MEDTECH INSIGHT
CITELINE COMMERCIAL

26 Feb 2024 | **News**

News We're Watching: Tricuspid Procedure Boom, Boston Scientific Borrows $2Bn, And More

by Reed Miller

Medtech Insight's News We're Watching highlights some recent business and R&D developments you may have missed. This week, GE Healthcare and Biofourmis announced a deal to collaborate on virtual care; Cleerly touts a new CPT code for its Ischemia cardiac diagnostic software; Boston Scientific announced how it plans to pay for Axonics; a Wells Fargo survey suggests the market for transcatheter tricuspid valve repair and replacement will grow faster than previously imagined; Virtual Incision earns FDA de novo authorization for its MIRA miniaturized surgical system for colectomy procedures; and MMI and Fabric announce major financing rounds.

GE Healthcare And Biofourmis Collaborate On Virtual Care

GE Healthcare and *Biofourmis* announced a new strategic collaboration to provide safe, effective, and accessible care in the home.

“Biofourmis’ demonstrated success with care-at-home solutions will extend GE Healthcare’s current inpatient monitoring portfolio to support patient care from the hospital to home,” Ashutosh Banerjee, GE Healthcare’s general manager for diagnostic cardiology and virtual care at home, said in a 26 February announcement.

Biofourmis maintains cloud-based infrastructure and machine-learning analytics to serve both clinical providers and pharmaceutical development. (Also see "*Minute Insight: Biofourmis Raises $300M To Fund Digital Drug-Companion Therapies*" - Medtech Insight, 29 Apr, 2022.)

In 2023, the US Food and Drug Administration *cleared* Biofourmis' Everion+ platform for continuous monitoring of pulse rate, respiration rate, and movement. In 2019, the company earned FDA *clearance* for its Biovitals analytics engine that finds correlations between patients' vital signs and daily activities. Also in 2019, the FDA *cleared* Biofourmis' RhythmAnalytics cardiac arrhythmia-assessment software.

Insights from Biofourmis' artificial intelligence-guided algorithms will help care teams deliver efficient, personalized care at home to shorten hospital stays and reduce readmission rates while supporting patient recovery and safety, according to GE Healthcare.

"Combining our companies' demonstrated capabilities will help revolutionize the way we approach the patient care journey as well as help address current challenges faced by health systems including hospital capacity issues and clinical staffing shortages," Banerjee said.

Cleerly Secures CPT I Code For Ischemia Software

Cleerly announced that its Ischemia software for non-invasive coronary computed tomography angiography (CCTA) can be billed under a new code.

The US Food and Drug Administration *cleared* Ischemia in 2023 as an automated machine learning-based decision support tool to help detect ischemia associated with coronary artery disease. (Also see "*Cleerly Advances CCTA Digital Pathway To Stop Heart Disease*" - Medtech Insight, 6 Dec, 2022.)

The American Medical Association (AMA) recently established *code 75580* as a new category I current procedural terminology (CPT) code for "a complementary augmented intelligence tool for noninvasive estimates of fractional-flow reserve (FFR) to assist healthcare professionals in clinical diagnosis and decision making."

In December, Richard Frank, the co-chair of AMA's AI Working Group, *explained* that the new code recognizes that the software provides clinically meaningful output predicated on the standard of care.

The new code complements the category III CPT codes (CPT 0623T, 0624T, 0625T, 0626T) for Cleerly's advanced coronary atherosclerosis analysis technology.

"The Cleerly Ischemia software provides noninvasive estimates of FFR values that help health care professionals make critical decisions in the management of patients with suspected coronary artery disease," said Cleerly chief medical officer James Earls.

"Ischemia was purposely designed to output estimates of FFR values that are guideline-recommended by professional societies, and to allow comprehensive mapping of both anatomic and physiologic data for each and every coronary lesion across the entire vascular tree."

Boston Scientific Borrows $2Bn To Help Fund Axonics Deal

Boston Scientific announced that American Medical Systems Europe, its wholly owned finance subsidiary, has priced a public offering of €750m (aggregate principal amount) of 3.375% notes due in 2029 and €1,250m of 3.5% notes due in 2032.

The notes are fully and unconditionally guaranteed by the company and offered pursuant to a *registration statement filed with the US Securities and Exchange Commission* on 23 February.

The $2bn offering is expected to close on 27 February, subject to customary closing conditions.

Boston Scientific will apply the proceeds from this offering – along with borrowing through its existing commercial paper program and cash on hand – to the $3.4bn acquisition of Axonics, announced in January.

Axonics will add sacral neuromodulation therapy for incontinence to Boston Scientific's existing urology business. (Also see "*Updated: Boston Scientific Buys Axonics For $3.4BN; Adds Neuromodulation To Incontinence Lineup*" - Medtech Insight, 8 Jan, 2024.)

Tricuspid Repair Market Set To Boom, Wells Fargo Predicts

Wells Fargo analysts predict the nascent US transcatheter tricuspid valve repair and replacement market will reach $1.3bn within five years.

They previously projected this market would be worth $853m by 2028, but changed their estimate after surveying about 50 physicians who perform transcatheter valve procedures.

The physicians surveyed expect that their tricuspid repair and replacement procedure volume would eventually be about 20% as large as their volume of transcatheter aortic valve replacement (TAVR) procedures, which implies about 33,000 tricuspid procedures in the US annually.

Wells Fargo expects the total volume of tricuspid valve replacement procedures to match the volume of tricuspid valve repairs.

