



# Leonhardt Ventures

2019/20 Annual Report



With your help Leonhardt's Launchpads is leading a revolution to aide people in regenerating their own organs instead of getting artificial, animal, donor or cadaver implants or taking drugs. We believe we are on a path to change healthcare dramatically for the better!



**Howard J. Leonhardt**

Executive Chairman & Chief

Executive Officer

# Intense FOCUS on Organ Regeneration and Recovery

2019 was a spectacular year of progress! Some of our most exciting milestones achieved included...

- Over 800 patients enrolled in new organ regeneration and recovery clinical studies.
- Data on over 250 patients published or presented at major international conferences.
- Over 600 patent claims issued, pending, optioned or licensed for organ regeneration and recovery.
- 83% treatment success in clinical studies with no serious adverse events reported to date.
- 16 products at clinical stage of development and 14 at pre-clinical stage.
- Patent filed for bioelectric klotho expression a powerful anti-aging and regeneration protein.
- Patent filed for sonic hedgehog protein expression a powerful regeneration protein.
- Patent filed for COL17A highly powerful anti-aging and skin regeneration protein.
- Patent filed for combination SDF1 and PDGF stem cell homing signal.
- Patent claims issued for controlled expression of RANKL and OPG for accelerated teeth straightening and stabilization for OrthodontiCell.
- 9 issued patents acquired for bioelectric cancer tumor treatment for CancerCell with dozens of additional new patent claims pending.
- 90% of MyoStim ED Erectistim<sup>TM</sup> treated patients had substantial improvement. MyoStim ED has surpassed over 150 patients enrolled in clinical studies so far with more enrolling every week.
- 60% of OrthodontiCell treated patients had perfect straight teeth in only 3 months compared to only 14.3% with brace alone (braces alone group also had far more mild cases while OrthodontiCell had far more severe cases).
- OrthodontiCell treated patients had a 70% reduction of pain and discomfort compared to braces alone patients.
- HairCell treated patients had up to 30% increase of hair density.
- SkinStim treated patients had a significant reduction in noticeable wrinkles.
- BladderCell treated patients had a significant reduction of uncontrolled urination.
- 83%(5 of 6) of EyeCell wet macular degeneration treated patients had notable improvement in vision and none showed deterioration.
- Significant increases in visual acuity in dry macular degeneration treated patients were seen in the EyeCell pilot clinical study. 52% of EyeCell treated patients showed increased visual acuity compared to only 26% showing deterioration, with improvements often sizable, whereas deteriorations were usually very slight.
- Our first InStim treated patient exhibited substantial reduction of inflammation and associated pain that was lasting.
- Our first TestiStim treated patient exhibited substantial increase of testosterone without any side effects with our bioelectric underwear product.
- In a 21 patient pioneering clinical study KidneyCell's Brazilian research collaborators demonstrated a significant decrease in DNA damage in chronic kidney failure patients on hemodialysis.
- BioLeonhardt completed a feasibility small animal study for bioelectric heart regeneration with a team at the University of Utah and is now preparing for large animal studies in at Texas Heart Insitute.
- CancerCell completed a feasibility small animal study for bioelectric cancer tumor treatment at UCLA is now preparing for a 2nd round of studies in Brazil.
- Valvublator research collaborators in Italy completed a pioneering clinical surgical case of dental burr removal of calcified plaque and stem cell injection regeneration of a damaged heart valve. Valvublator is preparing for large animal studies now at the University of Minnesota with Dr. Richard Bianco for a percutaneous non-surgical system.
- Vascustim launched a 3rd clinical trial for critical limb ischemia and diabetic wound ulcer healing this time with a combination of bioelectrics and biologics. Previous studies were completed separately for bioelectric and biologics.
- PressureStim research collaborators at UCIrvine in Irvine, California have completed studies with over 100 clinical patients in the USA. Peak and average systolic blood pressure decreased by 8 and 6 mmHg, respectively, in response to electroacupuncture. Diastolic blood pressure was reduced by 4 mmHg after 8 weeks of treatment.
- Second Heart Assist completed a successful first in human study in Paraguay the summer of 2019 with

results presented at the Heart Failure Society of America, TCT Cardiology and Devices for Heart Failure annual 2019 meetings. A 400% increase in real output was reported in treated patients. Aortic pressure differential up to 37mm Hg was achieved at RPMs under 15,000. 10mm HG aortic pressure differentials were achieved at RPMs under 9000. Second Heart Assist is preparing to launch a cardio renal syndrome study soon.

