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News We're Watching: Potential Shockwave Sale, Medtronic Layoffs, Warning Letter For Abbott

by Brian Bossetta

This week, the US FDA announced the Class I recall of Fresenisu Kabi's Ivenix Infusion System. Also: Successful trial results from Boston Scientific, Ancora partners with Egnite, and trade groups object to the Environmental Protective Agency's proposed rules on ethylene oxide.

Boston Scientific May Acquire Shockwave

Boston Scientific is talking to *Shockwave Medical* about a possible acquisition deal, *Bloomberg* reported on 21 April, citing "people with knowledge of the matter."

Shockwave would be a natural fit for Boston Scientific, which has traditionally been a leader in interventional cardiology. Shockwave markets intravascular lithotripsy technology to treat calcified vascular disease and recently completed a $100m acquisition of Neovasc, the Vancouver, BC-based developer of Reducer, a minimally invasive device to treat angina. (Also see "*Shockwave Buys Neovasc, Hoping Reducer Angina Device Complements Coronary Lithotripsy*" - Medtech Insight, 18 Jan, 2023.)

Bloomberg points out that if Boston Scientific buys Shockwave, it could be its biggest acquisition since it bought Guidant for more than $27bn in 2006. Shockwave's current market cap is $9.6bn.

It recorded $489.7m in revenue in 2022, representing a 107% year-over-year increase, and the company expects its revenues to grow at least 35% in 2023.

Shockwave's stock price is up nearly 30% this year so far and jumped from $262 to over $290 after *Bloomberg* reported that the companies were negotiating a deal. At the same time, Boston Scientific shares dipped slightly, from $52.60 to just below $51.

In a 21 April note, Wells Fargo analyst Larry Biegelsen argued "The acquisition of Shockwave would make strategic sense for Boston Scientific as it already participates in Shockwave's two core markets, coronary and peripheral [intervention], and could leverage Shockwave's technology through its existing sales force on a global scale. [However,] financially, the deal is hard to justify."

Biegelsen also pointed out that Boston Scientific is already developing its own intravascular lithotripsy and could have bought Shockwave any time in the recent past when the price would have been much lower. "It's unclear to us why the timing makes sense now."

In a 21 April note, BTIG analyst Marie Thibault wrote, "There could be a potential antitrust risk [with this deal] given Boston Scientific's portfolio of existing rotational atherectomy systems."

However, Shockwave's intravascular lithotripsy technology would complement Boston Scientific's existing coronary and peripheral intervention portfolio, Thibault explained. She also pointed out that the deal could help Boston Scientific stay competitive with Abbott, which recently added coronary and peripheral atherectomy technologies to its interventional portfolio by acquiring Cardiovascular Systems for $890m.

Leak In Fluid Delivery System Results In Class I Recall

The US Food and Drug Administration has *labelled* a recall of the Ivenix Infusion System from *Fresenius Kabi AG* USA as class I, its most serious.

The company's March recall included 1,546 devices distributed in the US between October 2021 and 30 January. The Ivenix Infusion System is a large-volume pump used in hospitals and other clinical settings to give fluids to patients in a precisely controlled manner.

The company says the recall was due to a leak that allows fluid to enter system, which could lead to loss of power and failure. This issue, the FDA says, may cause serious injury or death to patients because of interruption to critical fluids, blood products, and medications.

The FDA says the company has received 14 complaints related to this issue, but no reported injuries or deaths.

Boston Scientific's Farapulse PFA Succeeds In One-Year Results

One-year results from 1,568 patients treated at 24 centers in the *MANIFEST PF* registry showed Boston Scientific's Farapulse pulsed field ablation system produces durable reductions in atrial

fibrillation.

Vivek Reddy of Mount Sinai Hospital in New York presented the MANIFEST PF results at the European Heart Rhythm Association conference in Barcelona.

In the study, 82% of the patients with paroxysmal (occasional) atrial fibrillation were free of atrial fibrillation one year after undergoing a pulmonary vein isolation ablation procedure with Farapulse. About 72% of the patients who entered the study with persistent atrial fibrillation were atrial fibrillation-free one year after treatment. Both outcomes are "among the highest success rates achieved in a registry this large," according to the company.

Reddy pointed out that the centers which had to perform fewer "re-do" ablations after the first one failed also tended to have better one-year results overall. "It raises the possibility, that needs to be tested, that if we can get good durability, even in [people with persistent atrial fibrillation], we could get very good clinical success," he told *Medtech Insight*.

