



# Leonhardt Ventures

2020/21 Annual Report

# 2021 Letter to Stakeholders

## **A highly FOCUSED organization on the brink of major contributions to healthcare**

Dear Stakeholders,

It is truly an honor to serve as Executive Chairman and CEO of Leonhardt's Launchpads by Cal-X Stars Business Accelerator, Inc. the innovation and startup accelerator arm of Leonhardt Ventures LLC. I feel blessed to be able to do work that I love every day, highly FOCUSED on developing breakthrough innovations with people I love working with as part of an amazing team. It is one of the great honors of my life to help lead this team with a long legacy of achievements in the medical industry. Our research team, board, and advisors have over 2000 peer-reviewed publications, over 2000 patent claims and have had leadership roles in over 500 pre-clinical and clinical studies. It is fair to say we have assembled an all-star team of industry veterans with proven track records, complemented by recruiting some of the brightest rising young stars.

In any given month we may have more than 300 people working on our projects in one form or another. This incredible team of inspiring leaders shares a common vision of leading healthcare into a new era, driven by applying bioelectronics and biologics with advanced delivery systems towards regenerating and healing organs.

Our team is highly focused on applying our core IP in bioelectronics, delivery systems, and biologics to meaningful innovations in one single FOCUSED area – organ regeneration and recovery. The competitive advantage of our organization is rapid innovation FOCUSED on

organ-specific applications of regeneration and recovery. This is precisely where we dedicate the lion's share of our resources and time.

The business model of our organization is simple and focused.

We patent, develop and accelerate, through first in human clinical trials, organ-specific applications of our core IP in bioelectronics, delivery systems, and biologics and then seek a strategic acquirer/partner to take them through commercialization. We keep our FOCUS where we believe we are amongst the best in the world – rapid breakthrough innovations in organ regeneration and recovery at low cost.



## **We focus on what our customers, our strategic asset acquirers, most desire and need:**

- ✓ **Patents.**
- ✓ **Positive supporting data.**
- ✓ **Positive press and peer-reviewed publications.**
- ✓ **Opinion leader endorsements.**
- ✓ **Regulatory progress.**
- ✓ **Low cost and high-quality manufacturing supply sources.**

Our team is approaching 800 patent claims that are issued, filed, in-process, pending, licensed, or optioned in the field of organ regeneration and recovery. We have 17 products at the clinical stage of development and more than 18 more in pre-clinical development. All of them FOCUSED in or-gan regeneration and recovery following our FOCUSED core IP estate. Over 1000 patients have been enrolled in clinical studies or evaluations of products that follow our patent claims. About 400 in studies sponsored by our company and another 600 by independent investigators not receiving financial support from our company.

## **2020 A Year Like No Other**

This past year was truly a unique challenge with the COVID-19 pandemic. I could not be more proud than I am of our co-researchers, co-inventors, manufacturing partners(,)and team members around the globe that kept our focus on advancing the patenting, developing, and testing of our or-gan regeneration products despite daunting obstacles. Our team proved their mettle and resilience in accomplishing so much in such a difficult time.

We remain focused on innovation our core strength and that FOCUS turned into results.

Four portfolio assets; Second Heart Assist Inc., OrthodontiCell Inc., MyoStim ED LTP, and Blad-derCell LTP have entered into over 60 meetings with over a dozen prospective strategic acquir-ers/partners. Clinical data on 169 patients have been gathered across these products to date with over 100 issued U.S. patent claims and another 100+ pending. Our team is highly focused on pa-tents and data to build value into our portfolio assets to put them in a position to garner this level of serious strategic acquirer interest.

Our core product group units all made major strides of advancement in 2020:

1. Heart and Cardiovascular Group
2. Brain Group.
3. Cosmetic, Personal Care and Reproductive Health Group.
4. Major Organ Regeneration Group.
5. Cancer Group.

All these product group teams are intensely focused on patents, data, regulatory progress, and opinion leader endorsements to build value into the portfolio assets.

## Heart & Cardiovascular Group

<https://leonhardtventures.com/heart-and-cardiovascular/>

Our Heart & Cardiovascular Group is the flagship group of our portfolio where we have dedicated the most resources to developments over our history and continue to do so today.

