



# ***BladderCell***

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## **EXECUTIVE SUMMARY**

2019



## Executive Summary Overview:



**BladderCell** uses standard vaginal probe as a carrier to deliver bioelectric signals and biologics to stimulate SDF1 and PDGF to proliferating and differentiating stem cells into bladder muscle. The use of Bioelectric signals for controlling release of follistatin, tropoelastin, EGF, HGF and other proteins for regenerating bladder function. Of the 25 million adult Americans suffering from urinary incontinence, 75-80% of those are women.

### **Vision:**

Improve urinary incontinence and improving the adverse complications associated with bladder control.

### **Problem:**

Of the 25 million adult Americans suffering from urinary incontinence, 75-80% of those are women. Urinary incontinence affects 200 million people worldwide, which includes 1 in 4 women over the age of 18 experiencing episodes of leaking urine involuntarily. On average, women wait 6.5 years from the first time they experience symptoms until they obtain a diagnosis for their bladder control problem(s). Urinary incontinence is commonly treated by costly surgeries, ineffective interventional therapies, and ineffective medications.

### **Product:**

The **BladderCell** therapy uses bioelectric signaling to regenerate health of tissues and increases elasticity and collagen, which uses stem cell homing. Combination of bioelectric signaling allows collagen, follistatin, and elastin to be formed with minimal to no pain that regenerates urinary incontinence to improve Bladder health.

### **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 endovascular stent graft system and the first percutaneous heart valve, both now a part of Medtronic. He has founded over 30 startups and has numerous successful exit.

**Professor Cristiane Carboni, CSO**, Master Degree in pelvic floor Rehabilitation (UB-Barcelona), Master degree in health sciences (UFSCPA-Brazil), Specialist in women's health (CREFITO-Brazil) and human sexuality (SBRASH-Brazil), Coordinator and Professor of pelvic floor rehabilitation post graduation- Inspirar Faculty- Brazil

**Dr. Leslie Miller, CMO**, has authored more than 241 peer reviewed publications and has helped lead over 80 clinical trials. He is formerly for over a decade the Chairman of Cardiovascular Medicine at the University of Minnesota. He is co-editor of one of the leading textbooks on regenerative medicine.

## Early Key Hires:

**Alex Richardson**, VP of Engineering and Product Development

**Dr. Brett Burton**, Director of R&D

**Jeremy Koff**, VP Business Development

**Dr. Stuart Williams**, VP Biologics Research

**Dr. Jorge Genovese**, VP Bioelectric Regeneration Research

**Dr. Nestor Gonzalez-Cadavid**, Chief Scientific Advisor

**Alexandra Shamir**, Director Business Development & Portfolio Manager

**Kapil Sharma**, R&D Engineer

**Laurelle Johnson**, Chief Marketing Advisor

**Larry Stevens**, Chief Regulatory Advisor

**Nick Kearley**, Research Assistant

## Market:



## **Facilities:**

2 research labs in Salt Lake City, Utah. One at BioInnovations Gateway and one at Center of Medical Innovation in Research Park. Access to animal labs at UCLA, LABioMed and University of Utah. Research offices in Los Angeles and Salt Lake City.

## **Patents:**

Over a dozen patent claims pending and new patent applications in process. Related patents issued for custom delivery of 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:**

The BladderCell stimulation technologies should cost less than \$2000 to produce and can sell for as high as \$27,000. By eliminating the need for laparoscopic surgery and hormonal drugs, the reoccurrence rates the Wave technology should reduce by 1/3rd or better the overall care costs for these patients.

## **Deal:**

Seed stage round. Raising \$1 million @ \$1 per share. Post money valuation \$10 million. Preferred shares for investors > \$250K with liquidation preferences.

## **Upcoming Milestones and Budget:**

**Fall 2018** = Build and test prototypes.

**Budget = \$150,000**

**Winter 2019** = File new patents for stimulation technology.

Note - a number of patent claims already filed.

**Budget = \$20,000**

**Winter 2019** = Launch clinical trial in Brazil and South Africa

**Budget \$250,000**

**Spring 2019** = safety data for FDA submission. Pre-sub meeting with FDA.

**Budget = \$250,000**

**Spring 2019** = File with FDA to begin clinical studies.

**Budget = \$100,000**

**Summer/Fall 2019** = Full launch U.S. clinical studies up to 350 patients.

**Budget = \$1,000,000**

**Fall /Winter 2019-2020** = Analysis of interim data and exit to strategic partner.

**Budget = \$250,000**



# ***BladderCell***

## **BladderCell:**

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