

# INVESTOR LETTER AUTUMN 2025

This fall marks an exciting phase for Neola Medical as we continue to make progress in our ongoing clinical pilot study in Sweden. With the study now at its halfway point, our team will gain valuable experience on-site together with the clinicians and nurses caring for some of the most fragile patients. These real-world insights are an important part of refining Neola® and ensuring that our technology meets the unique needs of preterm born babies in neonatal intensive care.

As we move deeper into the clinical phase, we have reinforced our leadership team with the appointment of Eva Bondesson as Clinical Director. With long-standing experience in medtech and pharma and a PhD in lung physiology, she brings deep expertise in clinical development and regulatory processes. Her background, including close collaboration with the FDA and global authorities, strengthens Neola Medical as we advance toward market authorization and our mission to improve outcomes for preterm born babies.

During the autumn, our intellectual property portfolio was further expanded with a newly granted European patent that extends protection for lung monitoring beyond preterm born babies. Together with previously granted patents in the U.S. and China, this broadens the potential application of our technology and reinforces our long-term competitiveness.



I am also honored to once again participate in the Stanford Impact1 CEO Summit, this year in Austin, Texas. Our role as an Impact1 company, joining this exclusive forum of global innovators, investors, and pediatric health experts, continues to provide strategic value—offering unique collaboration opportunities with world-class clinicians and regulatory experts.

With progress in our Swedish pilot study, stronger patent protection in Europe, recognition through Stanford Impact1, and added senior clinical expertise, Neola Medical continues to make steady progress toward upcoming milestones, with the long-term vision of giving preterm born babies a safer, stronger start in life.

*Hanna Sjöström*



# NEWS NEOLA MEDICAL

Neola Medical granted European patent enabling lung monitoring beyond preterm born babies. [Click here to read the press release.](#)



Neola Medical strengthens leadership team with appointment of Clinical Director. [Click here to read the press release or read more below.](#)



CEO Hanna Sjöström invited as panelist at Sanford Impact1 CEO Summit. [Click here to read the press release or read more below.](#)



Neola Medical published the Q2 report of 2025. [Click here to read the report.](#)



CEO Hanna Sjöström and CFO David Folkesson presented the Q2 report at Finwire TV. [Click here to watch the presentation.](#)



Redeye interviewed CEO Hanna Sjöström following the Q2 report of 2025. [Click here to watch the interview with Redeye.](#)



## Clinical Director to Neola Medical

Neola Medical is pleased to announce the appointment of Eva Bondesson as Clinical Director, effective October 1, 2025.

With 30 years of experience in medical technology and in the pharmaceutical industry, combined with a PhD in advanced medical research, with a focus on lung physiology and how the body functions in health and disease, Eva Bondesson brings deep expertise in global clinical development, regulatory processes, and study execution. She has successfully led clinical development strategies to support product approvals and launches across several therapeutic areas, with a particular focus on lung and respiratory diseases. [Read more below.](#)

## Neola Medical granted European patent enabling lung monitoring beyond preterm born babies


Neola Medical has been granted a European patent for an invention aiming to enable lung monitoring in broader patient groups. This new patent complements the granted protection in the U.S. and China and strengthens Neola Medical's intellectual property portfolio in the European market. The innovation has the potential to expand the application of Neola Medical's technology beyond preterm born babies to older children, and potentially adults, thereby broadening the future market potential.



*"Europe, together with the U.S. and China, represents our most important future markets. This granted patent not only strengthens our protection of core technology but also opens opportunities to apply our innovation in additional patient groups. That represents an exciting future growth potential for Neola Medical,"* says CEO Hanna Sjöström.

## CEO Hanna Sjöström invited as panelist at Stanford Impact1 CEO Summit 2025

For the third consecutive year, CEO Hanna Sjöström will participate in the Stanford Impact1 CEO Summit on Pediatric and Maternal Health Innovation. [Read more below.](#)

 *As a Stanford Impact1 company, Neola Medical benefits greatly from the expertise and networks that this exclusive forum provides.*


*- CEO Hanna Sjöström*

# CLINICAL PILOT STUDY IN SWEDEN



Earlier this year, Neola Medical took an important step forward as the first preterm baby was successfully enrolled in our ongoing clinical pilot study in Sweden with the company's continuous lung monitoring device, Neola®. This marked the very first time Neola® was used to continuously monitor the lungs of a preterm born baby in neonatal intensive care - a milestone that represents years of development and the beginning of an important phase in validating Neola® in its target patient group.