- Second Heart Assist published a demonstration video of its patented wireless powered chronic implant completed at Queensland University of Technology in Australia.
- Second Heart Assist completed large animal studies in pigs, sheeps and cows at 4 different clinics.
- Second Heart Assist completed multiple rounds of mock loop tests at three different research centers up to 9 days duration.
- Second Heart Assist completed 2 rounds of computational fluid dynamics studies at enModes Germany.

This year marks Leonhardt Venture's 32nd Anniversary since we published our first cell composition based organ (heart) regeneration study working with Dr. Race Kao and Dr. George Magovern in Pittsburgh in 1988. To honor this pioneering work we co-sponsored the McGowan Regenerative Medicine Retreat in that same city in 2019. It is also the 21st anniversary year of our landmark first American Heart Association Circulation paper on bioelectric regeneration working with Dr. Shinichi Kanno in Japan - <https://www.ahajournals.org/doi/10.1161/01.CIR.99.20.2682>. ; No other research team has longer deeper experience in organ regeneration research and product development than our amazing team of people! The current organ regeneration product platform combining the best of bioelectrics and biologics is the derived from this unmatched cumulative experience.

Our Second Heart Assist and Valvublator product platforms build on our decades of experience in developing market leading endovascular devices. The TALENT stent graft is now achieving over \$1 billion in annual sales and is the un-disputed market leader in endovascular aortic aneurysm repair. Our pioneering patented technology in percutaneous heart valve placement is part of one of the leading product platforms in the world.

Over 700,000 patients have been treated with Leonhardt inventions to date since the 1980's.

Led by an amazing team with a potent combination: multiple decades of experience which includes one breakthrough market leading innovation after another with the ambition and energy to conquer fresh new opportunities rapidly.

## Heart & Cardiovascular

Bioleonhardt [www.bioleonhardt.com](http://www.bioleonhardt.com) our flagship product development is poised in 2020 to establish a position as the undisputed leader in total heart regeneration with its combination implantable bioelectric stimulator, re-fillable implantable micro infusion pump and proprietary fifteen component heart regeneration composition. The development is the culmination of over 30 years of trial and error experimentation and uninterrupted development. Large animal studies are scheduled to take place at Texas Heart Institute 1H 2020 and pilot clinical trials OUS 2H 2020. We believe this product has the chance to be the ultimate treatment of choice for over 23 million people in heart failure worldwide.

**Second Heart Assist** [www.secondheartinc.com](http://www.secondheartinc.com) plans to secure a strategic partnership by June of 2020 following its cardio renal syndrome clinical study results and another round of wireless power chronic implant pre-clinical studies. We believe this product will be the leader in treating patients in cardio-renal syndrome due its high flow at low rpms and high improvement in renal output. Our aortic stent based pump is the only one known that combines stability of position with maintaining aortic wall pulsatility essential for optimal organ health and hemodynamics. Second Heart Assist is positioned to be the first percutaneously (non surgical) placed wirelessly powered chronic circulatory assist pump on the market which addresses market numbers 300 to 500% great than external drive line systems. Abiomed the only competitor on the USA market with a catheter based external drive system pump peaked at \$21 billion valuation last year addressing a much smaller market.

**Valvubator** [www.valvublator.com](http://www.valvublator.com) seeks to totally disrupt the heart valve market by providing a tool to allow cardiologists help patients regenerate their own heart valve instead of getting an artificial, cow, pig or cadaver implant. During the TCT Cardiology Meeting in San Francisco this past fall the Valvublator engineering team (internal staff teamed with Rev1 Engineering) unveiled a revolutionary simplified Valvublator II design. As part of disrupting this marketplace the Valvublator team hopes to open up a new paradigm where physicians intervene early to decalcify and regenerate heart valves BEFORE they are so diseased an implant may be necessary. Valvublator is planning large animal studies in 1H

2020 at the University of Minnesota with Dr. Richard Bianco and pilot clinical studies OUS in 2H 2020.

**PressureStim** [www.pressurestim.com](http://www.pressurestim.com) has a goal to nearly eliminate the 23 billion spent on blood pressure drugs annually with non-drug bioelectric alternative to blood reduction and control. Initial data has been highly promising! This product is a simple bioelectric wrist watch sometimes combined in severe cases with a bioelectric thigh and/or ankle band. PressureStim plan to complete additional new studies in Brazil and the USA 1H 2020 and to seek to secure a strategic partnership in 2H 2020.

