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News We're Watching: Intuitive Plans da Vinci 5 Launch; Roche's CGM Plan; ReWalk Rebrands, And More

by Reed Miller

Medtech Insight's News We're Watching highlights medtech industry developments we are following: Intuitive announced an FDA filing for its da Vinci 5 surgical robot; Roche hits at CGM plans; Abbott launches a new smaller rechargeable deep brain stimulator; CroiValve starts transcatheter tricuspid valve trial; ReWalk rebrands as Lifeward; and more news you may have missed.

Intuitive Announces da Vinci 5 And Bags SP CE Mark

Intuitive Surgical submitted a 510(k) application to the US Food and Drug Administration for da Vinci 5 next-generation multi-port platform robotics surgery system.

During the company's 23 January sales and earnings call, CEO Gary Guthart said Intuitive completed the submission in August 2023 after completing trials in May 2023.

He said the new system will help bring minimally invasive surgery to more patients, with better performance and customer satisfaction, while lowering the per-procedure cost.

"Once cleared, we believe da Vinci 5 will make a positive impact on each of these objectives through hundreds of design changes that respond to surgeon and care team inputs and fulfill our design priorities," Guthart said. For example, da Vinci 5 possesses "four orders of magnitude greater processing power than our generation four products."

Once the da Vinci 5 is cleared, the company will release it in stages throughout the US, he said. Intuitive is also in discussions with Japanese and Korean regulators about an imminent release.

He said that he "hoped" this would begin in 2024.

Guthart hinted that the company was working on a new system during his presentation at the J.P. Morgan Healthcare conference in early January. (Also see "*IPM 2024: Intuitive And J&J Both Weigh In On Growth For 2024*" - Medtech Insight, 12 Jan, 2024.)

Alongside news of da Vinci 5, Intuitive's Ion single port system was awarded a CE mark in Europe, the *company announced on X*. Ion is most commonly used in lung procedures. Its flexible, endoluminal format allows surgeons to precisely enter all 18 segments of the lungs, where lesions can be removed.

Roche Set To Unveil Its CGM Soon

Roche will probably unveil a new continuous glucose monitoring (CGM) system at the Advanced Therapeutics & Treatments for Diabetes (ATTD) meeting in Florence on March 6, according to Wells Fargo analyst Larry Biegelsen.

In a 26 January note, Biegelsen predicted Roche will say more about it at the ATTD meeting because the title of Roche's symposium at ATTD is *A novel CGM solution using the power of prediction - Simply prepared for what's next in daily diabetes therapy.* At that symposium, Julia Mader from the Medical University of Graz will give a lecture titled "Precision unveiled: Exploring the accuracy of a novel CGM solution."

The company previously announced that it would offer more detail on its CGM system, among other new technologies, at its Diagnostics Day for investors in May 2024.

Biegelsen believes the company will not compete with Abbott or Dexcom in the US CGM market – at least not soon – the because Roche does not have a US diabetes commercial organization. (Also see "*Analyst Expects Roche's Newly FDA-Cleared Insulin Patch Pump Will Have 'Limited Impact'*" - Medtech Insight, 22 Aug, 2023.)

"We think it will take years for Roche to re-build its commercial presence in the US if it chooses to market its CGM device here," Biegelsen wrote.

CroíValve Starts Tricuspid Valve IDE Trial

Dublin-based CroíValve announced the start of *TANDEM II*, a 15-patient early feasibility trial of its DUO transcatheter tricuspid coaptation valve system in US patients with severe symptomatic tricuspid regurgitation (TR).

According to the company, DUO is a coaptation valve with a novel anchor system designed to work in tandem with the native tricuspid valve without interfering with the function of the right heart and native valve.

The European First in Human TANDEM I trial showed DUO promoted symptomatic improvement in patients across all parameters at 30 and 90 days.

CroíValve CEO Lucy O'Keeffe said, "We are confident it has the potential to revolutionize the standard of care by redefining how TR is treated, and ultimately enhancing the lives of patients in need."

CroíValve also announced that Martin Leon, a renowned cardiovascular trialist, device innovator, and interventional cardiologist at Columbia University, will chair CroíValve's clinical advisory board.

"The DUO system can simplify the treatment of TR patients, with a predictable procedure that can be performed with standard imaging techniques," Leon said. "Additionally, with minimal anatomical exclusions, it can reach a broad population. It has the potential to emerge as a meaningful advancement in the field of TR treatment."

The transcatheter tricuspid repair market is currently dominated by *Edwards Lifesciences* and *Abbott*. Edwards markets the Pascal Precision system for both mitral valve repair and tricuspid valve repair and is developing the Evoque transcatheter tricuspid valve replacement system.

Pascal competes with Abbott's TriClip, a tricuspid-valve version of Abbott's successful MitraClip transcatheter mitral repair system.

Rewalk Rebrands To Lifeward Following AlterG Acquisition

ReWalk Robotics, which markets the ReWalk Personal Exoskeleton, ReStore Exo-Suit and MyoCycle FES systems, announced on 29 January it rebranded itself as Lifeward.

