

# MARKETWATCH

Weekly News Bulletin– Issue No.7

March 16, 2018

## In this issue...

Here are a few wearables from SXSW that aim to bring value to humans on earth and space  
*(Power of start-ups)*

Transforming health is hard enough on the blue planet, but some entrepreneurs are hoping that their newfangled innovations will work for astronauts in space. Some of them participated in a quickfire pitch session on Saturday as part of a panel at South by Southwest in Austin moderated by Dorit Donoviel, who runs the NASA-funded Translational Research Institute for Space Health.

Here are a few of those that pitched:

### Cossinuss

Based in Germany, this startup makes in-ear sensors that monitor vital signs continuously. They sit inside the ear canal to monitor signs like heart rate, core body temperature, blood-oxygen saturation and in combination with an ECG strip, it can also track blood pressure.

### iAssay

Located in San Diego, this diagnostics company makes a small diagnostic device meant to be used at home. The device has 129 approved tests that require body fluids such as urine or blood and eliminates the need for multiple readers to read the tests.

### Motiv

Instead of monitoring through wrist-worn trackers, this San Francisco company makes the Motiv ring that can monitor heart rate and sleep and unlike other wearables can last a long time on one charge. Full charge is achieved in two hours.

### Sencetech

The company's website talks about being able to track emotion for improved well-being through the SenceBand. But at SXSW the company's c0founder described a working prototype of a wearable able to track and measure blood pressure noninvasively around the clock. After hearing the above and a few more companies present, the well-known entrepreneur and angel investor, Esther Dyson, stressed that the success of wearables hinges on a few things. "Things like charging [and battery life] really matter a lot," Dyson said.



## In This Issue

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MedCity, March14, 2108

Marketwatch

BIÇAKCILAR, Corporate Marketing

## In this issue... *cardiac related...*

### Janssen reports positive findings from ECG monitoring patch trial

Janssen Pharmaceutical has announced encouraging one-year results from the mSToPS clinical trial that evaluated the wearable continuous electrocardiogram (ECG) monitoring iRhythm ZIO XT Patch to identify asymptomatic atrial fibrillation (AFib).

The single-use, 14-day wearable sensor is designed to monitor and retain data from the continuous ECG of the user for up to two weeks.

Trial data revealed that the patch can identify people with AFib earlier and more efficiently than standard care. The home-based trial was conducted in alliance with Scripps Translational Science Institute (STSI), Aetna and iRhythm Technologies.

STSI founder and director Eric Topol said: "We hope that a digital infrastructure will help reimagine how clinical trials can be performed and that this study will be a useful template for remote enrolment and participant engagement."

### Cardiac pump improves long-term outcomes for heart failure patients

By Charlotte Edwards, March 12, 2018

In the trial 366 patients were randomised to receive either the centrifugal flow pump or the axial flow pump. The researchers reported that 79.5% of patients on the centrifugal flow pump did not experience a disabling stroke or need a re-operation compared to 60.2% of patients on the axial pump.

Only three people who received the centrifugal-flow pump needed a re-operation compared to 30 who received the axial pump. No re-operations occurred due to blood clots in the centrifugal-flow pump. Deaths or disabling strokes were similar between the two groups, but overall, stroke rates were less frequent in the centrifugal-flow pump group. Bleeding and infection rates were no different between the two groups.

MOMENTUM 3 was launched in 2014 and was designed to dramatically reduce the overall timeline for clinical trials. All patients with refractory heart failure who needed a cardiac pump were eligible for the trial, regardless of whether the pump was intended as bridge to transplantation or destination therapy.

The HeartMate 3 includes several technological adaptations intended to reduce the risk of complications. Abbot claims that the fully magnetically levitated device runs like a bullet train – its rotor has no mechanical bearings in it and so it pushes the blood using only magnetism. It is designed to reduce stress, which is thought to cause blood clots to form in pumps.

In its next phase, MOMENTUM 3 will evaluate 1,028 patients at the two-year mark to further validate the current findings. Results of this are expected by the end of 2019.



### OHSU says new device can be permanent artificial heart

Physicians and researchers at the Oregon Health & Science University (OHSU) in the US are developing a new device to offer a permanent solution for heart failure patients. The total artificial heart was designed by now-retired Richard Wampler, who was a surgical resident at OHSU. Currently, only one artificial heart is approved in the US for human use but it is said to be a temporary fix until patients get a human heart transplant. "The OHSU total artificial heart is intended to permanently replace a failing heart in nearly all adults and children aged 10 years or above." However, whilst approximately 4,000 people in the US have been waiting for a heart transplant, only around 3,400 human donor



hearts were transplanted in 2017. The OHSU total artificial heart is intended to permanently replace a failing heart in nearly all adults and children aged 10 years or above. It is designed to replace the heart's two ventricles with a titanium tube made of a titanium alloy-coated hollow rod that shuttles back and forth to allow circulation of blood to the lungs and various other body parts. The capability of the device to duplicate a natural human pulse is expected to reduce blood damage, decrease blood clotting risk and possibly minimise certain complications associated with devices that don't pulse. OHSU Knight Cardiovascular Institute CEO Sanjiv Kaul said: "Considering the human heart beats 14 million times a year, it's crucial that an artificial heart is durable and robust. "The simple, efficient design of our total artificial heart makes its potential for failure very low."

