Lookbook 2023

MEDTECH INNOVATOR

MedTech Innovator is the world's largest medical technology accelerator. In partnership with leading medtech firms, MedTech Innovator advances the development of best-in-class startups to ensure their innovations successfully reach patients with the maximum value possible. Selected companies receive unparalleled access to leading manufacturers, providers, investors, and other members of the global MedTech Innovator ecosystem.

Since 2013, MedTech Innovator has reviewed over 9,500 applications and accelerated 612 companies from 38 countries who have gone on to raise over $7 billion in follow-on funding and bring over 281 products to market. 95% of MTI graduates are still in business or have been acquired. Visit us at medtechinnovator.org to learn more about partnering with us or our startups.

MEDTECH INNOVATOR

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Meet Our Team

Paul Grand
Founder & CEO

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Vice President, Strategic Alliances

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Senior Director of Marketing

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Marketing & Events Assistant

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Assistant Manager in Marketing & Events, Asia Pacific

https://medtechinnovator.org/about-us/

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AdvaMed Advanced Medical Technology Association

MedTech STRATEGIST

AdvaMed Accel

MEDTECH INNOVATOR SHOWCASE SCHEDULE

Monday, October 9

Location: Hall A, Booth 101

9:15 AM - 9:45 AM
Telehealth

Moderated by Rahul Sathe
Cambridge Consultants

JuneBrain	45
Senseye	72
Sonavi Labs	75

9:50 AM - 10:20 AM
Advanced Materials

Moderated by Jonathan Trexler
Becton Dickinson

Cellulora	23
Newrotex	55
Nininger Medical	56
Renovos Biologics	68

10:25 AM - 10:55 AM
Cardiology

Moderated by Suneer Verma
Edwards Lifesciences

EchoPixel	28
IFPx	38
InterShunt Technologies	42
Pumpinheart	66

11:00 AM - 11:30 AM
Critical Care & Emergency Medicine

Moderated by Hisatoshi Abe
Nipro

MACH32	47
Opticyte	58
Perceptive Medical	61
StrokeDx	77

1:45 PM - 2:15 PM
Neurotechnology

Moderated by Tasha Bond
ERI

INBRAIN Neuroelectronics	41
MicroTransponder	50
NeuraStasis	62

2:20 PM - 2:50 PM
GI & Colorectal Surgery

Moderated by Mirren Mandalia
Johnson & Johnson

Mirai Medical	51
Plio Surgical	62
SafeGuard Surgical	69
Savage Medical	71

2:55 PM - 3:25 PM
Remote Patient Monitoring

Moderated by Jason Halac
Dexcom

CardieX	22
Happitech	33
Neurava	53
ProtonIntel	64

3:30 PM - 4:00 PM
Oncology

Moderated by Biren Mehta
Johnson & Johnson

PanTher Therapeutics	60
Prana Thoracic	63
Xcision Medical Systems	87

4:05 PM - 4:35 PM
Improving Clinical Workflow

Moderated by Bill Perry
ASPS

3EO Health	11
4th Dimension EMR	13
Ankr Health	20
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MEDTECH INNOVATOR SHOWCASE SCHEDULE

Tuesday, October 10

Location: Hall A, Booth 101

1:45 PM - 2:15 PM
Healthcare AI

Moderated by Kristi Nakayama
Veranex

Cerebraai	25
DASI Simulations	27
Invenio Imaging	43
Vitestro	85

2:20 PM - 2:50 PM
Orthopaedics & Rehabilitation

Moderated by Amar Patnaik
Zimmer Biomet

Adcura	15
Alyve Medical	17
Fingy3D	31
Purgo Scientific	67
Sparta Biomedical	76

2:55 PM - 3:25 PM
Connected Medical Devices

Moderated by Josh Magnuson
Fujikura

AMI	19
HIVE Medical	36
NXgenPort	57
Universal Brain	83

Wednesday, October 11

Location: Hall A, Booth 101

9:45 AM - 10:15 AM
Surgical Tools & Advancements

Moderated by Nicolle Cannon
Cannon Quality Group

Thermidas	79
XTremedy Medical	88
270Surgical	10

10:20 AM - 10:50 AM
Vascular Solutions

Moderated by Jake Goble
W.L. Gore

Covellus	26
Sentante	73
Total Flow Medical	80
VeinWay	84

10:55 AM - 11:25 AM
Next-Gen Surgical

Moderated by Abby Hunter-Syed
Olympus

Endocision	30
Hypervision Surgical	37
ImmersiveTouch	40
Medical Devices Corner	48

MedTech Innovator Founding Partner

RESEARCH CORPORATION TECHNOLOGIES

www.rctech.com

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Johnson&Johnson
MedTech

Revolutionizing Minimally Invasive Surgery with the world's first FDA Cleared Surround View laparoscope visualization system. Dramatically expanding the field-of-view for SAFER, FASTER, and EASIER surgery.

Israel | 270surgical.com

270Surgical is a medical device startup that has developed the SURROUNDSCOPE™ - a pioneering laparoscopic platform, enabling surgeons a new, safer, and more efficient way to operate. Resulting in better patient outcomes and substantial hospital cost savings. The groundbreaking surround 270˚field-of-view allows surgeons to operate entirely under vision with minimal blind spots throughout the case. Also, additional innovations eliminate interferences of fog and surgical smoke, making the SURROUNDSCOPE™ the most advanced visualization platform in the market.

With over 500+ successful human cases, support from world-leading KOLs, and an FDA Cleared product, 270Surgical is well-positioned to start the commercialization phase and impact an entire industry.

Watch what surgeons say about the SURROUNDSCOPE™ here.

Avi Levy
Founder & CEO

Chad Croasdale
President & CCO

Didi Nishlis
Vice President of Business Development

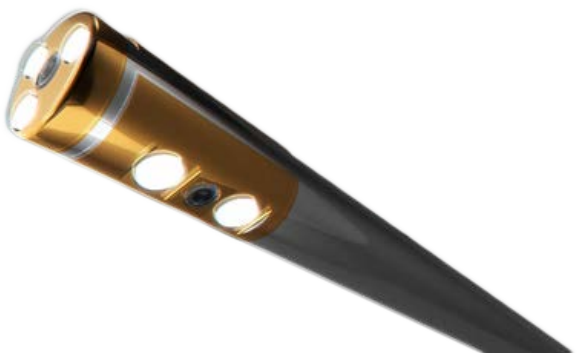
Moshe Levi
Vice President of R&D

Dr. Shirley Shapira
Vice President of Clinical

DEVELOPMENT STAGE: Paying customers

REGULATORY STRATEGY: 510(k) - FDA Approved

SEEKING: $30MM Series B, Conventional Debt (Loan) - B



Molecular POCT system for clinic, community, and home costing 70% less than prevailing technologies

Beverly, MA | 3eohealth.com

Jeremy Schubert
CEO

The US Point of Care Testing market is large and expanding rapidly. It is also highly fragmented and underserved.

Due to the cost and complexity of molecular, ~45% of the 300MM respiratory oriented tests ordered by physicians each year are sent to a central lab with 80% of testing executed near patient utilizing antigen. This despite clear benefits of locating such testing near the patient and the performance advantages of molecular technologies.

Due to the cost / complexity trade-off, two markets (antigen and molecular) have developed in a space that only requires one standard of care. If only there was a single solution that had the performance of molecular, the price of antigen, and ease-of-use that transcends both.

Now there is.

3EO Health has brought to market a patent protected molecular technology (3TR) that provides molecular results at near antigen pricing. 3TR is dilution free eliminating the cost associated with complex instrumentation and consumable based microfluidics. However, physicians don't need to sacrifice performance. 3EO's clinical trial demonstrated 99% accuracy and offers groundbreaking ease-of-use with a "sample-to-test" workflow.

With a price 70% lower than prevailing molecular technologies and unprecedented ease of use, 3EO Health is poised to unify the point of care respiratory testing market into a single category … simultaneously taking share from antigen, molecular, and send-out tests.

DEVELOPMENT STAGE: Pre-market (Launch Q4, 2023)

REGULATORY STRATEGY: EUA Approved / 510K upcoming

SEEKING: $8MM Series B

OLYMPUS

INVESTING IN PASSIONATE FOUNDERS REVOLUTIONIZING MEDICAL SOLUTIONS.

With over a century of leadership in the medical industry, Olympus Innovation Ventures (OIV) leverages Olympus' industry expertise to support early stage teams building customer-driven solutions in medical device, diagnostic and digital health. OIV invests across the key clinical areas where Olympus operates, including GI, Respiratory, Urology, Women's Health, ENT and General Surgery.

Contact Olympus Venture Capital

olympusamerica.com/olympus-venture-capital

4D EMR

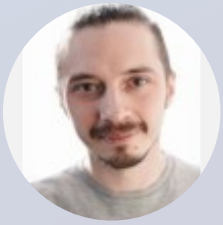
Private practice medical office management / EMR cloud software driven by AI, built by a plastic surgeon, and focused on ease of use for doctors, staff, and patients

San Diego, CA | 4d-emr.com

4D EMR is the next evolution of specialty medical office practice management/EMR software specifically built for the plastic and cosmetic surgical practice. Founded and built by a board-certified plastic surgeon with 35 years clinical experience, it is a cloud-based program with an intuitive interface, HIPAA-compliant telehealth, appointment reminders, photo and video storage, paperless consents, patient portal, quote generation, ePrescribing, product inventory, and much more. As a true cloud program 4D EMR is platform agnostic meaning the user can access their office information from any device with an internet connection, including mobile devices. View multiple side-by-side office calendars and customize appointments unique to the office. Run one of over 60 reports to review office metrics to maximize revenue. Securely save unlimited numbers of before and after patient photos and send them directly to patients via HIPAA compliant email. Our integrated patient portal allows new patients to complete their medical intake and electronically sign their consent forms prior to their first appointment. Our point-of-sale section allows purchase of products, services, and packages with built-in commission tracking and inventory management, With our credit card clearinghouse integration the office can process credit card transactions directly within our software.

Robert Pollack MD
Founder & CEO

Carol Lee
CFO

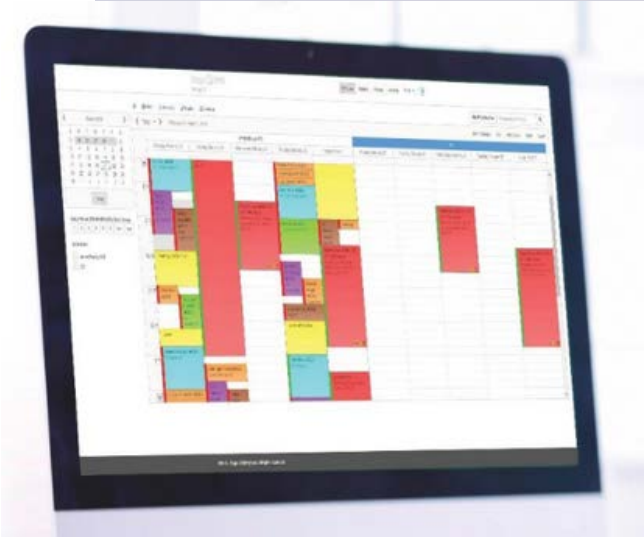


Arthur Stankevich
CTO

DEVELOPMENT STAGE: Customers

REGULATORY STRATEGY: Not Applicable - Not Applicable

SEEKING: $3.5MM Series A



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At Zimmer Biomet, it's our mission to alleviate pain and improve the quality of life for people around the world. To keep patients moving through life without pain and healthcare providers moving and supported throughout their careers.

Zimmer Biomet | Moving You Forward.

Find out more at www.zimmerbiomet.com

ZIMMER BIOMET
Moving You Forward.™

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The only FDA cleared adjustable expandable spinal implant with independent adjustment of both height and angle for a patient specific fit

Eden Prairie, MN | adcuraspine.com

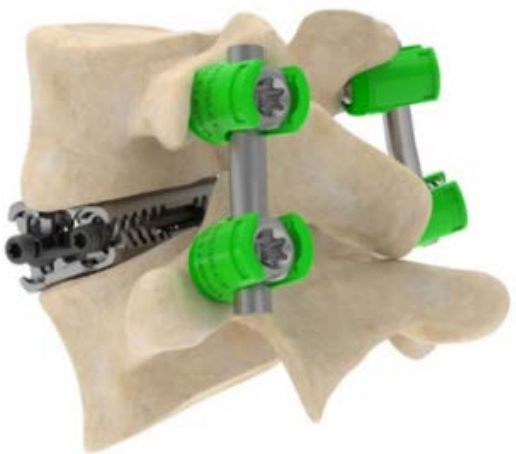
Surgical platform to address patient specific anatomy in lumbar spinal fusion surgery and thereby reduce revision surgeries and poor outcomes. Unlike static implants, our proprietary adjustable implant can be fit to a patient's specific anatomy while reducing inventory by over 90%. Being implanted in a collapsed state also reduces the trauma necessary to complete the procedure. Accompanying tools give the surgeon the ability to carry out precise surgical plans.

Eric Blossey
CEO

DEVELOPMENT STAGE: Customers

REGULATORY STRATEGY: 510(k) - FDA Approved

SEEKING: 5.0 Series Other



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ALYVE MEDICAL

Deploying innovative sensor-based tools and patented algorithms, Alyve Medical has two revolutionary technologies changing the delivery of musculoskeletal care

Denver, CO | alyvemedical.com

Alyve Medical has two solutions which solve shoulder pain, improve function and address several other musculoskeletal problems. Their leading technology is a therapeutic, substantially differentiated, next-generation neuromuscular electrical stimulation (NMES) wearable device, Neuralign S™, which treats the majority of shoulder pathologies. Accompanied by a companion tablet, containing validated protocols for instability, dyskinesis, rotator cuff repair, and reverse shoulder replacement, along with the device, offers trimodal biofeedback, increasing patient compliance. The key feature of the device however is the patented Motion Activated Stimulation™ (MAS), which provides dynamic interaction with the patient during exercise, and induces neuroplasticity or a retraining of the brain. This is what results in improved outcomes that are sustained for the long term. Their second technology is ShowMotion™, a diagnostic kinematic sensor kit which objectively documents normal and/or abnormal movement in joint function in about 5-10 minutes. It is non-invasive, mobile, and provides instant graphic results, actionable for the healthcare provider.

DEVELOPMENT STAGE: Customers

REGULATORY STRATEGY: 510(k) - FDA Approved

SEEKING: $2MM Seed

Yvonne Bokelman
CEO

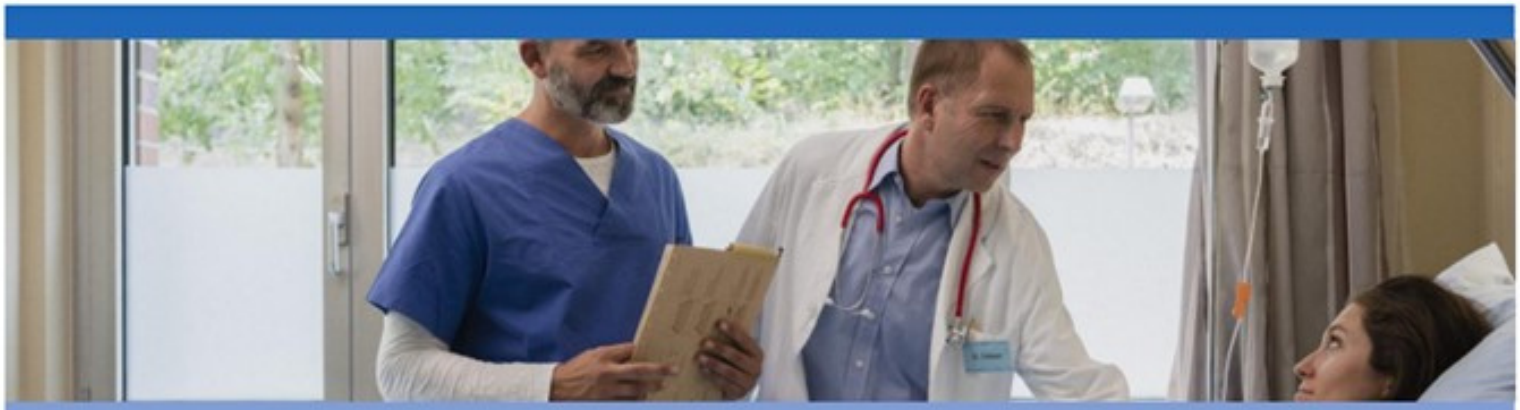
Sean Murphy
VP of Strategy

Matteo Mantovani
Chief Research Officer

Live Longer. Live Better.

NIPRO

https://www.nipro.co.jp/en/



AMI Inc.

Evaluate cardiovascular diseases by analyzing your heart sounds, including infrasounds, non-invasively

Kagoshima, Japan | ami.inc

SSS is a digital stethoscope with uses in the hospital and at home. AMI Inc. understands the future of our aging society. This compact device will enable you to screen and monitor cardiovascular diseases (CVDs) non-invasively, wherever you are.

The traditional stethoscope was invented two centuries ago. Even though we learned over the years that human ears have limitations, the current innovations are focused on augmenting human abilities. SSS can collect very low-frequency sounds, with high definition; this multi-patented technology has been regulatory approved in Japan.

Acoustic data correlates to mechanical and biochemical markers which are standard of practice for monitoring HF.

We have implemented a digital auscultation service in Japan where doctors can remotely evaluate heart sounds. Using the acoustic sounds that we have collected, we are developing an AI algorithm that computes mechanical and biochemical biomarkers that are the standard of practice for evaluating CVDs. We will use our AI technology to support clinicians in detecting the trend of CVD aggravation.

We have collected data from more than 3,000 patients and have collaborated with more than 20 medical institutions. This database enables us to create an AI algorithm with exceptional accuracy and reliability.

In Japan, we are now experiencing an aging society earlier than in any other country, and there are 1.8 million patients with CVDs in Japan today. As global aging continues, we believe that our technology will rapidly increase in value, as it opens up new possibilities to save lives.

DEVELOPMENT STAGE: Pre-approval

REGULATORY STRATEGY: 510(k) - Preparing Submission

SEEKING: $4MM Series C

Shimpei Ogawa, M.D.
CEO

Ginga Sato
Lead of International Business Development

Toshitaka Yamakawa, Ph.D.
General Manager

Tomoyo Mori, M.D.
Director of International Business Development

Ankr

Side effect management platform for cancer & surgery clinics

Houston, TX | ankrhealth.com

Side effects result in poor patient outcomes, lost chemo and value-based reimbursements, and disproportionately high staff utilization for oncology and surgery clinics. The current side effect management protocols are reactive ("treat when sick") and result in a staggering $200B/year cost for stakeholders in healthcare. Ankr's predictive ML algorithms prevent over half of these side effects and give patients tools to manage mild side effects at home.

