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News We're Watching: Layoffs At Illumina, Canary's Heart Sensor; SCS To Help Amputees; Samsung's Apnea Monitor

by Reed Miller

Medtech Insight's News We're Watching highlights a few medtech industry developments we are following: Illumina will lay off 111 people from its San Diego headquarters as it comes to grips with the impending Grail divestiture; a team of researchers have devised a way to use spinal cord stimulators to give amputees "feeling" in a leg that is no longer there; Samsung earns FDA de novo for sleep apnea monitor.

Illumina Lays Off 111 People

<u>Illumina</u> will lay off 111 people from its San Diego headquarters according to California Worker Adjustment and Retraining Notification Act (WARN) data collected by the <u>San Diego Union</u> <u>Tribune</u>.

"As always, we are guided by the needs of our customers around the world," a company spokesperson told the newspaper.

"Illumina continues to invest in critical areas of innovation that have high customer demand, while also ensuring our structure, talent, and operating costs are aligned with our strategy. We understand the impact that this reduction has on our employees, and we are committed to continue treating all with respect and compassion."

Illumina employs about 10,000 people worldwide.

The company previously cut 230 jobs in 2023 as part of a plan to cut annual costs by \$175m as it divests liquid- biopsy manufacturer Grail. (Also see "*IPM 2024: Illumina Publishes Results And*

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Speaks On Future Efforts Towards Stabilization" - Medtech Insight, 10 Jan, 2024.)

The company reported its fourth-quarter and full-year earnings on 8 February. Revenue was down 2% to \$4.5bn in 2023, but up 4% year-over-year in the fourth quarter. The company recorded a loss of \$7.34 per share for 2023, including goodwill and intangible impairments of \$821m related to Grail.

Illumina shipped 352 NoaSeq X sequencing instruments in 2023, including 79 in the fourth quarter.

"Illumina is focused on three key priorities to accelerate value creation: driving our top line; focusing on operational excellence, including boosting productivity, cost savings and customer-focused innovation; and working to resolve Grail as quickly as possible," said CEO Jacob Thaysen.

Pitt Researchers Restore Sensory Feedback To Amputees Using SCS

Researchers at the University of Pittsburgh have shown that spinal cord stimulation can evoke sensations from a missing limb in people with transtibial amputation. This <u>somatosensation</u> can improve balance control and gait stability and reduce so-called "phantom limb pain."

The research group, led by PhD candidate Ameya Nanivadekar, developed a closed-loop device with commercially available electrodes to modulate spinal cord stimulation in real time based on signals from a wireless pressure-sensitive shoe insole.

Results of a three-patient study, published in <u>Nature Biomedical Engineering</u>, showed this stimulation improved the users' balance control, as measured by the Sensory Organization Test, and gait stability, as measured by the Functional Gait Assessment.

The three individuals reported a clinically meaningful decrease in phantom limb pain with an average reduction of nearly 70% on a visual analogue scale.

"Translation will still require substantial technical and clinical development, [but] this study shows the feasibility of using spinal cord stimulation to restore somatosensation from the missing foot with the potential to improve quality of life for people with lower-limb amputation," Nanivadekar explained. "Our findings support the further clinical assessment of lower-limb neuroprostheses providing somatosensory feedback."

Canary Launches Feasibility Study Of Acoustic Cardiac Sensor

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<u>Canary Medical</u> is sponsoring a first-in-human trial of a unique cardiac auscultation monitoring sensor device to be an implantable sensor that can provide daily cardiac parameter measurements for patients with congestive heart failure.

Multiple trials of Abbott's CardioMEMS system have demonstrated the value of closely monitoring heart failure patients with an implantable hemodynamic monitor. (Also see "*Abbott's CardioMEMS Monitor Improves Quality Of Life In Study*" - Medtech Insight, 15 Jun, 2023.)

CardioMEMS measures the pulmonary arterial pressure with a barometer, while Canary's monitor relies on acoustic signals to help quantify the level of heart valve stenosis or regurgitation, cardiac function, and fluid balance.

The two-patient trial in Paraguay demonstrated that Canary's sensor can distinguish mitral regurgitation sound signals from normal acoustic heart signals. It is about the size of a pacemaker, and with enough power to monitor and transmit for several years.

The sensor will rely on the same alert and analysis system that Canary originally developed for the Persona IQ "smart" knee implant marketed by Zimmer Biomet. (Also see "<u>AAOS 2022</u> <u>Roundup: Stryker, Zimmer Biomet, J&J's DePuy Synthes, Canary Medical</u>" - Medtech Insight, 29 Mar, 2022.)

"[The cardiac auscultation monitor is] the first step in expanding our sensor technology applications outside of orthopedics [and it is] just one of the exciting new products that will drive the future growth of our company," Canary CEO Bill Hunter wrote in a *LinkedIn post*, .

FDA Authorizes Sleep Apnea Feature For Samsung's Galaxy Watch

The US Food and Drug Administration has granted <u>de novo authorization</u> to a new sleep apnea feature on the Samsung Health Monitor app for Samsung's Galaxy smartwatch.

According to the company, the feature is the first of its kind to be authorized by the FDA. It was approved by Korea's Ministry for Food and Drug Safety in October 2023.

The sleep apnea feature lets users who have not previously been diagnosed with sleep apnea to detect signs of moderate to severe obstructive sleep apnea over a two-night monitoring period. It is indicated for adults 22 and older.

The company will launch the new feature in the third quarter.