Our Heart & Cardiovascular Group in our long history at Leonhardt Ventures LLC have achieved some incredible milestones including...

1. First-ever latex-free thermodilution catheter 1988	2. First cell repair of an infarcted animal heart 1988	3. First predictably compliant cardiovascular balloon catheter 1989	4. First successful biological pacemaker implantation in an animal 1990	5. First successful test of an intravascular lung catheter 1991
6. First vibrational energy device to prevent blood clots 1992	7. First stem cell delivery catheter developed 1992	8. First non-surgical percutaneous repair of an aortic aneurysm 1995	9. First bioelectric regeneration peer-reviewed paper 1999	10. First cell repair of a human heart without surgery 2001
11. First repeat injection muscle stem cell study published 2009	12. First FDA clearance for combination gene and cell therapy study for heart failure - 2010	13. First biologics therapy clinical study for limb salvage 2011	14. First bioelectric therapy clinical study for limb salvage 2015	15. First clinical percutaneous placement of a true aortic stent pump - 2019

**Second Heart Assist, Inc.** [www.secondheartinc.com](http://www.secondheartinc.com) focused on aortic stent-based circulatory assist pumps advanced into cardio-renal syndrome heart failure clinical studies after multi rounds of the successful long-duration mock loop and animal studies. They were featured in an educational video series of Texas Heart Institute receiving high marks from world opinion leaders. Both pre-clinical and clinical data were presented at many meetings and were published in the ASAIO Journal. They completed successful lab tests of their patented wireless powered chronic implant device. Second Heart Assist is on track to be the first in the world to bring a percutaneous delivered (non-surgical) aortic stent-based pump that is wirelessly powered to market. This single innovation could save the lives of over 1 million people over the next decade. The Second Heart Assist team had numerous new patent claims published and filed in 2020. They converted their long-standing option with CalTech for numerous supporting patents into an exclusive license. Second Heart Assist has engaged Wilson Sonsini as M&A counsel to help sell a strategic acquirer their prime product assets in 2021.

**BioLeonhardt** [www.bioleonhardt.com](http://www.bioleonhardt.com) the flagship product development of our entire organization advanced greatly in 2020 with over 30 new patent claims issued including new bioelectric stem cell homing claims via combination expressions of SDF1 and PDGF. Issued patents including a pioneering patent combining a stimulator, pump, and composition for heart regeneration. The team is preparing now for another round of large animal studies at the California Medical Innovations Institute in early 2021.

**PressureStim** [www.pressurestim.com](http://www.pressurestim.com) launched a clinical study in Brazil with IRB approval and advanced dozens of new patent claims with the USPTO. They also entered discussions with independent investigators in Asia and the USA they have accumulated positive data on over 300 patients treated with bioelectric stimulation for blood pressure control already. The team sourced and tested ankle and wrist electrodes. The hypertension treatment market is over \$23 billion annually. PressureStim already has pioneering issued patents that establish its leadership position in this emerging new method of treating hypertension with bioelectric stimulation.

**BioPace** [www.bio-pace.com](http://www.bio-pace.com) advanced a new patent application with the USPTO in collaboration with the University of Utah.

**AortaCell** lined up a license for a complementary nano-particle technology and is seeking funding to move into large animal studies. A protocol and budget for these studies have been prepared.

**Valvulator** [www.valvulator.com](http://www.valvulator.com) selected an OEM manufacturing partner and is testing a new prototype just delivered in preparation for upcoming planned large animal studies.

**VibroCell** continued to advance its patent application with the USPTO for controlling blood clot formations, calcification, and plaque on blood contact surfaces.

**Vascustim** [www.vascustim.com](http://www.vascustim.com) is preparing to launch clinical studies combining our bioelectric and biologics therapies for accelerated wound healing after the previous completion of successful stand-alone biologics and bioelectric pilot studies.

**PulseGraft, Inc.** [www.pulsegraft.com](http://www.pulsegraft.com) launched and is working with Design Engineering Services in Flagstaff, Arizona led by our long-standing advisory board member Dr. Robert Kellar to build and test prototypes of a pulsating hemodialysis graft.

