INVESTOR LETTER SPRING 2025

As spring unfolds in Lund, so does a new chapter in Neola Medical's development. The first quarter of the year has brought steady progress in our mission to advance neonatal intensive care. Most notably, we have recieved approval from Swedish authorities to initiate our first clinical pilot study in Sweden. For the first time, Neola® is going to be used to monitor the lungs of our target patient group, preterm born babies, in a real-world neonatal intensive care setting. This marks a significant milestone in our clinical development and is the result of years of dedicated work, demonstrating the company's ability to navigate complex regulatory requirements. The insights gained from this study are expected to inform further refinement of Neola® and support the design of our planned pivotal clinical study in the U.S., which will be a key component in the regulatory pathway toward FDA market approval.

In parallel, we've strengthened our financial position through a successful directed share issue of approximately SEK 20 million. The financing was supported by new institutional investors, including Cicero Fonder and Adrigo Fonder, as well as existing shareholders, including Anmiro AB. Welcoming our first institutional investors is an important milestone that reflects the long-term confidence in Neola Medical and our ambition to deliver sustainable value. Their participation complements our already strong shareholder base, and I would like to sincerely thank all participants for their trust and commitment.

This spring also saw further progress in our intellectual property strategy. A new patent has been granted in China, strengthening the protection of our core technology for non-invasive lung monitoring. This is the first in a new family of patents aimed at detecting pulmonary and aeration-related complications. Applications are currently under review in both the U.S. and Europe, and we remain committed to expanding our international IP portfolio in preparation for future commercialization.

I would like to take this opportunity to welcome all shareholders to Neola Medical's Annual General Meeting on 21 May 2025 at our headquarters at Ideon Gateway in Lund. We remain grateful for your continued support as we work to advance neonatal care and deliver long-term value.

Hanna Sjöstrand

NEWS NEOLA MEDICAL

CEO participated at the J.P. Morgan Healthcare Conference 2025 in San Francisco, USA. Click here to read more about the premier global healthcare investment conference.

Neola Medical has completed a directed share issue of approximately SEK 20 million and strengthens capital ahead of clinical studies. Click here to read the press release.

Neola Medical received approval by Swedish authorities to initiate clinical pilot study on preterm born babies in Sweden. Click here to read the press release or read more below.

Neola Medical signs agreement with Södra Älvsborgs Sjukhus to initiate clinical pilot study on preterm born babies. Click here to read the press release or read more below.

Neola Medical published the Q4 report and financial statement of 2024. Read the Q4 report of 2024 here and watch the Q4 presentation at Finwire TV here.

Recieved approval to initiate clinical study on preterm born babies

Neola Medical has received approval from the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten) to initiate a clinical pilot study on preterm born babies in Sweden, with its medical device for continuous lung monitoring, Neola®.

To initiate the clinical pilot study on preterm born babies in Sweden, approval is required from both Läkemedelsverket and Etikprövningsmyndigheten. The received approval from both regulatory bodies now paves the way for the commencement of the clinical pilot study on preterm born babies in Sweden. Read more below.

Neola Medical secured financing ahead of clinical studies

The Directed Share Issue has been subscribed for by a number of institutional investors, including Cicero Fonder and Adrigo Fonder, as well as certain existing larger shareholders, including Anmiro AB. The subscription price was set at SEK 2.50 per share through an accelerated bookbuilding procedure conducted by Svenska Handelsbanken AB and Neola Medical will receive approximately SEK 20 million before issue costs.

"I would like to extend my sincere gratitude to both new and existing shareholders for your trust in this directed share issue. It is a true strength for Neola Medical to welcome our first institutional investors, who complement our already strong shareholder base and share a long-term commitment to the company. With this directed share issue, we are now continuing our work on clinical studies on preterm born babies and preparations for the planned FDA application for market approval of Neola® in the U.S. Your support is essential to our ambition of providing preterm born babies around the world with a safer and stronger start in life, as we continue to drive the company forward and create sustainable, long-term shareholder value," says CEO Hanna Sjöström

Redeye interviewed CEO Hanna Sjöström following the completed directed share issue. Click here to watch the interview with Redeye.

Redeye interviewed CEO Hanna Sjöström following the Q4 report of 2024. Click here to watch the Redeye interview with CEO Hanna Sjöström.

Neola Medical granted new patent family in China, strengthening the protection for lung monitoring. Click here to read the press release or read more below.

"A Major Milestone" – CEO Hanna Sjöström in interview with Life Science Sweden. Click here to read the interview.

CEO Hanna Sjöström joins the Walk the Valley Podcast to discuss the "valley of death" in medtech. Click here to visit their website or read more below.

