

EXECUTIVE SUMMARY

2020



HTTPS://BLADDERCELL.COM/

Executive Summary Overview:



BladderCell uses non-invasive nerve stimulation bioelectric signals to stimulate SDF1 and PDGF known stem cell homing factors, follistatin, klotho, 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. For very severe cases **BladderCell Plus** directs bioelectric signals and biologics via an implantable catheter to the bladder for an invasive bioelectric + biologics advanced therapy.

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 intended to regenerate health of bladder tissues, including muscle strength, and is designed to increase elasticity and collagen. **BladderCell Plus** for severe cases uses invasive bioeletric signaling and biologics delivery of the proprietary BC-15 compositon to attempt to regenerate bladders.

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. Ph.D. Rehabilitiation.

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, CTO Dr. Brett Burton, VPof R&D Jeremy Koff, VPBusiness Development Dr. Stuart Williams, VPBiologics Research Dr. Jorge Genovese, VPBioelectric Regeneration Research Jon Dillon, VP of Mergers and Acquisitions Dr. Nestor Gonzalez-Cadavid, Chief Scientific Advisor Kapil Sharma, R&D Engineer Laurelle Johnson, Chief Marketing Advisor Larry Stevens, Chief Regulatory Advisor Dr. Robert Gelfand - Los Angeles Lab Research Manager Dr. Cristiane Carboni - Brazil Research Coordinator

Market: \$3.7 billion and growing.



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 research labs at UCLA, Brazil, LABioMed and University of Utah. Research offices in Los Angeles, Pittsburgh, Santa Rosa, Australia, Brazil and Salt Lake City.

Patents:

Over a dozen patent claims pending and new patent applications in process. Related patents issued for reading cancer tumors and 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:

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 BladderCell technology could reduce by 1/3rd or better the overall care costs for these patients.

Upcoming Milestones and Budget:

Fall 2018 to 1Q 2020 = Build and test prototypes.
Budget = \$150,000
2019/20 = File new patents for stimulation technology. Note – a number of patent claims already filed.
Budget = \$20,000
Spring 2020 = Launch pilot clinical trial in Brazil and South Africa
Budget \$250,000
Summer 2020 - Secure a strategic partner



BladderCell:

A Leonhardt's Launchpads accelerator startup

Leonhardt's Launchpads by Cal-X Stars Business Accelerator, Inc.

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Research Lab #1 @ BioInnovations Gateway 2500 S State St. #D249, 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