



EXECUTIVE SUMMARY

2019



Executive Summary Overview:



Peach uses standard vaginal probe as a carrier to deliver bioelectric signals and biologics to stimulate collagen formation and growth, elastin for elasticity improvement and via controlled follistatin release improved muscle function. When new collagen, elastin, and muscle is built, patients will see improvements of vaginal moisture, strengthen vaginal muscles, improved painful intercourse, reduce of urinary leakage, vaginal looseness, and vaginal sensitivity.

Vision:

Improve vaginal laxity and improving the adverse complications associated with vaginal laxity.

Problem:

Vaginal laxity disorder affects an approximately of 13 million women in the USA during their reproductive years. Vaginal laxity was self-reported by 38% of women and significantly associated with parity, symptoms of prolapse, stress urinary incontinence, overactive bladder, reduced vaginal sensation during intercourse, and worse general sex life. Vaginal laxity treatment now is limited primarily to painful scar forming surgeries and laser treatment that are ablative.

Product:

The **Peach** 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 the Vaginal Laxity to improve vaginal 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.

Alexandra Shamir, Co-Founder and CTO, has authored 8 peer reviewed papers and has a B.S. in Chemistry and Business from the University of Utah and is currently enrolled in the Masters Program for Artificial Intelligence and Robotics at the University of Utah. She is co-founder of two startups.

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, Over 30 years experience many serving Alfred Mann companies in Los Angeles.

Dr. Brett Burton, Director of R&D, Ph.D. Bioengineering University of Utah, 7 years experience.

Jeremy Koff, VP Business Development, Over 25 years experience. Formerly with Alfred Mann Companies. Helped launched Advanced Bionics sold to Boston Scientific.

Kapil Sharma, R&D Engineer, M.S. in Bioengineering and Entrepreneurship University of Utah, 3 years experience.

Market:

Vaginal Laxity disorder affects an approximately of 13 million women worldwide. Each procedure is approximately \$600 and command high margins. The global consumable market is **\$7 billion dollars and growing in Vaginal Laxity consumables. In the USA alone, the market is \$1.9B.**

Women's intimate wellness is a rapidly growing market need.

In a survey² of American women:

93% had not had any vaginal rejuvenation treatments

43% had heard of vaginal rejuvenation, labiaplasty, labial tightening and pigmentation treatment

66% suffer from Stress Urinary Incontinence to some degree

63% would consider a non-surgical procedure to tighten the vaginal canal

75% suffer from vaginal dryness and of these, **90%** say that it negatively affects their lives

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 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 Peach stimulation technologies should cost less than \$2000 to produce and can sell for as high as \$60,000. 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



Peach:

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
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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