The US Food and Drug Administration recently approved *Edwards Lifesciences'* Evoque

transcatheter tricuspid valve replacement system. Edwards is also developing the Pascal Precision system for both mitral valve repair and tricuspid valve repair. (Also see "*Cardio Catch-Up: FDA Approves Edwards Evoque Transcatheter Tricuspid Valve Sooner Than Expected*" - Medtech Insight, 6 Feb, 2024.)

The FDA will likely approve Abbott's TriClip G4 transcatheter edge-to-edge repair device by the middle of 2024 after an advisory panel almost unanimously agreed that its benefits outweigh its risks. Abbott has not announced specific plans for a transcatheter tricuspid valve replacement device. (Also see "*Abbott Moves Forward With TriClip G4 TTVR After Successful Advisory Panel*" - Medtech Insight, 15 Feb, 2024.)

"Our current tricuspid forecast assumes 60% Edwards share and 40% Abbott share in 2028," Wells Fargo analyst Larry Biegelsen wrote in a 25 February report. "Our higher share for Edwards assumes that Pascal for tricuspid repair is launched before 2028 and Edwards can offer both a replacement and repair device, whereas Abbott only has a repair device."

Most of the survey respondents plan to use both Evoque and TriClip G4 – 90% said they will use Evoque and 87% said they will use TriClip G4. Among the few physicians who said they would not offer TriClip, some said they have more confidence in Evoque as a long-term therapy, Biegelsen reported.

Wells Fargo's survey also asked physicians about their expectations for TAVR volumes. Based on the responses, Wells Fargo expects the overall volume of TAVR in the US to grow in the low double digits over the next two years, with Abbott's new Navitor system taking a few percentage points of market share from Medtronic's CoreValve and Edwards' Sapien TAVR systems. (Also see "*Minute Insight: Abbott Rolls Out Navitor Next-Gen TAVR System To Catch Up To Medtronic And Edwards*" - Medtech Insight, 25 Jan, 2023.)

FDA Authorizes First Minaturized Robotic Assisted Surgery Device

The US Food and Drug Administration *granted de novo authorization* to *Virtual Incision*'s MIRA surgical system for colectomy procedures in adults.

Virtual Incision plans to start commercialization of MIRA through a first access program in select US centers and expand to additional centers as it ramps up MIRA's production.

The Nebraska-based company calls it the world's first miniaturized robotic-assisted surgery (miniRAS) device.

The authorization is based on results from a trial in 10 patients showing the MIRA system was

safe and effective for right and left colectomy, with excellent clinical and quality outcomes. John Marks, from Lankenau Medical Center near Philadelphia, presented *the results* last June at the American Society of Colon and Rectal Surgeons (ASCRS) conference in Seattle.

Virtual Incision CEO John Murphy announced the de novo authorization on 24 February at the Society of American Gastrointestinal and Endoscopic Surgeons Next Big Thing Innovation Weekend in Houston.

“Whether as a complement to the existing mainframes or as a stand-alone platform, miniaturization has the potential to accelerate the adoption of robotic-assisted surgery,” Murphy said.

Virtual Incision recently sent MIRA to the International Space Station to test its automated and remote surgical capabilities. (Also see "*News We’re Watching: LivaNova Names CEO; Surgical Robot Goes To Space, And More*" - Medtech Insight, 5 Feb, 2024.)

MMI Raises $110M For Microsurgery Innovation

Medical Microinstruments (MMI) announced the completion of a $110m series C financing led by Fidelity.

The round is the largest ever investment in microsurgery innovation, MMI announced on 22 February. The Florida company has raised over $200m in funding to date.

The funds will support commercialization of MMI’s Symani surgical system in high-growth markets, and help MMI scale its global operations while continuing to generate clinical evidence and enable indication expansions.

Symani is a unique micro-scale robotic technology designed to replicate the natural movements of the human hand and expand the options for soft-tissue repair.

“Against a backdrop of plateauing investments in medical robotics, this support builds on our confidence in a new, less invasive solution for open surgery, a significant market that can benefit from the smallest wristed microinstruments,” said MMI CEO Mark Toland.

Fabric Raises $60M To Fund Care Automation

Fabric, a New York-based clinical intelligence engine company, secured a $60m series A round led by led by General Catalyst.

The funding also includes continued participation from Thrive Capital, Google Ventures, Salesforce Ventures, Vast Ventures, Box Group, and Atento Capital.

Fabric said it will dedicate a large portion of the funding to growing its staff and advancing a "care-enablement system that delivers convenience and workforce automation through a unified platform that replaces a patchwork of fragmented technology solutions."

Fabric's technology relies on intelligent adaptive interviews to automate symptom gathering and provider documentation. The company said its technology can reduce contact center volume by 30%, call-center waiting time by 35%, and hospital readmission rates by more than 10%.

So far, Fabric has 70 enterprise health customers on its platform, including Luminis Health, a non-profit health system providing care for 1.8 million people.

"Fabric addresses capacity constraints by streamlining workflows before, during, and after an encounter – across virtual and in-person care," said Luminis' chief digital and information officer Saad Chaudhry. "Fabric's expanded suite helps us drive automation and efficiency from onset through post-visit care – removing barriers to access."

Fabric recently acquired Gyant, developer of a conversational care assistant and patient engagement tool, and Zipnosis, which specializes in "asynchronous care" to expand access and affordability of care.

[Editor's note: *For a complete listing of recent financings, alliances and acquisitions in medtech and diagnostics, see* Medtech Insight's *Medtech Financing and M&A trackers or Citeline's Biomedtracker. All of the trackers can be accessed from the Data pulldown menu on the home page.*]