



EXECUTIVE SUMMARY

2022



Executive Summary Overview

OrthoStim is a regenerative medicine startup company focused on using bioelectric stimulation and mixed stem cell compositions to restore mobility, reduce pain, and regenerate diseased or damaged joints, tendons, and muscles. The company is incubating in Leonhardt's Launchpads, an innovation accelerator owned by Leonhardt Ventures. Based on tissue and organ regeneration work that began in the 1980s by Howard Leonhardt and a team of scientists and physicians, OrthoStim provides new approaches to the regeneration of bone, muscle, tendon, cartilage, and the repair of soft tissue injuries. The OrthoStim technology platform includes the InStim technology for real-time reading and bioelectric signal modulation and management of inflammation, which may be especially useful in patients with painful arthritis.

Vision

OrthoStim is dedicated to developing innovative bioelectric and biologic treatments that facilitate faster, more complete healing of arthritis and tendon, muscle, bone, cartilage, and soft tissue injuries, diseases, and conditions.

Problem

Soft-tissue and joint injuries and diseases are some of the most common medical issues experienced worldwide. Recovery from injuries can be time-consuming and costly. Sometimes, injuries do not heal fully, and people are left with impaired bodily function and quality of life. In cases of arthritis and autoimmune diseases, current treatments often focus on treating symptoms but do not address the underlying causes of the disease.

Product

Our primary therapeutic intervention for joint recovery incorporates the reading of inflammation in the joint via bioelectric signal and cytokine sensing and then designing a bioelectric stimulation sequence to deliver a patient-specific solution. Electronic sequences from previous optimal healing recoveries that serve as a baseline are stored in the bioelectric reader and stimulator micro-processors.

Our bioelectric therapy is provided via two platforms: 1) a high-fidelity high-precision benchtop in-clinic stimulator, which is utilized for two, 20-40 minute

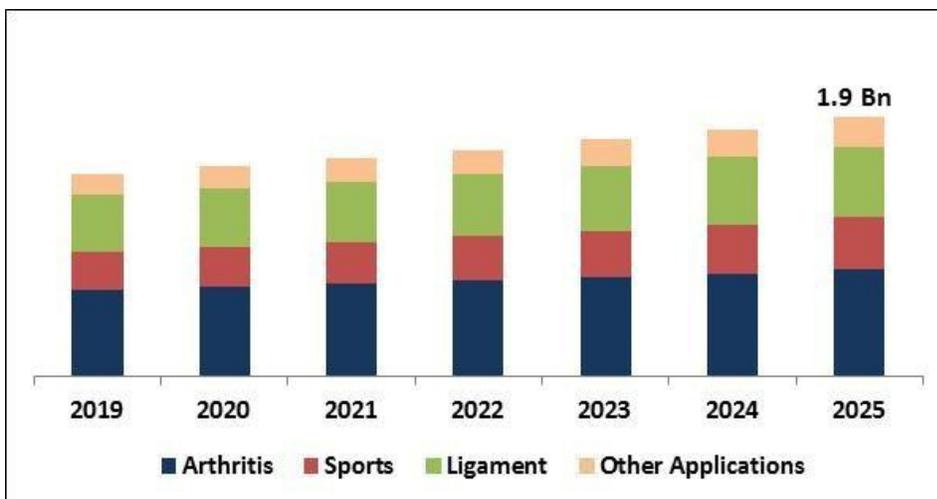
treatment sessions a week for approximately 8 to 12 weeks, and 2) a portable stimulator used at home which is worn within a conductive wrap placed over the affected joint.

In severe cases, bioelectric regeneration therapy is combined with a fifteen component joint regeneration and recovery composition comprised of stem cells, growth factors, amniotic fluid, platelet-rich fibrin, BMP-9, exosomes, selected microRNAs, selected alkaloids, engineered nutrient hydrogel, and a joint specific matrix delivered via a refillable micro infusion pump.

