



INVESTOR LETTER SUMMER 2025

As summer arrives, Neola Medical reached a key clinical milestone with the start of our first clinical pilot study in Sweden on preterm born babies. In May, the first baby was successfully enrolled, marking the first real-world use of Neola® to monitor the lungs of a baby in neonatal intensive care. This milestone represented the culmination of years of dedicated development and marked the beginning of an important phase in validating the safety and performance of Neola® in its target patient group.

At the same time, we advanced preparations for our upcoming pivotal study in the U.S., an essential component in building the clinical evidence base required to support the planned FDA application for market authorization. We are honored to collaborate with Dr. Vineet Bhandari, one of the world's most respected key opinion leaders in neonatology, following the signed agreement and IRB approval at Children's Regional Hospital at Cooper. His clinical leadership at Cooper's NICU brings significant credibility and momentum to this strategically important study site, which will play a central role in our U.S. regulatory pathway.

Neola Medical's intellectual property portfolio continued to strengthen with a newly granted European patent for continuous lung monitoring, our second within a new patent family, following approval in China earlier this year. These two strategically important markets represent key steps in our ongoing IP expansion, which

is central to protecting our core technology and further strengthening our competitive edge ahead of commercialization.



We were also honored to be named one of eight finalists for Sweden's new global innovation award, the Pioneer Prize. As part of the official Swedish delegation to World Expo Osaka, led by HM The King of Sweden, I proudly represented Neola Medical. The nomination brought international recognition and opened new opportunities for global collaboration and market growth.

With the pilot study underway, a solid financial foundation in place, and progressing pivotal clinical study preparations in the U.S., we remain focused on delivering key milestones, bringing us closer to our mission of giving preterm born babies a safer, stronger start in life.

Hanna Sjöström

NEWS NEOLA MEDICAL

Neola Medical successfully enrolled the first baby in the ongoing clinical pilot study in Sweden. Click here to read the press release or read more below.



Neola Medical signed agreement with leading U.S. hospital for pivotal clinical study on preterm born babies. Click here to read the press release or read more below.



Neola Medical granted European patent for lung monitoring, strengthening the protection in key markets. Click here to read the press release or read more below.



Neola Medical published the Annual report of 2024. Click here to read the report.



The Annual General Assembly 2025 was held at Neola Medical's premises. Click here to read the press release following the Annual General Assembly 2025.



Agreement signed with leading U.S. hospital for Pivotal Clinical Study

Neola Medical AB announced it has signed an agreement with a prominent neonatal intensive care unit (NICU) in the U.S., located at Children's Regional Hospital at Cooper in Camden, New Jersey, USA, to enable the initiation of the pivotal clinical study on preterm born babies with its medical device for continuous lung monitoring, Neola®. The agreement follows the Institutional Review Board (IRB) approval at Children's Regional Hospital at Cooper, a key regulatory milestone, confirming that the study complies with the requirements for patient safety and clinical ethics. Read more below.



First baby successfully enrolled in ongoing clinical pilot study in Sweden

Neola Medical announced that the first baby has been successfully included in the ongoing clinical pilot study on preterm born babies in Sweden with the company's continuous lung monitoring device, Neola®.

This marks the very first time Neola® has been monitoring the lungs of a baby in its target patient group in neonatal intensive care, representing another step forward in the company's efforts to validate the technology's potential to enhance neonatal care by enabling earlier detection and intervention for pulmonary complications.

Once all enrolled babies have completed the study and the data has been analyzed, results will be concluded in accordance with common practice and established standards for clinical evaluations. Read more below.



Neola Medical published the Q1 report of 2025. Click here to read the report.



Redeye interviewed CEO Hanna Sjöström following the Q1 report of 2025. Click here to watch the interview with Redeye.



Neola Medical was named finalist for Sweden's new global innovation award at World Expo 2025 Osaka. Click here to read the press release or read more below.



CEO Hanna Sjöström was elected to the board of SwedenBIO. Click here to read the article or read more below.




CEO Hanna Sjöström hosted SwedenBIO's Business Strategy working group seminar on strategic expansion to the U.S. market. Click to watch or read more below.

CLINICAL PILOT STUDY IN SWEDEN



Neola Medical announced that the first baby has been successfully included in the ongoing clinical pilot study on preterm born babies in Sweden with the company's continuous lung monitoring device, Neola®. This marks the very first time Neola® has been monitoring the lungs of a baby in its target patient group in neonatal intensive care, representing another step forward in the company's efforts to validate the technology's potential to enhance neonatal care by enabling earlier detection and intervention for pulmonary complications.

 *This marks a truly meaningful milestone for Neola Medical. For the first time, our medical device, Neola® is being used for monitoring the lungs on its target patient group, preterm born babies, in neonatal intensive care.*

– CEO Hanna Sjöström

The clinical pilot study focuses on the safety and continuous monitoring with Neola® in a neonatal intensive care setting. In addition, it is designed to demonstrate both the utility of the product and its compatibility with the clinical environment. The study team at Södra Älvsborgs Sjukhus in Borås, consisting of experienced neonatologists and neonatal nurses, continues to enroll additional participants, with the goal of completing the clinical pilot study in the coming months.