## Brain Group

<https://leonhardtventures.com/brain/>

**CerebraCell** [www.cerebracell.com](http://www.cerebracell.com) added bioelectric klotho stimulation to its product and is preparing to launch clinical trials in Brazil for stroke recovery. They also are preparing to apply for California Institute of Regenerative Medicine (CIRM) funding for a study to take place in Southern California.

**MemoryStim** [www.memory-stim.com](http://www.memory-stim.com) was spun out of CerebraCell focused on bioelectric stimulation-based memory improvement. They are in discussions with numerous independent researchers that have already gathered positive supporting data.

**Second Brain** [www.secondbrainstim.com](http://www.secondbrainstim.com) was spun out of CerebraCell in 2020 and is focused on the bioelectric and biologic treatment of the gut microbiota to improve brain health via serotonin release and to improve immune system health.

**TremorStim** [www.tremorstim.com](http://www.tremorstim.com) was spun out of CerebraCell in 2020 and is focused on developing a bioelectric wrist and headband combination for essential tremor treatment.

**AddictStim** [www.addictistim.com](http://www.addictistim.com) (website under development) was spun out of CerebraCell in 2020 and is focused on bioelectric addiction treatment including electro-acupuncture.

**DepressiStim** [www.depressistim.com](http://www.depressistim.com) (website under development) was spun out of CerebraCell in 2020 and is focused on bioelectric depression treatment with a focus on suicide prevention.

**SpineStim** [www.spinestim.com](http://www.spinestim.com) (web site under development) was spun out of CerebraCell in 2020 and has entered a clinical study for spinal cord injury patients using our FDA 510K cleared stimulator at the Neuromuscular Connections Institute in Costa Mesa, CA with full grant support from the Luberski Family Foundation.

## Cosmetic, Personal Care and Reproductive Health Group

<https://leonhardtventures.com/cosmetic-and-personal-care/>

**OrthodontiCell** [www.orthodonticell.com](http://www.orthodonticell.com) completed their manuscript for bioelectric RANKL controlled accelerated teeth straightening and submitted it for publication. The USPTO also issued a pioneering patent – the first to cover precise bioelectric control of the key proteins RANKL and OPG involved with tooth movement acceleration and stabilization. They designed a proprietary new palm-size stimulator with a one-button operation and a new more comfortable and reliable mouthpiece. They prepared an FDA 510K application which will be filed soon.

**MyoStim ED** [www.erecristim.com](http://www.erecristim.com) has completed more than 105 patients with its patented Erectis-tim™ product with a nearly 90% treatment success rate and has submitted a manuscript for publication. This on

the heels of the publication of data on two previous pilot clinical studies. The team is working to patent and develop an ED treatment protein embedded gel electrode which includes sonic hedgehog as well as other regenerative proteins that are enhanced with the addition of bio-lectric stimulation.

**DentaCell Accelerator [www.dentacellaccelerator.com](http://www.dentacellaccelerator.com)** developed and tested multiple products in 2020 and spun out ImplantStim [www.implanstim.com](http://www.implanstim.com), ArchStim [www.archstim.com](http://www.archstim.com), BreatheStim [www.breathestim.com](http://www.breathestim.com), SinusStim, SnoreStim, BoneStim, and other portfolio assets currently in confidential stealth mode of development. ImplantStim and ArchStim competed successful pilot cases in preparation for clinical studies to begin in 2021. The team filed dozens of new patent claims in 2020.

**Stem Cell Bra [www.stemcellbra.com](http://www.stemcellbra.com)** recruited Henk Abbink our long-standing EVP of International Market Development to serve as President. Following multiple years of large animal safety studies and a pilot clinical safety study, the Stem Cell Bra team is now cautiously moving forward to launch the first efficacy study OUS for breast tissue regeneration.

**HairCell [www.haircellstim.com](http://www.haircellstim.com)** recruited Dr. Sanjay Batra as Chief Scientific Advisor and developed new protocols for clinical studies in both Europe and the USA which are about to launch. They developed and tested a new hair cap, concluded a collaboration agreement with Nu-lastrin for hair serum supply, and added COL17A1 bioelectric protein expression to the product. COL17A1 was demonstrated in studies in Japan to aid greatly in hair follicle regeneration. Hair-Cell published pilot clinical study results from South Africa and Utah that demonstrated up to a 30% increase in hair density with its combination bioelectric and biologics treatments.