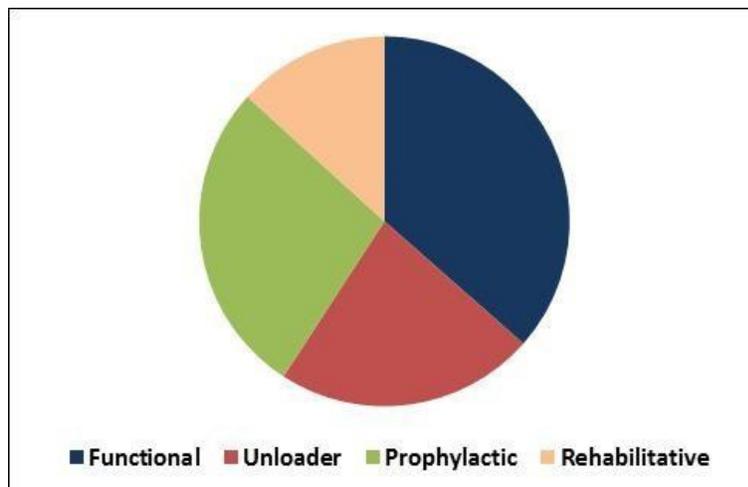
Market

The Global Knee Braces Market is expected to reach \$1.9 billion by 2025, with a growth rate of 4.25% CAGR forecast period.

Global Knee Braces Market Size



Knee Braces Market Share



Team

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 exits.

Tom Newman, President, has over twenty years of sales and sales management expertise working with well known companies such as Johnson & Johnson, Pfizer, and Biomet. Tom has built two medical distribution companies and also has served as a business development leader for two small startup companies.

Dr. Leslie Miller, Chief Medical Officer, has over 250 peer-reviewed publications. Leadership in over 100 clinical trials. Former Chairman of Cardiovascular Medicine at the University of Minnesota. Co-editor of one of the leading textbooks on Regenerative Medicine.

Jeff Donofrio, VP of Sales, has 25 years of MedicalSales and Sales management experience and has served as a senior consultant for several CardioVascular companies. He has experience in building both direct sales forces as well as distribution networks.

Brian Hardy, Director of Marketing, owner of FizzPopMedia, is a full-service marketing and advertising agency providing web and graphic design to businesses of all sizes from planning and strategy to design and creation.

Dr. Jorge Genovese, VP Bioelectric Research, Vice President of Research at Leonhardt's Launchpads, Director of the Laboratory at Irvine, California and co-inventor of many related patents. He is world renowned for his pioneering work over the past 30 years on bioelectric-controlled protein expression for regenerating hearts and other organs.

Lynn Hammerschmidt, Chief Marketing Advisor, is an entrepreneurial healthcare change advocate. Executive management experience in for-profit and nonprofit medical product and service companies. Passionate about patient empowerment and the intersection of the emotional and spiritual aspects of physical illness.

Facilities

OrthoStim, as part of Leonhardt's Launchpads, is based in Irvine and Mission Viejo, CA, with branches and subsidiaries in Minneapolis, MN, Pittsburgh, PA, Salt Lake City, UT, Norwood, Australia, Porto Alegre, Brazil, and Amsterdam, The Netherlands. The central research laboratory is located at the University of California, Irvine (UCI) Cove in Irvine, California.

Patents

OrthoStim incorporates more than ten patents and pending patents, including patents issued for bioelectric stimulation, Klotho, and COL17A1 modulation, as well as the combination of a bioelectrical stimulator and platelet-rich fibrin for accelerated healing and regeneration.

Business

The estimated cost of production per unit is \$90 with the projected retail sales price of \$799 per unit. The sales forecast post FDA clearance for the portable enhanced stimulator with full connectivity is 5,000 units in the first year, reaching 120,000 units by year 5.

Upcoming Milestones and Budget:

2021: Multiple new patent claims were issued in 2020 and hundreds of patent claims were filed

Q1 2022: Launch pilot clinical study in Brazil for joint recovery using bioelectrics and biologics

Q3 2022: Secure a strategic partnership fully to commercialization



OrthoStim:

A Leonhardt's Launchpads Accelerator Startup

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

At UCI Cove. 5270 California Avenue, Irvine, CA 92617

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