

Valvublator

HEART VALVE REGENERATION



EXECUTIVE SUMMARY

2020

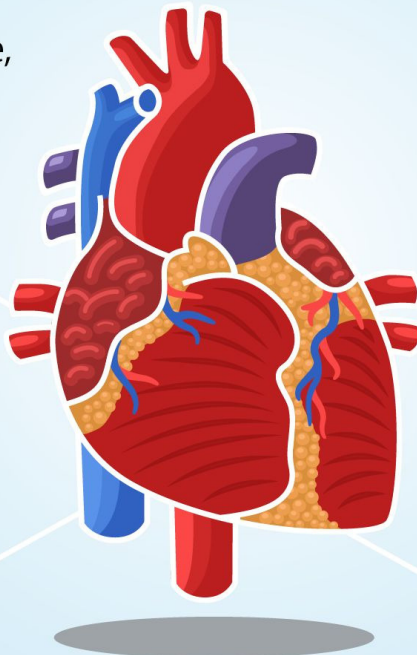
AT THE HEART OF AORTIC STENOSIS

Aortic Stenosis is a narrowed aortic valve, commonly due to calcium build-up, that limits its ability to open and close properly, which reduces blood flow to the rest of the body

100k



people in the U.S. are diagnosed with severe aortic stenosis each year*



33%



of these patients are deemed too high risk for open heart surgery*

50%



of patients at extreme risk for open-heart surgery will die from severe aortic stenosis within one year if left untreated†

* Lung B, Cachier A, Baron G, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? *Eur Heart J.* 2003;26:2714-2720.

† Makkar R, Fontana G, Jiliahawi H, et al. Transcatheter Aortic-Valve Replacement for Inoperable

Executive Summary Overview:

Valvublator intends to provide an effective and minimally invasive alternative to surgical and transcatheter valve replacement. This is envisioned to be a minimally invasive, percutaneous de-calcification system for (a)symptomatic patients with valvular regurgitation or other insufficiencies.

Vision:

Valvublator aims to address valvular insufficiency due to the calcification of heart valves and related structures. After the Valvublator treatment, the patient experiences restored heart functions.

Problem:

Structural cardiac interventions represent one of the biggest challenges in health care. In the USA, more than five million people are diagnosed with heart valve disease each year. By 2021, 70% of patients with severe symptomatic aortic stenosis will be untreated. Thus, leading to associated health challenges including congenital heart defect, stroke, endocarditis, heart failure, or death.

Product:

The Valvublator technology is a cost-effective, minimally invasive approach that could benefit those 5 million+ individuals suffering from aortic stenosis each year. Valvublator is designed to help patients keep their own heart valve instead of receiving a prosthetic valve such as a porcine, bovine, plastic, or steel implant. The Valvublator technology uses an innovated approach to treat aortic stenosis by implementing a combination of techniques aimed at restoring valve function. Such techniques include: 1) mechanical cleaning via a deflecting rotary burr for preliminary calcification removal, 2) ultrasonic cleaning for residual calcific regions, 3) vacuum removal of calcific emboli, 4) treatment with a biochemically safe solvent for removing trace amounts of calcified material from the valve, and 5) application of bioelectric stimulation to recruit stem cells and promote valvular regeneration and repair.

Founders:

Howard Leonhardt, Executive Chairman and CEO, is an inventor and serial entrepreneur with over 21 issued U.S. patents and dozens more pending. He developed the leading TALENT stent graft and the first percutaneous heart valve (**US5957949A**), both now a part of Medtronic. He has founded more than 30 startups and has numerous successful exits.

Dr. Leslie Miller, CMO, has been involved in the field of advanced heart failure for over 35 years, including over 90 clinical trials. He was the founder of the Working Group of Transplant Cardiologists, served as president of the International Heart Transplant Society meeting, and became the first non-nephrologist to hold the office of President of the American Society of Transplant Physicians. He has served as Chief of Cardiology for more than 15 years at the Universities of Minnesota, Georgetown, and University of South Florida. During his tenure, Dr. Miller has produced over 241 publications and has acted as lead editor of one of the leading textbooks on regenerative medicine.