**Vascustim** [www.vascustim.com](http://www.vascustim.com) seeks to be the therapy of choice for limb salvage, critical lower limb ischemia and diabetic ulcer healing with an optimal combination of bioelectrics and biologics. The team recently launched their 3rd clinical study in Mexico.

**AortaCell, Vibrocell and BioPace** are all in pre-clinical development working towards entering clinical studies soon. AortaCell plans to offer an alternative to endovascular implants for aortic aneurysm repair by regenerating the aorta. VibroCell has filed patent claims for a vibrational harmonic tuned resonance technology for preventing blood clot formation, plaque and calcification on natural and artificial blood contact surfaces. BioPace is seeking to bring to market the world's first reliable and practical biological pacemaker to eventually obsolete most steel can steel lead battery powered artificial pacemakers. They filed NIH and NSF SBIR grant applications which are under review at this time.

## Brain

CerebraCell [www.cerebracell.com](http://www.cerebracell.com) is launching a non-invasive bioelectric stimulation only stroke recovery study in Brazil and plans to have results available by summer ready for publication and presentation. CerebraCell is also developing a full business plan for an integrative Brain Health Institute to using multi-modality treatments for a variety of brain disorders including anxiety, depression, drug addiction, confusion and other traumatic brain injury recovery, Alzheimer's and Parkinson's in addition to the original indication of use of stroke recovery. Pre-clinical studies are planned for a more aggressive therapeutic approach combining an implantable stimulator + leads, re-fillable micro infusion pump and infusion catheters, focused ultrasound and multi component brain regeneration composition. CerebraCell has aspirations to advance greatly brain recovery with the combination of bioelectrics, focused ultrasound and repeat delivery of multi-component compositions via a re-fillable implanted micro infusion pump.

## Cosmetic & Reproductive Health

**OrthodontiCell** [www.orthodonticell.com](http://www.orthodonticell.com) completed a highly successful clinical study that followed two previous animal studies. The clinical study demonstrated up 70% improvement in accelerated teeth straightening and 70% reduction in pain and discomfort. 60% of treated patients had perfectly straight teeth in 3 months! The team is seeking a strategic partner at this time while it continues forward with new fixation and aligner studies as well as full development of an @ home use product. Align Technology and Smile Direct Club peaked at \$31 billion and \$8 billion valuations recently. They both take more than 18 months on average to straighten teeth and have no technology to keep them straight. We believe we will prove we can achieve 60% of treated patients with straight teeth in 3 months and the other 40% straight at 6 months and will keep them straight thus disrupting completely the entire industry in a big way!

**MyoStim ED ErectiStimTM** [www.erectistim.com](http://www.erectistim.com) has completed studies with over 150 patients enrolled to date is achieving remarkable improvement in treating ED over placebo treatments by a long margin. The company seeks now a strategic partnership while it continues to gather more supporting data.

**HairCell** [www.haircellstim.com](http://www.haircellstim.com) has demonstrating up to 30% increase in hair density in clinical studies substantially better than laser and other comparable technologies. The company seeks now a strategic partnership while it continues to gather more supporting data. Samumed of San Diego recently achieved a \$12 billion valuation with the WnT stimulation technology achieving just 10% hair density improvement.

**SkinStim** [www.skin-stim.com](http://www.skin-stim.com) completed successful clinical studies in Utah and South Africa and continue to enroll more patients as it seeks out a strategic partnership. Many patients demonstrated highly notable reduction of facial wrinkles. The breakthrough patent pending discoveries of bioelectric controlled expressions of Klotho, tropelastin (elasticity) and COL17A were major advances in our skin regeneration platform. Humans turn off their tropelastin elasticity expression at puberty and our team figured out the bioelectric signaling sequence code to turn it back on!

**Stem Cell Bra** [www.stemcellbra.com](http://www.stemcellbra.com) on the heels of completing 15 large animals with spectacular results complete a Phase I safety low dose clinical study also with success and is now preparing in 1H 2020 to complete its first efficacy clinical study. In animal studies breast tissue volume grew by 20 to 30% with only 1 hour of stimulation every other day for 4 weeks only. It is estimated that up to 2 billion worldwide would choose a safe, convenient, low cost means to increase their breast fullness and shape if available especially following post child birth changes to breast shape and volume.