Ankr's digital health platform:
- keeps cancer patients on life-saving treatment for 1.8 extra months
- generates $14K/patient in additional chemo revenue while decreasing global cost of care
- prevents ER visits for surgery patients during 90-day global peri-operative period
- decreases unnecessary calls to clinic for mild side effects

Backed by:
Y Combinator, Wordquant Ventures, MedTech Innovator

DEVELOPMENT STAGE: Customers

REGULATORY STRATEGY: Not Applicable - Not Applicable

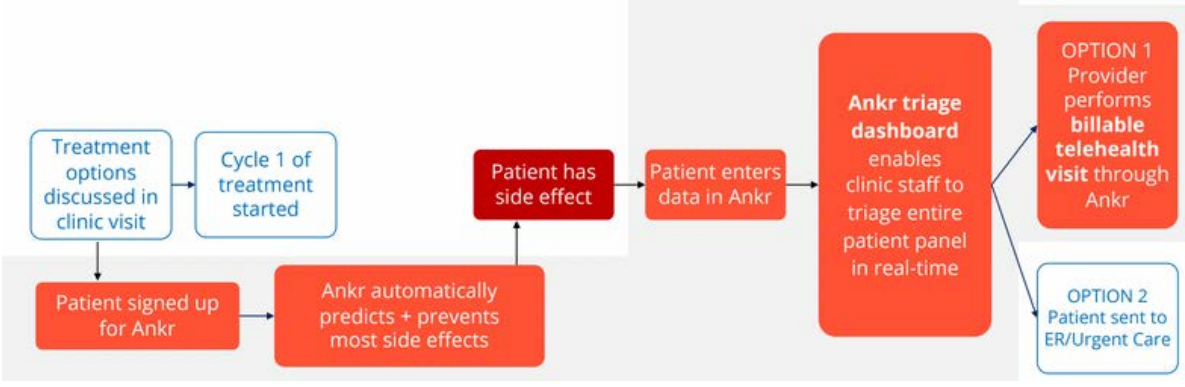
SEEKING: $5MM Series A

Arpit Rao
CEO

Shivani Rao, MHA
Director of Operations

Chris Knoedler, MD
Advisory Board Member

Merrill Shum, MD
Advisory Board Member



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It's about uncovering bold advancements, innovating structural heart and critical care technologies – and dreaming big to imagine brighter futures.

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... and life is now.

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CARDIEX

Making arterial health screening affordable and accessible for everyone with a heart

Sydney, Australia | cardiex.com

CardieX pioneered the technology for noninvasive measurement of vascular biomarkers that measures arterial stiffness and the pressures experienced by major organs including the heart, brain, and kidney. Our newly launched CONNEQT product suite offers comprehensive insights into an individual's cardiovascular health status currently not accessible outside of critical care settings. Our vision is to be the leading provider of home, wearable, remote patient monitoring, and clinical trial solutions for common health disorders related to high blood pressure including hypertension and other major vascular health conditions. Based on our unique patented, FDA-cleared SphygmoCor® technology, our devices are designed to be deployed as part of a remote patient monitoring regimen to extend care and improve health outcomes.

Our first target market is in maternal health. There is now a recognition that impaired arterial function and structure may occur during pregnancy and impact a woman's cardiovascular health long term, and studies have shown vascular biomarkers to be useful for early intervention and management of hypertensive disorders of pregnancy (HDP). Recent studies have demonstrated that vascular biomarkers representing arterial stiffness can detect altered hemodynamic responses in the first trimester of pregnancy in women who subsequently develop HDP. We offer an end-to-end telemedicine platform that enables OB/GYNs to effectively diagnose and monitor the development of HDP during pregnancy. Our goal is to offer the most comprehensive monitoring of the heart health status of pregnant women, as we believe access to clinically-relevant vascular biomarkers will enable providers to intervene early, extend care to the home, and improve maternal health outcomes.

Craig Cooper
CEO

Catherine Liao
Chief Strategy Officer

Dr. Mark Gorelick, PhD
Chief Product Officer

Dr. Steven Kesten, MD
Chief Medical Officer

DEVELOPMENT STAGE: Product: Approved

REGULATORY STRATEGY: 510(k) - FDA Approved

SEEKING: $15MM Series Other

Cellulora™

The World's First Permanent Implant, that's Reversible

Philadelphia, PA/ New York City, NYC
cellulora.com

Cellulora Inc. is developing the world's first injectable, plant-based implants for soft tissue restoration that are non-degradable yet reversible. The implants are biocompatible to ISO standards and do not require a blood supply, unlike fat grafts. Cellulora was granted Breakthrough Device Designation from the FDA and we anticipate initiating our first-in-human studies within the next year. The device includes a pre-loaded dual barrel syringe with a 25-gauge needle. Upon injection, the material conforms to any size anatomical defect providing an immediate bulking effect for optimal visualization. It then thermally gels and cures in situ within minutes, leaving a stable, non-degradable implant. Dual thermal gelation and chemical crosslinking mechanisms prevent migration, resorption, or contraction, and unique surface chemistry resists fibrous encapsulation. Ease of delivery, facile tunability and excellent biocompatibility allow it to be used anywhere in the body, and if the patient or physician are dissatisfied, it is also reversible via enzymatic treatment.

Steven C. Davis
CEO

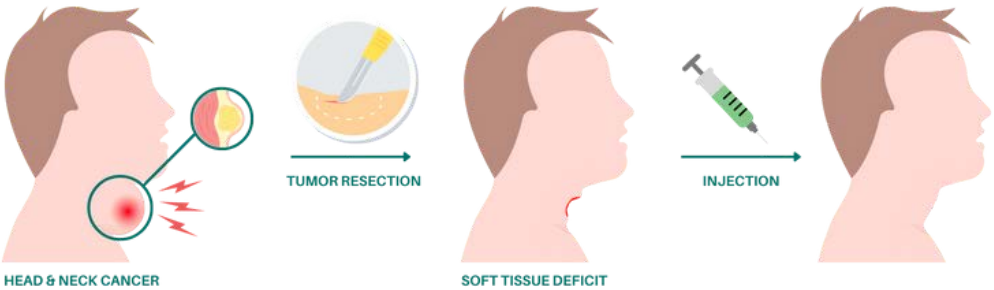
Steven B. Nicoll
PhD
CSO

Peter J. Taub MD
Medical Advisor

DEVELOPMENT STAGE: Pre-clinical / Clinical

REGULATORY STRATEGY: PMA - Scheduled FDA Pre-Submission Meeting

SEEKING: $1.7MM Series Seed



Fujikura

PICORAMEDIC.

Picoramedic® CMOS Camera Systems Miniaturized CMOS cameras in 160K & 40K resolution for the ideal balance of image quality and minimal invasiveness.

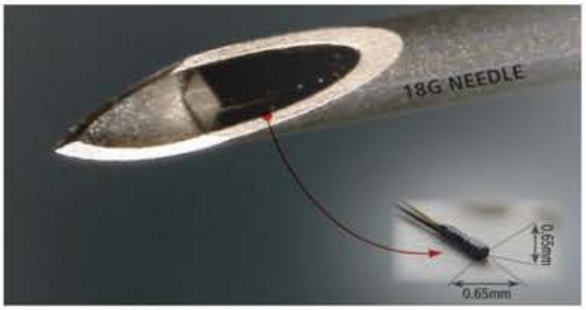
"WABE" Technology™ Wafer and Board level Embedding technology offers outstanding package/substrate miniaturization by utilizing unique embedded die technology, perfect for wearable/implantable technology

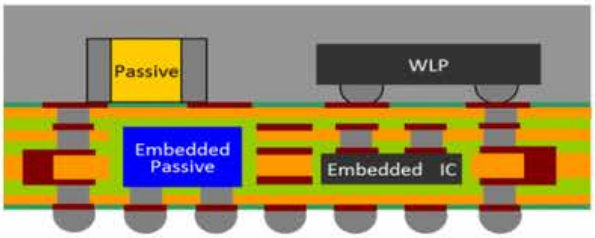
Ultra-small Side-firing Laser Probe [USLP] Fujikura's ultra-small side-firing laser probe is designed for multimodal catheters or endoscopes that include optical modalities. Its minimized scale and unique design deliver better imaging and analysis to physicians than ever before.

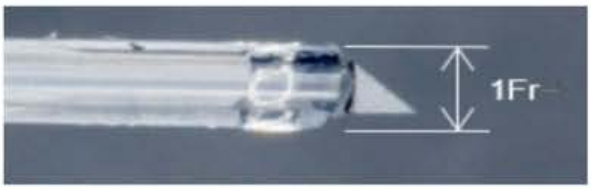
CONTACT

Web: http://www.fujikura.com/solutions/medical/

Inquiries: medical@jp.fujikura.com







take better control of diabetes without fingersticks*

The **Dexcom G6 Continuous Glucose Monitoring (CGM) System** sends glucose readings to your smart device† in real time. Unlike fingersticks that give you a single reading, with Dexcom G6 you always know where your levels are and where they're headed so you can make better diabetes management decisions.

- Proven to lower A1C and increase time in range[1,2]
- No painful fingersticks* or inconvenient scanning
- Alerts you before you go too low or when you are high
- Easy to get started[3] and easy to use[4]

Learn more at dexcom.com

Dexcom G6

*If your glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.

†Smart devices sold separately. To view a list of compatible devices, visit dexcom.com/compatibility. 1 Beck RW, et al. Ann Intern Med. 2018;168(7):526-7. 2 Welsh JB, et al. Diabetes Technol Ther. 2019;21(3):128-132. 3 Shah V LL, et al. Diabetes Technol Ther. 2018;20(6). 4 Dexcom, data on file, 2020. Dexcom is a registered trademark of Dexcom, Inc. in the U.S. and may be registered in other countries. ©2022 Dexcom, Inc. All rights reserved. LBL-1001696 Rev 001

CerebraAI

Revolutionising Emergency Medicine: Unleashing Non-Contrast CT's Full Potential with the Power of Generative AI

Palo Alto, CA | cerebraai.ai

CerebraAI, a unique case from Kazakhstan, specializes in cutting-edge medical software development. Their advanced Generative AI solution has achieved success in detecting ischemic stroke based solely on NCCT scans. The company aims to target the US market by installing their solution in Emergency Departments (EDs) to address stroke detection challenges. Their technology has the potential to transform untapped EDs into efficient stroke detection and early treatment units, improving patient outcomes.

Since 2018, CerebraAI has received recognition from organizations in the medical field such as Medtronic APAC, Bayer CIS, Johnson & Johnson, StartUs, and EY. They have also been accepted into prestigious programs, including the StartX Summer 2023 acceleration program at Stanford University and the MedTech Innovator Acceleration Program Cohort 2023. These achievements highlight the company's commitment to excellence and potential impact in stroke management and patient care.

DEVELOPMENT STAGE: Prototype: pre-clinical

REGULATORY STRATEGY: BDD - Preparing Submission

SEEKING: $6MM Seed 3 bridging Seed to Series A

Doszhan Zhussupov
Founder/CEO

Timur Tuspayev
CTO

Zhuldyz-Zhan Sagimbayev
Head of ML/AI

Meruyert Saifullakyzy
Medical lead

Covellus

Next generation intravascular lithotripsy to address the challenges of vascular calcium, and modular balloon catheter solutions tailored for outpatient endovascular environments, like OBLs and ASCs

Belmar, NJ | covellus.com

Bradley Beach
CEO/Founder

Covellus is packaging our Intravascular Lithotripsy (IVL) technology into multiple catheter solutions to address vascular calcium (VC) across all vascular beds. Vascular calcium (VC) is a major challenge when treating arterial disease. Our Stand-Alone IVL Catheter product provides ultra low-profile calcium fracturing solutions for tight and total occlusions in coronary and below-the-knee (BTK) segments. While our IVL Adapter product is used with the Covellus Modular Peripheral Balloon Platform to add IVL capability to any size or length angioplasty balloon for iliac, femoral, and popliteal segments.

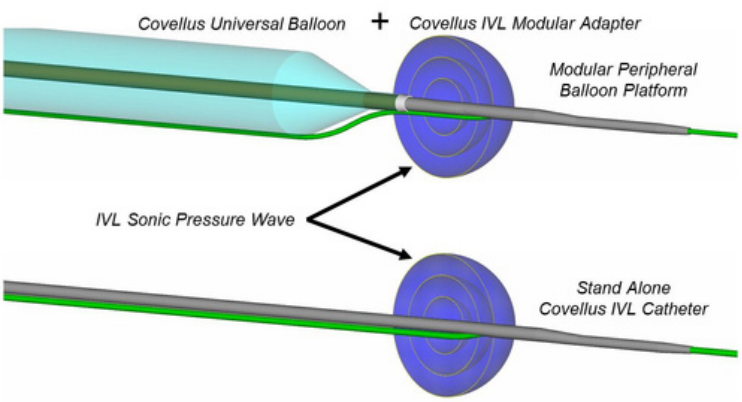
We have developed the Modular Peripheral Balloon Platform to address the limitations and SKU complexity of integrated balloon catheters used in peripheral vascular interventions. The Covellus Balloon Platform allows physicians to create custom angioplasty balloon catheters to meet the clinical needs of their patients and complexities of these procedures. Customization options create both procedural and workflow efficiencies tailored to each hospital, or outpatient setting like the growing base of office-based labs (OBLs) and ambulatory surgery centers (ASCs) angioplasty.

Our mission is to improve clinical workflow and economics, while advancing interventional therapies and techniques using our patented Modular Peripheral Balloon Platform.

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: 510(k) - Had FDA Pre-Submission Meeting

SEEKING: $10MM Series A



AI Predictive Planning Software for Surgical/Interventional Treatment

Dublin, OH | dasisim.com

The DASI Simulations technology is a novel AI-powered medical platform that transforms routine imaging (CT, MRI, etc.) into an interactive four-dimensional (4D) predictive environment accessible on mobile, tablet, or web browsers. This technology solves the current problem where physicians rely on highly manual planning steps on images without the ability to predict whether a treatment will work or not. As the physicians interact with the DASI predictive platform with different device implants or surgical treatment options, the AI instantly lets them see the predicted impact on patients' unique anatomy and functional treatment efficacy and reveals patient-specific complications associated with each treatment option. The power of AI eliminates manual measurements, with the AI automatically identifying anatomical landmarks of interest and making all the measurements with unsurpassed accuracy. The technology is the co-pilot for physicians and patients to seamlessly navigate clinical decision-making to optimize treatment and consider the patient's unique time course (such as future interventions s/he will need) as part of the decision-making.

This novel technology is already FDA-cleared in heart disease, a $40B addressable market, with future planned expansions into orthopedics, neurosurgery, and ob-gyn. The 4D predictive environment will also integrate into the operating room in the form of augmented reality. Clinical studies using AI-powered DASI technology have demonstrated improved patient outcomes by eliminating complications and reducing costs. The data-science foundation of the technology helps democratize the latest medical knowledge and distill it to the patient-specific level with the 4D interactive platform - allowing physicians unsurpassed ability to use foresight to optimize each patient's personalized treatment plan.

DEVELOPMENT STAGE: Paying Customers

REGULATORY STRATEGY: 510(k) - FDA Approved

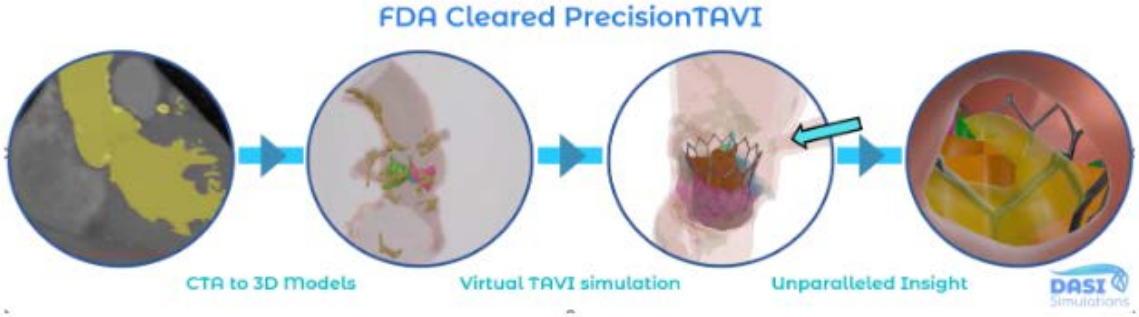
SEEKING: $2MM Seed (Convertable Note Round)

Teri Sirset
Co-Founder/CEO

Lakshmi Prasad Dasi, Ph.D.
Co-Founder/CTO

Sean McKibben
COO

Rich Gray
VP of Sales



echopixel

Immerse yourself in the procedure through a real-time hologram

Santa Clara, CA | echopixeltech.com

EchoPixel's FDA-cleared software platform comprised by True3D (t3D) and Holographic Therapy Guidance (HTG) helps operators easily obtain, visualize and navigate a real-time 4D hologram of a patient's heart using standard medical images.

A holographic digital twin of a patient simplifies modern more complex non-invasive procedures allowing operators and hospitals to achieve better, safer and faster results in more patients.

In structural heart and electrophysiology procedures, EchoPixel provides operators with an enhanced spatial awareness of their tools (catheters) and a patient's anatomy allowing them to increase accuracy in both navigation and delivery of treatment options using less contrast, radiation and smaller teams.

Sergio Aguirre
CEO

Jacob Dutcher MD
CMO

Tony Chen
Software Product Manager

DEVELOPMENT STAGE: Approved

REGULATORY STRATEGY: 510(k) - FDA Approved

SEEKING: $12MM to $15MM Series B

Made for today, tomorrow and for what's needed next

At BD, we understand that care at the right place, with the right treatment, and at the right time means nothing if it's not for the long haul. That's why, even after 125 years of using scientific expertise to develop breakthrough innovations, we continue to strive to develop products and solutions that provide better outcomes to patients throughout their journey.

Visit **bd.com** to learn more.

BD

Advancing the world of health™

Endocision

Portable and detachable bronchoscopic catheter system for safer diagnosis and treatment of lung pathologies

Montreal, QC | endocision.com

Interstitial Lung Disease affects ~15 million people globally, severely reducing life expectancy and quality of life. Many patients will need a biopsy to confirm their diagnosis, and while guidelines recommend bronchoscopic lung cryobiopsy, the technique is seldom performed as severe complications (e.g., significant bleeding or lung collapse) still occur in over 10% of cases. As a result, few patients can access these procedures.

Endocision's Celsio platform is set to bring safer cryobiopsy for lung disease diagnosis. Our proprietary Detachable Over-The-Scope (DOTS) system allows the bronchoscopist to deliver and retrieve a flexible cryogenic catheter to obtain a sufficiently large tissue sample without losing the scope's position or visualization. This unique benefit reduces procedure risks and increases the physician's confidence by simplifying the management of potential complications.

Celsio also eliminates cumbersome consoles and upfront capital purchase barriers. It is completely portable and fully disposable, expanding bronchoscopic cryo access to other care settings (e.g., ICU, critical care, anesthesia, ER) for removal of blood clots, mucus plugs, and foreign bodies. Celsio is compatible with traditional and robotic bronchoscopy, endobronchial ultrasound, and can also be applied for high-yield lung cancer and nodule biopsy, tumor debulking and devitalization, and stenosis relief.

Endocision is in parallel developing a system for cryoablation for bronchoscopic indications.