CLINICAL PILOT STUDY IN SWEDEN

Neola Medical's first clinical pilot study will be conducted at a neonatal intensive care unit at Södra Älvsborgs Sjukhus in Borås, Sweden. Extensive preparations have been finalized, including a signed contract with the hospital and regulatory approvals from the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten). The study is designed to evaluate the safety and performance of Neola® in monitoring the lungs of preterm born babies, marking the first clinical study with Neola® on its target patient group. Additionally, the study serves as a preparatory step for the pivotal clinical study on preterm born babies in the U.S. The study is expected to run for approximately four months, with initiation planned in 2025.

This study marks a milestone as the first evaluation of Neola® in its target patient population, preterm born babies, underscoring our commitment to improving neonatal care. Securing approval for clinical studies in this vulnerable population is a rigorous process, highlighting the company's ability to navigate stringent regulatory requirements.

- CEO Hanna Sjöström

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.

The clinical need

Every year, approximately 15 million babies worldwide – about one in ten – are born preterm (prior to pregnancy week 37), many of them with underdeveloped lungs that can advance to life-threatening conditions during their stay in the hospital and risk disabilities later on in life. Although significant progress has been made to increase the survival rate of preterm born babies over the past 50 years, approximately 1.1 million babies still die every year. The fact is that preterm birth is the most common cause of death for babies under five years of age (after pneumonia), and the leading cause of death in preterm born babies is respiratory distress syndrome (RDS), a serious lung condition whose complications can affect up to 80 percent of babies born extremely preterm. The methods used by neonatal health care professionals today do not provide continuous information for decision making.

CLINICAL PILOT STUDY IN SWEDEN

The signed contract with Södra Älvsborgs Sjukhus ensures access to the neonatal intensive care unit (NICU) at the hospital, where the study will be conducted by a team of experienced neonatologists and nurses. The Neola Medical team has been on-site and comprehensive training for clinical staff on the use of Neola® has been conducted and preparations for the start of the study are in progress.

"We appreciate the engagement of the NICU team at SÄS, and with the training now completed, we look forward to taking the next steps towards study initiation and gathering valuable insights," says Magnus Johnsson, Director Quality Assurance & Regulatory Affairs at Neola Medical

Photo: Pernilla Lundgren

Clinical Pilot Study In Sweden

- The study will evaluate the safety and performance of Neola® in preterm born babies
- 10 babies in neonatal intensive care from 28 weeks gestational age and weight between 1000-3000 grams
- Neonatal intensive care unit at Södra Älvsborgs Sjukhus i Borås

Södra Älvsborgs Sjukhus

- Provides advanced care for preterm and critically ill newborns
- 11 NICU beds and consists of two intensive care units and a family unit
- Serves as a training center in neonatology at Södra Älvsborgs Sjukhus i Borås

"The hospital's neonatal expertise and commitment to advancing care for preterm born babies make them an ideal study site for this important phase of our development.