The target patient group



Conducting clinical studies with Neola® on its target patient population is important, as preterm born babies differ significantly from full-term newborns. Findings from this first clinical study on preterm born babies can contribute additional input to optimizing and refining Neola®, aiming to ensure it meets the specific needs of this vulnerable and unique patient group. The results will furthermore guide preparations for the pivotal U.S. clinical study that will be instrumental in supporting our planned FDA application for market approval in the U.S.


About the Clinical Pilot Study in Sweden

Neola Medical's first clinical pilot study is being conducted at the neonatal intensive care unit at Södra Älvsborgs Sjukhus in Borås, Sweden. The study is designed to evaluate the safety and performance of Neola® in monitoring the lungs of preterm born babies. A total of 10 babies in neonatal intensive care with a gestational age from 28 weeks and a weight between 1000-3000 grams are included. The study is expected to run for approximately four months. Findings from this first clinical study on preterm born babies can contribute additional input to optimizing and refining Neola®, aiming to ensure it meets the specific needs of this vulnerable and unique patient group. The results will furthermore guide preparations for the pivotal U.S. clinical study that will be instrumental in supporting the planned FDA application for market approval in the U.S.

PIVOTAL CLINICAL STUDY IN THE U.S.



Neola Medical AB announced it has signed an agreement with a prominent neonatal intensive care unit (NICU) in the U.S., located at Children's Regional Hospital at Cooper in Camden, New Jersey, USA, to enable the initiation of the pivotal clinical study on preterm born babies with its medical device for continuous lung monitoring, Neola®. The agreement follows the Institutional Review Board (IRB) approval at Children's Regional Hospital at Cooper, a key regulatory milestone. As one of Neola Medical's strategically important study sites, Cooper's NICU plays a central role in building the clinical evidence base required to support the planned FDA application for market authorization.

 *I am looking forward to evaluating the innovative non-invasive Neola® lung monitoring device at Children's Regional Hospital at Cooper NICU with the potential and hope of improving the care of the newborn.*

- Vineet Bhandari, MD, DM, FAAP, principal investigator and division head of Neonatology at Children's Regional Hospital at Cooper and professor at Cooper Medical School of Rowan University



Cooper Medical School
of Rowan University



"The IRB approval at Children's Regional Hospital at Cooper and the signed agreement to initiate the pivotal clinical study, mark an important milestone in advancing the clinical validation of our medical device, Neola®, in the U.S. We are especially honored to work with Dr. Vineet Bhandari, one of the world's most prominent key opinion leaders in neonatology. His clinical leadership at Cooper's NICU adds significant weight to this strategically important study site, which will play a central role in building the clinical evidence base for our planned FDA application and long-term market expansion," says CEO Hanna Sjöström

About Children's Regional Hospital at Cooper

Cooper University Health Care is one of the leading academic medical centers in the U.S., renowned for its expertise in neonatal and pediatric care. Cooper treats patients from all 50 states and 35 countries. Children's Regional Hospital at Cooper houses a Level III Neonatal Intensive Care Unit (NICU) with 35 beds, providing comprehensive care for full-term and premature infants with various medical and surgical conditions related to premature birth, respiratory, neurologic or immunologic disorders. Visit www.cooperhealth.org to learn more.

VOICES FROM NEONATAL CARE

In Sweden's neonatal units, the most fragile patients are cared for, preterm born babies who require meticulous monitoring and early detection of complications. Linda Nilsson, an intensive care nurse at Skåne University Hospital in Lund, emphasizes the critical importance of early detection and continuous monitoring in the acute phase of neonatal care, where even small changes in a newborn's condition can signal serious complications. At the same time, Veronica Hermansson, a specialist physiotherapist at the Pediatric Clinic at Södra Älvsborgs Hospital in Borås, who highlights the long-term challenges faced by preterm born babies. Their immature brains make them especially vulnerable to neurodevelopmental issues, requiring careful support beyond the neonatal period. Together, their perspectives illustrate the complexity of neonatal care, from intensive care in the first hours of life to long-term developmental support, and the need for a comprehensive, lifelong approach for this vulnerable patient group.

SS *A vital part of the job is recognizing early symptoms to detect problems before they become serious. A preterm born baby's condition can change rapidly, which makes continuous monitoring essential.*

– Linda Nilsson, intensive care nurse at Skåne University Hospital in Lund



[Click here to read the interview with Linda Nilsson](#)

SS *Preterm born babies are a growing patient group who may require extensive support throughout life. Their brains are underdeveloped and highly sensitive, making them more vulnerable and at increased risk for neurodevelopmental challenges.*

– Veronica Hermansson, specialist physiotherapist at the Pediatric Clinic at Södra Älvsborgs Hospital in Borås



[Click here to read the interview with Veronica Hermansson](#)

NEOLA MEDICAL AT WORLD EXPO 2025 OSAKA

Neola Medical was named one of eight finalists for the Pioneer Prize, a new global award recognizing Swedish innovation with international impact. The finalists were presented during the World Expo in Osaka, Japan, where CEO Hanna Sjöström represented Neola Medical in conjunction with the official Swedish delegation, led by HM The King of Sweden and Minister for International Development Cooperation and Foreign Trade, Benjamin Dousa.



