Second Heart

Minimally Invasive Circulatory Assist Devices

Product Summary

Second Heart is developing a minimally invasive circulatory support platform based on proprietary aortic stent pump technology. The platform will be deployed using low profile catheter-based techniques and will provide either temporary or chronic circulatory support, depending on the specific needs of the patient. Second Heart's initial product will be a catheter-based temporary assist pump to treat patients with acute decompensated heart failure and to provide circulatory support to those undergoing high-risk percutaneous coronary intervention (PCI). The second application will be a wirelessly powered circulatory assist pump that will provide chronic circulatory support for heart failure patients.

Key features of Second Heart's platform include:

- A higher flow (with lower RPMs) rate than other systems at over 7 liters per minute.
- Pump placement just above the renal arteries will provide additional benefit for heart failure patients with kidney dysfunction.
- A choice of pulsatile or continuous flow to optimize hemodynamics and lessen the risk of thrombosis.
- The only system to use the full inner diameter of the aorta to increase pump stability and reduce pump migration.
- Lower risk of mechanical failure due to simple impeller deployment mechanism, improved bearings, and liquid cooled drive shaft.

FAQ

Is heart failure a significant problem? In the U.S. over 6 million people suffer from heart failure with up to 20% suffering from an advanced form of the disease (Class 3 and 4). This results in over 1 million hospitalizations each year that cost the healthcare system over $30 billion. According to the American Heart Association, the prevalence of heart failure is expected to increase by 46% through 2030, resulting in over 8 million patients.

What is the regulatory status of Second Heart's products? Second Heart is currently conducting preclinical studies and has identified the sites that will be used for the clinical trials that will be necessary for FDA and CE Mark approval.

What is Second Heart's intellectual property? Second Heart has a formidable intellectual property portfolio that includes patents from leading cardiovascular physicians and CalTech.

How does Second Heart compare to the competition? Competing products are more difficult to place, have lower flow rates, and do not provide the improvements in renal function that are anticipated with Second Heart's platform.

Problem

Currently available circulatory assist devices face a number of significant limitations and drawbacks, including: Low flow rates that do not provide the full assistance patients need. Device-associated thrombosis that can block blood flow to vital organs, potentially resulting in a stroke, myocardial infarction, etc. High impeller speeds that can cause hemolysis and pump migration. Risks and complications associated with invasive implantation procedures that are required to deploy many circulatory assist devices. External equipment can decrease patient comfort and quality of life while limiting the range of activities a patient can participate in (swimming, etc.).

Solutions

Second Heart's technology is a minimally invasive solution that provides circulatory assistance to patients while overcoming many of the limitations of current options: Collapsible stent pump design allows for low profile catheter-based introduction for easy and secure placement in the aorta. Mechanical design provides high flow rates (over 7 liters per minute) while minimizing the risk of mechanical breakdown and reduces damage to blood cells (hemolysis). Thrombosis-resistant material, harmonic vibrational energy technology, and pulsatile flow all help to prevent blood clotting that can lead to stroke or myocardial infarction. Our patent-pending removable (and wirelessly powered) pulsating cuff stent is situated above the impeller pump providing a two pump "in-series" system. This wireless power source eliminates the need for percutaneous equipment that can serve as a site of infection and limit a patient's quality of life.