- CEO Hanna Sjöström

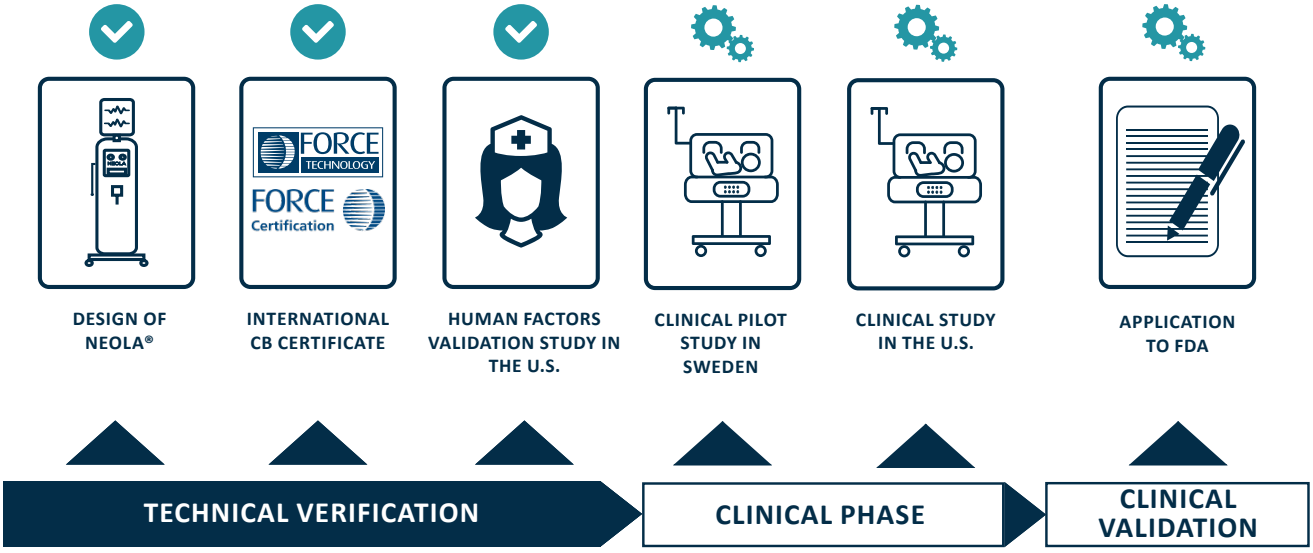
About Södra Älvsborgs Sjukhus

Södra Älvsborgs Hospital (SÄS) in Borås provides specialized care for preterm babies and critically ill newborns who require more advanced medical attention than what can be offered in a standard maternity ward. The department has 11 NICU beds and consists of two intensive care units and a family unit. SÄS is also a teaching hospital for neonatology.

TOWARDS THE CLINICAL PHASE

In 2024, Neola Medical advanced from the technical verification phase to the clinical phase – a significant milestone for Neola® in the regulatory process toward obtaining FDA approval in the U.S.

Neola Medical has, to date, generated the majority of the product documentation and data required , as Neola® successfully completed a Human Factors Validation Study with neonatal nurses in the U.S. and obtained CB certification for verification of electrical and product safety, fulfilling parts of the regulatory requirements for market approval in the U.S. These achievements mark the transition from the technical verification phase to the clinical phase. Following approval from Swedish authorities, Neola Medical is now initiating its first clinical study on preterm born babies in Sweden.



Clinical study history with the technology:

- **2021-2022:** A large investigator-initiated and independent clinical study was conducted at the INFANT Centre at Cork University Hospital in Ireland. A total of 100 full-term newborns participated in the study, and the results demonstrated that the technology is safe and well tolerated for measuring the oxygen in the lungs. The results were presented at University College Cork (UCC).
- **2015-2018:** An EU-funded project, including preclinical and clinical studies on healthy full-term newborns, laid the foundation for the company's product, Neola®. An additional clinical study involving 12 full-term newborn babies was conducted in Lund. The study demonstrated clinical acceptance of the measurements and the design of the probes, which are attached to the baby's chest.
- **2012-2013:** Clinical research studies involving a total of 32 full-term newborns were conducted, and the results demonstrate the feasibility of measuring gas in the lungs of full-term newborns.
- **2011:** The initial lung measurements were conducted on one full-term newborn baby at Lund University Hospital.

SCIENTIFIC PUBLICATIONS WITH THE TECHNOLOGY

White paper: Neonatal Lung Analyze
Tetiana Kovtiukh and Martin Hansson, Neola Medical AB, 2023

CLICK TO READ!

Laser absorption spectroscopy measurements of different pulmonary oxygen gas concentrations in transmittance and remittance geometry: phantom study
Andrea Pacheco, Jean Matias, Konstantin Grygoryev, Martin Hansson, Sara Bergsten and Stefan Andersson-Engels, *Journal of Biomedical Optics, 2023*

Non-Invasive Lung Oxygen Monitoring in Term Infants: A Pilot Trial
Jurate Panaviene, Konstantin Grygoryev, Andrea Pacheco, Eugene Dempsey and Stefan Andersson-Engels, *Biophotonics congress OPTICA, 2022*

Numerical investigation of the influence of the source and detector position for optical measurement of lung volume and oxygen content in preterm infants
Andrea Pacheco, Baptiste Jayet, Emilie Krite Svanberg, Hamid Dehghani, Eugene Dempsey and Stefan Andersson-Engels, *Journal of Biophotonics, 2022*

Evolution of gas in scattering media absorption spectroscopy as a neonatal pulmonary monitoring device
Hemananda Kumar Muniraman, Judith Klein-Seetharaman and Vineet Bhandari, *Pediatric Researsch, 2022*

Gas in scattering media absorption spectroscopy as a potential tool in neonatal respiratory care
Jurate Panaviene, Andrea Pacheco, Christoph E. Schwarz, Konstantin Grygoryev, Stefan Andersson-Engels and Eugene M. Dempsey, *Pediatric Research, 2022*

Changes in pulmonary oxygen content are detectable with laser absorption spectroscopy: proof of concept in newborn piglets
Emilie Krite Svanberg, Jim Larsson, Martin Rasmussen, Marcus Larsson, Dennis Leander, Sara Bergsten, Joakim Bood, Gorm Greisen and Vineta Fellman, *Pediatric Research, 2020*

Comparison of dermal vs internal light administration in human lungs using the TDLAS-GASMAS technique–Phantom studies
Jim Larsson, Dennis Leander, Märta Lewander Xu, Joakim Bood and Emilie Krite Svanberg, *Journal of Biophotonics, 2019*