There was a single case of sustained phrenic nerve palsy, no pulmonary vein stenosis and no esophageal injury, so the researchers concluded that Farapulse is safe in this real-world experience.

Reddy pointed out the median procedure time in the MANIFEST PF registry was just under an hour, "which is pretty remarkable. It was a highly efficient procedure."

Farapulse PFA system has been available commercially in Europe since 2021 and Boston Scientific is one of many companies trying to earn US Food and Drug Administration approval for a PFA system. (Also see "*Medtronic Earns CE Mark For Affera Ablation System, Touts New PFA Results*" - Medtech Insight, 17 Mar, 2023.)

Boston Scientific is also sponsoring *ADVENT*, a randomized trial comparing Farapulse to radiofrequency ablation and cryoablation in the US, and *ADVANTAGE AF*, a 400-patient randomized trial of Farapulse in patients with persistent atrial fibrillation. (Also see "*IPM 2023: Boston Scientific Sees Transformational Potential In PFA, BD Sticks To '2025' Investment Strategy*" - Medtech Insight, 11 Jan, 2023.)

Ancora Heart Partners With Egnite To Accelerate Trial

Ancora Heart will use novel digital health technology to accelerate enrollment in the pivotal trial of its heart failure therapy.

Ancora Heart is currently sponsoring *CORCINCH HF*, a 400-patient randomized trial comparing

Ancora's AccuCinch ventricular restoration system to guideline medical therapy in patients with heart failure and reduced left-ventricular ejection fraction. (Also see "*Cardio Catch-Up: Medtronic, Abbott, Ancora Devices Headline ACC, CRT, THT*" - Medtech Insight, 23 Mar, 2023.)

On 19 April, the Silicon Valley medtech company announced a new partnership with egnite, a Southern California artificial intelligence company, and The Christ Hospital, a Cincinnati-based hospital network, to accelerate enrollment in the trial.

The egnite Trial Accelerator technology applies artificial intelligence and "big data processing" technology to rapidly search thousands of patient records to identify potential trial participants. The alternative is manual chart review requiring many hours of staff time. (Also see "*Cardio Catch-Up: Updates From B-Secur, egnite, Vektor, And Other Under-The-Radar Companies*" - Medtech Insight, 20 Jun, 2022.)

"Identifying patient candidates for clinical trial participation can be a complex task that requires many hours to review medical charts in the search for matching clinical criteria," said Dean Kereiakes, president of The Christ Hospital Heart and Vascular Institute and co-principal investigator for CORCINCH-HF. "The use of AI technology streamlines the trial screening process by identifying candidates more quickly and efficiently, thereby freeing up critical resources needed for clinical trial success."

Christ Hospital has already begun using egnite's technology to enroll patients in the trial and the other trial sites will adopt it soon, according to the companies.

Medtronic Starts Layoffs

Medtronic plc will begin to announce staff cuts in the coming weeks as part of an ongoing restructuring and cost-cutting initiative.

Medtronic CEO Geoff Martha has told employees to expect job cuts in the coming weeks and months, according to a 18 April report from *The Star-Tribune*, the largest newspaper in Medtronic's home state of Minnesota.

The company has not said how many positions will be cut, but that the impact will vary by team, region and country. Medtronic currently employs about 100,000 people worldwide.

"These decisions are never easy, and we're taking great care to treat all impacted employees with dignity and respect," Erika Winkels, Medtronic senior director of corporate relations told *The Star-Tribune*. "Medtronic will follow fair, consistent processes and provide comprehensive transitional resources to impacted employees during this time."

The company began a major restructuring process when Martha became Medtronic's CEO in 2020 and he implied that job cuts were coming during the company's third-quarter conference call in February. (Also see "*UPDATED: JPM 2023: Baxter, Medtronic Pursue Simplification As Path To Growth*" - Medtech Insight, 9 Jan, 2023.)

"The aggressive transformation at Medtronic is advancing," Martha said. "We're progressing on our plans for significant cost reductions. These are aimed at partially mitigating the continued impacts from macro conditions such as inflation and [foreign exchange] on our profitability and cash flow. These cost reductions also create room on our [profit and loss] so that we can increase our growth investments."

Medtronic's stock price jumped from $81.64 to over $85 following the company's announcement to employees, but has since settled around $83.50.

