CWRU for commercializing medical devices. Revenues to date have come from grants and investments. Cash balance is very low, consisting of working capital. Current products are contracted to manufacturers.

Commercial Infrastructure

Interventional Imaging is an early development company with outsourced manufacturing, no sales organization, and limited corporate functions. Current contract manufacturers are limited to prototype production, so production quantities will be relocated to contract manufacturing organizations (CMOs) in Ohio. While certain potential Ohio CMOs have been identified, no future CMOs are involved with this project. Production will be outsourced to CMOs, and final assembly will be performed in-house, location to be determined. Sales of the product will be handled by a partner organization, yet to be indentified.

Mission Impact

Overall Score = 4.67

Cluster Formation

Interventional Imagine is a part of, and plans to continue its reliance and support of the Ohio medical device cluster through its collaborations with CWRU and the University Hospitals. Interventional Imaging plans to sell the products through a partner organization, but plans to produce the products via Ohio CMOs and utilizing the Ohio supply chain.

Ohio Economics

Interventional Imaging predicts contract manufacturing in Ohio to begin in 2014, with sales of $3.6 million beginning in 2015. In 2014 Interventional Imaging plans to hire 8 FTE's, and will hire 3 to 6 more in 2015.

Business Model

Interventional Imaging will use a partnership model. Interventional Imaging intends to generate a revenue stream based on catheter sales (re-usable electronic adapter for the MRI system, and disposable single-use catheter) via a corporate partner. This strategy allows Interventional Imaging to focus on outsourced manufacturing and final in-house assembly, while the corporate partner takes the lead on clinical trials needed to support a PMA registration with the FDA and for the selling effort to medical centers performing cardiac ablation procedures.