MEDICAL TECHNOLOGY AND DIGITAL HEALTH INDUSTRY REPORT

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Highlighting Private Companies Across the Medical Technology and Digital Health Landscape – Vol. 32

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WHAT YOU SHOULD KNOW: Each month, the Medical Technology and Digital Health team at BTIG highlights multiple private companies that we believe investors, both public and private, should be paying attention to across the landscape. This month, our 32nd "Private Company Feature" includes Advanced NanoTherapies, Laxmi, Micro Interventional Devices, NanoVation-GS, and NovaSignal. Our features on this month's companies are below. Check out past issues of this monthly feature on the BTIG Research portal.

- **Advanced NanoTherapies (ANT)** is an early-stage medical device company based in Los Gatos, California, that has developed a differentiated drug-coated balloon (DCB) platform for the treatment of coronary and peripheral artery disease. ANT is currently undergoing a first-in-human clinical study evaluating the SirPlux Duo™ in de novo lesions for patients with symptomatic coronary artery disease (ADVANCE-DCB). The company is planning to submit for U.S. IDE approval in the latter half of 2024.
- **Laxmi:** California-based Laxmi is an early-stage diabetes technology company that is working to develop a more accurate and real-time continuous glucose monitor (CGM). The company is developing a proprietary sensor that measures glucose levels within the dermis as opposed to the deep subcutaneous layer. This approach removes a significant physiological time delay.
- **Micro Interventional Devices:** Newtown, PA-based Micro Interventional Devices (MID) has developed the PolyCor™ anchoring technology for use in percutaneous repair of the tricuspid and mitral valves. The PolyCor anchors are the basis for the investigational MIA™-T Percutaneous Tricuspid Annuloplasty System and the MIA™-M Percutaneous Mitral Annuloplasty System. The MIA-T System was studied in STTAR (Study of Transcatheter Tricuspid Annular Repair) in Europe, showing safe, durable, significant reductions in annular dimensions and tricuspid regurgitation as well as significant improvements in quality of life.
- **NanoVation-GS:** Israel-based NanoVation is a medical device and digital health company that has developed SenseGuard, a noninvasive and user-friendly monitoring solution to measure key respiratory parameters in patients with chronic lung diseases. This may enable early identification and intervention for deteriorating patients in the hospital and at home. With CE Marking already in hand, NanoVation is initially targeting the chronic obstructive pulmonary disease (COPD) market. Data gathered can also be uploaded via cloud connectivity to support a remote monitoring ecosystem.
- **NovaSignal:** NovaSignal is a commercial-stage MedTech and Digital Health company with a platform that can be used to gather comprehensive cerebral hemodynamic data. The NovaGuide Intelligent Ultrasound is a non-invasive, ultrasound-based robotic platform with integrated artificial intelligence capabilities to help diagnose cerebrovascular conditions such as stroke. NovaGuide 2, the latest generation system, was cleared in March 2022. Additionally, NovaSignal offers hospitals NovaGuide View, a cloud-based platform for remote access to exam data. NovaSignal is also developing a data analytics service with which both hospitals and industry can leverage its proprietary and expansive cerebral blood flow data set.

Advanced NanoTherapies Inc.

Primary Technology

ANT uses its nanoparticle drug encapsulation and delivery platform to deliver a dual-drug solution that is intended to be safe, reliable, and provide sustained drug bioavailability to effectively treat vascular disease and minimize reintervention. The company's novel SirPlux Duo™ DCB combines and releases Sirolimus and Paclitaxel simultaneously through its proprietary nanoparticle-based delivery platform. The DCB delivers lower doses of the drugs compared to competing DCBs and drug-eluting stents inside the vessel and over a sustained period. It is thought this may improve safety and efficacy while enabling higher patency and lower risk of restenosis. ANT exclusively licensed the nanoparticle technology from the Cleveland Clinic in 2019. SirPlux Duo™ has FDA Breakthrough Device Designation for coronary artery disease (CAD) in small vessels (<3mm), coronary in-stent restenosis (ISR), and peripheral below-the-knee (BTK) lesions.

Recent Updates

In September 2022, ANT received FDA Breakthrough Device Designation for its SirPlux Duo™ DCB for CAD in vessels smaller than 3mm. Earlier in the year, the company raised $7.2M in a Series A equity financing. An additional $4.0M investment from an undisclosed strategic investor closed in July 2023 to accelerate pre-clinical activities toward U.S. IDE approval. In August 2023, ANT announced it had successfully treated 13 patients in its ADVANCE-DCB first-in-human trial, demonstrating initial short-term safety using SirPlux Duo in patients with de novo coronary artery disease.