Abbott Branch Warned For Selling Unauthorized Test Kit

Abbott Point of Care Canada Ltd. has landed an *FDA warning letter* after the agency found the company is selling a version of its i-STAT cTnI Test that does not have regulatory clearance. The test, which measures cardiac troponin I in whole blood or plasma, is used in the diagnosis of heart disease.

The warning letter, which is dated 8 November 2022 but was published this week, says that Abbott has made several changes to the test since it was cleared via 510(k) in 2003. These include changes to the sensor chip, reagent, and other test components that could affect the reliability of the test, potentially leading to false negatives or false positives.

Further, the FDA says that Abbott violated good manufacturing practices by failing to properly document design changes and lacking accessible records.

"For example, during the inspection the investigator asked to review a copy of the original design to compare to any current changes. Your firm could not locate the original cartridge design files because the person in charge of storing the cartridge design history files had retired from the company and your firm had been trying to locate the person in retirement to try to find where the original design files where stored," the warning letter states.

While Abbott had responded to the Form 483 inspectional observations, the agency said that response was inadequate in parts, and insufficient in others.

BARDA Awards $54M COVID, Flu Assay Contract To Aptitude Medical Systems

California-based Aptitude Medical Systems has received a contract worth up to $53.7m from the Biomedical Advanced Research and Development Authority (BARDA) to support the development and validation of at-home molecular diagnostic assays for COVID-19 and influenza.

The company is working to develop molecular diagnostics that can be sold over the counter and will deliver reliable results in less than half an hour, at a price point similar to that of rapid antigen tests. The tests will run on Aptitude's Metrix testing platform, which incorporates electrochemical reporting technology and real-time loop-mediated isothermal amplification (RT-LAMP).

Aptitude's saliva-based Metrix COVID-19 assay received emergency use authorization (EUA) from the FDA last fall.

Trade Groups Push Back Against EPA's EtO Proposal

Medtech groups are pushing back against proposed rules by the Environmental Protection Agency regulating ethylene oxide, a chemical used to sterilize medical devices.

On 11 April, the EPA proposed two rules to manage EtO emissions in the US: the first rule updates emission standards for EtO sterilizers, while the second aims to protects workers exposed to EtO in facilities. (Also see "*FDA, EPA Take Action Against EtO Emissions*" - Medtech Insight, 12 Apr, 2023.)

Medtech advocacy group AdvaMed recently asked the EPA to push back its comment deadline, increasing the comment period by 60 days for both the NESHAP (Facilities National Emission Standards for Hazardous Air Pollutants) rule and the PID and draft risk assessment for ethylene oxide.

"After waiting 17 years for an updated regulation from the EPA… an extra 60 days to ensure that the final rule is clear, reasonable, based on clear science, and will not lead to a shortfall of the critical medical technologies patients depend on is critically important," said AdvaMed president and CEO Scott Whitaker in a release.

AdvaMed reaffirmed it is aligned with the commitment of the EPA, FDA and industry, which is "a safe sterilization process that protects employees and the communities surrounding these facilities and maintains an uninterrupted supply of… medical supplies millions of American patients depend on every day."

The Ethylene Oxide Sterilization Association also released a statement on 21 April expressing

concern about the EPA's risk assessment and proposed rules.

"In making its final determination on EtO, the EPA relied on only a narrow subset of the available data, conducted a flawed analysis of that data, and dismissed other data that contradicted its evaluation," claimed the organization in an email release.

WHO Issues Tuberculosis Diagnostics Guidance Doc

The World Health Organization has issued its first set of recommendations aimed at ensuring universal access to tuberculosis diagnostics. The document, "*WHO standard: universal access to rapid tuberculosis diagnostics*," includes benchmarks across the four steps of the diagnostic process: identifying presumptive TB, accessing testing, being tested and receiving a diagnosis.

The document also recommends diagnostics known to be reliable and cost-effective and discusses goals such as increasing the rate of TB cases confirmed through bacteriology, detecting drug resistance, and reducing the time to diagnosis.

"Enabling universal access to rapid TB diagnostics recommended by WHO, will ensure that people with TB get on the pathway to cure faster, cutting transmission and the impact of this debilitating disease on their lives and families," said Dr Tereza Kasaeva, Director of WHO's Global TB Programme. "We encourage countries to rapidly implement the standard and call for investments and support from partners, donors and civil society to ensure universal access to WRDs".