**SkinStim [www.skin-stim.com](http://www.skin-stim.com)** completed additional clinical cases in South Africa and Utah and is preparing to launch larger-scale clinical studies at multiple locations around the world including Europe. COL17A1 was a great addition to the SkinStim lineup. Studies in Japan demonstrated COL17A1 is instrumental to powerful skin regeneration. The research team also further validated our patent-pending bioelectric signaling sequences for un-locking the release of tropoelastin the precursor of elastin and a key protein for restoring elasticity to the skin.

**TestiStim [www.testistim.com](http://www.testistim.com)** on the heels of an issued U.S. patent and a successful pilot clinical case is preparing for a pilot 10 patient clinical study OUS in 2021.

## Major Organ Regeneration Group

**BladderCell [www.bladdercell.com](http://www.bladdercell.com)** completed a successful 30 patient pilot clinic study and launched two additional new studies 30 patients each, with one adding pelvic stimulation and the other adding biologics injections directly into the bladder. BladderCell has numerous new patent claims issued in 2020 and filed dozens of additional new claims. BladderCell is the only bladder regeneration technology focused on muscle, nerve, blood vessel, and elasticity regeneration via bi-oelectronics and biologics. BladderCell spun out B-AliveStim [www.b-alivestim.com](http://www.b-alivestim.com) to focus on applications and marketing of its platform technology specifically for women's needs founded by women and run by women. BladderCell has entered discussions already with numerous potential strategic partners/acquirers.

**LiverCell [www.livercellstim.com](http://www.livercellstim.com)** greatly upgraded its website in 2020 adding numerous supporting scientific articles and initiated relationships with many of the leaders of liver regeneration re-search worldwide. LiverCell has multiple new patent claims issued in 2020 and filed dozens of new patent claims.

**KidneyCell [www.kidney-cell.com](http://www.kidney-cell.com)** competed a pilot clinical study in Brazil demonstrating an ability to increase circulating klotho by over 150%. KidneyCell had multiple patent claims issued in 2020 and filed dozens of new claims currently pending.

**EyeCell [www.eye-cell.com](http://www.eye-cell.com)** on the heels of two previous clinical studies published by collaborating research team members has prepared an IRB application to launch a new clinical study in the USA. In 2020 they developed and tested a new generation of eye area stimulation goggles. The team developed a portable bioelectric stimulator with one button simple operation for up to 6 bioelectric signaling sequences in succession. EyeCell has multiple new patent claims issued in 2020 and filed additional new patent claims.

**PancreaCell <https://leonhardtventures.com/pancreacell/>** is in discussions with numerous leaders in pancreas regeneration research. In 2020 they had multiple new patent claims issued and filed several new claims.

**OrthoStim [www.ortho-stim.com](http://www.ortho-stim.com) and OrthoStim Accelerator [www.orthostimaccelerator.com](http://www.orthostimaccelerator.com)** made some great strides in 2020 in further developing and validating bone, muscle, and nerve re-generation technologies. Multiple new patent claims were issued in 2020 and many new patent claims were filed. The team developed a proprietary portable bioelectric stimulator and sourced and evaluated off-loading braces to be used with our product. The team launched a clinical study in Mexico that we delayed for enrollment due to COVID 19 restrictions. The team hopes to complete a pilot clinical study in 2021. They are in discussions with independent investigators that have completed over 300 clinical cases with success for joint recovery using bioelectronics or biologics. OrthoStim plans to complete the first study which combines biologics in 2021. OrthoStim supply partners for PRF, adipose-derived stromal fraction and cells, and amniotic fluid have documented success with their therapies on a stand-alone basis for joint recovery. OrthoStim hopes to be in a position to secure a strategic partnership to take their joint recovery and bone healing technologies fully to commercialization by the end of this year.

**EarCell [www.ear-cell.com](http://www.ear-cell.com)** is preparing to enter a non-invasive hearing recovery study in Brazil with a team that previously completed pre-clinical animal studies for hearing regeneration.

**InStim [www.instimcell.com](http://www.instimcell.com)** completed a successful pilot clinical case and in January of 2021 received a Letter of Allowance from the USPTO for its pioneering patent claims covering reading of inflammation and customized bioelectric signaling sequences and cytokine expressions for inflammation management based on that reading.

