SECOND HEART ASSIST

REVERSING CARDIO-RENAL DYSFUNCTION

Executive Summary

Product Summary

Second Heart Assist Inc. has developed a minimally invasive circulatory support platform based on a proprietary aortic stent pump technology. This platform is executed in two product offerings: 1) a low profile catheter-based device for temporary circulatory support 2) a wirelessly powered device to better provide long-term chronic circulatory support, depending onthe specific needs ofthe patient. Second Heart's initial, temporary, catheter-based assist, pump product is designed to treat patients with acute decompensated heart failure and to provide circulatory support to those undergoing high-riskpercutaneous coronary intervention (PCI). The second generation wirelessly powered circulatory assist pump product will provide chronic circulatory support for heart failure patients.

Key Features of Second Heart Assist include:

- ~ 4L/min flow rate over native depending on native aortic diameter.
- Pump placement just above the renal arteries provides additional benefit for heart failure patients with kidney dysfunction.
- Continuous pulsatile flow to optimize hemodynamics and lessen the risk of thrombosis while maintain low RPMs.
- The only system to occupy the full inner diameter of the aorta to increase pump stability and prevent pump migration.
- Lower risk ofmechanical failure dueto simpleimpeller deployment mechanism.

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: Second Heart's collapsible stent pump design allows for low profile catheter-based introduction for easy and secure placement in the aorta. This mechanical design provides high flow rates (over 7 liters per minute) at significantly lower RPMs, thus, minimizing the risk of mechanical breakdown and reducing damage to blood cells (hemolysis). Thrombus-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 that limits a patient's quality of life. Second Heart's wirelessly powered device provides a superior solution to long-term chronic heart failure.

Market

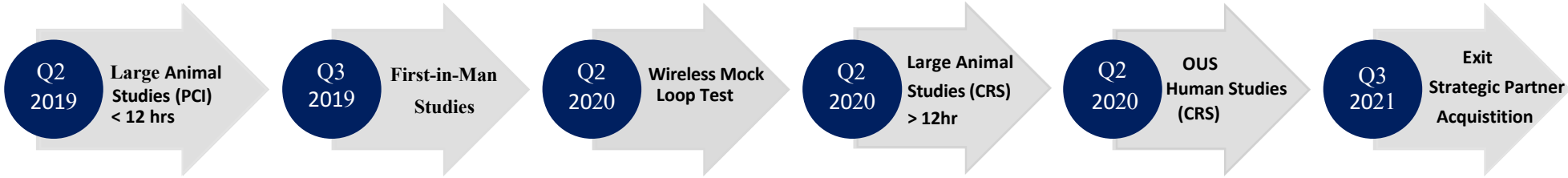
The target markets for Second Heart's temporary circulatory assist pump include:

- Acute decompensated heart failure - Of the estimated 1 million annual
  complicated by reduced kidney function. Due to the Second Heart device's placement just above the renal arteries, patients with reduced kidney function stand to significantly benefit and represent ~150,000 potential patients per year (150,000 patients per year x $25,000 Average Selling Price (ASP) = $3.75B per year from the Cardio-Renal Syndrome (CRS) market segment).
- Class III Heart Failure (HF) - Approximately 6.5 million adults (550,000 new diagnosis per year) in the United States suffer from heart failure out of which 1.4 million to 1.95 million maintain the advanced form of Class III HF prevalence. As a result, Second Heart directly addresses the Class III HF patient population (incidence of 110,000 - 165,000 Class III patients per year).
  (estimated 125,000 chronic HF patients per year x $80,000 ASP = $10B per year from the Chronic Heart Failure (CHF) market segment).
- High-risk PCI — The estimated number of PCIs that occur each year in the U.S. ranges from 650,000 to 1.2 million. Current estimates indicated 10% of PCIs are considered high risk and could potentially benefit from a supportive device such as Second Heart. As a result, this market segment includes 65,000 to 120,000 patients (120,000 HRPCI patients per year x $25,000 ASP = $3B per year from the HRPCI market segment).

Combined, these segments encompass 325,000 to 570,000 heart failure patients every year in the US and result in a total serviceable addressable market of approximately $31 billion annually ($3.75B CRS + $24B CHF + $3B HRPCI). Another comparable that confirms the market's 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 36% annual growth with Impella sales generating $570 million of revenue in 2018. Even with less than 15% of their projected market, Abiomed has achieved a market capitalization of over $18 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 3 years to reach a total revenue of roughly $900 million in 2021.

Key Milestones



Completed Milestones

- **Q2 2017** - Completed first wireless power test
- **Q2 2017** - Licensed 5+ Patents from Caltech
- **Q4 2017** - Completed 4 Large Animal Feasibility Study
- **Q1 2018** - FDA Pre-sub meeting Early Feasibility Study
- **Q2 2018** - Completed Mock Loop Testing at University of Louisville
- **Q2 2018** - Filing of Second Heart patents for thrombosis and hemolysis reduction
- **Q3 2018** - Completed 2 Rounds of Computational Fluid Dynamics Testing with enModes in Germany
- **Q3 2018** - Filing of Second Heart patents for flow optimization, auto adjust, and power management
- **Q3 2018** - New alarm box build from DeviceLab in Tustin, CA
- **Q3 2018** - Completed large animal testing at Q Test Ohio State University
- **Q1 2019** - Finalize Risk Analysis and Mitigation
- **Q1 2019** - Endurance challenge test in physiologic correct model ViVitro Labs Canada
- **Q2 2019** - 4 large animals at APS Minneapolis including Hemolysis assessment
- **Q2 2019** - First wireless power demo
- **Q3 2019** - 4 clinical cases completed OUS (High Risk PCI)
- **Q3 2019** - 51hr Pulsatile Flow Mock Loop Testing at Vivitro Labs Canada
- **Q1 2020** - 108hr Durability Testing at Biomerics

Upcoming Milestones

Pre-Clinical

- **Q2 2020** - IEC 60601 electrical safety testing
- **Q2 2020** - Wireless Device Mock Loop Test
- **Q2 2020 -** Large animal 36-hour CRS test
- **Q1/Q2 2020 -** Biocompatibility and Sterility testing fully complete
- **Q1/Q2 2020 -** Wireless power mock loop and large animal studies

- **Clinical**
- **Q2 2020** - 5 cases scheduled (CRS) OUS
- **Q3 2020** - 10 cases done (5 PCI 5 CRS) at OSU via FDA Early Feasibility Study Program

Management 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.

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.

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.

Alex S. Richardson

Chief Technology Officer

VP Engineering & Product Development

Alex has 30 years of experience in high-reliability manufacturing. He has spent the last 14 years supporting several Alfred Mann companies and maintaining successful partnerships with Advanced Bionics, Biotronik, Boston Scientific, Medtronic, St. Jude Medical and other world-class organizations.

Ken Evans

VP Corporate Development

Ken Evans has over 40 years of sales and marketing expertise in working with well known companies such as MAKO Surgical, Intuitive Surgical, and Pfizer Hospital Products as well as with small startup companies within the medical device and capital equipment arena.

Board of Directors

Howard Leonhardt (Chairman and CEO)

Jeff Donofrio (President)

Leslie Miller, MD (Chief Medical Officer)

Ken Evans (Vice President of Corporate Development)

Dinesh Patel, PhD (Sr. Advisor and Investor)

Alex Richardson (CTO and Vice President of Engineering & Product Development)

Mark Cunningham, MD (Senior Advisor Cardiovascular Product(s) Development)

Ghannam "Alex" Al-Dossari, MD, MSc, MBA, ACHE (Sr. Advisor and Investor)

Paul Norman (Managing Partner, non-voting)