Early Key Hires:

Dr. Stuart Williams - VP Cardiovascular Research

Dr. Mark Cunningham - Chief Scientific Officer (Cardiothoracic Surgeon)

Alex Richardson -VP Engineering and Product Development

Dr. Jorge Genovese -VP Bioelectric Regeneration Research

Dr. Brett Burton - VP R&D

Larry Stevens - Chief Regulatory Advisor

Brian Hardy - Director of Marketing

Alexandra Shamir - Director Business Development

Kapil Sharma - Director Bioengineering

Nick Kearley - Research Assistant

Dr. Warren Sherman - Senior Advisor Cardiologist

Dr. Ron Waksman - Senior Advisor Cardiologist





Dr. James Margolis - Senior Advisor Cardiologist

Dr. Paulina Margolis - Senior Advisor Cardiologist

Kurt Kruger - Senior Advisor Bioengineer

Market:

- On average, TAVR procedures (Transcatheter Aortic Valve Replacement) cost \$61,433
- On average, SAVR procedures (Surgical Aortic Valve Replacement) cost \$58,546
- The Global aortic valve replacement and repair market generated \$5.6 billion in revenue in 2017
- The aortic valve market is projected to grow at a 10.3% CAGR from 2018-2023
- The increased preference for minimally invasive surgeries (MISs) and favorable reimbursement scenario are the major factors driving the market growth.

	 Pi-Cardia improving valve repair	 SHOCKWAVE MEDICAL INC	 CSI. CARDIOVASCULAR SYSTEMS, INC.	 Valvublator HEART VALVE REGENERATION
Reduces arterial calcium	✓	✓	✓	✓
Enables successful stent delivery	X	X	✓	X
Does not rely on a prosthetic valve	✓	✓	✓	✓
Uses balloon dilatation catheters	✓	✓	X	X
Uses ultrasonic cleaning and biochemical solvents to remove emboli	X	X	X	✓
Recruits stem cells and promote valvular regeneration and repair.	X	X	X	✓

Facilities:

Valvublator is supported by 3 research facilities within Salt Lake City, Utah. First, our research laboratory at the Bioinnovations Gateway offers prototyping and wet lab facilities for preliminary studies and device design. Second, The Center for Medical Innovation provides resources for rapid prototyping and device testing. Last, our laboratory in the University of Utah's Research Park provides a place for direct efficacy testing of our device on biological tissues. In addition, access to animal research facilities at UCLA, LABioMed, and the University of Utah provide a space for performing verification testing in live specimens prior to any use in human subjects. We also have access to lab space at The Cove @ UCI in Irvine, CA.

Intellectual Property:

- Over a dozen patent claims pending and new patent applications in process.
- Related patents issued for custom delivery of apoptosis bioelectric signal sequences.
- Patents issued for SDF-1 stem cell homing signals and VEGF blood vessel growth signals as well as signals for controlling differentiation of stem cells.
- Numerous patent claims pending for inflammation management.

Business Model:

The Valvublator technologies cost \$10,000 to manufacture per device and would sell for \$60,000:

- 1) Mechanical cleaning via a deflecting rotary burr for preliminary calcification removal
- 2) Ultrasonic cleaning for residual calcific regions
- 3) Vacuum removal of calcific emboli
- 4) Treatment with a biochemically safe solvent for removing trace amounts of calcified material from the valve
- 5) Application of bioelectric stimulation to recruit stem cells and promote valvular regeneration and repair.

Proposal:

Seed stage round. The current price is \$1 per share with current valuation \$3,000,000. Valvublator has 3,000,000 shares.

Upcoming Milestones and Budget:

Winter 2018/Spring 2019 = File new patents technology.

Fall **2019** = Build and test prototypes.

Summer 2019 = Large animal studies.

Winter 2020 = Launch OUS pilot study in Italy.

Fall 2020 = Analysis of interim data and exit to strategic partner.

Valvublator



HEART VALVE REGENERATION

Valvublator:

A Leonhardt's Launchpads accelerator startup

Leonhardt's Launchpads by Cal-X Stars, 12655 W Jefferson Blvd,
Los
Angeles, CA 90066

Leonhardt's Launchpads Utah, Inc. 370 S, 300 E, Salt Lake City, UT
84111

Research Lab #1

@ BioInnovations Gateway
2500 S State St. #224, Salt Lake City, UT 84115

Research Lab #2

@ Center for Medical Innovation Research Park
Research Park at 417 S. Wakara Way, Suite 3321, Salt Lake City, UT