**BioLeonhardt Whole Body and BodStim <https://leonhardtventures.com/bioleonhardt-whole-body/>** had numerous new patent claims issued in 2020 and have dozens of new patent claims pending including whole body klotho stimulation. BodStim evaluated a half dozen electrical stimulation bodysuits and is set to select a key supply vendor in early 2021. BioLeonhardt Whole Body is preparing an NSF SBIR grant application.



**RegenaLung** <https://leonhardtventures.com/regenalung/> had numerous new patent claims issued in 2020 and filed numerous new claims. The team is reaching out to develop collaborations with lung regeneration research teams around the globe. RegenaLung spun out CovidStim [www.covidstim.com](http://www.covidstim.com) (web site under construction) that has completed 70 clinical COVID 19 patients in Brazil with bioelectric stimulation focused on klotho release and inflammation management so far to reduce ICU and ventilator recovery time by 25%. Results will be submitted for publication in 2021. The RegenaLung team also spent time in 2020 developing and patented a pulsating bio-electric stimulation ECMO catheter –EcmoCath which may be spun out into a separate LTP asset in 2021.

## Cancer Group

**CancerCell** [www.cancercellinc.com](http://www.cancercellinc.com) has 9 U.S. patents issued already and received a Letter of Allowance in early 2021 on related bioelectric inflammation management. They filed a new patent-pending in 2020 for bioelectric OPG treatment for blood and bone-related cancers treatment which has been published. The team is preparing to launch the 2nd round of large animal studies in Brazil in 2021 this time with a longer duration of stimulation. Bioelectric stimulation klotho expression seems to have a strong therapeutic effect on cancer tumor growth which will be explored further in 2021 with well-designed experiments. CARRYING THE SHARED VISION FORWARD

## Focused on Good Science with Well Designed and Implemented Study Protocols

The strength of our organization is the integrity and peer respect of our scientists and collaborative researchers. This is gained and maintained via practicing good science and good clinical practice with properly designed protocols and check and balances enduring patient safety first.

Dr. Leslie Miller our Chief Medical Officer has authored more than 250 peer-reviewed publications and over 12 book chapters. He was the lead editor for two major textbooks in the field; Mechanical Circulatory Support and Stem Cell and Gene Therapy for Cardiovascular Disease. I have been involved in clinical and basic research throughout my career, including being the Principle Investigator in 94 clinical trials, including trials funded by the NIH, AHA, as well as industry, as well as on the Steering Committee for over 20 trials and National PI for 4 studies. Dr. Miller in 2020 FOCUSED the lion's share of his time on the few portfolio assets closest to exit opportunities.

Alex Richardson our CTO and VP of Engineering and Product Development FOCUSED nearly 100% of his time in 2020 into the portfolio assets nearest to exit especially Second Heart Assist, Inc. and OrthodontiCell, Inc.

Dr. Brett Burton our VP of R&D and Startup Launches also FOCUSED the majority of his time on the top 5 or 6 portfolio assets nearest to exit opportunities in 2020. His focus was on designing and implementing well-controlled and good science pre-clinical and clinical studies.

Dr. Alonso Moreno and Sejal Chaudhary lead efforts at our two dedicated R&D laboratories in Utah with a focus on supporting the discovery of new bioelectric signaling sequences for regenerative protein expressions. This team believes in good science and goes to great lengths to ensure the integrity of our data. In 2020 they made great strides in validating bioelectric signaling sequences for COL17A1 a key regeneration protein for hair and skin. They helped validate in clinical studies our bioelectric stimulation signals for increasing circulating klotho with a greater than 150% gain documented. The team worked extensively on the discovery of additional bioelectric signaling sequences and protein expressions for nerve regeneration including sonic hedgehog and LIM muscle. They completed numerous lab tests to support our BladderCell and B-AliveStim product platforms. A breakthrough was proving that bioelectric stimulation can unlock, amplify, extend and enhance regenerative protein expressions, such as PDGF, from platelet-rich fibrin (PRF). In 2020 they completed over 1000 discovery experiments with a small team working long hours.