Jean-Pierre Desmarais
CEO

Marc Chelala
COO

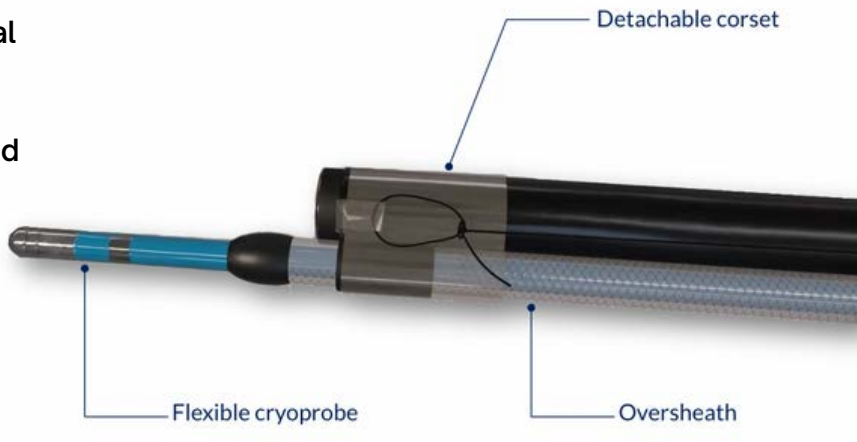
Moishe Liberman
CMO

Bruno Chabot
Principal R&D Specialist

DEVELOPMENT STAGE: Prototype: Pre-clinical

REGULATORY STRATEGY: 510(k) - Not Started

SEEKING: $7MM Series A



FINGY3D

A custom-on-demand, finger prosthetic ordered from a smartphone picture and delivered to your home for under $300

Morgantown, WV | fingy3d.com

There are currently over 3M finger amputees in the US alone with an additional 50k finger amputations occurring each year. Most amputees are under 10 and over 60 years of age. Commonly, finger amputations result in loss of grip strength, object stability, and fine motor abilities. Amputees are often found to be financially or geographically disadvantaged resulting in poor prosthetic access and utilization that could improve their daily lives. Fingy3D is the first 3D-printed prosthetic that can be customized, ordered, manufactured on demand, and shipped directly to the patient using a web application on their phone. The design system produces prosthetics that optimize fit, function, at a low cost of around ~$300. To order a Fingy3D a customer visits www.fingy3d.com chooses the preferred model and features, and takes a picture of his or her hand using our novel web application. The hand is analyzed and measured using dynamic image processing and artificial intelligence (AI) and an engineer. The measurements are connected to CAD software that generates a custom-sized prosthetic. Finally, a beautifully designed, high-quality, and functional prosthetic is 3D printed from durable PA2200 nylon and mailed to the customer's home.

Justin Chambers, PhD
Co-Founder

Thomas McClellan, MD
Co-Founder

DEVELOPMENT STAGE: Paying customers

REGULATORY STRATEGY: FDA Approved

SEEKING: $2MM Series Seed

FLOW

Flow's clinically-validated brain stimulation headset + therapy app delivers drug-free depression treatment at home with better results than drugs and none of the side effects

Sweden | flowneuroscience.com

Flow's clinically-validated neuromodulation platform delivers holistic, drug-free clinical treatment for depression at home with results as good or better than pharmaceuticals. Flow's platform provides an integrated solution for both patients and clinicians: - Patients can access personalized, at-home treatment using a combination of the Flow Headset (targets the physical root cause of depression) and an app-based behavioral training program (targets the psychological & environmental factors of depression) - Clinicians have full visibility into patient adherence and outcomes, with the ability to customize and set treatment protocols remotely using Flow's Clinician Portal.

DEVELOPMENT STAGE: Paying customers (Live EU/UK market)

REGULATORY STRATEGY: PMA - Preparing Submission, Targeting FDA Approval Q2 2024

SEEKING: $20-30MM Series B

Erin Lee
CEO

Daniel Mansson
Co-Founder & Chief Clinical Officer

Erik Rehn
Co-Founder/CTO

Patients:
Personalized, at-home treatment that starts in days, not weeks

Clinicians:
Full visibility into patient adherence and response with ability to customize

Happitech uses only a smartphone camera to detect heart disease accessible to 86% of the world population

Netherlands | happitech.com

Heart disease is the #1 killer of people in the U.S., yet 80% of Cardiovascular disease, including heart disease and strokes, is preventable if detected timely. Our goal is to make early detection of cardiovascular disease possible using something that 86% of the world population already has: A smartphone.

Our first product is the first CE-marked software medical device capable of detecting heart rhythm irregularities using photoplethysmography (PPG) with only a smartphone By placing your finger on the camera for 90 seconds

Initially focusing on heart rhythm disorders, Happitech now has several active research and development (R&D) projects dedicated to detecting other cardiovascular conditions such as ischemia, heart failure, and aortic valve disease.

Our CE-marked solution is backed by clinical studies evidence and enables clinicians a scalable and accessible way to instantly monitor their patients. In addition, Happitech's solution ensures “interoperability” by seamlessly integrating into leading Remote Patient Monitoring platforms. This ensures our data flows from the patient's phone to the physician's EHR, one of the important reasons why hospitals love our solution. This year we'll deploy our solution to 160,000 elderly in one of the largest European cardiac screening campaigns.

Happitech is CE and TGA certified and anticipates 510K clearance by the end of Q2 2024. Happitech is looking for a strategic partner (commercial, distribution) to accelerate its entry into the US market.

Yosef Safi Harb
CEO/Founder

Dr Jonas de Jong
CMO

Claire Donnelly
Head of Sales

Sarah Fisher
Marketing Lead

DEVELOPMENT STAGE: Paying customers

REGULATORY STRATEGY: 510(k) - Had FDA Pre-Submission Meeting

SEEKING: $2MM Seed

JABIL HEALTHCARE

JABIL.COM/HEALTHCARE

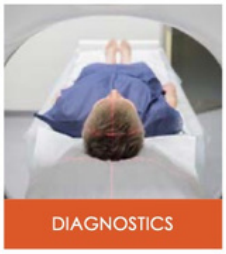
Jabil Healthcare is the industry's largest, most comprehensive healthcare solutions and capabilities provider — giving our customers access to an array of engineering, design, and manufacturing solutions across multiple sectors in the healthcare industry. In the face of challenging technology and value-based mandates, we are committed to customer-centric operational excellence driving positive patient outcomes.

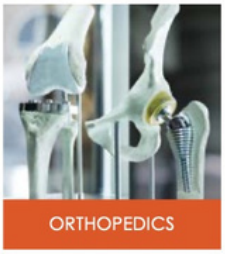
END-TO-END SOLUTIONS

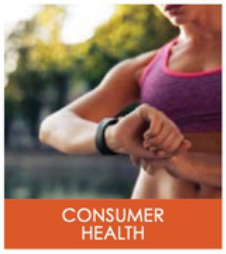
INNOVATE — DESIGN — DEVELOP — MANUFACTURE — DELIVER — SERVICE


MEDICAL DEVICES


PHARMACEUTICAL DELIVERY SYSTEMS


DIAGNOSTICS


ORTHOPEDICS


CONSUMER HEALTH

ENGINEERING & TECHNOLOGY

The Jabil Healthcare Engineering and Technology Team provides a range of services for the design and development of healthcare products, including product design, design for manufacturability, electrical, mechanical and software design, prototyping, CT scanning, design validation services and more. Our production teams take products from prototyping to New Product Introduction (NPI) and into full scale manufacturing.

HEALTHCARE LOCATIONS

AMERICAS | EUROPE | ASIA

JABIL STRENGTH & SCALE

1966	54M	260K+	$27.3B	100+
FOUNDED IN MICHIGAN, USA	SQUARE FEET OF MANUFACTURING SPACE	DEDICATED EMPLOYEES	REVENUE IN FY20	SITES WORLDWIDE

STRATEGIC CAPABILITIES

- ACOUSTICS
- ADDITIVE MANUFACTURING
- ADHESIVES
- ADVANCED ASSEMBLY
- AUTOMATION
- CONNECTED HEALTH
- FLUIDICS
- HUMAN INTERFACE
- INTELLIGENT DIGITAL SUPPLY CHAIN
- MATERIALS TECHNOLOGY
- MINIATURIZATION
- OPTICS
- PCBA
- POWER ENGINEERING
- PRECISION INJECTION MOLD TOOLING
- PRECISION MECHANICS
- PRINTED ELECTRONICS
- ROBOTICS
- REAGENT HANDLING & FILLING
- SENSOR INTEGRATION
- SMART CLOTHING
- TEST ENGINEERING
- VALUE ENGINEERING
- WIRELESS CONNECTIVITY

hertility

Reproductive healthcare from menstruation to menopause with at-home testing, telemedicine & treatment

London, UK | hertilityhealth.com

Hertility is a regulated biomedical health company on a mission to solve the current invisible infertility crisis and transform women's healthcare.

By pioneering tailored diagnostics and next-generation advancements through predictive algorithms, Hertility provides end-to-end care from menstruation through menopause.

Hertility specialises in female health assessments and online consultations with experts in fertility, menopause, PCOS, endometriosis, and gynaecology both direct to consumers and to organisations as an employee benefit, alongside scanning and treatment referrals. The Company believes that proactive and early diagnosis of reproductive health issues, as well as hormonal monitoring, can improve women's well-being, health and the chances of avoiding invasive procedures.

Hertility's core focus is on its longitudinal data to enable earlier detection and diagnosis. At present, they can screen over 18 gynaecological pathologies - including predicting the onset of menopause and fertility decline.

They aim to change attitudes around reproductive health, including in the workplace, and encourage women to be proactive by tracking their reproductive health and fertility. They work with corporates to become "Reproductively Responsible™" by providing workforce health screening, accredited educational workshops and policy support.

They are calling this the Reproductive Revolution.

DEVELOPMENT STAGE: Customers

REGULATORY STRATEGY: 510(k) - Not Started
Fully Regulated across Europe & UK

SEEKING: Other - Amount Undisclosed

Dr. Helen O'Neill
CEO/Co-Founder

Dr Natalie Getreu
COO/Co-Founder

Deirdre O'Neill
CCO/Co-Founder

Dr Tharni Vasavan
Head of Scientific Product Research

HIVE

HIVE Medical's mission is to deploy objective sensors to catch and eliminate intravenous medication errors and automate documentation in homes, infusion clinics, and hospitals

St Louis, MO | hivestlouis.org

Medication errors are a widespread and preventable challenge in healthcare, affecting over a billion patients globally who receive venous catheters each year. In the US, one in three patients relies on these catheters, but poor adherence to IV maintenance protocols results in bacterial growth and blockages. Studies show less than 10% compliance with disinfection protocols, with up to 45% contamination of needleless connector hubs. While alcohol-soaked caps were introduced to address this, nurses forget to use them up to 40% of the time, leading to preventable complications, including costly central line-associated bloodstream infections (CLABSIs). Annually, the US sees 71,900 preventable CLABSIs, with high costs and mortality rates. Preventable medication non-adherence in home IV therapy adds to the problem, resulting in health risks and expensive readmissions. Clinicians lack effective tools, relying on inefficient manual calls by nurses, and 74% of home health agencies lack monitoring teams, a significant barrier to safe home IV therapy.

Our flagship product, IVsight, is a patented sensor that automatically detects connection and disconnection events at IV line access points called needleless connectors. IVsight externally attaches to the needleless connector and seamlessly tracks every step in an infusion including premedication, saline flushes, medication administrations, heparin locks, and cap usage. This actionable and objective data is delivered to a dashboard for clinicians in real time, empowering them to easily track and reduce medication errors at home and in the clinic.

Joe Beggs
CEO

Sai Dodda
CMO

Jake Eshelman
CTO

Glen Kleinschmidt
COO

DEVELOPMENT STAGE: Prototype: Clinical

REGULATORY STRATEGY: Class I, 510(k)-exempt, GMP-exempt, started

SEEKING: $2.5MM Seed

HYPERVISION

Hypervision Surgical – Revolutionizing Surgical Precision with Ultra-Fast Hyperspectral Imaging

United Kingdom | hypervisionsurgical.com

Intraoperative decision-making is a complex process, heavily reliant on surgeons' subjective judgments based on what the human eye can see. Across surgical disciplines, this approach often results in suboptimal surgical outcomes and avoidable complications, as seen in colorectal cancer surgery (15% anastomotic leakage complication with 35% associated mortality rate), brain tumour surgery (30% leave significant tumour behind), and prostate cancer surgery (85% erectile dysfunction).

At Hypervision Surgical, we've pioneered ultra-fast intraoperative hyperspectral imaging (HSI) technology, poised to provide surgeons with a 'superhuman' level of vision that has the potential to transform how they operate. Our technology seamlessly integrates with and is compatible with various surgical vision systems, including those used in open, minimally invasive, robotic, and microscopic surgeries. Our software modules are carefully designed to customize visualized tissue analytics information to effectively differentiate healthy from unhealthy tissue thereby enhancing surgical precision.

Our inaugural product comprises a sophisticated yet seemingly conventional camera for open and laparoscopic surgery, enhanced with HSI capabilities. It provides objective tissue perfusion information without the need for any contrast agent. Designed for colorectal surgery to mitigate anastomotic leakage, it is on track to secure US regulatory clearance within the next six months.

Michael Ebner
CEO & Co-Founder

Tom Vercauteren
CSO & Co-Founder

Seb Ourselin
NED & Co-Founder

Jonathan Shapey
Clinical Lead & Co-Founder

DEVELOPMENT STAGE:

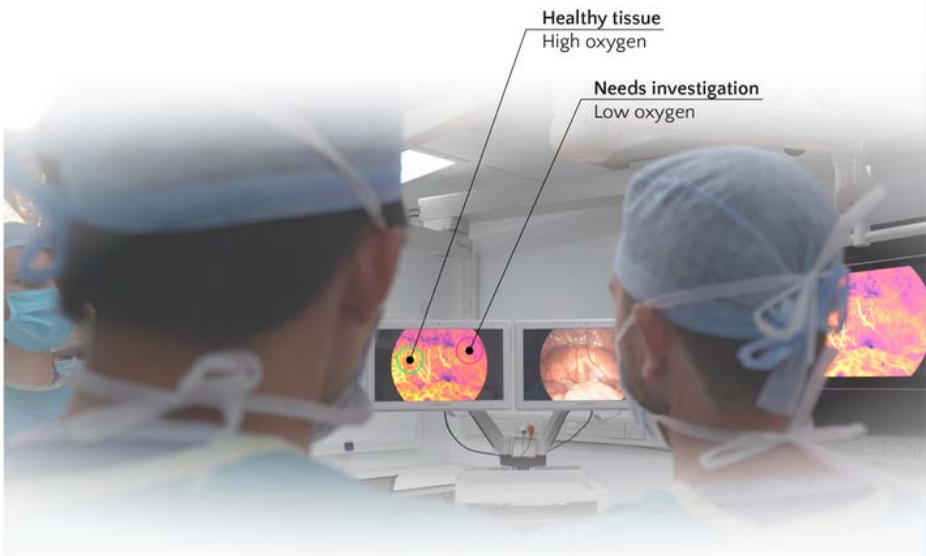
Product: Pre-Approval

REGULATORY STRATEGY:

510(k) - Preparing Submission

SEEKING:

$25MM Series A



Subcutaneously implantable multiparameter heart failure sensor with interstitial fluid pressure measurement

Irvine, CA | ifpxmedical.com

IFPx has developed the first and only sensor that directly monitors interstitial fluid pressure - providing a direct signal on the progression of congestion, which is the #1 driver for heart failure hospitalizations. This is important because heart failure is a debilitating chronic condition that impacts millions of Americans and will drive $70B in healthcare costs by 2030. The majority of this cost is driven by unnecessary hospitalizations due to inadequate proactive tools for patient management, and the majority of hospitalizations are driven by fluid overload. Without a way to measure fluid buildup, clinicians rely on surrogate parameters, but the technology is expensive, invasive, and ineffective - leaving the massive unmet need largely unsolved.

The IFPx system is being developed to address this critical unmet need. The device is a subcutaneously implantable minimally-invasive device that continuously monitors interstitial pressure alongside other important physiologic parameters in a form-factor like implantable cardiac monitors. The IFPx digital health platform is poised to deliver rich, longitudinal data to support timely and individualized heart failure treatments with the aim of reducing hospitalizations and healthcare costs while improving patients' quality of life.

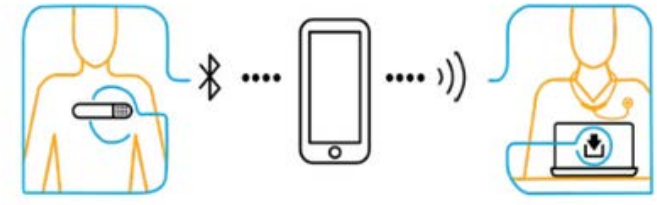
Amanda French, *Co-founder/CEO*

Joe Passman, *Co-founder/R&D Lead*

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: De-Novo - Completed informational meeting with FDA

SEEKING: $4.0MM Series Seed



ImmersiveTouch®

FDA-cleared Spatial Computing for Personalized Surgical Planning and 3D Printing

Chicago, IL | immersivetouch.com

Surgeons face chaos as trauma and cancer patients emerge with distorted anatomy. These cases require immediate planning, but current planning methods take weeks. ImmersiveTouch AI detects and reduces trauma fractures in seconds, not weeks. Our interactive spatial computing allows surgeons to plan in real-time with greater precision, improving outcomes. We're FDA-cleared, CE-marked, patent-protected and have planned more than 3,000 cases. We're in over 100 hospitals and officially collaborating with Mayo Clinic to develop new applications. ImmersiveTouch is more than a tool; it's the next dimension in personalized healthcare.

DEVELOPMENT STAGE: Paying customers

REGULATORY STRATEGY: FDA Approved

SEEKING: Growth Round

Dr. Pat Banerjee
Co-CEO

Jay Banerjee
Co-CEO

Jay Bergamini
Head of Sales

Dr. Jia Luo
Head of Product Engineering

INBRAIN NEUROELECTRONICS

Graphene-based high density & resolution neurotech platform, enabling Intelligent & personalized neuroelectronic therapies at scale

Barcelona, Spain | inbrain-neuroelectronics.com

INBRAIN is developing a minimally invasive Neurotechnology platform for the treatment of central and peripheral nervous system applications with the first indication being Parkinson's disease, but many others to follow. INBRAIN's graphene-based neural system interfaces allow spatially selective activation of target circuits as well as recording of low and high frequency signals that contain disease biomarkers. Such outstanding features pave the way towards the detection of therapy-specific biomarkers, increasing outcomes of adaptive and personalized neuroelectronic therapies.