## MARKET INSIGHT IN ASSOCIATION WITH GLOBAL DATA– March 13, 2018

### MITRAL VALVE REPAIR: THE NEXT FRONTIER

Heart valve repair and replacement is one of the most innovative and exciting areas in the cardiac devices market. Competitors are constantly fighting to be the first to market with new and innovative technologies. In many markets, such as the coronary stent market, the technology is largely mature; one clear technology is preferred over the others, with niche uses for the rest. However, due to the incredible complexity of replacing and repairing heart valves, the technology is still far from being 'solved'. In recent years, the heart valve market has seen the advent of transcatheter aortic valve implantation (TAVI) technology, which has vastly improved care in the aortic replacement space as well as providing high growth for many companies pursuing it. TAVI is the next step in the evolution past open-heart surgery to repair the valve. Open-heart surgery was a high-risk procedure with a relatively high rate of death, stroke, or other side effects. TAVI enables surgeons to treat high-risk patients with a fraction of the time and training needed or open-heart surgery. As time passes, more and more evidence seems to point in favour of TAVI being superior to open-heart surgery in terms of surgical outcomes as well.

### NEW SOLUTIONS ARE CATCHING UP

However, as TAVI develops further, new frontiers are being explored. For example, competitors are already homing in on the mitral valve market. Mitral valve repair has proven to be much harder than aortic valve repair, with its solutions lagging behind TAVI by at least a decade. The Mitraclip, the world's first transcatheter mitral valve repair (TMVR) device, was released five years ago and continues to gain ground as the only solution in the TMVR market. However, other companies are working hard to develop and sell their own technologies. Edwards Lifesciences hopes to gain a foothold in the TMVR market and compete with Abbott Vascular, the market leader. In early December 2017, Edwards Lifesciences bought a mitral valve repair startup, Harpoon Medical. With the promising clinical results of Harpoon Medical's technology, Edwards Lifesciences hopes to gain a foothold in the TMVR market and compete with Abbott

### Abbott gets FDA approval for smallest pediatric mechanical heart valve

Abbott has secured approval from the US Food and Drug Administration (FDA) for its Masters HP 15mm rotatable mechanical heart valve. The valve, which is claimed to be the world's smallest mechanical heart valve, will help doctors to replace mitral or aortic valve in babies and toddlers. Abbott's dime-sized new valve is said to be the first and only pediatric mechanical heart valve developed for newborns and infants. Surgeons generally use a range of larger-sized valves to replace a pediatric heart valve, which cannot be repaired easily.

To provide the body with oxygen-rich blood, the heart's mitral and aortic valves move blood across the heart. When functioning correctly, both valves open and close sequentially as blood enters and leaves the heart with each contraction. Heart failure is expected to occur when either valve doesn't work properly. The approval was based on the data of a clinical trial that recruited pediatric patients five years of age or younger who had a diseased, damaged or malfunctioning heart valve. The Masters HP 15mm, which is a rotatable and bileaflet mechanical heart valve, is part of the Masters Series line that comprises seven valves with diameter sizes ranging from 15mm to 27mm. First approved in 1995, the valves are provided with pyrolytic carbon leaflets and orifice rings, as well as 85-degree leaflet opening angle to improve flow and reduce turbulence and controlled torque rotation mechanism for rotation and intraoperative adjustment. A sewing cuff includes additional suture markers for accurate placement. Abbott's structural heart business vice president Michael Dale said: "There's an urgent need for the smallest babies and children who need a suitable replacement valve in order to survive. "Abbott's new mechanical pediatric heart valve is a life-changing technology for the smallest pediatric patients, giving them a better chance at a long, healthy life with a fully functioning heart."



## New Devices

### Product Launch

## Canon Medical launches new version of Aplio i900 cardiovascular ultrasound system

(March 12, 2018)

Canon Medical Systems USA has expanded its Aplio i-series ultrasound platform with the introduction of a new version of Aplio i900 cardiovascular ultrasound system.

The new Aplio i900 cardiovascular ultrasound system will provide cardiologists with better imaging clarity, helping to quickly diagnose the conditions.