Since then, the study team, at Södra Älvsborgs hospital in Borås has continued enrolling patients, and we are pleased to share reflections from our Neola Medical team who are present in the neonatal intensive care unit (NICU) during the study sessions alongside the clinicians and nurses working with Neola® in practice.

 *Being part of our first clinical study on preterm born babies has been an unforgettable experience. Meeting the babies and their parents in the NICU truly brings home the importance of our work and why we are developing this technology.*

*- Wilma Olsson, Development Engineer at Neola Medical*



Neola Medical's Wilma Olsson and Sara Bergsten



## About the Clinical Pilot Study

Neola Medical's first clinical pilot study is designed to evaluate the safety and performance of Neola® in monitoring the lungs of preterm born babies. In addition, it is designed to demonstrate both the utility of the product and its compatibility with the clinical environment. 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. 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.



# CLINICAL PILOT STUDY IN SWEDEN



In this investor letter, we are pleased to share some of these reflections through an interview with Magnus Johnsson, Director QA & RA at Neola Medical, who has been closely involved throughout the pilot study. Magnus provides his perspective on the experience of working side by side with the medical staff, what the team has learned so far, and how these observations contribute to the ongoing development of Neola®.



**The pilot study in Borås has now reached its halfway point. How would you describe the progress so far?**

We are pleased to have reached the halfway mark in the study, with several babies already included. The study team at Södra Älvsborgs Hospital has been fantastic to work with, and we can see how dedicated they are to caring for these extremely small and fragile patients. Every baby enrolled is unique, and it is both humbling and motivating to be part of such an important process.

**What has it been like for you and the Neola Medical team to be present at the hospital during the study?**

It's a very special experience to be present in the NICU during the study sessions. Before the study began, we spent time training the hospital team on-site, making sure everyone felt confident in using Neola®. Now, being able to stand side by side with the doctors and nurses while they use the device gives

us invaluable insights into both usability and workflow. It is something quite rare for a company team to be this close to clinical practice, and we feel privileged to contribute in this way.

**What stands out most to you personally from this experience?**

What makes the deepest impression is of course the babies themselves – how incredibly small and vulnerable they are. It is also very moving to meet the

*Being able to stand side by side with the doctors and nurses while they use the device gives us invaluable insights into both usability and workflow. It is something quite rare for a company team to be this close to clinical practice, and we feel privileged to contribute in this way.*

*– Magnus Johnsson, Director Quality Assurance & Regulatory Affairs at Neola Medical*

parents, who show such strength in difficult circumstances. Knowing that our technology could one day help make their journey safer gives an extra sense of purpose to everything we do.



Neola Medical's Magnus Johnsson and Sara Bergsten outside NICU at Södra Älvsborgs hospital



# STANFORD IMPACT1



For the third consecutive year, CEO Hanna Sjöström will participate in the Stanford Impact1 CEO Summit on Pediatric and Maternal Health Innovation. The summit, hosted in Austin, Texas, convenes leading MedTech entrepreneurs, investors, pediatric experts, and representatives from the U.S. Food and Drug Administration (FDA) to accelerate innovations that can transform pediatric and maternal healthcare.

This year, CEO Hanna Sjöström has been invited as a panelist in “Managing Board and Investor Relationships”, a session highlighting how leadership can successfully navigate strategic partnerships, governance, and capital markets to advance breakthrough healthcare technologies. Read more [here](#).



Panelists Hanna Sjöström (Neola Medical), Kim Rodriguez (Vitara Biomedical), Janene Fuerch (Co-Director Impact1) and Beverly Tang (Starlight Cardiovascular) at Impact1 CEO Summit 2025

**SS** *It is an honor to return to the Stanford Impact1 CEO Summit and to contribute to the important dialogue around board and investor relationships. The exclusive CEO Summit is an invaluable forum to share our journey, connect with thought-leaders, and exchange perspectives on how to bring impactful innovations like Neola® to pediatric patients worldwide.*

– CEO Hanna Sjöström





# STANFORD IMPACT1



Neola Medical was selected in 2023 as a Stanford Impact1 company, recognized for its pioneering work with Neola® (Neonatal Lung Analyzer). The program was founded to accelerate innovations that can make a difference from day one in the clinic and provides unique support from Stanford University's experts in neonatology, medical technology, and commercialization. Read more [here](#).