Background

Advanced NanoTherapies (ANT) is an early-stage medical device company based in Los Gatos, California, that has developed a differentiated drug-coated balloon (DCB) platform for the treatment of coronary and peripheral artery disease. ANT is currently undergoing a first-in-human clinical study evaluating the SirPlux Duo™ in de novo lesions for patients with symptomatic coronary artery disease (ADVANCE-DCB). The company is planning to submit for U.S. IDE approval in the latter half of 2024.

- **Founded:** 2019 **Total funding:** $16.5M **Sector:** Cardiovascular

Estimated Market Opportunity

According to ANT, the global interventional device market is estimated to be $6.1B for CAD and $4.5B for PAD, with CAGRs of 8.5% and 8.7%, respectively.

Source: Advanced NanoTherapies

Laxmi

Primary Technology

Traditional subcutaneous continuous glucose monitors measure glucose levels within the lipid layer of the skin, which results in physiologically delayed readings. Laxmi is developing a proprietary sensor that instead measures glucose levels in the dermis. This could enable more accurate and real-time glucose measurements, which may drive further improvements in glucose control and clinical outcomes such as time in range (TIR) and HbA1c. In addition to the sensor, Laxmi's user-friendly app allows patients to conveniently assess their glucose measurements.

Recent Updates

Laxmi recently completed an 8-hour, dermal in vivo IRB trial and is now commencing a 7-day, 50-person IRB study. Positive results would be followed by a pivotal trial.

Source: Laxmi

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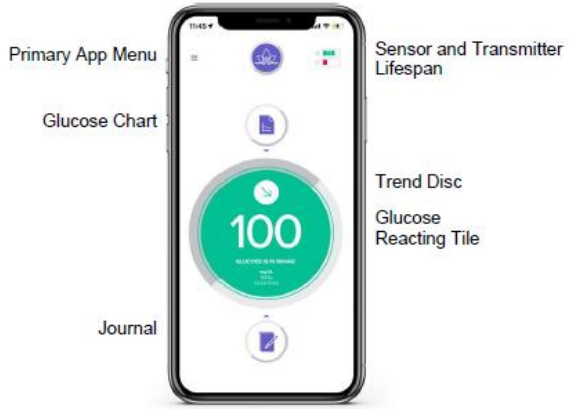
Background

California-based Laxmi is an early-stage diabetes technology company that is working to develop a more accurate and real-time continuous glucose monitor (CGM). The company is developing a proprietary sensor that measures glucose levels within the dermis as opposed to the deep subcutaneous layer. This approach removes a significant physiological time delay.

- **Founded:** 2016 **Total funding:** $38M **Sector:** Diabetes

Estimated Market Opportunity

According to the American Diabetes Association (ADA), ~37M Americans have diabetes, 1.9M of whom have Type 1 diabetes. The ADA estimates that another 96M Americans aged 18 and older have prediabetes.



Source: Laxmi

Micro Interventional Devices, Inc.™
Taking Aim at Structural Heart Disease

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Primary Technology

The PolyCor anchors, intended for use in cardiac tissue, are designed to be ultra low-mass, compliant anchors that provide secure purchase in soft-tissue and comply with the beating heart after deployment. The anchors are delivered via high-speed delivery catheters and have radiopaque markers for image-based guidance while being deployed during an off-pump procedure. The MIA-T Percutaneous Tricuspid Annuloplasty System is a 12F catheter-based system designed to treat moderate-to-severe tricuspid regurgitation. PolyCor anchors are delivered to the tricuspid valve via 12F delivery catheters. Proper placement is confirmed with imaging and the anchors are deployed into the tricuspid annulus rapidly, each in 4/1000th of a second. A proprietary suture lock is used to approximate the anchors, reduce the dimensions of the valve annulus, and reduce or eliminate tricuspid regurgitation. The company's MIA-M Percutaneous Annuloplasty System for mitral repair uses the same PolyCor anchors and delivery system to treat mitral regurgitation.

Recent Updates

The FDA granted the MIA-T System Breakthrough Device Designation. MIA-T may enter a U.S. pivotal trial in 2024.

Background

Newtown, PA-based Micro Interventional Devices (MID) has developed the PolyCor™ anchoring technology for use in percutaneous repair of the tricuspid and mitral valves. The PolyCor anchors are the basis for the investigational MIA™-T Percutaneous Tricuspid Annuloplasty System and the MIA™-M Percutaneous Mitral Annuloplasty System. The MIA-T System was studied in STTAR (Study of Transcatheter Tricuspid Annular Repair) in Europe, showing safe, durable, significant reductions in annular dimensions and tricuspid regurgitation as well as significant improvements in quality of life.

