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News We're Watching: Medtronic To Buy EOFLow, Neuralink Cleared For Human Trials, NICE Backs Genetic Tests

by Brian Bossetta

This week, Medtronic said it would pay $738m for insulin patch firm EOFlow; Neuralink got an FDA OK for first-in-human trials; and UK agency NICE backed genetic tests for stroke patients and digital therapeutics for mental health conditions.

Medtronic To Buy Korean Insulin Patch Company EOFlow For $738m

Medtronic plc plans to acquire *EOFlow Co., Ltd.* for up to $738m and integrate EOFlow's tubeless, disposable insulin patch with its own continuous glucose monitor (CGM) technology. The companies expect the deal to close in the second half of 2023.

EOFlow's EOPatch relies on a proprietary microfluidic technology to precisely and reliably deliver insulin from a wearable patch. It is available in Europe, South Korea, Indonesia, and the United Arab Emirates with a compatible smartphone application.

Medtronic plans to quickly integrate the EOPatch device with the next-generation sensor and Meal Detection Technology algorithm offered in its MiniMed 780G hybrid-closed loop insulin delivery system. (Also see "*Medtronic's 780G – Finally! – Gets FDA Approval*" - Medtech Insight, 25 Apr, 2023.)

Medtronic announced the deal during its fiscal 2023 fourth-quarter sales and earnings call on 25 May.

"We're very familiar with the technologies in the patch space, as well as the manufacturing challenges there," Que Dallara, the president of Medtronic's diabetes business, said during the call. "EOFlow has proven manufacturability at scale … so, it is relatively straightforward integration and approval process to get that to market."

“From a strategic perspective, we are the only integrated player in the diabetes technological space with both CGM algorithms as well as dosing systems; and very well-positioned for [automatic insulin delivery (AID)],” she said. “This acquisition accelerates the introduction of an AID patch into the market, and we expect to be the next to market with a differentiated product.”

Medtronic’s tubeless insulin delivery system could compete with Insulet’s Omnipod insulin pumps. Dallara pointed out that Medtronic has a covenant with Insulet not to sue each other over intellectual property for these devices.

“We're very confident about our IP position,” she said. “This is a very differentiated device with Medtronic's algorithms and our sensor technology, so we're very confident in the product differentiation in the market.”

However, Wells Fargo analyst Larry Biegelsen wrote “The Medtronic/Insulet agreement does not allow for cloning each other's products, [so] depending on the changes Medtronic makes to the EOFlow pump, we could envision addition litigation between Medtronic and Insulet because it is our impression that Insulet believes the current EOFlow pump is essentially a clone of their pump.”

Biegelsen expects Medtronic will integrate EOFlow’s technology into its Simplera continuous glucose monitor. Given that it will have to run a clinical trial to earn regulatory approval for the new integrated device, Medtronic will not be able to launch an AID system with EOFlow’s technology until 2026 at the earliest, he wrote in a 25 May note.

Nevertheless, Medtronic’s acquisition of EOFlow “puts increased pressure on Tandem to accelerate [development] of its Sigi pump and to look for ways to distribute that product through the pharmacy channel which may be challenging since Sigi is not a disposable pump like Omnipod and EOFlow.”’

Increased competition from Medtronic may fuel speculation that Dexcom is trying to acquire Insulet. Bloomberg reported last year that Dexcom was considering buying Insulet to develop a hybrid closed-loop insulin delivery system that could compete with Medtronic’s 780G. At the time, Dexcom said it was not in discussions to make a major acquisition. (Also see "*Dexcom Raises Another Billion, But Why?*" - Medtech Insight, 5 May, 2023.)

William Blair analyst Margaret Kaczor wrote, “Overall, we believe that the acquisition is an interesting one for Medtronic given our long-held belief that a patch pump form factor offers the most simple and efficient form of insulin delivery for diabetic patients.”

The specific terms of the deal call for Medtronic to buy EOFlow shares from three EOFlow executives for 30,000 Korean won (KRW) per share and buy new shares at a price per share of

KRW 24,359 to fund EOFlow's ongoing operational and research and development requirements. Medtronic will also undertake a public tender offer to acquire up to all outstanding public shares at a price per share of KRW 30,000.

So, if all the public shares participate in the tender offer, the total deal will be worth about KRW 971 billion, or $738m, at current exchange rates.

Neuralink Finally Cleared For First-In-Human Trials

Neuralink Corp. said the US Food and Drug Administration has approved its plan for a first-in-human trial of its Link brain-interface device, according to a 25 May *Twitter announcement*.

The company did not offer more details on the design of the study. “This is the result of incredible work by the Neuralink team in close collaboration with the FDA and represents an important first step that will one day allow our technology to help many people,” according to the Tweet.

According to Neuralink, the first clinical version of Link will help people with quadriplegia control a computer.

Neuralink founder Elon Musk has predicted the company was about to begin human trials multiple times over the last four years but did not actually apply to the FDA for an investigational device exemption until 2022, according to Reuters.

The agency previously rejected the company’s application to begin human trials. ((Also see "*News We’re Watching – FDA Nixes Neuralink Trials, Layoffs at J&J, Novel Knee Implants*" - Medtech Insight, 10 Mar, 2023.)

