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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

Company Profile

Industry Sector: Medical Devices

Company Overview: FocalCool is a small research and development company designing advanced hypothermia medical devices. The company was started in the basement of Tom Merrill in November 2004 and over the past 5 years with combined personal and NIH Phase I SBIR funding several early device prototypes have been tested both in vitro and in vivo. Based on these preliminary findings, in March 2008 FocalCool received a \$950,000 SBIR Phase II grant from NIH's National Heart, Lung, and Blood Institute. Through this and other funding support, FocalCool currently conducts their developmental research from the South Jersey Technology Park at Rowan University located in Mullica Hill, NJ.

Target Market(s): Heart attack, stroke, and cardiovascular diseases.

Key Value Drivers

Technology*: FocalCool develops products that fully harness the protective power of hypothermia. The company's emphasis is not whole-body or systemic cooling methods, but rather devices that cool individual organs rapidly. FocalCool's premier device, the CoolGuide catheter, specifically targets the heart for use in interventional cardiology during a heart attack.

Competitive Advantage: Systemic coolers require 1 hour's time to cool the whole body and cause several detrimental side effects such as shivering. This poses challenges to their clinical usability. CoolGuide's local cooling ability is realizable within 5 minutes and does not yield the negative side effects experienced with systemic cooling methods, making it more desirable for clinical application. Faster cooling will save more organ tissue; reducing treatment costs and improving patient outcomes and quality of life.

Plan & Strategy: Exit options include technology licensing, profit sharing, sale of the company, and or an initial public offering, or partnering with larger device company.

*Technology funded by the NHLBI and being commercialized under the NIH-CAP

Management

Leadership:

Thomas Merrill, Ph.D., Project Manager & CEO: Former medical device developer at Abiomed, Inc. and heat transfer expert in both industry and academia

Jay Yadav, M.D., Chairman: Interventional Cardiologist and CEO of CardioMems, Inc., former director of Cardiology at the Cleveland Clinic, and was featured in the American Heart Association's Top Ten Advances in Scientific Research Report

Scientific Advisory Board:

Simon Dixon, M.D.: Director of Cardiac Catheterizations Laboratory at William Beaumont Hospital

Robert Gorman, M.D.: Director of Cardiac Surgical Research at University of Pennsylvania

Matthew Gillespie, M.D.: Pediatric Cardiologist at Children's Hospital of Philadelphia

Sujata Bhatia, M.D., Ph.D.: Medical Researcher for DuPont

Product Development

Product Description: FocalCool has developed CoolGuide, a novel guide catheter that locally cools heart tissue while maintaining the functionality of guide catheters currently used in treating heart attacks. CoolGuide has a tri-lumen design which circulates cold isotonic saline in a closed loop while providing a central blood lumen for standard interventional tools and to deliver cold blood directly to the area at risk. FocalCool's strategy is to market the CoolGuide catheter as an adjunct therapy for percutaneous transluminal coronary angioplasty.

Product Research & Development: CoolGuide prototypes are designed, manufactured, and tested in vitro and in vivo. Pre-clinical safety and cooling-only studies have been completed. Current pre-clinical studies are investigating device efficacy using a large animal model of myocardial infarction.