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News We're Watching: Amazon Drops Wearables, FDA Warns Of Cyber Threat, Researchers Find Parkinson's Biomarker

by Reed Miller

This week, the FDA issued a cybersecurity threat to gene sequencing platforms from Illumina and Amazon announced it was getting out of the fitness wearables business, while researchers announced a breakthrough in Parkinson's diagnostics.

Analysts Doubt Boston Scientific Will Buy Shockwave

Boston Scientific executives have refused to discuss reports that the company may acquire *Shockwave Medical*, and the Wall Street analysts suspect the rumored deal may not happen.

Bloomberg reported on 21 April that Boston Scientific was considering a deal to add Shockwave's successful intravascular lithotripsy technologies to its vascular intervention business. (Also see "*News We're Watching: Potential Shockwave Sale, Medtronic Layoffs, Warning Letter For Abbott*" - Medtech Insight, 21 Apr, 2023.)

The company will not comment on the report. "As a matter of practice, we never comment on rumors or speculation in the marketplace," Boston Scientific CEO Mike Mahoney said during its 26 April first-quarter 2023 sales and earnings call.

> *"We came away feeling comfortable that the probability of a Shockwave deal is fairly low." – Lee Hambright*

Chief Financial Officer Daniel Brennan added, “We’re committed to looking at deals that are high growth and 'tuck-in' acquisitions as we’ve done [in the past],” referring to Boston Scientific’s recent acquisitions of *Apollo Endosurgery*, *Acotec Scientific*, *Baylis Medical* and *Farapulse*. (Also see "*Boston Scientific Makes Half Billion Dollar GI Endosurgery Play*" - Medtech Insight, 30 Nov, 2022.)

“[Our] first priority is high-quality tuck-in adjacent-type growth M&A,” Brennan said.

Wall Street analysts interpreted the executives’ comments to mean that a deal for Shockwave is possible, but not likely.

“While management responses on the call seemed to leave the door open to a potential Shockwave deal, we came away feeling comfortable that the probability of a Shockwave deal is fairly low,” Bernstein Research analyst Lee Hambright wrote on 27 April.

On the same day, Jayson Bedford of Raymond James wrote “Boston Scientific’s response [to questions about Shockwave] was mixed, and could be read both ways.”

Boston Scientific has historically prioritized “tuck-in” acquisitions, but Shockwave would probably cost Boston Scientific more than $10bn, so it would not be considered a "tuck-in,” he explained. Besides, Boston Scientific has enough potential growth-drivers in its product pipeline, such as the Farapulse pulsed field ablation system. (Also see "*News We’re Watching: Potential Shockwave Sale, Medtronic Layoffs, Warning Letter For Abbott*" - Medtech Insight, 21 Apr, 2023.)

"Strategically, the deal makes sense. Financially, it could be a stretch depending on the amount of equity used, and the resulting cost synergies," Bedford concluded. “This deal is unnecessary, given the momentum in the business, and the pipeline.”

BTIG analyst Marie Thibault agreed that buying Shockwave would be a deviation from a strategy that is working well for Boston Scientific. “We heard plenty of trepidation about the media-reported speculation of a tie-up with Shockwave Medical and believe Boston Scientific shareholders would prefer the company stick to truly 'tuck-in' acquisitions.”

A few analysts suggested that uncertainty about the potential Shockwave deal is weighing on Boston Scientific’s share price.

The company’s revenue grew 14% year-over-year in the first quarter of 2023, easily beating its previous guidance of 6-8%. The company’s stock price grew modestly, from $50.49 on the morning of 26 April to near $52.75 by the end of the week.

Amazon Discontinues Halo Health

Amazon is exiting the fitness wearables business.

“We are incredibly proud of the invention and hard work that went into building Halo on behalf of our customers, and our priorities are taking care of our customers and supporting our employees,” the company said in a *26 April announcement*.

The retail and tech giant will stop supporting Halo wearable fitness devices and the associated health data service as of 31 July and the devices will no longer work after that date.

Amazon will fully refund Halo purchases made in the preceding 12 months – including Amazon Halo View, Amazon Halo Band, Amazon Halo Rise, and Amazon Halo accessory bands. It advises anyone who has a Halo device to send it back to the company to be recycled.

Amazon launched the Halo service and the first Halo wearable device, Halo Band, in August 2020. At the time, the company touted Amazon Halo as a combination of advanced sensors and artificial intelligence that would provide actionable insights into the users’ overall wellness.