Photo: Nordic Pavilion at Expo 2025

SS *Our technology addresses a critical global need in neonatal care. This nomination brings valuable international exposure and opens doors for future global expansion. We were proud to represent Swedish technology innovation and honored to be part of the official Swedish delegation to Expo Osaka.*

– CEO Hanna Sjöström



Photo: Nordic Pavilion at Expo 2025


About the Pioneer Prize

The Pioneer Prize is organized by the Swedish Institute in partnership with Business Sweden to promote Sweden's most promising innovation companies globally. All eight finalists are alumni of Business Sweden's Catalyst program, a scale-up initiative supporting international growth for high-potential startups across life science, energy, industry, and tech. The finalists, selected from over 200 small and medium-sized Swedish companies, represent scalable solutions contributing to the green and digital transition.

SWEDENBIO NETWORK

CEO Hanna Sjöström elected to the board of SwedenBIO

Neola Medical's CEO Hanna Sjöström was unanimously elected to the board of SwedenBIO, Sweden's largest industry organization for life sciences. The decision followed the nomination committee's proposal and was confirmed during the association's Annual General Meeting on May 6.

 *I am honored to join SwedenBio's board and look forward to strengthening Sweden's life science industry, supporting our innovative companies to thrive*

– CEO Hanna Sjöström




Hanna Sjöström's appointment strengthens the voice of MedTech within SwedenBIO and reflects her continued engagement in advancing Sweden's position in life science innovation, commercialization, and international growth. Sjöström has previously been profiled for her role in SwedenBIO's expert network, where she leads the Medtech Working Group, a forum focused on key strategic issues such as market access, regulatory alignment, and internationalization. Read more about her role in the expert network [here](#).

In SwedenBIO's latest annual report, Hanna Sjöström shares her perspective on the current landscape for MedTech companies, including the opportunities and challenges facing innovative life science businesses with global ambitions. Find the full interview with CEO Hanna Sjöström in SwedenBIO's annual report [here](#).



From Innovation to Impact: Neola Medical's Journey to the U.S.

CEO Hanna Sjöström was invited to speak at SwedenBIO's Business Strategy working group seminar on strategic expansion to the U.S. market. At a well-attended seminar, CEO Hanna Sjöström shared insights on the company's U.S. market journey, underscoring the importance of having a local presence to access opportunities and navigate the landscape successfully. Read more about the seminar and SwedenBIO [here](#).

 *Having a local presence in the U.S. has been essential for building networks and accessing clinical study opportunities through the right connections.*


– CEO Hanna Sjöström

MORE NEWS

Neola Medical granted European patent for lung monitoring, strengthens protection in key markets

Neola Medical has been granted a European patent that strengthens the protection of its core innovation for continuous lung monitoring using gas absorption spectroscopy. The European patent broadens the company's portfolio of medical patents and complements existing protections in other key markets, including the recently granted Chinese patent from the same patent family. The patent application is pending in the U.S.



 Europe represents one of our main markets alongside the U.S., and the granted patent strengthens our strategic position in this important region. It further reinforces our intellectual property portfolio around our core medical technology for non-invasive lung monitoring and detection of pulmonary complications.

– CEO Hanna Sjöström

The granted medical patent is the second validation within the new patent family focused on the protection of advanced methods for detecting pulmonary and aeration complications. The patented innovation combines gas absorption spectroscopy with the measurement of transmitted light through the body to enable continuous, non-invasive monitoring of lung physiology.

About the new patent family

This new patent family “A device for monitoring a pulmonary system of a subject” complements the protection of the company's first patent family, “Human cavity gas measurement device and method”, a general patent that protects the fundamental concept of measuring gases in body cavities using diode laser spectroscopy.

Redeye interview Q1 2025 – CEO Hanna Sjöström on clinical and strategic milestones

Following a strengthened shareholder base and the first baby enrolled in Neola Medical's Swedish clinical Q1 pilot study, CEO Hanna Sjöström joins Redeye to discuss recent milestones and what lies ahead.

She shares insights into the company's clinical progress, recent international patent grants, and the path toward U.S. market readiness, including upcoming plans for the pivotal clinical study and key strategic considerations around manufacturing. Find the full interview [here](#).

Access additional insights from Redeye [here](#).



Neola Medical featured in Life Science Sweden

Life Science Sweden highlights Neola Medical's latest clinical milestone – the inclusion of the first baby in the ongoing clinical pilot study on preterm born babies in Sweden. Read the full article in Swedish [here](#).



Neola Medical mentioned in Placera's most-read Telegram

Neola Medical is highlighted in a recent article by Placera, listing healthcare stocks attracting fund interest. Read the full article in Swedish [here](#).

Please note that Neola Medical has not been involved in the production of this article and has no influence over its content.



Read more information about risks and uncertainties at our website [here](#).

FINANCIAL CALENDAR

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Reports, annual reports and press releases can be downloaded from www.neolamedical.com

The next investor letter will come in the autumn of 2025!

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