Carolina Aguilar
CEO/Co-Founder

Jurriaan Baker
CTO

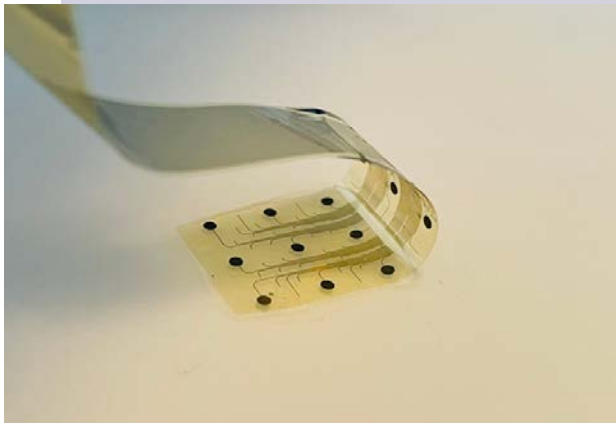
Jose A Garrido
Chief Science Officer/Founder

Joan Adan
Finance & Operations Head

DEVELOPMENT STAGE: Prototype: Clinical

REGULATORY STRATEGY: 510(k) - Breakthrough Designation - Had FDA Pre-Submission Meeting

SEEKING: $55MM Series B



INTERSHUNT

Relief for millions suffering from heart failure

Minneapolis, MN | intershunt.com

InterShunt is an early clinical stage medical device company that is developing an interatrial shunting catheter to relieve symptoms and improve quality of life in patients with heart failure. Heart failure is the leading cause of hospitalization among the elderly leaving those who suffer chronically short of breath.

InterShunt's minimally invasive procedure creates a small opening in the interatrial septum to relieve elevated left atrial pressure. This helps to clear pulmonary congestion allowing patients to breathe easier and maintain an independent lifestyle. InterShunt's proprietary catheter uses mechanical cutting only, causing no scar tissue formation and leaving no permanent implant. The result is an opening that is compliant to the hemodynamic needs of the heart.

Early human clinical trials demonstrate that the InterShunt procedure is safe, the results are durable and meaningful clinical improvements have been consistently observed in heart failure patients.

Harlee Sorkin
CEO

Maggie Wallner
VP of Clinical Development

Alan Eskuri
Director of Engineering

Gil Vardi, MD
CMO

DEVELOPMENT STAGE: Clinical

REGULATORY STRATEGY: Pivotal trial anticipated – had FDA Pre-Submission Meeting

SEEKING: $20MM Series B

INVENIO

The NIO uses laser imaging and artificial intelligence to instantly detect cancer in tissue biopsies in the OR

Santa Clara, CA | invenio-imaging.com

Real-time tissue analysis impacts more than 13 million cancer patients every year. Existing techniques for on-site evaluation of biopsies are inconsistent, slow, and thus underutilized. This results in non-diagnostic biopsies, samples inadequate for molecular analysis, and incomplete surgical resections.

The NIO Laser Imaging System uses laser spectroscopy to image fresh tissue in the OR in under 3 minutes. Our consumable, the NIO Slide, is designed for easy use by the nursing staff and allows retrieving the sample for downstream molecular analysis. We are combining this technology with artificial intelligence (AI) to enable instant detection of cell and tissue morphology suspicious for cancer and provide accurate decision support to treating physicians.

In a study involving 273 patients, we demonstrated that our AI has the same accuracy as pathologists based on traditional methods for predicting diagnosis. We have recently demonstrated that it can further predict specific molecular markers, paving the way to triaging patients for targeted therapies and immediate treatments.

The NIO Laser Imaging System is FDA-registered, has already been purchased by 12 hospitals, and has been used in 3,000+ cases. We are in the process of executing a study to obtain FDA clearance of the first AI algorithm for detecting lung cancer in bronchoscopic biopsies.

Jay Trautman, Ph.D.
President/*CEO*

Chris Freudiger, Ph.D.
CTO

Steve Pastore, MD
VP Clinical Affairs

Taren Nguyen, MS
VP of Quality Assurance and Regulatory Affairs

DEVELOPMENT STAGE: Paying customers for imaging system & pre-approval for AI

REGULATORY STRATEGY: De Novo - Had FDA Pre-Submission Meeting

SEEKING: $7MM Series A

JuneBrain

JuneBrain is revolutionizing retinal imaging by offering an accessible, AI-driven solution to improve brain and eye health

Baltimore, MD | junebrain.com

At JuneBrain, we strive to make eye and brain disease monitoring more accessible to the 1.3 billion individuals worldwide suffering from conditions like macular degeneration, multiple sclerosis, and Alzheimer's disease. It is often difficult to detect eye and brain diseases early on, particularly among groups with traditionally poor access to healthcare. This includes people who are low mobility, disabled, or who live in rural areas. Optical coherence tomography (OCT) is the gold standard for imaging the eye, but bulky and expensive machines limit access to specialized clinics.

JuneBrain has developed the Neuro-i SS-OCT, an AI-driven wearable retinal imaging device that can be used to detect changes in disease progression and treatment efficacy inside and outside the clinic. Our product will allow for regular, remote monitoring of low mobility patients by eye and neurology clinics, as well as bring OCT to new markets including diagnostic laboratories, assisted living homes, and primary care clinics.

Based in Baltimore, MD, JuneBrain includes a diverse and accomplished team of 10 and collaborates with prestigious universities like Johns Hopkins, University of Maryland Baltimore, and Texas A&M University. Our company has $300k in sales backlog and the Neuro-i is patented in the US. To date, we have raised $2.8M, including $2M in non-dilutive grant funding.

Dr. Samantha Scott
Founder/CEO

Smaa Koraym
Product Manager

Dr. Wande Ajose
Clinical Research Manager

Danielle Jones
Marketing & Brand Manager

DEVELOPMENT STAGE: Clinical

REGULATORY STRATEGY: 510(k) - Had FDA Pre-Submission Meeting

SEEKING: $2MM Seed

Knowtex

Knowtex empowers clinicians with voice AI automated note-taking and coding from natural conversation to combat burnout and capture revenue leakage

San Francisco, CA | knowtex.ai

Knowtex is transforming clinical workflows through leveraging voice and generative AI. Our completely AI software empowers clinicians by creating visit notes with codes and extracting orders from clinician-patient conversations. Knowtex captures ambient conversation, identifies relevant medical information, and generates a pre-filled structured note with billing codes and orders which can be submitted into the EHR, for clinician review.

For clinicians, we're decreasing time spent on manual administrative work and allowing them to focus on what they pursued medicine for in the first place: patient care. For clinics and hospitals, we're improving accuracy and efficiency in coding and billing to help with reimbursement.

Our goal is to be the clinician's all-in-one visit assistant, allowing them to focus on what they pursued medicine for in the first place: patient care.

Caroline Zhang
CEO

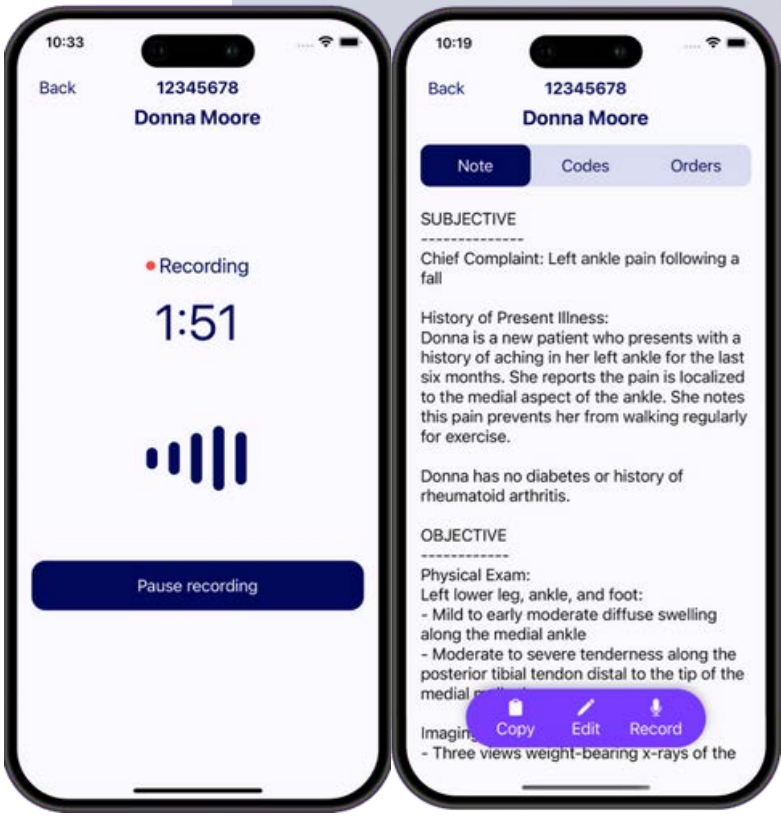
Jocelyn Kang
CTO

Tony Fu
Founding Engineer

DEVELOPMENT STAGE: Customers

REGULATORY STRATEGY: Not Applicable - Not Applicable

SEEKING: $15MM Series A



MACH32

IMSAFE is an "EpiPen for Trauma"; stop patients from bleeding to death BEFORE they reach the hospital

Edmonton, AB | mach32.net

Marc Curial
Founder/CEO

Kelly Mottet
COO

Massive hemmorhage is a massive problem. Trauma and hemmorhage are responsible for 9% of worldwide deaths; more than HIV, Tuberculosis, and Malaria combined. IMSAFE is an "EpiPen for Trauma"; designed to stop patients from bleeding to death BEFORE they reach the hospital.

IMSAFE delivers a generic, “standard of care” medication that has been clinically proven to decrease relative risk of death due to hemorrhage by 1/3! However, this medication must be delivered rapidly for peak effect and currently can only be given through an IV due to its large volume. Often the ideal window to administer this medication has passed by the time patients receive hospital level medical care.

IMSAFE will empower civilians, first responders, and military personnel to save lives by simplifying the administration of this proven medication. IMSAFE is a high volume autoinjector that delivers over 15 times the capacity of a standard autoinjector in under 2 seconds.

By increasing the injection volume and concentrating the medication MACH32 has revolutionized the administration of a lifesaving medication which is currently endorsed for use in trauma by Advanced Trauma Life Support (ATLS), Tactical Combat Casualty Care (TCCC), and most EMS services. Our prototype device has been tested by the Canadian Armed Forces and reaches therapeutic drug concentration in less than a minute in an animal model.

Faster administration = less bleeding. Save time, money, and lives with IMSAFE.

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: Combination Product (CDER) - Preparing for Pre-IND Meeting

SEEKING: $5MM Series Seed

Revolutionizing surgery with a novel robotic system that provides physicians direct access inside imaging scanners

Menlo Park, CA | meddevcorner.com

At MDC, we are creating a new chapter in minimally invasive surgery. We're focused on improving cancer diagnosis and treatment and we do this with a novel robotic device that provides interventional radiologists remote access inside the MRI and CT scanners. Our system allows physicians to perform cancer biopsy and ablation procedures from an imaging control room with the patient remaining inside the scanner itself. This significantly reduces procedure duration and improves targeting precision. Our device is fully MRI compatible and is controlled directly by the physician. Physician motions and forces are mapped one-to-one between the input and output, resulting in a safe and dexterous system. While we are initially focused on biopsies and ablations, our long-term vision is to enable non-invasive, live image guidance for a wide range of interventions. Our system will provide physicians with the ability to perform surgical interventions on patients lying inside imaging scanners, revolutionizing capabilities for minimally invasive surgery.

Samuel Frishman
CEO/Founder

Peter Whitney
Lead Technology Engineer

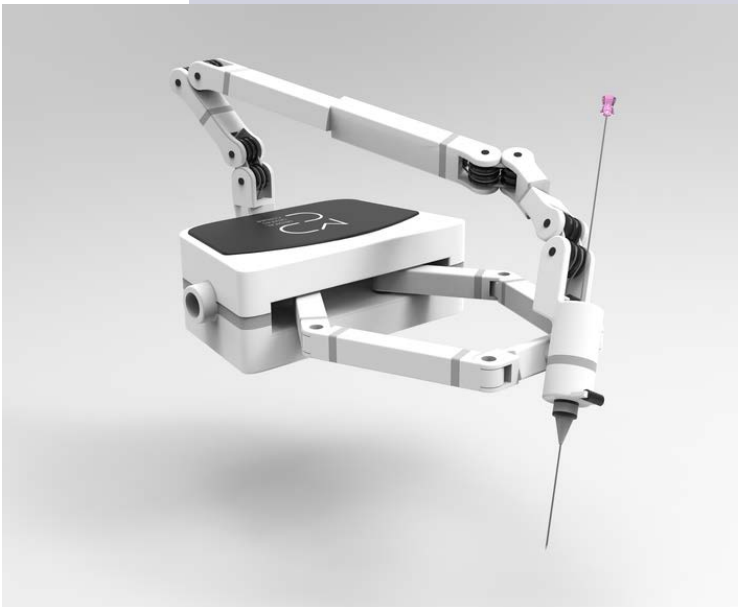
Stephen Lin
Software & Electrical Engineer

Tianyang Lei
Design & Mechanical Engineer

DEVELOPMENT STAGE: Prototype: Pre-clinical

REGULATORY STRATEGY: 510(k) - Not Started

SEEKING: $8MM Seed

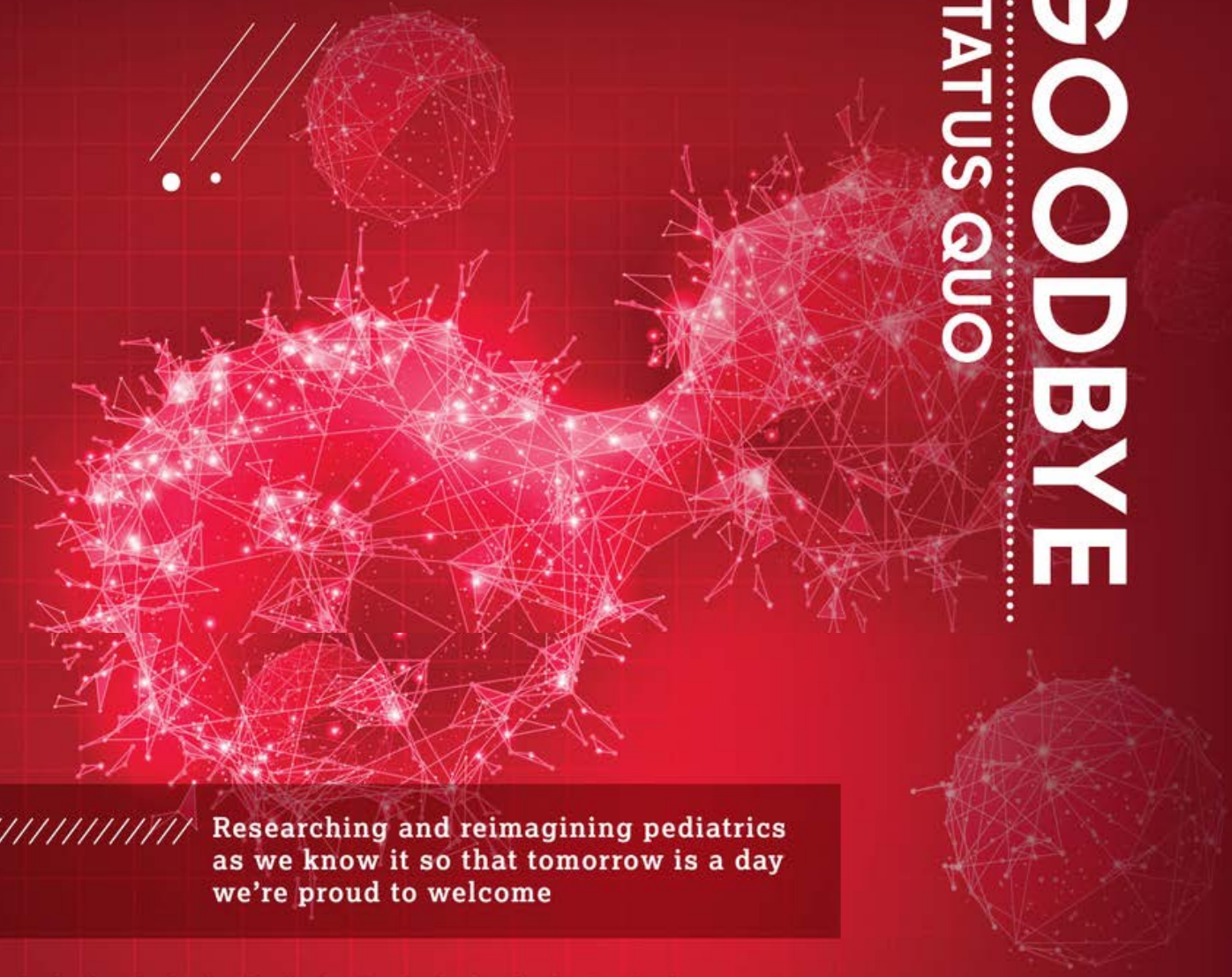


HELLO

STATE-OF-THE-ART ‹‹‹‹

GOODBYE

STATUS QUO



Researching and reimagining pediatrics as we know it so that tomorrow is a day we're proud to welcome

Scan the QR Code to see how we're innovating the care of tomorrow.

Children's National

MicroTransponder®

MicroTransponder®, Inc. is a privately held, global medical device company committed to developing research-based neuroscience solutions. The company's FDA-approved Vivistim® Paired VNS™ System is a first-of-its-kind, clinically proven medical technology that helps restore dignity and enhance daily living for stroke survivors.

Austin, TX | microtransponder.com

MicroTransponder®, Inc. is a global medical device company that focuses on restoring dignity and enhancing daily living for people suffering from stroke-related neurological conditions that impair sensory and motor function.

Having received the Breakthrough Device designation and pre-market authorization in August 2021, MicroTransponder introduced the FDA-approved Vivistim® Paired VNS™ System to stroke survivors and their health care professionals amid much anticipation because it's the first innovation to enhance the effectiveness of stroke rehabilitation therapy and improve motor function in nearly 30 years.

Stroke therapists acknowledge that occupational and physical therapy, the standard of care for stroke rehabilitation, have limited effect on the restitution of upper limb function for stroke survivors, especially those 6 months or more post-stroke. The Vivistim System presents a solution to this challenge by helping to increase neuroplasticity and enhance the effectiveness of therapy.

This Paired VNS™ Therapy helps generate two to three times more improvement in hand and arm function than traditional rehabilitation alone for ischemic stroke survivors after six weeks of in-clinic therapy. Additionally, an at-home component enables users to conveniently activate Vivistim with a magnet to further enhance hand and arm function after therapy.

As a result, 98% of Vivistim users report being satisfied with their Paired VNS™ Therapy. The results of three randomized controlled trials have been published demonstrating that Vivistim users not only improve their upper limb function but those improvements remained durable at 3-year follow-up assessments.

As further support of Vivistim's game changing technology, the Centers for Medicare and Medicaid Services (CMS) awarded the Vivistim® Paired VNS™ System transitional pass-through status, expanding access to Medicare beneficiaries at many premier comprehensive stroke centers and rehabilitation centers across the country.

This early industry adoption and positive clinical outcomes fuel MicroTransponder's commercialization strategy as the company elevates the Vivistim System from novel therapy to standard of care in stroke recovery.

