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Digital Health Roundup: Black Friday Hits – Digital Twins, Biowearables, Robotics, Cardiology

by Marion Webb

In this month's Digital Health Roundup, *Medtech Insight*'s Marion Webb highlights interviews with Abbott's head of Lingo Biowearables and top executives at Twin Health. Reed Miller provides an update on J&J MedTech's launch of the Ottava soft-tissue robotic surgery system and Barnaby Pickering talks about his recent interview with Leo Grady, former CEO of Paige AI, to talk about his new start-up Jona.

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Twin Health's platform uses daily data points and artificial intelligence to help people collect daily data points from continuous glucose monitors, wearables that track multiple biomarkers, blood pressure meters and smart scales to help people with chronic disease, such as diabetes, get off their medications and live healthier lives.

In a clinical study of 199 people who had been diagnosed with diabetes for an average of about four years, after six months of using the Twin Health program, 94.9% of participants reached an HbA1C of less than 6.5% using no medications or only metformin; 83.9% achieved diabetes remission based on the criteria of the American Diabetes Association. The findings were presented at the ADA's annual scientific meeting in New Orleans last June.

Twin partners with self-insured employers that offer its Twin platform as a wellness product to their employees as well as with health plans to help members live free from chronic metabolic

disease by addressing the root cause of the disease, John Davis, Twin's chief commercial officer told *Medtech Insight*. (Also see "*Can Digital Twin Technology Help Beat Chronic Disease? Twin Health Is Getting Users Hooked, And Off Their Meds*" - Medtech Insight, 1 Nov, 2023.)

<u>Abbott</u>'s CEO Robert Ford first introduced the company's new line of consumer biowearables called Lingo, starting with glucose monitoring, at the Consumers Electronics Show in Las Vegas in 2022. This October, Ford returned to Las Vegas, this time to take the stage at the HLTH conference, to talk about Lingo's evolution.

"We're so steeped in scientific and medical expertise that we never really learned how to talk to or with regular people," Ford told HLTH attendees on 10 October. "At Abbott, we're working on changing that."

This August, Abbott first introduced Lingo to consumers in the UK to monitor their metabolic health, and thus far, the reception has been "extremely positive," Olivier Ropas, division vice president of Abbott's Lingo Biowearable told *Medtech Insight* at HLTH. Abbott plans to file for US Food and Drug Administration clearance of the device by year-end, then make Lingo more widely available in the UK. (Also see "*Abbott's Metabolic Biowearable Gets 'Extremely Positive' UK Reception; Next Up, US Filing*" - Medtech Insight, 18 Oct, 2023.)

Robotics

After a series of delays, *Iohnson & Johnson (Pty) Ltd* MedTech is set to start a first-in-human clinical trial of its Ottava soft-tissue robotic surgery system next year.

The company expects to submit the IDE application in the second half of 2024, putting it on track to start the trial in 2025 and earn a de novo authorization for Ottava by the end of 2026.

J&J also markets the Monarch robotic platform for bronchoscopy and urology procedures and the Velys robot for orthopedic surgery. Ottava is intended to address "a broad spectrum of procedures," according to the company. The company has not specified which types of surgery will be included in the first-in-human trial. (Also see "*After Two-Year Delay, J&J Plans To Start Trial Ottava Surgical Robot In 2024*" - Medtech Insight, 7 Nov, 2023.)

Cardiology FDA Clearances

The FDA granted breakthrough status to Toku's CLAiR AI technology platform for real-time cardiovascular disease risk assessment.

CLAiR analyzes images of the tiny blood vessels in the retina to find signals of cardiovascular risk factors, including hypertension and high cholesterol. The system is designed to be integrated into routine retinal imaging exams performed by ophthalmologists, primary care clinics, and pharmacies. (Also see "News We're Watching: Breakthrough Retinal Scan For CV Disease,

<u>InfoBionic's AI-Powered Remote Monitoring, And More</u>" - Medtech Insight, 6 Nov, 2023.)

The FDA also cleared InfoBionic's MoMe ARC wireless ambulatory electrocardiogram (ECG) monitoring and detection system, their third-generation remote-ECG monitoring device, to be paired with a new Bluetooth diagnostic six-lead sensorn. (Also see "News We're Watching:

Breakthrough Retinal Scan For CV Disease, InfoBionic's AI-Powered Remote Monitoring, And More" - Medtech Insight, 6 Nov, 2023.)

MoMe ARC is indicated to help doctors diagnose cardiac arrhythmias in patients with a "demonstrated need for cardiac monitoring." It builds on the success of the MoMe Kardia II by providing a decoupled two-channel – six-lead sensor.

The company also announced the closure of a series D financing to support domestic growth and international expansion for MoMe ARC as well as a new deal with Mayo Clinic to "incorporate its extensive know-how" into cardiac patient monitoring, AI-ECG, and virtual telemetry.

Microbiome

Former CEO of Paige AI, Leo Grady has debuted his next venture Jona emerging from stealth. Paige AI successfully developed the first AI-based histology software to earn FDA approval.

Biblically named for a reason, Grady and the team at Jona hope to un-muddy the waters around microbiome testing. In an interview with *Medtech Insight*, Grady explained that current market leaders in the space are predominantly "wellness" companies which offer limited insights at high prices. (Also see "*Leo Grady's Jona Hopes To Repair Microbiome Testing's Murky Reputation*" - Medtech Insight, 1 Nov, 2023.)

Jona's plan is to offer much more detailed information to patients by using metagenomic sequencing, a relatively new approach capable of sequencing all genes in all organisms present in a sample.

Initially, Jona's tests will be available to consumers. Grady explained that launching this way unlocks two opportunities for the company; it can prove its worthwhile also collecting bulk amounts of data for cheap.

Funding

*Medtech Insight s*poke to Sofinnova Partners about the closure of their latest fund focused on digital medicine.

Partner Simon Turner spoke at length about Sofinnova's focus on enabling technologies, or the "picks and shovels" that will bring digital technology to the forefront of patient care.

CITELINE COMMERCIAL

So far, Sofinnova Digital Medicine I has invested in five companies, having raised a total of \$200m. These companies run the gamut of health care and share common features that Turner discussed. (Also see "*Investing In Digital: Slow And Steady May Win This Race*" - In Vivo, 1 Nov, 2023.)

Other noteworthy recent articles on digital health topics:

- NIH Supports AI Brain Imaging at IU
- <u>Dupont Teams Up With STMicroelectronics On Wearables</u>
- Insulet Gets A 'Big Win:' FDA Clears Omnipod 5 App For IPhone