The company started doing business as Lifeward on 29 January and its stock will start trading under the new NASDAQ ticker symbol "LFWD" on 30 January.

This comes after ReWalk Robotics's acquisition of AlterG, a provider of anti-gravity systems for physical and neurological rehabilitation.

AlterG uses NASA-derived differential air pressure technology to reduce gravitational load and body weight, which enables patients and athletes to move without restrictions or pain. (Also see

"*ReWalk Robotics' Planned Acquisition Of Anti-Gravity Maker AlterG For $19M Paves Way To Profitability*" - Medtech Insight, 10 Aug, 2023.)

"With the recent addition of innovative solutions like the AlterG Anti-Gravity systems to our portfolio, we have surpassed the vision of our original name," said Lifeward CEO Larry Jasinski. "The transformation of ReWalk Robotics into Lifeward speaks to the broader goal of the company to be the driving force to elevate the standard of care in overcoming physical limitations and disabilities to empower individuals to do what they love."

Abbott Launches Liberta RC DBS

Abbott announced the US launch of the Liberta RC deep brain stimulation device for chronic neurological conditions including Parkinson's disease and essential tremor.

Abbott touts Liberta RC as the "world's smallest rechargeable system with remote programming capabilities to treat movement disorders." It is about 31% smaller than other implantable, rechargeable DBS devices currently available in the US and it is the Liberta RC is also the only rechargeable DBS device compatible with Abbott's proprietary NeuroSphere Virtual Clinic connected care technology.

NeuroSphere allows doctors to remotely communicate with DBS patients and monitor the devices' performance. Doctors can also modify the device's settings as needed without requiring the patient to visit a clinic. (Also see "*Abbott Launches NeuroSphere Virtual Clinic For Remote Neurostim Programming*" - Medtech Insight, 8 Mar, 2021.)

Remote access is critical because the average Abbott DBS user in the US lives at least 150 miles from their movement-disorder specialist.

Liberta RC also offers the longest battery life of any available DBS; it only needs to be recharged about 10 times a year using a wireless charger, but patients can also recharge it weekly in about 30 minutes.

FUSE-AI Launches Radiology AI

FUSE-AI is launching its Prostate.Carcinoma.ai software now that it has been certified under the EU Medical Device Regulation (MDR).

Prostate.Carcinoma.ai automatically segments magnetic resonance images (MRI) of the prostate gland and independently identifies pathological changes, allowing radiologists to read prostate

MRIs about 30% faster than they could otherwise, according to the company.

FUSE-AI can integrate their AI algorithm into existing radiology software, so manufacturers and providers of radiology software (PACS) will serve as “resellers,” the company explained in a 29 January press release. “This enables FUSE-AI to optimally leverage the multiplier effect and reach a large number of clinics at once.”

Prostate.Carcinoma.ai is the first part of FUSE-AI’s planned suite of AI-powered diagnostic assistance software.

"Receiving certification is a pivotal step, transitioning preliminary agreements into binding contracts and fully leveraging the software's capabilities in clinical settings,” FUSE-AI CEO Matthias Steffen said. “This milestone substantially lowers investment risks into our company."

Accelus Closes $20m Debt Facility

Spine-implant company Accelus secured a $20m debt facility from Symbiotic Capital to fund the commercialization of its expandable spinal implant technologies, the company announced on 29 January.

The funding will support “the aggressive expansion” of Accelus’ sales force into previously underpenetrated markets as well as research and development for the company’s flagship FlareHawk and innovative Toro expandable interbody spine fusion systems.

Featuring Accelus’ Adaptive Geometry technology, FlareHawk conforms to the patient’s own endplate geometry. The company hopes to invest in further analysis to conclusively prove FlareHawk’s efficacy.

Also on 29 January, Accelus launched the LineSider modular-cortical system. “Designed for greater procedural visibility, versatility and efficiency, the modular screw design provides surgeons with enhanced visualization by allowing the placement of screw shanks early in the procedure,” according to the Florida company.

Noah’s Galaxy Used in 500th Procedure

Adding to its list of accomplishments in the last year, Noah Surgical announced that its Galaxy robotic bronchoscope tool has just been used in its 500th procedure, performed at CHI Memorial in Chattanooga by Krish Bhadra.

Galaxy received US Food and Drug Administration approval in March, and the system has been sold in the US since May. (Also see "*News We're Watching: Activist Investor Causes Kerfuffle At Nevro, Lifespin Launches Antibiotic Dx, And More*" - Medtech Insight, 11 Dec, 2023.)

Galaxy is a "highly-intelligent bronchoscope holder" that lets surgeons easily guide their bronchoscope in and around areas of interest.

It also features integrated tomosynthesis to allow high resolution limited-angle tomography at doses similar to those used in projectional radiography, and additional fluoroscopic imaging provide "tool-in-lesion" confirmation. In a "blind" bronchoscopic system, confirming the precise location of a cutting instrument can be difficult. But, in an animal *study*, 95% of nodules could be identified with Galaxy's "tool-in-lesion" technology.

Noah recently announced the first biopsy procedures with Galaxy in Asia. In April, it closed its series B funding round, raising $150m in order to scale its single-port platform.