**DentaCell** [www.dentacellaccelerator.com](http://www.dentacellaccelerator.com) DentaCell Accelerator collaborating investigators and their network of colleagues have completed over 2000 clinical cases utilizing frequency specific microcurrent for various applications in dentistry including inflammation and pain management and accelerated healing. DentaCell is now organizing controlled clinical studies with statistical significance to prove out these therapies with vigorous clinical data management.

**TestiStim** [www.testistim.com](http://www.testistim.com) following a successful pilot case is moving forward to launch a formal clinical study for bioelectric testosterone management.

## Major Organ Regeneration

**EyeCell** - [www.eye-cell.com](http://www.eye-cell.com) has published results on 176 clinical patients so far and is launching now two new clinical studies. They are seeking a strategic partner at this time as they gather new supporting data with newly designed eye google and additional new bioelectric signaling sequences.

**BladderCell** [www.bladdercell.com](http://www.bladdercell.com) collaborating researchers published successful clinical trial results and now a team in Brazil is enrolling in a new clinical study with new bioelectric signaling sequences added. The company plans to seek a strategic partnership the 2H of 2020. BladderCell has multiple issued and pending patent claims.

**OrthoStim** [www.ortho-stim.com](http://www.ortho-stim.com) is launching clinical studies in Mexico and Brazil with plans to follow with a study at Hoag Hospital Irvine in California for joint regeneration (knees, elbow, finger joints, elbows).

**KidneyCell** [www.kidney-cell.com](http://www.kidney-cell.com) completed one successful 21 patent clinical study in Brazil and is now launching a new study with additional measures and new bioelectric signaling sequences for kidney regeneration including our new Klotho signal.

**InStim** [www.instimcell.com](http://www.instimcell.com) completed a successful first pilot case and is now planning a formal clinical trial for inflammation management. InStim has over 21 inflammation management specific patent claims pending with the USPTO at this time - <https://patents.justia.com/patent/20190022389>

**PancreaCell** is working with an OUS team to soon launch a clinical study for pancreas regeneration.

**EarCell** [www.ear-cell.com](http://www.ear-cell.com) is launching a new clinical study in Brazil with a group that previously published multiple studies on electrical stimulation based hearing regeneration.

**BioLeonhardt Whole Body** - <https://vimeo.com/179280204> is our most ambitious product development project with aspirations to introduce by 2023 the world's first safe and effective whole body regeneration chamber "a regeneration womb for adults". The team is also developing a more modest goal based body suit called BodStim™ designed to provide mild rejuvenation to yoga and pilates practitioners as well as athletes.

**LiverCell** for liver regeneration, PolypStim for bioelectric polyp treatment and RegenaLung for lung regeneration are all in discussions with potential research collaborators with plans to announce soon shared research initiatives.

## Cancer

**CancerCell** [www.cancercellinc.com](http://www.cancercellinc.com) has developed the most comprehensive bioelectric cancer tumor treatment platform known with 9 issued patents already and dozens of new patent claims pending. The CancerCell therapeutic platform is the only one known to read a cancer tumor and customize the deliver of bioelectric signaling sequences based on that read real time. The therapy is designed to (1) jam the communication of the tumor, (2)

change the surface proteins and charge to illicit and immune response, (3) release anti-angiogenic proteins to starve a tumor of blood supply, (4) to heal a tumor and manage inflammation, (5) to cause apoptosis stopping cell division, (6) to cause resonant rupture of cancer tumor cells, (7) to reprogram cancer tumor cells and finally (8) to regenerate the organ back to health after the the cancer tumor is eradicated. The team completed a pilot feasibility small animal study at UCLA last year which has laid the foundation for more studies this year. The CancerCell team has high confidence it is on a path to develop a cancer therapy that can be more effective with less side effects than current therapeutic options such as chemo therapy or radiation treatments. Three other companies in recent years have published successful results for electro-magnetic and bioelectric cancer therapies including Novocure which recently surpassed \$8 billion valuation.

I wish to thank the more than 200 people who in one form or another participated in advancing our product developments in 2019. We all continue to work hard to meet our goals set forth for 2020. We believe our work represents the best hope for many patients that are failed by current therapeutic options and we feel the sense of urgency felt by their families to come forward with a better solution soon. Our team members believe the combination of bioelectrics and biologics are on path to herald in a new area of patient care and we plan to help lead the way!

**Sincerely,**  
**Howard J. Leonhardt**  
**Executive Chairman & CEO**