ASX ANNOUNCEMENT

30 June 2026

Saluda Medical Receives U.S. FDA Approval for New CAP24™ Surgical Paddle Lead

Saluda Medical, Inc. (ASX: SLD, "Saluda" or the "Company"), a commercial-stage medical device company focused on developing treatments for chronic neurological conditions using its novel closed-loop neuromodulation platform, today announced that the U.S. Food and Drug Administration ("FDA") has approved Saluda's CAP24 paddle lead, allowing it to be marketed and sold in the U.S. Paddle leads are an alternative to percutaneous leads and this approval enables the Company to target neurosurgeons and orthopedic surgeons, who generally prefer the surgical implantation of a paddle lead when performing a spinal cord stimulation ("SCS") procedure and who account for approximately 30% of all SCS implants in the U.S., meaningfully expanding Saluda's addressable market and growth profile beyond its current percutaneous lead-focused customer base.

Saluda plans a phased U.S. launch beginning in the second half of calendar 2026, with broader commercial rollout commencing later in calendar 2026, as surgeon training and field inventory scale. The Company expects a gradual contribution to revenue as the surgical channel develops. The addition of a paddle lead is expected to enhance productivity within Saluda's existing U.S. commercial organization by enabling engagement with neurosurgeons and orthopedic surgeons and expanding procedural coverage within existing accounts.

The CAP24 paddle lead expands Saluda Medical's SCS portfolio and enables use of the Evoke® System with EVA™ Sensing Technology in surgical paddle lead procedures, extending access to the Company's physiologic closed-loop, ECAP-based therapy in the U.S.

The CAP24 surgical paddle lead is the first and only SCS paddle lead purpose-built to deliver Evoke®'s physiologic closed-loop neuromodulation. Unlike traditional paddle leads originally designed for open-loop stimulation, CAP24 is the first and only SCS paddle engineered from the ground up for closed-loop neuromodulation, enabling therapy informed directly by each patient's unique neural signals. Its low-profile, anatomically contoured design provides stable, precise placement with broad lateral and longitudinal coverage, supporting consistent ECAP sensing and reliable therapy delivery.[1]

Featuring a unique 24-electrode, three-column configuration, the CAP24 paddle lead senses and measures evoked compound action potentials (ECAPs) and works with the

Evoke System and EVA Sensing Technology to automatically adjust stimulation to each patient's physiology, enabling objective optimization and consistent therapy delivery. The Evoke System is supported by prospective, randomized clinical evidence demonstrating durable outcomes through 36 months.[1]

"The FDA approval of the CAP24 surgical paddle lead marks an important milestone for Saluda Medical," said Barry Regan, Chief Executive Officer of Saluda Medical. "CAP24 was engineered from the ground up to bring closed-loop therapy to surgical paddle lead procedures, enabling surgeons and clinicians to more fully leverage the benefits of the Evoke System and EVA Sensing Technology in these cases."

"The CAP24 paddle was clearly designed with closed-loop therapy in mind," said Erika Petersen, MD, Professor of Neurosurgery at the University of Arkansas for Medical Sciences (UAMS). "Its anatomical design, stability, and integration with the Evoke System and EVA Sensing Technology allow surgeons to deliver objective, physiology-based neuromodulation in a surgical paddle lead, which is an important advancement for spinal cord stimulation."

1. Mekhail NA et al. ECAP-Controlled closed-loop vs open-loop SCS for the treatment of chronic pain: 36-month results of the EVOKE blinded randomized clinical trial. Reg Anesthesia Pain Med 2023;0:1-9.

This announcement has been authorized for release by Saluda Medical's Board of Directors.

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About Saluda Medical

Saluda Medical is a commercial-stage medical device company focused on developing treatments for chronic neurological conditions using its novel neuromodulation platform. The Company's closed-loop, dose-control platform senses and measures neural responses to stimulation and automatically adjusts therapy based on real-time neurophysiological feedback. The Company's first product, the Evoke System, is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain, and is designed to treat chronic neuropathic pain by providing spinal cord stimulation (SCS) therapy that senses and measures neural activation to optimize therapy and reduce patient and clinician burden. 12-month results from the EVOKE study, the first and only prospective, multi-center, parallel-arm, double blind, randomized controlled pivotal study with a voluntary crossover arm in SCS,

that demonstrated clinically superior pain relief to open-loop therapy, were published in The Lancet Neurology, 24-month results were published in JAMA Neurology, and 36-month data, that demonstrated sustained pain relief, were published in Regional Anesthesia and Pain Medicine. To learn more, including risks and important safety information, visit www.saludamedical.com/us/safety/.

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