DEVELOPMENT STAGE: Paying Customers

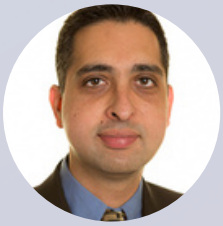
REGULATORY STRATEGY: PMA - FDA Approved

SEEKING: Engagement with Growth Equity/Crossover partners

Richard Foust
CEO

Doug Ellison
Chief Revenue Officer

Prashant Rawat
Chief Operating Officer



Navzer Engineer, MD, PhD
Co-Founder, Chief Scientific Officer

MIRAI MEDICAL

ePORE® : Precision Gastrointestinal Tissue Ablation

Ireland | mirai-medical.com

Mirai Medical is a clinical stage company focused on outpatient endoscopic treatment of gastrointestinal disease, specifically complex colorectal polyps.. The company's CE Mark approved and patented technology comprises a proprietary pulsed field generator, single-use delivery probes and pulse parameters optimised to ablate premalignant and tumour cells without damaging the surrounding healthy tissue structures.

What makes the Mirai approach unique is the ability for any endoscopist to treat with consistent procedure times taking just minutes as a low risk, highly reproducible solution delivered as an outpatient therapy.

Four clinical trials have been published in peer-reviewed journals and initial commercial cases have been completed. Mirai is currently finalising a 510(k) submission and is raising a Series A to finance further clinical trials, indication expansions, and market roll-out.

Advances in colorectal screening results in over 1 million premalignant lesions being detected annually in the US. Current treatment options for their removal require patient hospitalisation with significant hospital resources and are only carried by highly trained and experienced endoscopists or surgeons. ePORE® offers a safer more efficient and profitable treatment option.

Declan Soden, PhD
CEO

Seán Kinsella
CTO

Colin Forde
COO

DEVELOPMENT STAGE: Approved

REGULATORY STRATEGY: 510(k) - Had FDA Pre-Submission Meeting

SEEKING: $25MM Series A

NEURASTASIS

Empowering stroke survivors to reclaim their lives through neurostimulation

Houston, TX | neurastasis.com

NeuraStasis is changing the paradigm of care for stroke survivors. Using proprietary non-invasive neuromodulation, NeuraStasis harnesses the body's innate reflexes to modulate neuroplasticity and cerebral perfusion. Packaged into an easy-to-use and intuitive device, NeuraStasis aims to increase access to care and enable more survivors to remain functionally independent.

NeuraStasis is developing a product to service the neuro-rehabilitation markets by reinforcing rehabilitation and promoting neural network rewiring. NeuraStasis coordinates the activation of cranial nerves that modulate cerebral blood flow and neurotransmitter release. By tying activation to everyday motions, they empower stroke survivors to take their recovery into their own hands at home.

NeuraStasis is NIH-funded and expecting a new $1MM grant to begin in Q4 2023. It has completed its 1st clinical pilot, showing safety and a dose-dependent increase in cerebral blood flow, with an abstract presentation at Neuroscience in Nov 2023. The team has developed a strong clinical partnership with UT Health Houston to complete a 2nd clinical pilot measuring treatment effect (Feasibility testing to start by Dec 2023). The team is supported by an experienced strategic (ex-Medtronic, Kaiser Permanente) and clinical (combined 400+ publications in stroke) advisory board. NeuraStasis is seeking investment partners to expedite its clinical validation.

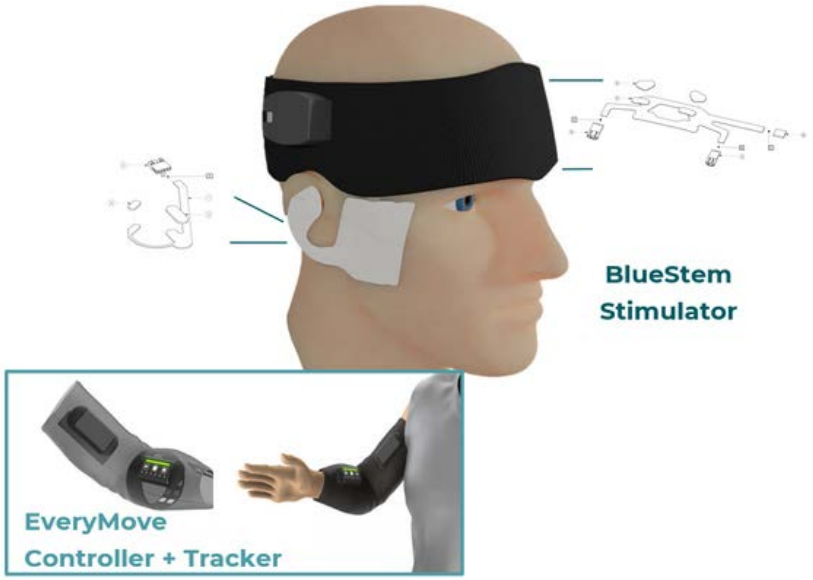
Kirt Gill, MD
CEO / Co-Founder

Joe Upchurch, MBA
COO / Co-Founder

DEVELOPMENT STAGE: Prototype: Clinical

REGULATORY STRATEGY: De Novo - Had FDA Pre-Submission Meeting

SEEKING: Open Convertible Note (Angels to expedite clinical testing and introductions to Leads) : $3-5M next round



NEURAVA

Wearables to give back control to patients with uncontrolled epilepsy

West Lafayette, IN (HQ) & Baltimore, MD | neurava.com

Neurava is leveraging over a decade of epilepsy research to develop novel wearables on the arm and neck that monitor and alert for seizures, cardiac and respiratory dysfunctions known to occur prior to Sudden unexpected death in epilepsy (SUDEP). We are designing our wearables to be worn only at night, while epilepsy patients are asleep, since almost all SUDEP cases occur at night, when parents and caregivers face enormous stress and anxiety as they try to monitor loved ones. Our wearables are soft, flexible and held in place with disposable adhesive patches co-developed with our partners 3M and Marian. All recorded data from our wearables is transmitted via Bluetooth to a smartphone app. Using our AI algorithms, we can wirelessly alert designated caregivers for seizures, cardiorespiratory dysfunctions and potential SUDEP risk, enabling real-time preventative action from a caregiver, including CPR and/or administering rescue medications. All data is further uploaded to our secure cloud database, which physicians can access through a custom-designed portal. Data captured from patients remotely will allow physicians to assess the efficacy of treatment in all patients, triaging those at highest risk of SUDEP, who can then be placed on more effective treatment plans.

Jay Shah
CEO, Co-Founder

Vivek Ganesh, PhD
CTO & Co-Founder

Trevor Meyer
Principal Algorithms Engineer

Pedro Irazoqui, PhD
Scientific Advisor

DEVELOPMENT STAGE: Prototype: Clinical

REGULATORY STRATEGY: 510(k) - Preparing Submission

SEEKING: $8MM Series A

Three Bridges
MANAGEMENT & CONSULTING

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Three Bridges provides advisory services to help startups and growing **MEDTECH COMPANIES** to **maximize their value** and **draw toward success.**

Visit our website: www.threebridges.it

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BARDA provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, devices, and diagnostic tools for public health medical emergencies.

Interested in partnering withBARDA? Learn more about our programs:

Broad Agency Announcements (BAA): Funding opportunities for companies with solutions to health security threats

TechWatch Meetings: Request a meeting with government experts to discuss your technology and potential partnerships

BARDA Industry Day 2023: Join us in Washington, DC on November 13-14, 2023, to engage and network with BARDA

Visit medicalcountermeasures.gov to learn more

EZ-BAA: Funding opportunities for awards up to $750K and + Phase awards up to $20M

BARDA Ventures: Equity Investment in health security medical countermeasures.

BLUE KNIGHT: Incubation and residency opportunities at select J&J JLABS locations

BARDA Accelerator Network: Wrap-around acceleration and business support for health security innovators

Visit www.drive.hhs.gov to learn more

Newrotex

Silk conduit with luminal fibres - the first off-the-shelf device to effectively treat nerve injury

Oxford | newrotex.com

Peripheral Nerve Injury (PNI) refers to damage or crushing of nerves outside of the brain or spinal cord, caused by trauma, surgery or cancer. The gold standard treatment is an "autograft", a complex, lengthy and harmful procedure that sacrifices another nerve from the patient to act as a donor. These have high complication rates and only offer limited successful recovery, leaving a significant unmet need.

Newrotex is introducing a new treatment approach for all PNI patients – improving clinical outcomes, lowering costs, expanding the number of patients who can be treated & removing the need for harmful autograft surgery.

Newrotex's unique nerve repair technology harnesses the incredible regenerative properties of silk. It comprises a simple luminal silk technology (Silk AxonsTM) which works as a scaffold to guide nerve regeneration and the Oxford Nerve ConduitTM a silk sheath which has excellent handling and mechanical properties. These properties of silk enable Newrotex to offer a true "off-the-shelf" device, available over large gaps, which is simple to implant and easily stored/transported.

This silk technology has recorded promising results in pre-clinical trials by exhibiting excellent motor recovery in larger gaps than any device on the market; and collaborators in the EU have demonstrated the safety and efficacy of silk in humans.

We have recently received a large non-dilutive grant (€2.5M) and are seeking a tranched funding round to support this and allow us to complete First-in-Human studies and achieve FDA clearance.

Dr Alex Woods MD
CEO

Andrew Elphick
MBA
CCO

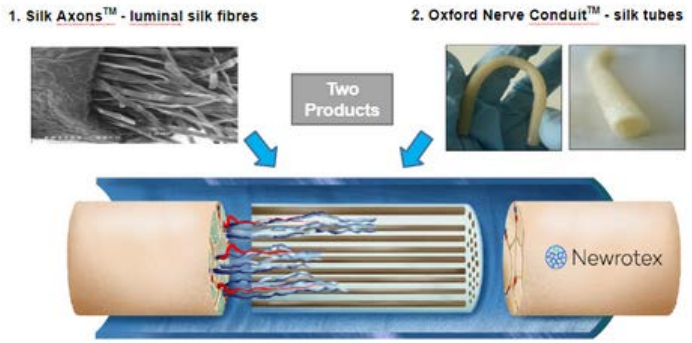
Dr Robyn Plowright
CSO

Jessica Howells
Research Scientist

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: 510(k) - Had FDA Pre-Submission Meeting

SEEKING: Seed/Series A - Tranched $5MM Raise



Nininger Medical

1.6M urgently needed tricuspid replacements will be enabled by Nininger Medical's thin film valve

Houston, TX | niningermed.com

Nininger Medical's life-saving technology will fix leaky heart valves for the 1.6M patients in the US alone who desperately need treatment for life-threatening tricuspid regurgitation (TR, or backwards flow through the tricsupid valve). There is no good medical, surgical, or transcatheter therapy available for these patients. Failing tricuspid valves will be replaced using Nininger thin-film technology 10x thinner than the material currently used in most heart valve devices. This will allow a smaller delivery catheter, allowing use in even the most challenging anatomy, and providing increased durability and significantly reduced manufacturing cost compared to pericardial tissue valves. Nininger has successfully prototyped a valve using this technology and is raising a pre-seed round to advance from proof-of-concept to pre-clinical studies. Nininger recently completed work under a SBIR Phase I grant of $256k from the NSF and have submitted our Phase II application, which would include $1M in funding over the next 2 yrs if awarded. Currently a resident company in the Center for Device Innovation @ Texas Medical Center in Houston, we were also selected for the 2021 cohort at Endless Frontier Labs, a program of NYU's Stern School of Business, and chosen as a finalist for the 2021 pitch contest at Innovation in Cardiovascular Interventions, Israel's main cardiovascular conference.

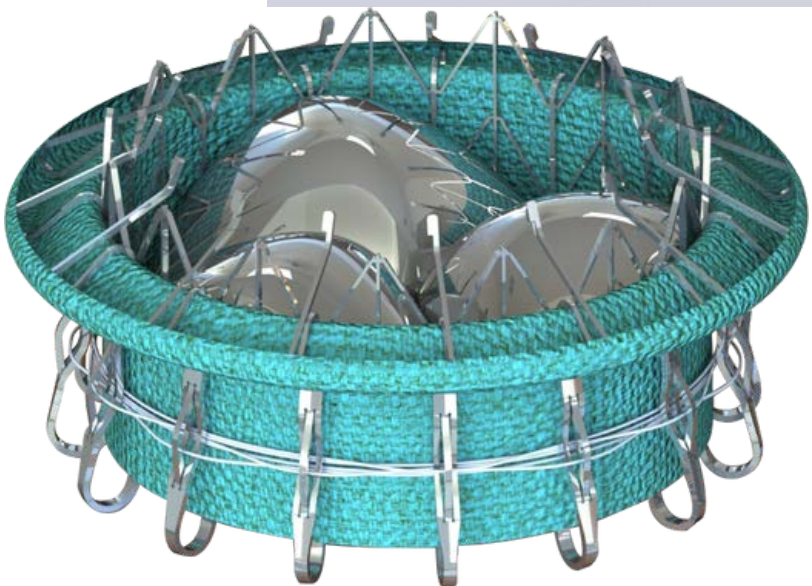
Daniel Anderson
Founder / *CEO*

Andrew Schombs
COO

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: PMA - Not Started

SEEKING: $4MM Series Seed



NxGenPort

NXgenPort is a combination medical device and software company harnessing the power of machine learning and remote patient monitoring to transform the way physicians manage cancer patients over the course of their treatments

Saint Paul, MN | nxgenport.com

NXgenPort is addressing an unmet need in cancer care by remotely managing patients between chemotherapy treatments with a Software as a Medical Device (SaMD) and an implanted Smart Port with intravascular cytometry sensors. By using machine learning to measure changes in blood cell counts, vitals, and heart function in vivo, NXgenPort will alert physicians to early signs of infection, determine a patient's readiness for next treatment, and improve health equity and access. With the acceleration of Hospital at Home, care providers, cancer researchers, and pharma stakeholders find value in monitoring a patient's biological response to interventions with a robust data package to improve outcomes.

DEVELOPMENT STAGE: Prototype: Pre-clinical

REGULATORY STRATEGY: 510(k) Strategy - Pre-sub to the FDA in Q1:2024

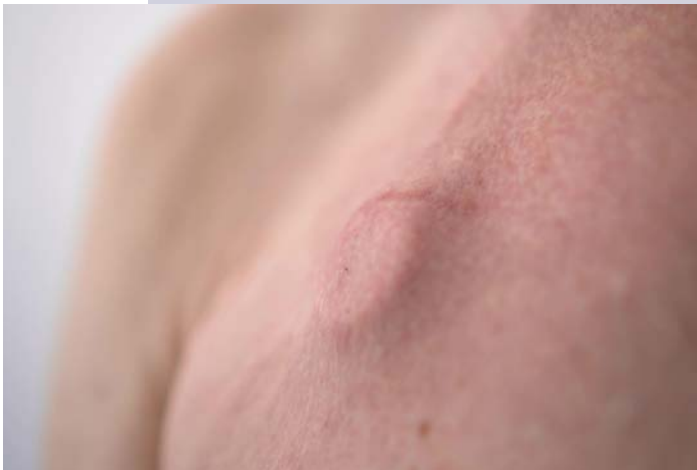
SEEKING: $2MM Series Seed

Cathy Skinner
CEO

Dr. Rosanne Welcher
COO

Kelly Christian
VP R&D & Engineering

John Slump
Board Chair



Opticyte

By accurately measuring oxygen supply in arteries down to organs, the VitalO2™ will save lives by allowing clinicians to immediately recognize organ dysfunction and initiate earlier treatment, thereby avoiding vital organ failure in patients across all races and skin tones

Seattle, WA | opticyte.com

Opticyte has developed a noninvasive medical device to address one of healthcare's most compelling unmet needs, the early detection and treatment of organ failure. An accurate, full picture of systemic oxygenation from oxygen supply in arteries to oxygen delivered by the microcirculation to vital organs is essential and does not exist today. Early detection of organ dysfunction and treatment to avoid organ failure will reduce hospital costs and save lives. The VitalO2™ is the only device that detects systemic oxygen deficiency by simultaneously and noninvasively measuring 1) arterial O2 supply with new, accurate pulse oximetry that is immune to the influences of skin tone, and 2) oxygenation inside cells provided by the microvasculature (Cell O2). The two measurements provide a complete picture of how O2 is supplied and delivered to organ cells. Sustained, low cellular oxygen in vital organs can result in organ damage, failure, and death.

Opticyte has performed initial clinical research studies that support the utility of the VitalO2™ in sepsis, cardiac surgery, and trauma. Based on clinical research data, the Company is developing an AI system to predict sepsis and identify organ dysfunction early using data from the electronic medical record and most importantly, Cell O2, as inputs. Having the only device that measures oxygen supply in arteries down to organ cells in people of all skin tones, clinicians will be able to improve management of patients to reduce organ failure. Beginning with a limited commercial launch, the VitalO2™ will be placed in selected hospitals to prove the value proposition and demonstrate revenue traction.

Lori Arakaki
CEO

Robert Barry
Board Chair

David Ataide
Director

Stefan Kraemer
Director

DEVELOPMENT STAGE: Prototype: clinical & Product: pre-approval

REGULATORY STRATEGY: De Novo - Had FDA Pre-Submission Meeting

SEEKING: $4.5MM Series Seed

AliraHealth

Trusted Advisor and Clinical Development Partner for MedTech Companies Globally

info@alirahealth.com | www.alirahealth.com | Alira Health | Alira Health

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cambridge consultants
Part of Capgemini Invent

PanTher Therapeutics

Clinical stage oncology company leveraging minimally invasive procedure to provide localized, sustained, clinically validated, treatment directly at tumor site

Austin, TX/Watertown, MA | panthertx.com

PanTher Therapeutics is a clinical-stage oncology company revolutionizing cancer care by harnessing sustained treatments engineered for localized applications. While there have been tremendous advances in cancer treatment, critical challenges remain including the ability of drugs to successfully reach tumors, short half-life and therefore short duration of action, and low retention at the tumor site. PanTher has reimagined cancer therapies to tackle these long-standing challenges in order to successfully treat the deadliest cancers. By harnessing interventional oncology and directly administering therapy to tumors, we have the ability to bypass the circulatory system, enabling maximal locoregional accumulation, bringing the fight against cancer precisely to the target. Through our proprietary treatment platform, Sagittari™, we engineer solutions that supplement current standard of care, empowering oncologists to better treat cancer patients by unlocking a drug's full potential and applying drug where it is needed, and not where it isn't. Our innovative Sagittari™ platform enables us to engineer optimized therapeutic solutions to address the specific challenges dictated by tumor type, location, and ideal therapeutic regimen. Our lead candidate, PTM-101, is a minimally invasive, implantable treatment for pancreatic cancer that provides direct, sustained release of the therapeutic agent at the tumor site. PTM-101 is placed directly in the peritumoral area at the time of staging, utilizing a standard laparoscopic procedure, enabling initiation of neoadjuvant treatment as early as possible in a disease with high mortality rates. PTM-101 is currently being evaluated in a Phase 1 clinical trial as neoadjuvant therapy for localized non-metastatic pancreatic cancer.

