

Neola Medical's CEO shares clinical progress and recent milestones in summer 2025 investor letter

As summer unfolds, Neola Medical highlights important progress in its clinical development program. The company has successfully enrolled the first baby in the ongoing clinical pilot study on preterm born babies in Sweden, marking the first real-world use of Neola® to monitor the lungs of a baby in neonatal intensive care. In parallel, preparations advance for the pivotal clinical study in the U.S., following IRB approval and a signed agreement with a prominent neonatal intensive care unit (NICU) at Children's Regional Hospital at Cooper, Camden, New Jersey, USA. This agreement with one of Neola Medical's strategically important study sites enables the initiation of the pivotal clinical study on preterm born babies with its medical device for continuous lung monitoring, Neola®, which will play a central role in building the clinical evidence base required to support the planned FDA application for market authorization.

"The first real-world use of Neola® to monitor the lungs of a baby, in our ongoing clinical pilot study in Sweden, marks a historic milestone for the company. At the same time, we are making important progress in preparing our pivotal clinical study in the U.S., which will support the foundation of our planned FDA application for market authorization," says CEO Hanna Sjöström.

Read more in the investor letter summer 2025, attached to this press release and available on the company's website www.neolamedical.com

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About Neola Medical

Neola Medical AB (publ) develops an innovative medical technology device for non-invasive, continuous lung monitoring and real-time alerts of potentially life-threatening lung complications in preterm born babies. By enabling instant detection, the technology aims to support earlier intervention, improve clinical decision-making, enhance long-term outcomes, and ultimately contribute to saving lives. The patented, cutting-edge technology was developed at Lund University in Sweden and is based on a spectroscopic method that measures changes in lung volume and oxygen gas concentration. Neola Medical builds on Sweden's longstanding legacy of medical technology innovation and contributions to global health care. Neola Medical was founded in 2016 and is listed on NASDAQ First North Growth Market (ticker: NEOLA). Read more at www.neolamedical.com. The company's Certified Adviser is FNCA Sweden AB.

Attachments

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