Amazon's decision to exit the business is part of a series of cost-cutting moves, including plans to cut about 27,000 jobs. In August 2022, Amazon closed its Amazon Care health care service just a few months after announcing plans to expand it. (Also see "*Minute Insight: Amazon Gives Up On Amazon Care, Shifts Focus To Acquisitions*" - Medtech Insight, 26 Aug, 2022.)

“While we’ve taken several actions to streamline our costs, we’ve been able to do so while still pursuing the key strategic long-term investments that we believe can meaningfully make customers lives better and potentially change what Amazon is,” Amazon CEO Andrew Jassy said during the company’s 27 April first-quarter 2023 earnings call.

The company has notified the employees who supported Halo and is providing packages that include a separation payment, transitional health insurance benefits, and external job placement support.

FDA Warns Of Cybersecurity Risk To Illumina Gene Sequencing Diagnostics

The US Food and Drug Administration posted a *warning* about a cybersecurity threat to *Illumina* clinical diagnostic devices that sequence human DNA for research applications.

According to the FDA, the Universal Copy Service software in the Illumina MiSeqDx, NextSeq 550Dx, iScan, iSeq 100, MiniSeq, MiSeq, NextSeq 500, NextSeq 550, NextSeq 1000/2000, and NovaSeq 6000 sequencing instruments are all vulnerable to this cyber threat.

The FDA warns that unauthorized users could exploit the vulnerability by taking control remotely; altering settings, configurations, software, or data on the instrument or a customer's network; or impacting genomic data results in the instruments intended for clinical diagnosis, including causing the instruments to provide no results, incorrect results, altered results, or a potential data breach.

The warning also provides recommendations for providers and personnel to avoid this risk.

However, as of 27 April, neither the FDA nor Illumina have received any reports indicating this vulnerability has been exploited.

Abbott Closes Cardiovascular Systems Deal

Abbott announced the completion of its planned acquisition of Cardiovascular Systems (CSI) on 27 April.

In February, Abbott announced an agreement to buy Minnesota-based CSI for $890m, but did not project when the deal would close. (Also see "*Abbott Buys CSI To Add Peripheral And Coronary Atherectomy Technologies*" - Medtech Insight, 9 Feb, 2023.)

CSI gives Abbott vascular atherectomy devices that complement its existing vascular intervention portfolio.

"For patients with complex cardiovascular disease, new and innovative therapies such as CSI's leading atherectomy system are an opportunity to live better, fuller lives," said Lisa Earnhardt, the executive vice president of Abbott's medical devices division. "The acquisition of CSI is a component of an overall investment in our vascular portfolio that enhances our ability to care for patients with peripheral and coronary artery disease."

FDA Clears Two Abbott CentriMag Life Support Devices

Abbott announced two US Food and Drug Administration clearances for two components of the company's CentriMag life-support system.

The agency expanded the indication for Abbott's CentriMag blood pump. It was *previously cleared* for up to six hours of circulatory support and is now labeled to provide longer-term life support to critically ill patients.

The FDA also cleared Abbott's CentriMag Pre-Connected Pack – a packaged system with several

pre-connected components of the CentriMag system designed to accelerate the deployment of the life support system.

"With the two new FDA clearances, physicians can deploy support in fewer steps and are provided more time to get their patients the necessary treatment during a critical window," said Robert Kormos, vice-president for global medical affairs in Abbott's heart failure business.

Researchers Identify 'Breakthrough' Parkinson's Biomarker

The Parkinson's Progression Markers Initiative (PPMI) has developed an assay that classifies people with Parkinson's disease with high sensitivity and specificity.

In a paper in *The Lancet Neurology*, researchers led by Andrew Siderowf of the University of Pennsylvania in Philadelphia describe their alpha-synuclein seed amplification assay (αSyn-SAA) and present the results of an 1,123-patient study showing that the αSyn-SAA can distinguish Parkinson's from control volunteers with an 88% sensitivity and 96% specificity.

> *"Validation of this biomarker launches a new, biological era in Parkinson's research." – Kenneth Marek*

"Validation of this biomarker launches a new, biological era in Parkinson's research," said PPMI principal investigator Kenneth Marek. "Using αSyn-SAA, we are already unlocking new understanding of Parkinson's, which will transform every aspect of drug development and ultimately clinical care."

PPMI is funded by the Michael J Fox Foundation and about three-dozen pharmaceutical companies and philanthropies.

Michael J. Fox said, "I am deeply moved by this breakthrough and endlessly grateful to the researchers, study participants and funders who have endeavored to bring us this far. When we started PPMI, we weren't casting about for fish — we were going after a whale. Now, here we are. Together we are making a cure for Parkinson's inevitable."