Founded: December 2010 **Last equity funding:** Not disclosed **Sector:** Cardiovascular

Estimated Market Opportunity

Edwards Lifesciences (EW, Neutral) has estimated that there are 4M+ U.S. patients with moderate-to-several mitral or tricuspid disease, with very few patients receiving intervention.

Source: Micro Interventional Devices

NanoVation-GS

Primary Technology

SenseGuard uses nanosensors to measure tidal (normal) breathing biomarkers including respiratory rate, expiratory time, inspiratory time, expiratory pause, and total breath time.

Recent Updates

In the September 2023 issue of the *Advances in Medical Sciences* journal, researches published their findings from a 15-patient feasibility study evaluating SenseGuard's ability to detect changes in the respiratory condition in hospitalized patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD). Data showed substantial changes in tidal breathing ratios in patients who showed significant clinical improvements, while smaller changes were measured in patients who showed mild or no clinical improvements. Linear regression analyses between change in physician's assessment score and the median change in tidal breathing parameters was significant for a subset of measures.

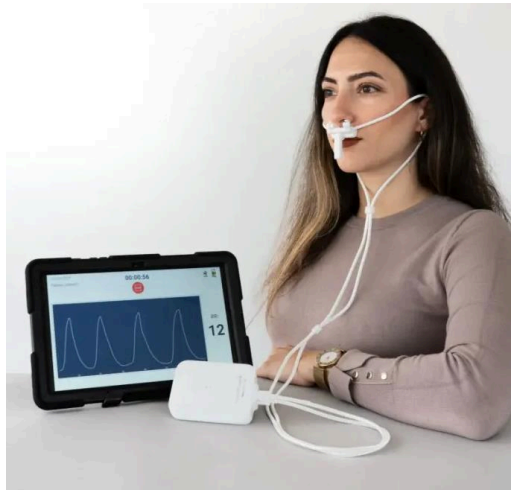
Estimated Market Opportunity

According to NanoVation, more than 1.5M people in the EU are admitted annually due to COPD exacerbations, over 20% of whom are readmitted within 30 days.

Background

Israel-based NanoVation is a medical device and digital health company that has developed SenseGuard, a noninvasive and user-friendly monitoring solution to measure key respiratory parameters in patients with chronic lung diseases. This may enable early identification and intervention for deteriorating patients in the hospital and at home. With CE Marking already in hand, NanoVation is initially targeting the chronic obstructive pulmonary disease (COPD) market. Data gathered can also be uploaded via cloud connectivity to support a remote monitoring ecosystem.

- **Founded:** 2014 **Last funding:** €5M in 2021 **Sector:** Respiratory



Source: NanoVation

NovaSignal™

Primary Technology

NovaGuide is a robotic-assisted transcranial doppler ultrasound (TCD) system that autonomously aligns and positions the transducers on each side of the patient's head at the temporal acoustic windows. The system is intended for use during diagnostic exams and surgical procedures as an adjunct for measuring and displaying cerebral blood flow velocity and the occurrence of transient emboli within the arteries of the head and neck. This can enable greater access to TCD ultrasounds to rapidly diagnose and monitor stroke and more efficient workflows since it does not require a registered vascular technologist to operate the system. Embedded algorithms are then applied to rapidly assess right-to-left shunt, vasospasms, emboli, and blood flow velocity. The system can be utilized across the inpatient setting, including in the NICU, operating room, emergency room, and general floor, in addition to the outpatient setting.

Recent Updates

In 2021, NovaSignal launched the second-generation NovaGuide Intelligent Ultrasound system and NovaGuide View. In 2020, Diane Bryant was named CEO and Chairman of the company.

Estimated Market Opportunity

According to NovaSignal, penetration into U.S. hospitals and clinics represents a $5.5B TAM.

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Background

NovaSignal is a commercial-stage MedTech and Digital Health company with a platform that can be used to gather comprehensive cerebral hemodynamic data. The NovaGuide Intelligent Ultrasound is a non-invasive, ultrasound-based robotic platform with integrated artificial intelligence capabilities to help diagnose cerebrovascular conditions such as stroke. NovaGuide 2, the latest generation system, was cleared in March 2022. Additionally, NovaSignal offers hospitals NovaGuide View, a cloud-based platform for remote access to exam data. NovaSignal is also developing a data analytics service with which both hospitals and industry can leverage its proprietary and expansive cerebral blood flow data set.

- **Founded:** 2013 **Last funding:** $37M in 2021 **Sector:** Imaging

Source: NovaSignal

BTIG Covered Companies Mentioned in this Report

Edwards Lifesciences Corporation (EW, Neutral, Closing Price: $75.90; Analyst: Marie Thibault)

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