Laura Indolfi
Co-Founder/CEO

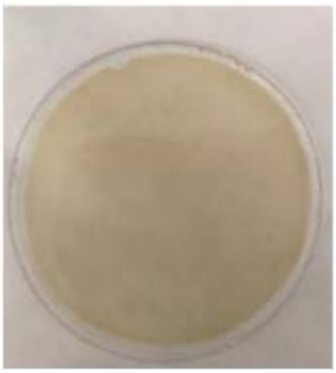
Leslie S. Sloan
SVP Development and Operations

Dan Wildman
Strategic Advisor & Board Director

DEVELOPMENT STAGE: Clinical

REGULATORY STRATEGY: Combination Product (CDER) - Preparing Submission

SEEKING: Series B, amount not disclosed



PERCEPTIVE MEDICAL

BAROHAWK

The BaroHawk System is a critical care device for elimination of preventable hypotension

Newport Beach, CA | perceptivemedical.com

Mortality during the 30 days after surgery is the third-leading cause of death in the United States, with the largest attributable factor being myocardial injury. The only modifiable factor associated with perioperative myocardial injury is hypotension (low blood pressure). The standard of care to definitively manage hypotension is to start an infusion of a 'vasopressor' medication to raise blood pressure. This infusion is currently hand-adjusted by an anesthesia provider (in the operating room) or bedside nurse (in the intensive care unit). Data shows patients still experience significant low blood pressure time when managed this way. We are completely upending this paradigm by automating these infusion adjustments using the BaroHawk System's patented "continuous micro-titration". Our clinical studies have shown we can move patients from 60% time in target to >95% time in target, virtually eliminating hypotension. There is a critical need for this novel approach to management of vasopressors in these environments; otherwise, evidence has shown that no amount of directed education or attention to this problem will significantly change current performance and patients will continue to suffer preventable morbidity and mortality as a result.

Joseph Rinehart MD
CEO

Doug Patton
Chief of Design

Morgan McKeown
Chief of Strategic Marketing

Maxime Cannesson MD, PhD
Medical Officer

DEVELOPMENT STAGE: Pre-approval

REGULATORY STRATEGY: PMA - Preparing Submission

SEEKING: $8MM Series A

Control Panel & Fluid Pump (reusable capital) +Advanced Monitoring

Sterile Tubing Cartridge (disposable; 1 per patient)

PLIO SURGICAL

An Innovative Implant for the Creation of an Intestinal Anastomosis

Dublin, Ireland | pliosurgical.com

Leakage at the site of an anastomosis is a highly critical complication that often arises following bowel resection surgery. This condition puts patients at a significant risk of developing sepsis, necessitating a re-operation or the creation of a stoma. As a consequence, patients experience a significant decline in their quality of life, clinical outcomes are compromised, and healthcare systems bear the burden of increased costs.

Plio Surgical's innovative device is specifically designed to reduce the risk of leakage and simplify the anastomosis procedure in a minimally invasive surgery.

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: 510(k) - Not Started

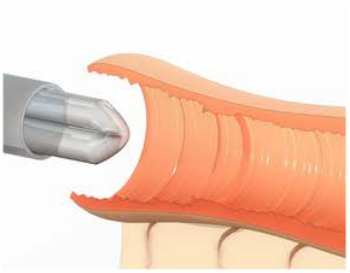
SEEKING: $6.5MM Series Seed

Cristina Purtill
CEO

Gareth Gallagher
CTO

Dr. Bruce Murphy
CSO

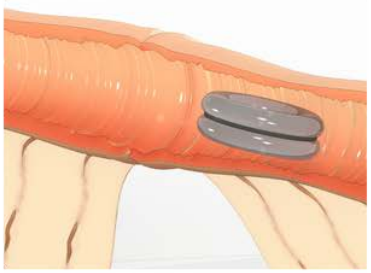
Stephen Johnson B
Design Manager



1. **Fully Laparoscopic**: memory shape rings are easy to deploy and create an intracorporeal anastomosis

2. **Wide applications**: the implant can be used in the upper and lower GI tract in a variety of configurations

3. **No sutures or staples at anastomosis site**: implant anchors inside the intestine with specially designed tissue barbs



4. **Nothing left behind**: once healing occurs, the implant detaches and passes naturally leaving no foreign body behind

The future of early intervention in lung cancer

Houston, TX | pranathoracic.com

Houston-based medical device startup Prana Thoracic, Inc. is dedicated to developing solutions for early intervention in lung cancer. We are an experienced team of surgeons, engineers and entrepreneurs on a mission to tackle lung cancer; the #1 cancer killer in the US.

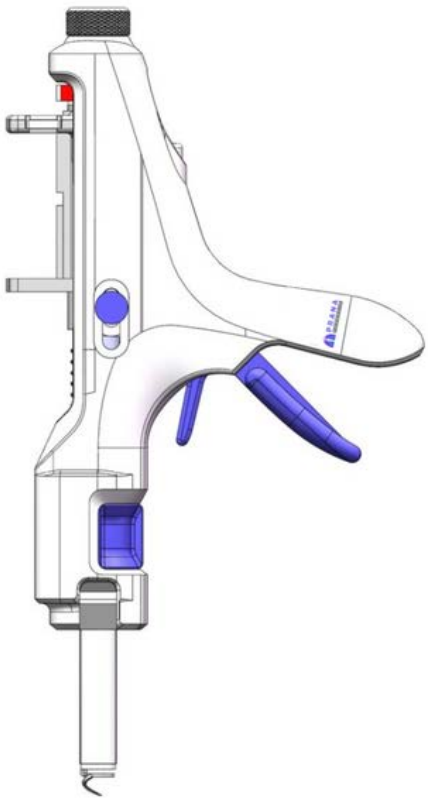
The paradigm of screening, detection, and early intervention that has been deployed in other major cancers has so far eluded lung cancer. As a result, only 16% of lung cancers are found at an early stage and the current 5-year survival rate is < 20%. Recent changes to lung cancer screening guidelines have illuminated a path to improving outcomes in lung cancer. However, these advances rely on excising suspicious nodules and providing sufficient tissue for definitive diagnosis. We believe this is the missing piece of the puzzle, and physicians need a new generation of surgical oncology tools for lung cancer.

Prana Thoracic plans to revolutionize the early diagnosis and treatment of lung cancer by making it easier and less invasive to deal with the rapidly growing number of early suspicious lung nodules; ensuring that we do not miss the window of opportunity to intervene early.

Joanna Nathan
CEO

Ken Bueche
COO

Carolyne Lu
Director of Clinical & Regulatory Strategy



DEVELOPMENT STAGE: Prototype: pre-clinical

REGULATORY STRATEGY: De Novo - Had FDA Pre-Submission Meeting

SEEKING: $20MM Series B

ProtonIntel

Transforming Hyperkalemia Management in CKD & Heart Failure with Continuous Potassium Monitoring

BC, Canada | protonintel.com

ProtonPetal CKM One is the only continuous potassium monitor (CKM) that can keep patients from crashing into dialysis. Nothing else brings together direct, accurate, real-time, monitoring of potassium, the marker that guides our heartbeat, in a way that is clinically actionable. Clinicians need CKM to get their pre-dialysis kidney patients up to guideline directed doses of kidney protecting therapies; patients need CKM to optimize their diet and lifestyle to stay in a healthy potassium range. It's also the only product capable of intercepting the sudden shifts in potassium that lead to dangerous arrhythmias and sudden cardiac death, which is the leading cause of death in CKD patients.

Like continuous glucose monitors (CGMs) for diabetes, the ProtonPetal CKM One is a wearable sensor to continuously and accurately measure potassium (K+) in the interstitial fluid of the skin for kidney care patients. The data from our sensor can be monitored by clinicians and patients, as needed, to take actions that personalize treatment and keep them safe – out of dialysis, out of the hospital. Although blood potassium concentration critically informs therapy decisions for over 10 classes of therapies, the only method of measurement available today is the venous blood draw. Our novel continuous data stream will allow for more timely, precise and personalized therapeutic decision making, ultimately reducing the risk of hyper- and hypokalemia, resulting in fewer emergency department visits, less hospitalization, and fewer deaths.

Sahan Ranamukhaarachchi
CEO & Co-Founder

Dr. Victor Cadarso
CSO & Co-Founder

Rory St Clair
Director of Product

Dr. Esma Dervisevic
Senior Scientist

DEVELOPMENT STAGE: Prototype: Pre-clinical

REGULATORY STRATEGY: De Novo - Had FDA Pre-Submission Meeting

SEEKING: $10M Seed

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Pumpinheart

A transcatheter-implantable heart pump treating advanced stage Diastolic Heart Failure

Ireland | pumpinheart.com

Advanced Stage Heart Failure patients present as breathless even at rest because their hearts fail to pump blood around the body effectively. Over two million people in the USA, Canada, UK and Europe are affected by advanced stage Diastolic Heart Failure also known as Heart Failure with preserved Ejection Fraction or HFpEF the dominant type of Heart Failure and a growing public health problem. In these patients, heart walls are stiff due to age and chronic hypertension as a result of obesity, diabetes and other health problems. These patients face a very grim and terminal prognosis.

HFpEF is associated with high in-hospital, short-term, and long-term mortality rates. 5-year-survival among patients with HFpEF is 35% – 45% after hospitalization. There are no available effective treatments. Neither drugs nor devices reduce morbidity or mortality.

Pumpinheart's medical device addresses the core problem of elevated cardiac pressures. Pumpinheart's device is a tiny pump, the size of a triple A battery, implanted in the Left Ventricle in a cath lab. The pump draws just enough blood from the left atrium into the left ventricle during the resting phase of each cardiac cycle to relieve the elevated pressure in the left atrium and ease congestion. This device would allow advanced stage HFpEF patients to survive this dreadful disease, breathe freely and return home to lead active and fulfilling lives.

The primary therapeutic benefit is a reduction of Left Atrial (LA) pressure by 3mmHg to 5mmHg during diastole. Pumpinheat's system includes an implanted ECG-gated pump with a mechanism of action to reduce LA pressure during diastole; a transcatheter delivery system to deploy implant (minimally invasive); a subdermal power and control unit and; a wireless power system (Transcutaneous Energy Transfer System).

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: PMA - Not Started

SEEKING: Euro $4.2MM (US $4.8MM) Series Seed at a pre-money valuation of Euro $3.5MM

Donald Hickey
CEO

Darragh Colgan
CTO

Andrew Malone
CSO

Aamir Hameed
CMO

Purgo Scientific

Purgo Scientific has developed a refillable, local drug delivery device called Purgo Pouch that sustains high dose antibiotic therapy where it is needed most—in an injury site

South Jordan, UT | purgoscientific.com

Each year, roughly 111,000 patients in the US suffer a bone fracture. When these fractures are open, meaning the bone protrudes through the skin, the risk of infection goes up exponentially. This is because open fractures are at increased risk of contamination by bacterial biofilms. Biofilms are communities of bacteria, which are very challenging to kill using current antibiotic therapies.

About half of the patients who suffer an open fracture get infected. The outcome causes prolonged pain and costs healthcare systems over $1 billion dollars a year in treatment, including hospital re-admittance. Surgeons are so desperate for a solution to this problem, they have resorted to sprinkling antibiotic powders directly into wound sites, or loading antibiotics into bone cements/void fillers to deliver antibiotics locally. Yet rates of infection remain essentially unchanged. Importantly, current approaches are used off-label.

Our team is developing a uniquely engineered de novo drug delivery device to address these problems. The device, called Purgo Pouch, sustains local, high dose antibiotic therapy where it's needed most—in an injury site. In sheep tests (Purgo Pouch has been tested in over 65 sheep to date and compared to another 80 sheep as clinical comparators), Purgo Pouch is up to 1,000x more effective at killing bacterial biofilms and managing traumatic injury site infection compared to current clinical standards. These outcomes, combined with solid theoretical basis, strongly support that this patent-protected platform technology has significant potential to improve on a decades-long gap in healthcare and provide better quality of life to hundreds of thousands of patients.

DEVELOPMENT STAGE: Pre-clinical

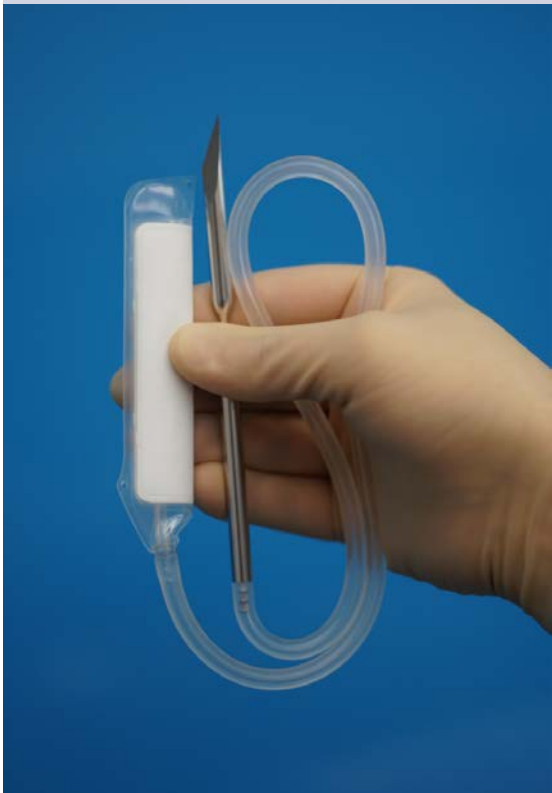
REGULATORY STRATEGY: De Novo - 1st Pre-Submission Meeting Completed Q4, 2022
Breakthrough - 2nd Pre-Submission Completed Q3, 2023

SEEKING: $2MM Series A.3

Michael Benjamin
CEO

Dustin Williams, PhD
Chief Science Officer

Nicholas Ashton, PhD
VP Technology Development



RENOVITE® - injectable carrier providing unprecedented retention of biologics for tissue repair

United Kingdom | renovos.co.uk

Renovos is pioneering the use of synthetic nanoclays as a technology platform for therapeutics delivery in regenerative medicine. Nanoclays are industrial ingredients and Renovos has refined and validated RENOVITE® gels for medical use, for better tissue formation exactly where needed. Renovos' innovation is an easy-to-handle, injectable and biodegradable RENOVITE® nanoclay gel that spontaneously sets into a stable gel in the body by interlocking with proteins present in blood. As well as providing a local environment that promotes cellular ingrowth, our first RENOVITE® product is designed to deliver the well-known and well-tested bone inducing agent, BMP2, to template bone formation by invading cells: increasing precision, safety and performance characteristics, in a minimally-invasive application.

RENOVITE® binds BMP2 providing localised and unprecedented retention. This differentiated mechanism of action allows for significant dose reduction, lower COGS and improved safety and efficacy of potent and costly biologics, expanding their use case and overcoming geographic limitations due to reimbursement, addressing a growing $5.7bn orthobiologics market.

Renovos has granted patents, established manufacturing process and a strong scientific and commercial team. We are now raising funding to complete pre-clinical development and enable clinical trials.

Agnieszka Janeczek
CEO

James Otter
Chair

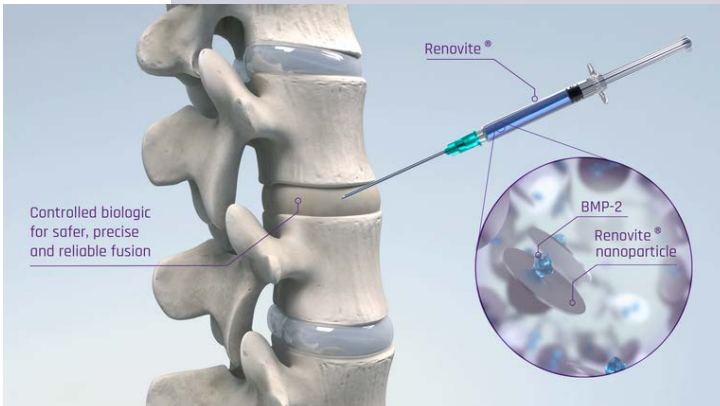
Richard Oreffo
CSO

Jon Dawson
CTO

DEVELOPMENT STAGE: Prototype: Pre-clinical

REGULATORY STRATEGY: PMA – Awaiting FDA Pre-Submission meeting

SEEKING: $3.2MM Series A



SafeGuard Surgical

LeakGuard is a patented, biodegradable stent that acts as a barrier against leaks from colorectal surgery - addressing a costly & deadly problem that surgeons, patients and payers face everyday. Our single surgery biodegradable solution is scalable across most surgeries: making our proprietary technology a platform, not just a product.

Nantucket, MA | safeguardsurgical.com

Colorectal cancer is a global epidemic. The number of adults under the age of 55 diagnosed with Colorectal cancer has doubled over the past decade for unclear reasons. Surgical leaks are one of the most common complications from surgery- resulting in increased length of stay, cost, cancer recurrence, morbidity and mortality. Apart from a colostomy bag, which is associated with a number of complications, requires another operation to remove it and a has a profound negative impact on quality of life, there is currently no FDA-approved method to protect patients from surgical leaks.

SafeGuard Surgical has developed and patented a biodegradable stent placed at the time of surgery to act as a barrier against surgical leaks- eliminating the need for costly and complicated colostomy bags. LeakGuard is the only biodegradable solution that does not require removal or a second procedure, creating cost savings for the healthcare system and improving the quality of life for millions of patients.

With colon resections now becoming one of the largest surgical markets, it is anticipated to overtake total knees in volume by 2026. The next raise for a 10M Series A will be used to: Build out the Executive team, finalize bench top and animal testing, complete product development (design freeze), complete a 'First in Man Study' and obtain FDA 510k (De Novo) clearance.

With LeakGuard being the ONLY single surgery biodegradable solution in the colon -and scalable to other areas of the body, it solves a costly problem that surgeons, hospitals, patients and payers face everyday.

Competitive Advantage:
*Huge TAM
*Double digit CAGR
*Addresses health inequities
*Saves lives (and money)
*Eco-friendly biotechnology
*Biodegradable therefore does not need to be removed
*Scalable and Versatile for other surgeries

SafeGuard Surgical's biodegradable and scalable technology is not just a product- it is a platform.

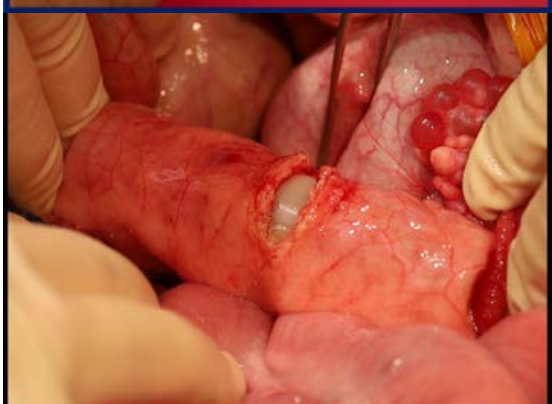
DEVELOPMENT STAGE: Prototype: Developed & Animal Tested

REGULATORY STRATEGY: 510k De Novo - Had FDA Pre-Submission Meeting

SEEKING: $10MM Series A

Dr. Scott Kelley
CEO & Co-Founder

Jill Kelley
Co-Founder



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At Proxima, we champion the future of healthcare by partnering with the next generation of pioneers in drug development, diagnostics, devices, and digital therapeutics.

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Why Proxima:

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our mission

From the factory to the operating room, it is our daily mission to deliver life-saving products. Our packaging is designed to the industry's highest levels of quality and care, so that our customers can deliver longer healthier lives.