With the new Aplio i900 system, the cardiologists and cardiovascular sonographers can access new 4D imaging capabilities such as 4D TEE transcatheter procedure guidance with advanced quantitative technologies, including MVA (mitral valve analysis), helping to deliver fast valve analysis during planning, implantation and post-op evaluation.

Canon's new system features automated analysis and measurement tools such as ejection fraction with global longitudinal strain, and 3D wall motion stages of cardiac in detail.

The system is also touch-control makes automatic button.

The company is cardiovascular American College meeting in March to 12 March.

Canon Medical director Dan Skyba provides a diagnostic cardiovascular pediatric, fetal echo, stress echo and transesophageal echocardiography.

"The enhanced 2D and 4D visualization made available on this new system empowers cardiologists to conduct complex cardiac imaging exams, while continuing to utilize a cost-effective, less invasive and safer tool than other traditional imaging modalities."



myocardial performance index (MPI) tracking, which will help to identify early disease and measure cardiac function

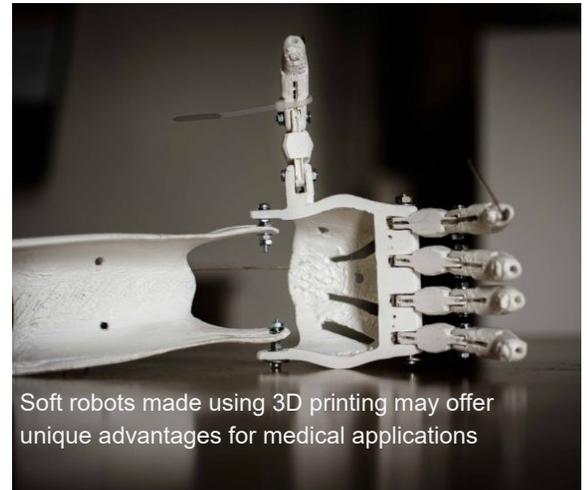
provided with advanced iSense and screens, and real-time quick scan that image adjustments without pushing a

exhibiting the new version of Aplio i900 ultrasound system at this year's of Cardiology (ACC) 2018 annual Orlando, which is being held from 10

Systems USA ultrasound business unit said: "The Aplio i900 offers health care complete solution that delivers confidence for a wide range of imaging needs, including adult,



Fever monitoring device aims to reduce strain on healthcare providers



Soft robots made using 3D printing may offer unique advantages for medical applications

## This is “For Us” page...

### We Can't Start at New Markets with an “inside-out” approach!

Put simply, there seems to be two ruling paradigms in business today: the Inside-Out approach and the Outside-In approach. In business, the overarching goal is to create [long-term] shareholder value. These two approaches use very different means to achieve that end.

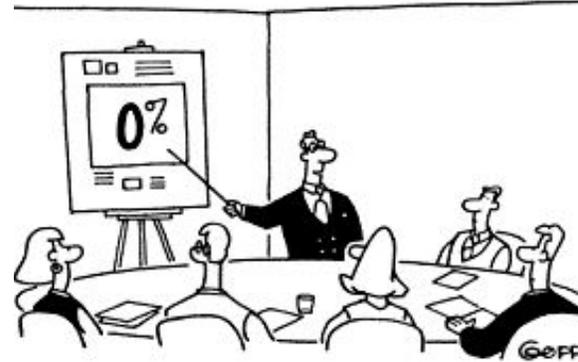
The Inside-Out approach is guided by the belief that the inner strengths and capabilities of the organization will make the organization prevail. The Outside-In approach is instead guided by the belief that customer value creation, customer orientation and customer experiences are the keys to success.

*From an Outside-In approach, long-term shareholder value is a consequence of listening and providing value to customers and helping them get their jobs done better than the competition while providing a seamless customer experience.*

The ideal organizational culture is market- and customer-oriented and the targeted customer segments – buyers as well as users – are the source of inspiration and development. There is also a strong belief that if the customers aren't satisfied with the solutions offered, the business will suffer and the shareholder value will diminish.

The Outside-In strategy takes customer value as its starting and end point. Companies using this approach are focused on creating and nurturing their customers by providing high calibre customer value. They put themselves in the position of their customers, and view themselves from their perspective. It's also about having a firm vision that drives you forward; there's no room here for looking behind your shoulder.

Customers buy the expectation of benefits they will receive from forming a relationship with a brand. Buying from and interacting with a business is guided by a businesses brand. An Outside In strategy means a change of focus and entering into a collaborative relationship with the customer.



"Our study concludes that this is the percentage of our customers who will buy from us without any effort whatsoever on our part."

#### Contact Us

If you have any specific area that you need information on, please contact Corporate Marketing so we can focus on the specific areas to research to speed up your efforts.

Gülden Somar, Director,  
Corporate Marketing



*"Yes, I saw all that from the vendor — but I'd rather hear what YOU think as their customer..."*