*I truly appreciate this as a neonatologist, as I frequently encounter cases of pneumothorax where a lung can collapse, and we do not detect it until vital signs begin to change.*

– Dr Janene H. Fuerch, Co-Director Impact1

## About Stanford Impact1 program

Stanford is one of the world's leading universities in research on preterm born babies and connected to the hospital that is ranked number one in neonatal care in the U.S. Stanford launched the Impact1 program with the vision of improving the health, safety and quality of life of pediatric and maternal patients globally. The name Impact1 comes from the purpose to promote innovations that provide precisely "impact from day 1". The FDA is supporting the program by awarding five years of funding to the Stanford Pediatric Device Consortium (PDC) in 2023, with the aim of supporting advanced technological innovation to reach the vulnerable pediatric patient group as quickly as possible. Visit [Stanford Impact1](#) to learn more.



Keynote speaker Vasum Peiris, FDA, Chief Medical Officer Peds and Special Populations at Impact1 CEO Summit 2025



Attendees Impact1 CEO Summit 2025




## MORE NEWS

### Neola Medical strengthens leadership team with appointment of Clinical Director

As Neola Medical advances through the clinical phase, Eva Bondesson brings extensive experience that will strengthen the leadership team and support the company's pathway toward market authorization of Neola®, the company's medical device for non-invasive, continuous lung monitoring, designed to detect potentially life-threatening lung complications in preterm born babies.

"We are very pleased to welcome Eva Bondesson to Neola Medical's leadership team. Her extensive experience in global clinical development, including collaboration with the U.S. FDA and other regulatory authorities, will be highly valuable as we advance through the clinical phase and prepare for our planned U.S. market authorization. With her strong expertise in lung physiology and proven track record in leading international studies, she brings an important complement to our team and to our mission of improving outcomes for preterm born babies," says CEO Hanna Sjöström.


 *Joining Neola Medical at this exciting stage of its clinical journey is both motivating and meaningful. With extensive experience in clinical studies and regulatory processes, and with a long-standing focus on lung physiology, I look forward to contributing to the company's next phase and its mission to advance neonatal intensive care.*

- Eva Bondesson, incoming Clinical Director at Neola Medical



### CEO Hanna Sjöström in the Spotlight with PRO TEMPORE

How do you lead a publicly listed medtech company with a heart for patient care and eyes set on the U.S. market? In a new Spotlight interview with PRO TEMPORE, Hanna Sjöström, CEO of Neola Medical, shares her career journey, perspectives on leadership in times of change, and why she believes in the powerful combination of technology and purpose.

 *I am inspired by people who combine professionalism with a strong sense of purpose.*

- CEO Hanna Sjöström

Read the full interview in Swedish [here](#).



## Presentation of the Q2 report 2025 at Finwire TV



CEO Hanna Sjöström shares Neola Medical's Q2 highlights, including the successful enrollment of the first preterm born baby in the clinical pilot study in Sweden and advancing preparations for the pivotal U.S. clinical study. CFO David Folkesson presents the financial results for Q2 2025.

Watch the full report presentation and stay for the Q&A session. Tune in [here](#).

## Redeye interview on Q2 achievements and the road ahead

In a new interview with Redeye's Gustaf Meyer, CEO Hanna Sjöström reflects on Q2 achievements and the road ahead. Redeye also provided a research update, raising their fair value range, now with a base case of SEK 3.3 (3.2).

Find the full interview [here](#) and additional insights from Redeye [here](#).



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

## FINANCIAL CALENDAR

**5**  
**NOVEMBER**  
Q3 report 2025

**12**  
**FEBRUARY**  
Q4 report 2025

**14**  
**APRIL**  
Annual report 2025

**19**  
**MAY**  
Q1 report 2026

Reports, annual reports and press releases can be downloaded from [www.neolamedical.com](http://www.neolamedical.com)

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

Follow us for ongoing updates on LinkedIn, Facebook and Twitter.