Medical device | Pharma | Di agnos t i cs

SAVAGE MEDICAL

Savage Medical is developing a diverting sleeve anchored in the colon after surgery, eliminating the need for temporary ostomies and their associated costs, complications and quality of life impacts

Fremont, CA | savagemed.com

Savage Medical has developed ColoSeal, an innovative solution aimed at eliminating the need for temporary ostomies. Ostomies are performed for various reasons, including for our $2 billion worldwide beachhead market in protecting anastomosis sites following rectal cancer resection. These ostomies guard the healing site from stool contact and are intended to be temporary, typically being reversed after 3-6 months. However, the creation and subsequent reversal of these ostomies constitute major surgical procedures, leading to notable complications, increased costs, extended hospitalizations, and considerable patient dissatisfaction. In a significant proportion of cases, they remain unreversed, compelling patients to live with this condition indefinitely.

As an alternative to this resource-intensive and life-altering practice, ColoSeal offers an effective means of protecting the anastomosis site during the healing process. This system comprises a flexible sheath anchored with a proprietary negative pressure system upstream of the anastomosis. The device is inserted and removed non-invasively, with the sheath aligned with the bowel and exiting through the patient's anus into a collection bag. The sheath facilitates the flow of bowel contents while ensuring the anastomosis is shielded from exposure to colon contents. The device remains in place for approximately 8-12 days until the anastomosis has adequately healed, thereby obviating the need for an ostomy. This development offers patients a less burdensome and more straightforward recovery process. ColoSeal reduces the need for major surgeries and long-term complications associated with traditional ostomies, providing enormous health economics benefits while improving the patient experience.

Kenton Daodyan Fong
Founder/CEO

Dean Hu
COO

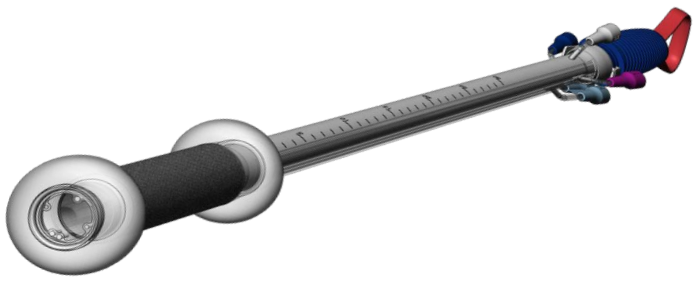
Jeffrey Etter
Co-Founder/VP Engineering

Grace Carlson
VP Regulatory & Clinical

DEVELOPMENT STAGE: Clinical

REGULATORY STRATEGY: PMA - Not Started

SEEKING: $10MM+ Series A



Senseye

Senseye is the first Standalone Diagnostic Device for Mental Health, starting with PTSD, MDD and GAD

Austin, TX | senseye.co

Senseye is a breakthrough diagnostic platform for mental health. We help clinicians personalize care with fast, accurate tools to establish a clear baseline and track long-term outcomes. To start, Senseye can identify PTSD in as little as 10 minutes. Traditional tests take up to 3 hours to complete, in addition to the weeks, months, and sometimes years spent waiting for an appointment in the first place. Our brain-based methodology makes diagnosis a truly objective process for the first time. We do not rely on self-reports or patient-reported outcomes. Instead, with smartphone cameras, we look for disruptions in the sympathetic nervous system through the eyes. Clinicians can also use Senseye longitudinally to understand patient adherence, assess treatment efficacy, and optimize titration. Our unique approaches to both deep learning and signal extraction are fully patented, and we continue investigating aggressively in Research and Development. Our pipeline includes diagnostics for anxiety, depression, and addiction. Senseye can run on most smartphones from any location — including a telehealth setting. No specialized equipment or upfront capital investment is needed.

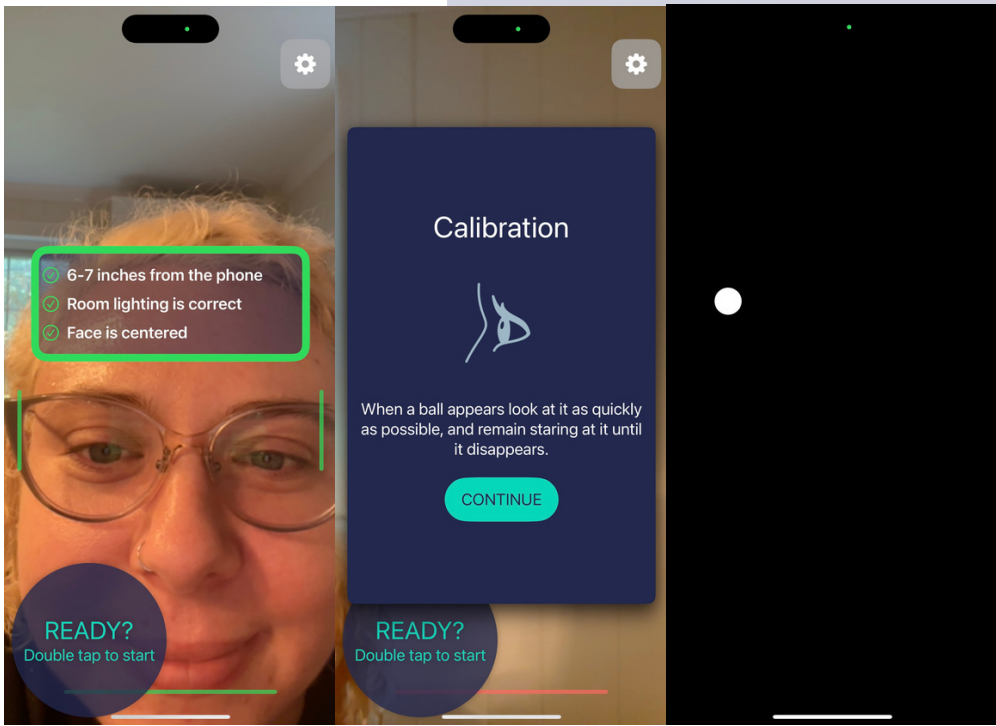
David Zakariaie
CEO & Founder

DEVELOPMENT STAGE: Clinical - Revenue Generating

REGULATORY STRATEGY:

De Novo - Had FDA Pre-Submission Meeting

SEEKING: $10.0MM Series A



sentante

Teleoperated endovascular robot system with haptic feedback

Lithuania | sentante.com

Robotic system for endovascular interventions Sentante - a smart, sensory, teleoperated robot system which allows an entire procedure to be performed remotely, from a different room, or even different hospital. It opens up tele-surgery possibilities thus saving time for urgent patients and improving access to care even in remote regions. Intuitively controlled, compatible with the conventional endovascular devices system senses operators' movements and provides close to natural haptic force feedback. While working remotely, physicians can feel the catheter and guidewire resistance in real time just as if they were standing near the patient. Tele-operated robotic system eliminates X-ray radiation for medical personnel and provides new functionalities enabled by robotic technology – extreme precision, motion scaling, enhanced instrument control, superior X-ray visualisation etc.

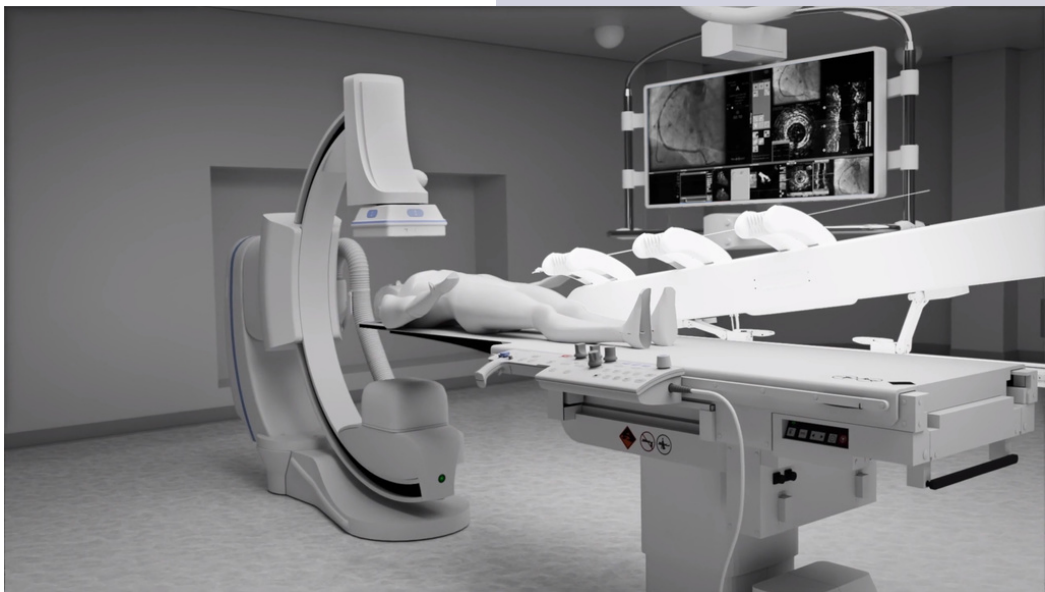
Edvardas Satkauskas
Co-Founder/CEO

Dr. Tomas Baltrunas
Co-Founder/CMO

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: 510(k) - Scheduled FDA Pre-Submission Meeting

SEEKING: $40MM Series A



SONAVI LABS

Sonavi Labs is a medical device and software company that harnesses the power of artificial intelligence to transform the way we detect, diagnose and manage respiratory diseases with Feelix® , our remote monitoring, chronic respiratory management system

Baltimore, MD | sonavilabs.com

Currently, there are no tools available that can objectively analyze respiratory abnormalities in real-time without the presence of a trained clinical provider. Developed by the world's leading acousticians, signal processing experts and mechanical engineers at Johns Hopkins University, Sonavi Labs was formed to deploy Feelix, the only FDA cleared, HIPAA compliant, user-friendly, Bluetooth enabled, remote monitoring platform embedded with state-of-the-art patented technology that uses clinically validated diagnostic software capable of detecting respiratory diseases and tracking longitudinal trends. The Feelix system is intended to enhance remote monitoring programs and ensure care teams have the most objective clinical data to triage, treat and monitor patients. Sonavi Labs aims to tackle the $65 billion market by ensuring broad access for all respiratory patients in need and offers the Feelix remote monitoring platform through a reimbursable Software as a Service (SaaS) model.

There are opportunities for Sonavi Labs in device sales, cloud-based services, and advanced analytics and integration of audio files into electronic health records. The defensibility and protection of the technology through the 9 patents awarded to the company, ensure Sonavi's exclusive ability to capture significant market share and be regarded as leaders in the space.

Ellington West
CEO

Dr. Eric McCollum -
CMO

Eric Solender
Director of Software

Cordellia Sawyer
Project Manager-Clinical Trials

Sandra Diaz
Director of Business Development

DEVELOPMENT STAGE: Product: Approved with beta paying customers

REGULATORY STRATEGY: 510(k) - FDA Approved

SEEKING: $3MM Seed+

Sparta Biomedical™

A revolutionary cartilage repair device that immediately restores mobility, while reducing pain in patients with knee osteoarthritis

Morrisville, NC | spartabiomedical.com

Knee osteoarthritis (OA) affects 651M people globally. OA must be addressed as it leads to lower quality of life, obesity (due to immobility), and a significant economic burden to individuals and payers. Sparta has developed a first-of-its-kind technology, Galene, to repair damaged cartilage. Our first indication is to treat chondral (cartilage) and osteochondral (bone-cartilage) defects in the knee. And over time we plan to leverage Galene across other devices to treat joints in which OA is common. Most in medtech trying to solve this problem are pursuing cartilage regeneration approaches. While this has merit, new cartilage takes a long time to grow and is not nearly as strong as the original. There have been many clinical failures and suboptimal results with such technologies over the last several years. Surgeons and insurers are determined to reduce the higher morbidity and mortality risk caused by knee osteoarthritis. And patients want to go about their day unencumbered. That includes moving without pain. The answer to the biological problem was born out of applying chemistry and materials science. Our Ormi knee implant contains Galene, which mimics the properties of healthy human hyaline cartilage day 1, directly addressing what our customers want. Ormi was granted Breakthrough Device Designation.

Dushyanth Surakanti
Co-Founder & CEO

Ben Wiley
CTO

Demetri Siachames
Head of Engineering

Dimitrios Angelis
Co-Founder and President

DEVELOPMENT STAGE: Prototype: Clinical

REGULATORY STRATEGY: PMA Pathway - Filing the IDE Winter 2023

SEEKING: Raised an oversubscribed convertible round

Revolutionizing Stroke Care with Point-of-Care Neuroimaging Devices

Pasadena, CA | stroke-dx.com

Stroke is a global health crisis, with millions affected annually and high mortality rates. The current approach to stroke care leads to delays, increased costs, and limited patient outcomes. StrokeDx offers a revolutionary solution.

StrokeDx's patented technology, validated in an NIH-funded clinical study, provides a low-cost, portable, non-invasive imaging modality. Our handheld and bedside devices offer rapid stroke assessment and monitoring, enhancing the efficiency of stroke care.

Currently, Neurocritical Care floors in America spend billions on redundant procedures. StrokeDx's point-of-care imaging solution aims to streamline these processes, translating into significant cost savings for healthcare facilities. Our initial device, developed at an astonishingly low cost of $80, has already demonstrated its ability to provide critical information within minutes (Published in *Nature's Scientific Reports*).

Our reusable device, coupled with per-patient disposable and annual software updates, ensures robust profit margins and stable recurring revenue.

Our success story is rooted in transformative technology, cost-efficiency, and a targeted approach to solving pressing challenges within stroke care. We invite you to join us on this exciting journey as we reshape the future of neurological care and generate substantial returns.

Alexander Ballatori
CEO

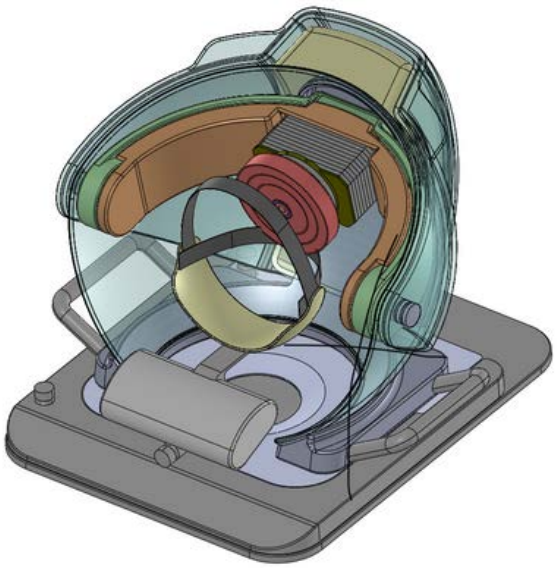
Shane Shahrestani
COO

Brian Nguyen
CTO

DEVELOPMENT STAGE: Product: Pre-Approval

REGULATORY STRATEGY: 510(k) - Had FDA Pre-Submission Meeting

SEEKING: $1.2MM Series Seed



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Questions? We're here to help.
Contact Hayden Smith: hsmith@figure.com for details.

	FIGURE EQUITY SOLUTIONS	Carta Starter	Pulley Startup
Employee equity plans	✓	✓	✓
Electronic certificates and signatures	✓	✓	✓
Equity, convertible notes, SAFEs, and warrant issuances	✓	✓	✓
Electronic option exercise and money movement	✓	✓	✗
Form 3921 generation and distribution	✓	✓	✗
Annual 409A valuation	✓	✓	✗
Native connection to Marketplace for capital raising	✓	✗	✗
Next round scenario modeling	✓	✗	✓
ASC 718 stock based compensation expense accounting	✓	✗	✗
Rule 701 document distribution	✓	✗	✗
83(B) elections	✓	✓	✗
White glove onboarding with fast setup	✓	✗	✗

THERMIDAS

Detecting Preventable Diabetic Foot Ulcers

Finland | thermidas.fi

Studies have shown that 75% of diabetic foot ulcers (DFUs) are preventable with early detection, yet with over 35 million DFUs each year, every second of every day, someone on the planet is afflicted. DFUs cost the global healthcare systems over $150Bn in annual treatment costs. Studies also show that amputations and infection are the greatest fears in patients with diabetes related foot complications. Thermidas' goal is early detection of preventable DFUs enabling healthcare systems to minimize their impact. The International Working Group on the Diabetic Foot (IWGDF), in their newly published 2023 guidelines, now recommends daily foot temperature monitoring for high-risk patients.

Early detection using Thermidas' low-cost, cloud-based, AI-assisted remote monitoring solution will ease the burden on healthcare professionals. Further, only 48% of foot ulcers are plantar, and our solution covers ALL aspects of the foot. Reimbursement is assured for healthcare providers by four Remote Patient Monitoring (RPM) Codes, and Health economic analysis indicates that our solution will deliver savings in a ratio of 9:1 for the payers.

Thermidas thermal imaging solutions were developed for medical use in partnership with University Hospitals and prominent clinicians. Our diagnostic tools can identify and diagnose underlying pathology up to 10 days earlier than current pathways. First-in-human data is being evaluated from a Feasibility Study by the NHS. Patient friendly, non-invasive, non-contact, no exposure to radiation - our solution will revolutionise diabetic foot care.

Jouni Kyllönen
CEO, Thermidas Oy

Karo Kujanpää
CEO, Thermidas Inc.

Stephen Taylor
President, UK

DEVELOPMENT STAGE: Pre-approval

REGULATORY STRATEGY: De Novo - Preparing Submission

SEEKING: $2MM Bridge Funding

Total Flow MEDICAL

A heart-lung bypass femoral arterial cannula which saves patients limbs by providing dedicated blood flow to the leg

Vancouver, BC | totalflowmedical.com

Our products will eliminate injury and death caused by equipment used to keep patients alive when they need the use of a heart-lung machine. There are two use cases for our devices, for patients requiring life support (ECMO) and for heart surgery (cardiopulmonary bypass). Our first product is a cannula, for use in heart surgery. The problem we are solving is caused by the current standard of care. During heart lung bypass, cannula which transfer blood from inside the patient to the heart lung machine can interrupt blood flow in the patient's leg, leading to ischemic reperfusion injury and limb ischemia. The burden of cost of this problem is currently over a billion US dollars per year and surgeons cannot predict who will be affected, which means every one of the 100k US patients need a solution. The only rescue or preventive option for this problem in the US is a MacGyver-style fix where a pediatric catheter is inserted in the artery distal to the cannula and is spliced into the bypass circuit in order to provide the leg with dedicated blood flow. Our patented technology will replace the current standard of care, which is causing the issue. Designed by clinicians: it is easy to use and integrates within existing clinical workflow. It functions as a standard femoral cannula, while providing surgeons with the option of dedicated blood flow to the limb with the activation of our patented features.