The company has been accused by former employees and animal activists of routinely mistreating animals in violation of federal good laboratory practices regulations. (Also see "*Activists Push US Government To Investigate Animal Abuse Charges Against Neuralink and UC Davis*" - Medtech Insight, 14 Dec, 2022.)

Onward’s Wireless Brain Interface Helps Paralyzed Person Walk

Onward's brain–spine interface implant allowed a man with a cervical spinal cord injury to regain some natural control his legs to stand, walk, and climb stairs, Swiss researchers reported in *Nature*.

In this case study of a 38-year-old main whose legs were paralyzed after a biking accident, Onward's ARC Therapy device allowed the user to "regain augmented control over when and how he moved his paralyzed legs."

ARC Therapy can be delivered by external ARC-EX or implantable ARC-IM systems to deliver targeted, programmed spinal cord stimulation.

The data published in Nature are part of Onward's ongoing STIMO-BSI clinical feasibility study investigating the safety and preliminary effectiveness of brain-controlled spinal cord stimulation after spinal cord injuries.

NICE Backs Genetic Test For Stroke Patients

England's health technology assessment (HTA) body, NICE, has recommended the use of genetic testing in stroke patients to determine whether the preventative drug clopidogrel is effective or not.

Clopidogrel is an antiplatelet drug often given to people who have had a stroke to prevent the risk of a secondary stroke occuring, but individuals with certain variations in the CYP2C19 gene cannot convert this drug to its active form.

This means that it is ineffective in these patients. The National Institute of health and Care Excellence (NICE) said on 19 May that stroke patients should be offered either laboratory-based or point-of-care testing for this mutation before they are treated with clopidogrel through the National Health Service.

It is estimated that 32% of people have at least one variant in the CYP2C19 gene that reduces the effectiveness of clopidogrel.

Digital Tech Backed For Mental Health Issues

Separately, NICE recently recommended the conditional reimbursement of digital technologies for adults with depression and anxiety, under its early value assessment (EVA) framework, for patients in England.

Three digital products that deliver cognitive behavioral therapy (CBT) for depression and three for anxiety will be funded through this scheme while more data are collected on their clinical and cost-effectiveness.

The digital CBT will be delivered via an app or website and include the support and involvement of a NHS Talking Therapies clinician or psychological wellbeing practitioner.

Philips Studies Imaging Equipment Energy Consumption

Continuing its drive to reduce its own carbon footprint and at the same time help other industry players do like likewise, *Royal Philips* has agreed to study the energy consumption of the imaging equipment used by the Vanderbilt University Medical Center (VUMC).

Philips will collect equipment lifecycle data, analyze operational workflows and build computational models on which to run simulations. Pilot projects will be set up to test the reduction of VUMC's department of radiology and radiological sciences' carbon footprint.

Publishing their findings will promote knowledge exchange and enable others in the industry to enhance their environmental strategies, the two organizations said on 22 May.

Philips is a front-runner in the carbon zero challenge. Carbon-neutral in its own operations since 2020, it was the first healthtech company to commit to science-based targets, head of global sustainability Robert Metzke told In Vivo. It was also the first healthtech provider to have Scope 1 to 3 targets approved by the Science Based Target initiative. (Also see "*The E in ESG: Philips Drives For Science-Based Targets In Carbon Zero Challenge*" - In Vivo, 22 Mar, 2023.)

The challenge of sustainability compliance was raised in Philips' recently published Future Health Index 2023, overseen by former Philips CMO Jan Kimpen. Kimpen is set to leave the company at the end of 2023. (Also see "*Leadership Report: More AI To Compensate For Healthcare Staff Shortages*" - In Vivo, 4 May, 2023.)

Draeger Medical Recalls Pediatric Breathing Circuit Kits

Draeger Medical Inc. is *recalling* the Seattle-Positive Airway Pressure (PAP), VentStar, and other breathing circuit/anesthesia kits because of a manufacturing error that may cause glued connections to loosen before or during ventilation.

The manufacturing glitch can interrupt the breathing circuit and may cause severe injury including lack of oxygen or death. This risk significantly increases for critically ill patients and newborns.

The FDA has labelled the recall class I, its most serious designation, though the company to date has reported no injuries or deaths related to the recall.

The Seattle PAP system supports infants who are struggling to breathe while in the hospital. The other products included in the recall are breathing circuit and/or anesthesia kits used together with ventilators during surgery or in the intensive care unit to support the breathing of infants, children, and adults.

The recall, initiated in April, includes 570,459 devices distributed in the US from January 2019 through February 2023.

Class I Recall For ICU Medical Infusion Systems Replacement Batteries

The US FDA has designated a *recall* from *ICU Medical, Inc.* as class I, its most serious type. The company recalled replacement batteries for its Plum 360, Plum A+, and Plum A+3 Infusion Systems due to diminished battery life that could result in the delay of infusion delivery. The systems are large volume pumps use to administer fluids to patients in precisely controlled amounts and rates.

Because of the diminished battery power, if there is no AC power backup available to run the pump, the system may shut down an ongoing infusion and power down sooner than expected potentially causing serious injuries, including death.

The recall, which the company initiated in March, included 1,904 devices distributed in the US between 7 February and 22 December 2022.

ICU Medical has received 519 complaints regarding this issue, but no injuries or deaths. However, the FDA says the agency has identified an adverse event potentially related to the recall.