DESTINATION STARTUP

Microsurgical Innovations

One-Sentence Summary of What You Do: Microsurgical Innovations (MSI) develops medical devices for use in microsurgical applications. MSI's first product for commercialization, a Vascular Coupling System (VCS), is intended to replace the hand suturing technique currently used to connect arteries and veins in microvascular and macrovascular end-to-end vascular repair surgeries.

Affiliated Institution: University of Utah

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Direct/Indirect University Support

Please describe your company and the problem you are trying to solve: The current state-of-the-art procedure in microsurgical vascular anastomosis is hand-suturing the two cut ends of an artery or vein together using ultrafine techniques with the assistance of an operating microscope. Hand suturing is time consuming (30-60 minutes depending upon the surgeon's ability), requires expertise, and is prone to human error. Sutures must penetrate through the wall of the vessel and can damage the vessel intima or inadvertently catch the vessel backwall, both of which can lead to thrombosis. The added time of manually hand-suturing vessels translates to significant cost in the operating room which are further exacerbated if complications such as thrombosis, leakage, or stenosis occur. There have been many attempts to improve the current manual suturing technique, all of which have fallen short. Venous coupling devices like the Synovis GEM offer a competing technology; however, these devices do not work well with thick walled arteries. Researchers at the University of Utah's Agarwal Research Lab have developed a vascular coupling system (VCS) that is intended for use in end-to-end anastomosis of veins AND arteries. It is easy to use, saves time and money in the operating room, and connects two vessel ends together in a watertight seal without leaving foreign material in the lumen to come in contact with blood flow. This patented device has been licensed to Microsurgical Innovations who is in the process of bringing its VCS device to market in collaboration with Accelerum Advisors, who provide it with operational expertise, fund raising capabilities, and corporate governance skills.

What is/was your go-to-market strategy? Market size estimates are based on the number of microsurgery operations performed each year, including plastic surgeries, reconstructive surgery after injuries or disease, replantation of severed appendages, and organ transplants. This total is estimated to surpass 100,000 procedures. Each microsurgery involves at least two anastomoses, thereby doubling the number of devices required. Due to the ease of use, reliability, and ability to couple arteries, this device has the potential for expanding the number of microsurgeries performed by enabling less experienced surgeons to undertake such procedures. It could also be used in

other surgical disciplines, including non-vascular procedures such as bile duct repair (laparoscopy) and reversal of tubal ligation or vasectomy procedures. Typically, microsurgeries are carried out in tertiary care settings, and a successful VCS that does not require additional physician training has the potential to expand these microsurgeries into the community hospital and battlefield settings. Future growth opportunities lie in Asia, as most Asian countries perform many more microsurgical procedures than are performed in the US. To effectively position this technology for market entry, the VCD addresses the needs of the market and provides compelling value. The VCD improves workflow efficiency by reducing surgery time, decreasing human technical error, and making the procedure much easier than suturing. Ease of use, time savings, and the ability to be used with arteries as well as veins will be validated through comparison to manual suturing and procedures with the comparable Synovis coupler.

How will/do you generate revenue? Preliminary projection of revenue of the VCD are based upon an assumed per unit price of $350 and a price of $3,000 for the instruments; both prices of which are based upon comparable prices for the Synovis GEM line of anastomosis coupling products. The size and engineering requirements for these devices are similar, as are their intended use propositions. The Financial Model assumes that the total addressable market in this segment is approximately 100,000 units per year with a yearly market growth rate of 3%. The Financial Model also assumes a penetration rate for the VCD and its instruments of only 5% per year, which then drives the unit sales numbers for the forecast. With those as inputs, the Model generates revenue projections of $3.9 million in the first year of sales (2022), $10.3 million in 2023, and $17.0 million in sales in 2024.

How will this showcase benefit your company or technology? The MSI founders have extensive experience working with each other over the last five years, completing foundational research for the VCD they developed, along with various other collaborative research efforts involving other medical devices. The MSI founders also have a track record for receiving federal funding from various agencies including SBIR/STTR funding for other projects. Additionally, the founders have developed an accomplished entrepreneurial track record, founding startup companies and delivering products to market. Based on invitro, animal, and early stage human results, MSI will also pursue licensing opportunities with larger companies as a platform for vascular anastomosis. MSI entered into a contractual agreement with Accelerum Advisors, a strategic and financial advisory firm, to advance the development and commercialization of its VCD in April 2020. This agreement represents a two-year commitment wherein Accelerum Advisors is dedicating its time and resources needed to drive the VCD to market, including providing personnel, management, and access to the capital funding market including angel investors, venture capital firms, and family offices. During this time, MSI and Accelerum Advisors will also seek strategic partnerships and potential buyers to enhance the growth opportunities and sales projections for the VCD. In addition to the grants already received, MSI is currently under review for a Phase IIB SBIR/STTR award, and MSI, working with Accelerum Advisors, is currently working on an equity capital raise of $600,000 with outside investors. This showcase will provide additional opportunities to meet with investors and strategic partners.

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Who are the members of your team and why is this the right team to get the job done?

MSI's founders and staff are all from the University of Utah and have successfully worked together on this and other projects:

- Dr. Jay Agarwal is the Chief of Plastic Surgery Division and is the President for MSI. Dr. Agarwal is a microsurgery specialist and experienced in animal models of nerve and vascular injuries.
- Dr. Bruce Gale is Professor and Chair, Mechanical Engineering, and Vice President of Engineering for MSI. He has successfully commercialized a high throughput microfluidic based protein printing technology through his company Wasatch Microfluidics with $2 million/ year in revenue.
- Dr. Himanshu Sant, Research Associate Professor, is the Vice President of Operations at MSI. Dr. Sant has extensive research experience in the development of microscale devices.

Additional MSI staff adds strong experience with device manufacturing, solidworks, mechanical testing and modeling:

- Research Director: Huizhong Li PhD developed much of the existing coupling technology. Engineer: Azur Azapagic, research assistant completing a PhD degree. He has ten years of medical device industry experience. Accelerum Advisors has partnered with MSI to commercialize the VCS.
- VP Finance: William Benz, MBA, CEO of Accelerum Advisors, is a former CFO formetlife Corporation and Energy Solutions among others
- Marketing Director: Nate Gibby, of Serfwerks has worked with 500+ companies in marketing strategy and implementation.
- Regulatory Director: Marcia Griffiths, MBA, Regulatory Lead, Marcia has 25 years' experience in medical device development and regulatory compliance.
- Project Director: Glynnis Tihansky, MS, has extensive diverse medical device experience ranging from Design Engineer and VP of Product Development to Marketing and Logistics.