Hillary Pierce
CEO

Martina Wan Lockwood
VP of Engineering

Marga Ortigas-Wedekind
Director

Dr. Anson Cheung
Medical Advisor

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: De Novo - Had FDA Pre-Submission Meeting

SEEKING: $8-10MM Series A

VELENTIUM

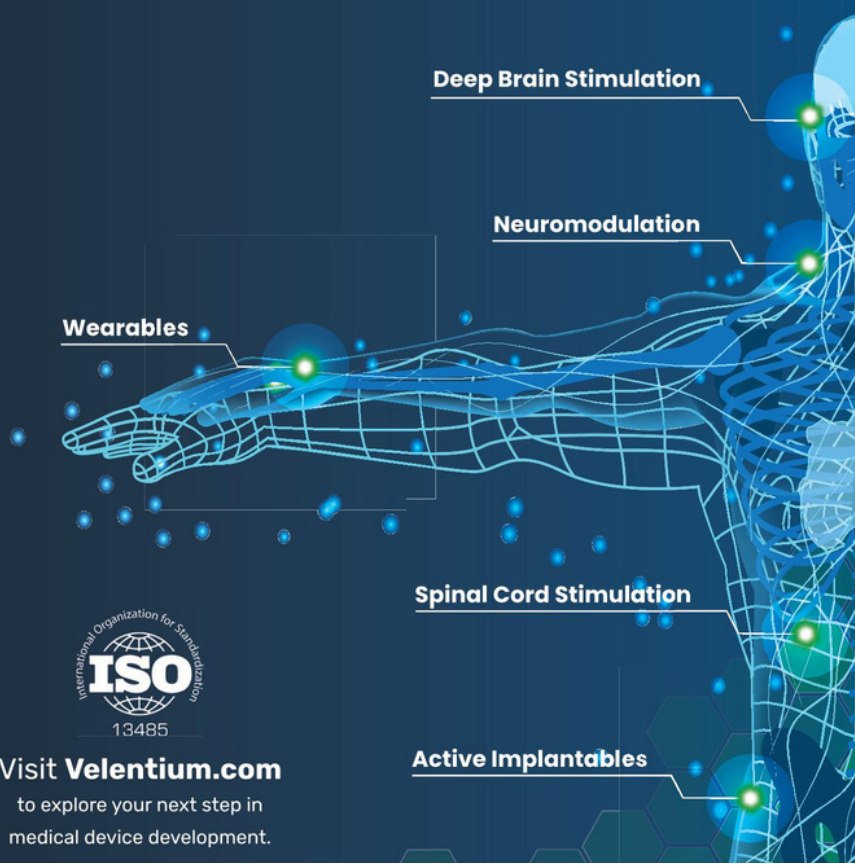
Velentium is a contract design and manufacturing firm specializing in the development, production, and postmarket support of diagnostic and therapeutic active medical devices, including implantables and wearables for neuromodulation and other Class III indications.

Velentium's **Core Competencies Include:**

- **Systems Engineering**
- **Electrical Design**
- **Firmware Development**
- **Mechanical Design**
- **Mobile App Development**
- **Embedded Cybersecurity**
- **HFE & Usability**
- **Automated Test Systems**
- **Contract Manufacturing**

Indications **Treated:**

- Chronic Pain
- Depression
- Epilepsy
- GERD
- Incontinence
- Memory Loss
- Migraine
- Opioid Withdrawal
- Paralysis
- Peripheral Pain
- Phantom pain
- Respiratory Care
- Sleep Apnea
- Stroke



International Organization for Standardization ISO 13485

Visit **Velentium.com** to explore your next step in medical device development.

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Breakthrough Device & STeP Applications
Regulatory Strategy
Regulatory Filing

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COMPLEX ELECTROMECHANICAL SYSTEMS
CAPITAL EQUIPMENT & DISPOSABLES

Class 1, 2, and 3 Medical Devices.
IVD + Laboratory Equipment

TRAVERA

Travera's Rapid Therapy Guidance test identifies personalized cancer therapies effective for each patient's unique cancer in two days

Medford, MA | travera.com

Clifford Reid
CEO

Travera has developed a new cancer therapy guidance test that predicts which cancer drugs are most likely to be effective for each individual cancer patient. It enables relapsed cancer patients who are running out of therapeutic options to discover additional options and continue their battle against their cancer. Travera's disruptive single-cell measurement technology measures the ex vivo response of a patient's live cancer cells to a broad range of cancer drugs. Its CLIA-certified Laboratory Developed Tests (LDTs) currently span virtually all cancers (breast, lung, colorectal, multiple myeloma, AML, etc.) and most cancer drugs (immunotherapies, targeted inhibitors, cytotoxics, etc.). The test has an unprecedented 2-day turnaround time. Travera was founded in 2018 to commercialize a breakthrough measurement technology, the Suspended Microchannel Resonator, invented at MIT. This unique technology has enabled Travera to overcome the problems that have prevented the many previous generations of therapy guidance tests from being effective in clinical practice. Travera has raised $13M of venture capital, with Khosla Ventures as the most recent investor, and commercially launched its Rapid Therapy Guidance Tests for a broad range of cancers and cancer drugs in 2022.

DEVELOPMENT STAGE: Approved

REGULATORY STRATEGY: PMA - Not Started

SEEKING: 15.0 Series B

At-home neurofeedback medical device for depression

San Francisco, CA | universal-brain.com

Universal Brain, founded by CEO Kazu Okuda, is a pioneering neuromodulation company committed to revolutionizing the treatment of depression with innovative, non-drug therapeutic solutions.

Our unique approach harnesses the power of personalization, non-invasiveness, and ease of use at home, addressing the urgent need for effective, comprehensive care for more than 21 million US adults who experience major depressive episodes annually.

Our groundbreaking technology combines hardware for detecting brain activity and software for neurofeedback training. This neurofeedback training, based on our proprietary algorithm that modulates brain activity using EEG, enables us to modulate the activity associated with depressive symptoms. We're conducting clinical research in partnership with top-level psychiatric hospitals, and our initial results with healthy participants are promising; we will start clinical research with depressive patients in 2023.

Unlike the invasive techniques of our competitors (ECT and TMS) or the limited efficacy of CBT-based digital therapeutic apps, our solution strikes an optimal balance. This approach is non-invasive, personalized, and backed by studies demonstrating its effectiveness in modulating the area associated with depressive symptoms.

We have prototyped our hardware and software, laying the groundwork for clinical studies. Our plan to obtain FDA clearance for our neurofeedback treatment by 2025 will open the door to two business models: a prescription plan and an OTC option, broadening access to our solution. Our diverse, experienced leadership team is composed of professionals with proven track records in AI medical devices, psychiatry, digital therapeutics, and MedTech entrepreneurship.

After raising more than $3M since we started last year, we're seeking an additional $8 million in Series A funding to propel our clinical trials in 2024 and drive our mission forward. Universal Brain embodies a new frontier in depression treatment, fusing innovative technology with compassionate, personalized care.

Kazutaka Okuda
CEO

Josh Sackman
Business development

Kern Bhugra
Research & Development

Greg Hajcak
Scientific Research

DEVELOPMENT STAGE: Prototype: Clinical l

REGULATORY STRATEGY: 510(k) - Scheduled FDA Pre-Submission Meeting

SEEKING: $8MM Series A

veinway

Venous Recanalization. Controlled. The first dedicated device for consistent, safe, and fast venous recanalization.

Israel | veinway.com

VeinWay has developed the first dedicated medical device for venous recanalization, purposely built to enable quick, reliable, and safe treatment of Chronic Venous Occlusions (CVO's). With its direct ability to steer and penetrate CVO's, the Traversa device is designed to recanalize occlusions in the venous peripheral and central vasculature in under 30 minutes, improving recanalization rate and outcomes. Currently, CVOs are difficult to cross, requiring 3 to 5 guidewires and multiple support catheters, and take between 2 to 6 hours to recanalize. While the market has yet to provide a device indicated for venous occlusive disease, other solutions that can allow for the needed level of control and penetrability require capital equipment or extremely expensive systems. As a single-use adjunct device, the Traversa is poised to democratize the venous recanalization procedure, allowing more physicians to participate and thus, leading to more patients being successfully treated.

Jordan Pollack
CEO

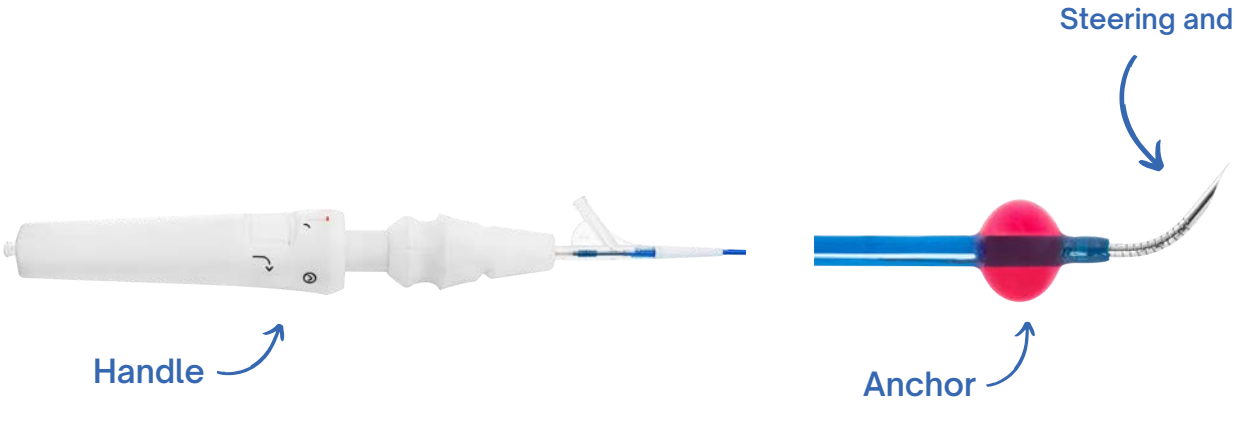
Ben Friesem
CTO

Yaron Eshel
VP Quality/Clinical

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: 510(k) - Had FDA Pre-Submission Meeting

SEEKING: $5MM Series A



VITESTRO

Autonomous venipuncture device to fully automate the manual blood drawing procedure in hospitals and laboratories

Utrecht, The Netherlands | vitestro.com

Vitestro's autonomous venipuncture device meets a largely unmet need of solving significant healthcare staff shortages partly caused by a labor intensive and unautomated blood drawing procedure performed ~10 billion times p.a..

Our device is state of the art technology using AI and robotics, clinically validated through >2,000 blood draws to date, with 8 patents filed and 2 intentions to grant.

With our team of >50 people and backed by Sonder Capital, we are in the final stage of development and expect to be on the European market in 2024 and the US market in 2025. Our target market is hospitals and laboratories where our device will replace the current manual blood drawing procedure.

Toon Overbeeke
CEO

Jim Lelivelt
CFO

Brian Joseph
Commercial Director/Co-Founder

DEVELOPMENT STAGE: Product: Pre-approval

REGULATORY STRATEGY: De Novo - Had FDA Pre-Submission Meeting

SEEKING: $25MM+ Series B

Drive Your Medical Device's Cloud Transformation with BioT

bioT

A comprehensive suite of configurable medical device modules such as:

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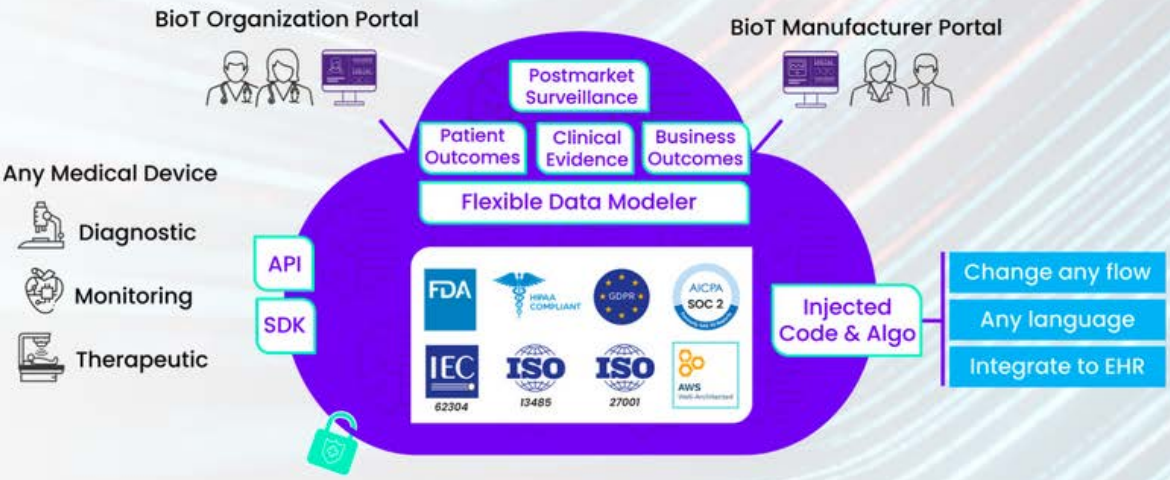


The BioT Platform provides configurable medical device modules and optional clinician and manufacturer portals. Your team can easily integrate via MQTT or REST API, customize data models, and extend any functionality with code or algorithm plugins. BioT prioritizes regulatory compliance (privacy, cybersecurity, quality, validation and operational requirements) to mitigate your risks. BioT's subscriptions match your device evolution to reduce costs and accelerate time to any milestone.

Excellence & Innovation: AAMI | AWS Well-Architected | United States Patent Vinograd et al. SYSTEMS AND METHODS FOR MANAGING A MULTI-REGION SAAS MODEL | Med4Tech BY 8400 | רשות החדשנות Israel Innovation Authority

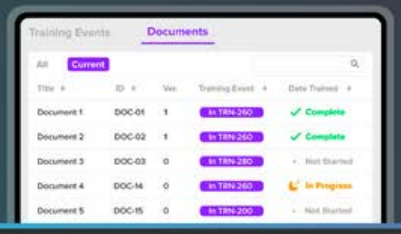
Learn more at: **www.biot-med.com | Info@biot-med.com**

greenlight guru **MedTechSuite**

Greenlight Guru provides the leading suite of quality, clinical, and education solutions, helping MedTech companies bring life-changing products to market faster, more efficiently, and with less risk.

greenlight guru **Quality**

The #1 QMS software purpose-built for medical device companies.

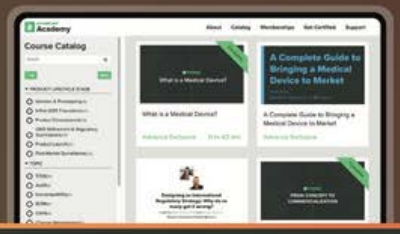


greenlight guru **Clinical**

The leading toolbox for MedTech clinical trial data collection.

greenlight guru **Academy**

Premium training and certifications taught by the best in the industry.



- Gain New Efficiencies
- Scale Faster
- Reduce Risk
- Stay Compliant

greenlight guru www.greenlight.guru **Moving MedTech Forward**

XCISION Raising Quality, Improving Lives

A radiotherapy device optimized for treating breast cancer by replacing 15-33 treatments with one treatment with lower toxicities

Columbia, MD | xcision.com

The GammaPod™ system is designed specifically for stereotactic radiotherapy of breast cancer. The GammaPod achieves unparalleled accuracy by immobilization of the breast in the prone position and stereotactic localization. The GammaPod is designed to minimize dose to tissue outside of the intended target, thus avoiding the high incidence of poor cosmetic outcomes observed in conventional treatments. The affected breast is immobilized using a vacuum-assisted breast cup that maintains the target at a consistent location relative to the cup's stereotactic coordinate system between the time of treatment planning and treatment delivery. The cup also minimizes geometric uncertainty during treatment. A low uncertainty in target position means that only a small inbuilt margin for error is required in the planning target volume. Use of a smaller target volume inherently reduces volume of normal tissue irradiated, independent of the beam geometry. University of Maryland and UTSW Medical Center are two of the early adopters of the GammaPod system. They have jointly conducted trials that replaces the traditional 8 to 33 treatments with 1 to 5 treatments and observed lower toxicities. We have sold 10 systems, and more than 500 patients have received GammaPod treatments without a single recurrence.

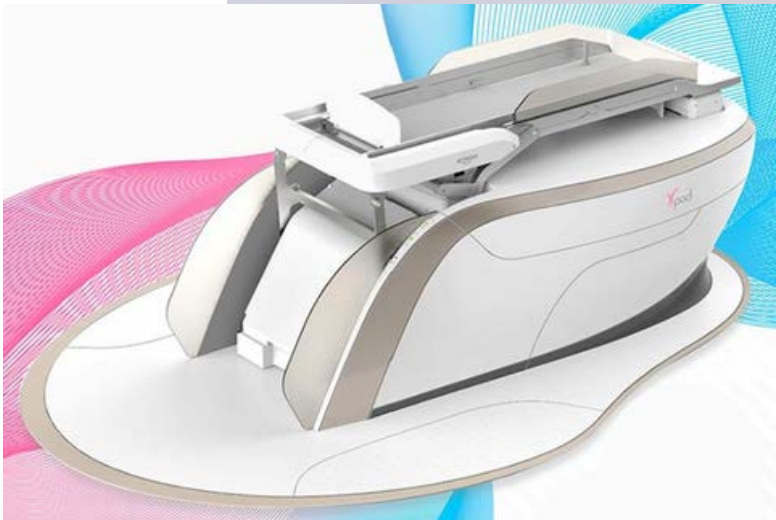
Cedric Yu, DSc
CEO

Michelle Crawley
President

DEVELOPMENT STAGE: Customers

REGULATORY STRATEGY: 510(k) - FDA Approved

SEEKING: $20MM Series B



XTREMEDY Medical

A surgical device to remove infections from wounds using pulsed field ablation so that patients can be treated effectively in the first surgery

Ireland | xtremedymedical.com

XTremedy Medical have developed BioBlate - the first surgical device to address the problem of infection and biofilm below the surface of the tissue. Surgical procedures are the cornerstone for infected wound treatment including diabetic foot ulcers, chronic wounds, trauma and surgical site infections. Despite 2.5 million surgeries being carried out every year to treat these infections, there are no effective surgical devices for removing bacteria and biofilms. As a result, patients require 2-3 surgeries on average to control the infection and lengthy hospital stays. Following treatment, 29% of patients will develop another infection, and these re-infections are 4.4 times more likely to be resistant. It is now more important than ever to treat these infections effectively first time.

BioBlate is a surgical device that uses PFA (Pulsed Field Ablation) to deliver high electric fields at the end of surgery to kill any biofilms and bacteria remaining in the wound. It's proprietary design allows for non-invasive delivery from above the tissue surface. An integrated smart system allows signal delivery to mixed tissue environments (bone and soft tissues) allowing for the most severe infections to be treated. Unlike other technologies, PFA has been shown to conserve tissue structures which is imperative for wound healing to occur. This overcomes the age-old problem in debridement surgery of balancing removal of all infected tissues and leaving enough tissue for wound closure. With PFA, infection below the surface can now be treated while maintaining tissue structures required for wound healing. This can have a huge impact on the patients journey - ensuring they are treated effectively in the first surgery and spend less time in hospital.

Lyn Markey
Co-Founder, CEO

Camille O'Malley
Co-Founder, CTO

Patrick O'Donnell
Strategic Advisor

Paul Gilson
Chairperson

DEVELOPMENT STAGE: Pre-clinical

REGULATORY STRATEGY: De Novo - Not Started

SEEKING: $4.1MM Series Seed, Equity round, lead investor secured

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