Market

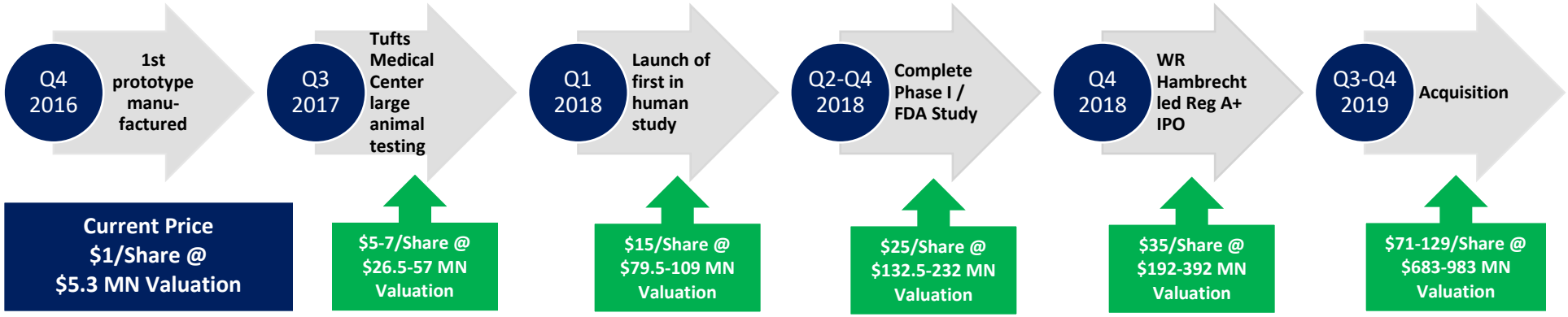
The target markets for Second Heart's temporary circulatory assist pump include:

- Acute decompensated heart failure — Of the estimated 1 million annual hospitalizations for decompensated heart failure, roughly 10% are complicated by reduced kidney function. Due to its placement, just above the renal arteries, patients with reduced kidney function stand to significantly benefit and represent 100,000 potential patients per year.
- High-risk PCI — The estimated number of PCIs that occur each year in the U.S. ranges from 650,000 to 1.2 million (based on the specific source). Current estimates are that at least 10% of PCIs are considered high risk and could potentially benefit from a support device such as Second Heart's. As a result, this market segment includes 65,000 to 120,000 patients.

Combined, these segments encompass 165,000 to 220,000 heart failure patients every year and result in an annual projected market of over $4.6 billion. A comparable that confirms the market potential is Abiomed, a manufacturer of catheter-based temporary circulatory assist devices indicated for high-risk PCI and cardiogenic shock. Over the past 5 years they have seen 30% annual growth with Impella sales generating $310 million of revenue in 2016. Even with less than 10% of their projected market, Abiomed has achieved a market capitalization of over $5 billion.

The market for Second Heart's chronic aortic implant will be heart failure patients who require long-term circulatory support. Since many of these patients are unable to receive a heart transplant (due to organ shortage, contraindications, etc.), they currently rely on cardiac assist devices such as ventricular assist devices (VADs). The LVAD market is expected to grow at 7.9% annually over the next 5 years to reach a total revenue of roughly $900 million in 2021.

Key Milestones and Estimated ROI



Note - Total valuations will be adjusted as more shares are authorized and issued for subsequent offerings.

Core Team

Howard Leonhardt

Chairman, CEO

Howard is a highly successful serial entrepreneur who has developed multiple cardiovascular devices that continue to lead the market including the TALENT stent graft and percutaneous heart valves.

Jeff Donofrio

President

Jeff has over 30 years of medical sales, management and business development experience (with 16 of those years specific to cardiovascular devices). He has worked for World Heart, ATS Heart Valves, Edwards Life Sciences, and Cardiac Assist, Inc.

Leslie Miller, MD

Chief Medical Officer

Dr. Miller is a board-certified cardiologist and one of the world's leading experts in the development and evaluation of circulatory assist devices. He has been involved in over 100 clinical trials and has published more than 250 manuscripts.

Team Members

Todd Seiger - Chief Advisor Reimbursement

Larry Stevens - Chief Advisor Regulatory Affairs

Jane Reedy - Chief Advisor Clinical Affairs

Alex Richardson - VP Engineering & Product Development

Dr. Nic Chronos - Chief Advisor Research

Dr. Mark Cunningham - Chief Advisor CardioThoracic Surgery

Dr. William Abraham - Chief Advisor Heart Failure

Dr. Barry Greenberg - Clinical Advisory Board Member

Dr. Dinesh Patel - Board Director

Dr. Samer Banihani - Chief Nephrology Advisor

Ryan Stanfield - Circulatory Assist Device Design Advisor

Kevin Arnal - Chief Project Engineer Biomerics Advanced Catheter