Dr. Cristiane Carboni led our work at Leonhardt's Launchpads Brazil with outstanding professionalism where we have active clinical trials enrolling or soon to launch for OrthodontiCell, BladderCell, B-AliveStim, InStim, Stem Cell Bra, PressureStim, OrthoStim, CerebraCell, Ear-Cell, CovidStim, and TestiStim. A new round of pre-clinical studies is about to launch for CancerCell in Brazil as well.

We were very proud to have Dr. Carmella Abraham one of the world-renowned leaders in klotho-based healing research join our Scientific Advisory Board and research team in 2020. Here is a link to a talk she gave on the high potential of klotho in fighting many aging-related diseases and disorders – <https://youtu.be/xRyT9-10G04>

We have engaged Wilson Sonsini as M&A Counsel, one of the top M&A firms in the world, to represent us in closing deals with strategic partners/acquirers for our portfolio assets.

## **Our Highly Focused Business Strategy and Operating Model**

The large medical device and biotech industry leaders can do almost everything better than a small group like ours with limited funding. They can manufacture at lower costs, they can sell better with their massive sales forces, they can manage finance better with their long-standing institutional investor support. The one thing they cannot do as well as us innovate fast at low cost.

So we decided some time ago to FOCUS on our competitive advantage in innovation and not try to compete with the giants in areas where they can truly outperform us. That is our business strategy > focus on developing breakthrough innovations in rapid succession.

Most of the medical device companies have focused on applying metals, plastics, and other artificial materials to propping people up to live with their failing organs not fixing those organs. Our FOCUS is regenerating a person's organs so they do not need artificial steel or plastic implant. We have been working on this since 1988 and our accumulative experience is unmatched. We know we can regenerate organs and believe we have a clear FOCUSED path to transform the industry.

By operating in an innovation accelerator model utilizing shared resources we can keep overhead to a minimum per innovation and can minimize dilution to shareholders. Our strategy to exit after first in human studies allows our early-stage investors and team members to develop the technology to have a larger piece of the sale prize than other models that require more capital and time to get to exit.

We believe FOCUSING people for 3 to 7 years intensely to get to a prized goal is more humane on the staff and shareholders avoiding the burnout that comes with 15 to 20-year time horizon paths taken by others. Keeping the eye on the near prize intensifies FOCUS which we see as the key to success.

At the very center of our business model is FOCUS on a common core platform technology that has many independent organ-specific unique applications of the use of value. With this model, we invent and develop something once but have the chance to sell it again and again perhaps more than 50 times for different applications of use one by one. We believe this strategy is one to maximize shareholder value by FOCUSING resources that are leveraged for maximum return.

## Nurturing An Innovation Culture

Speed and agility with the ability to turn on a dime when opportunity dictates we should do so is amongst the core culture values we nurture at Leonhardt's Launchpads.

We do everything we can to build a team of innovators. This includes an environment of failing forward fast. Rapid prototyping. Try, fail, adjust, try again continuous improvement culture. All while never compromising patient safety. We make our mistakes in the lab before the clinic so mistakes in the clinic are not made. We look at and test for and design for every potential failure mode. We do not leave a rock unturned.

Our team members learn to like drinking water from a fire hose taking in loads of information quickly. Constantly curious and reading everything we can get our hands on that may key us to product improvement.

## Carrying the Shared Vision Forward

Our FOCUS is crystal clear, to be the best innovation accelerator for organ regeneration and recovery technologies the world has ever known. To translate those innovations developed in rapid succession into saving and improving millions of lives forward. We see financial rewards for our stakeholders as a by-product of inventing and developing innovations that provide better results for patients. We have a target pace to have ready ripe, having finished first in humans clinical studies, for strategic acquirer/partner discussions to begin a minimum of 3 to 5 new organ-specific break-through applications for our core IP every year.

We are grateful to have the long-standing support of so many. We could not accomplish any of our goals without this support.

Leonhardt's Launchpads is committed to being the undisputed leader in accelerating organ regeneration and recovery innovations.

Thanks for being with us on this journey. We believe our intense FOCUS is about to pay big dividends in improving healthcare and at the same time provide a healthy return to our shareholders that have risked their hard-earned capital with us.

**Howard J. Leonhardt**  
**Founder, Executive Chairman & CEO**  
**Leonhardt's Launchpads**