Diode laser spectroscopy for noninvasive monitoring of oxygen in the lungs of newborn infants
Emilie Krite Svanberg, Patrik Lundin, Marcus Larsson, Jonas Åkeson, Katarina Svanberg, Sune Svanberg, Stefan Andersson-Engels and Vineta Fellman, *Pediatric Research, 2016*

Noninvasive monitoring of gas in the lungs and intestines of newborn infants using diode lasers: feasibility study
Patrik Lundin, Emilie Krite Svanberg, Lorenzo Cocola, Märta Lewander Xu, Gabriel Somesfalean, Stefan Andersson-Engels, John Jahr Vineta Fellman, Katarina Svanberg and Sune Svanberg, *Journal of Biomedical Optics, 2013*

MORE NEWS

CEO Hanna Sjöström in interview with Redeye: Neola Medical Strengthens Ownership Base with Institutional Investors

Redeye Equity Research Analyst Gustaf Meyer invited CEO Hanna Sjöström to discuss the company's latest capital raise of approximately SEK 20 million and its significance for the future. For the first time, the company has attracted institutional investors, Cicero Funds and Adrigo Funds, while existing major shareholders, including Anmiro AB, have continued to increase their holdings.

Watch the full interview where CEO Hanna Sjöström shares insights into what makes Neola Medical an attractive investment opportunity and how the capital will be utilized to finance the company's clinical studies and the planned FDA application here.

In Rapidus News: Neola Medical strengthens its ownership base through a directed share issue

Read the entire article by Rapidus here.

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It is a true strength for Neola Medical to welcome our first institutional investors, who complement our already strong shareholder base.

- CEO Hanna Sjöström

Redeye TV with Neola Medical following the Q4 report

Following the release of Neola Medical's Q4 2024 report, Redeye interviewed CEO Hanna Sjöström to discuss key takeaways, the company's progress toward the clinical phase, and the upcoming first clinical study on preterm born babies in Sweden. Watch the full interview here.

Redeye also provided a research update, including a strengthened fair value range for Neola Medical. Access the interview and additional insights from Redeye here.

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MORE NEWS

”A Major Milestone” – CEO Hanna Sjöström in interview with Life Science Sweden

In an interview with Life Science Sweden, CEO Hanna Sjöström discusses the significance of the received approval to initiate Neola Medical’s first clinical study on preterm born babies - what it means for the company, and how it supports Neola Medical’s strategy for entering the U.S. market, where Neola Medical sees significant potential for growth and impact in neonatal care. Read the full interview here.

New Patent Family Granted In China

Neola Medical AB has been granted a patent in China that strengthens the protection of the company’s fundamental concept of measuring gases in body cavities using gas absorption spectroscopy for continuous lung monitoring. The granted medical patent is the first in a new patent family, aimed at protection of lung monitoring for detection of pulmonary and aeration complications. The innovation relies on a combination of gas absorption spectroscopy and the measure of transmitted light through the body and is broadening the company’s portfolio of medical patents. The patent application is pending in the U.S. and Europe.

“With this patent, we strengthen our portfolio of patents related to our core medical technology of non-invasive monitoring and detection of changes in the lung physiology, adding an important layer of protection on our innovation for detection of pulmonary complications,” says CEO Hanna Sjöström

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.

Our IP strategy of actively pursuing patents for technical solutions and methods holds significant strategic importance, both as protection for Neola Medical’s proprietary technology and for its disposables.

– Ph.D. Sara Bergsten, CTO at Neola Medical

Surviving the Valley of Death: Neola Medical's CEO on Walk the Valley Podcast

In this episode of Walk the Valley Podcast, CEO Hanna Sjöström shares her insights on the often underestimated challenges of turning medical device innovations into viable commercial solutions, and why strong IP and promising technology are just the beginning.

Drawing on her leadership background from global consumer brands like Coca-Cola and L'Oréal, she reflects on how a strategic mindset, commercial thinking, and cross-functional execution are critical to navigating the "valley of death"– the phase where most medtech innovations fail to progress.

She also discusses Neola Medical's journey toward its first clinical study on preterm born babies, regulatory hurdles in Europe vs. the U.S., and the lessons she's learned about building the right team and avoiding common pitfalls on the road to market. Now available on YouTube, Spotify and Apple Podcast. Click on the icons below to listen!

YouTube **Spotify** **Apple Podcast**

Read more information about risks and uncertainties at our website here.

FINANCIAL CALENDAR

21 MAY
Q1 report 2025 & Annual General Assembly 2025 in Lund

25 AUGUST
Q2 report 2025

5 NOVEMBER
Q3 report 2025

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

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

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