

INVESTOR LETTER AUTUMN 2023

The leaves have shifted to yellow and autumn has arrived in Lund. With the seasonal change, we have entered an intensive period with continuing to focus on the market preparation work for the launch of Neola® in the U.S. During the first half of the year, we worked on strengthening the company's patent portfolio and it is gratifying that Neola® has been registered for trademark protection in the U.S. during the second quarter. Strong trademark protection enhances the company's positioning in the market for the launch of Neola®.

Our efforts to expand the American network of key opinion leaders in both academia and healthcare are bearing fruit. Doors are opening for us in the U.S. as we have been selected by Stanford as an Impact1 company. They believe that our medical technology for lung monitoring has the potential to make a significant difference in the care of children from day one in the clinic. This means that we now receive market launch support from Stanford's doctors and specialists, as well as the opportunity to work closely with their team in an exclusive collaboration program, partially funded by the US American Food and Drug Administration (FDA) and the Bill and Melinda Gates Foundation. During the quarter, we have had several meetings with the FDA and gained a good understanding of what is required to get Neola® approved for sale in the U.S.



At the same time, the Irish research team presented important final results from a large clinical study involving 100 newborn babies using Neola Medical's medical technology at the jENS conference in Rome. The results show that Neola® measured the oxygen in the lungs of all newborn babies and that the technology is recommended even for preterm born babies.

The report for the third quarter of 2023 has now been released where we provide more information about the financial position, the market preparation work for the launch of Neola®, the intensive work on technical verification studies and preparations for the upcoming clinical, preclinical and user studies in 2024.

We feel the wind in our sails with strong clinical results and Stanford's support and therefore, we look forward to an exciting autumn.
- Enjoy your reading!

Hanna Sjöström

NEWS NEOLA MEDICAL

The Neola Medical trademark was registered for trademark protection in the U.S. It is also previously registered in Europe, Australia and China. Read more [here](#).



Neola Medical published the report for the third quarter 2023. Read more [here](#) and hear CEO and CFO present the report [here](#).



New successful results from the clinical study on 100 newborn babies with Neola Medical's medical device were presented at the jENS conference. Read more below.



Neola Medical AB has elected ABG Sundal Collier as liquidity guarantor for the Company's shares listed on Nasdaq Stockholm. Read more [here](#).



Stanford selects Neola® as an important innovation with the potential to improve neonatal intensive care and the company receives support through Impact1. Read more below.



Neola Medical is selected as a Stanford Impact1 company

The market preparation work continues and gains momentum with an increased presence in the U.S. through the exclusive collaboration program Impact1 at Stanford Biodesign.

Neola Medical is one of the few companies and the only one in Europe that has been selected to receive support from Stanford through the Impact1 program, which have the purpose to bring more technological innovation aimed at children to the market and to patient. The company's Neola® is considered a promising innovation with the potential to improve neonatal intensive care from day one in the clinic.

In the program, Neola Medical gets access to company development from Stanford and Silicon Valley experts in development for medical technology products, regulatory experts and close collaboration with leading doctors in neonatal intensive care as well as the FDA's own pediatricians and regulatory experts.



CEO Hanna Sjöström and Dr. Valerie Chock, Lucille Packard, Palo Alto



CEO Hanna Sjöström and Dr. Janene H. Fuerch, Co-director of Impact1, Medical doctor in neonatology at Stanford University Medical Center

STANFORD IMPACT1 PROGRAM

Stanford Medicine is one of the world's leading universities in research on preterm born babies and is connected to the hospital that is ranked number one in neonatal care in the U.S. The Stanford Byers Center for Biodesign 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 of the program to promote innovations that provide precisely "impact from day 1". Neola Medical's medical device, Neola®, has been selected by Stanford's top neonatology experts as a promising innovation with the potential to improve neonatal intensive care from day one in the clinic.

The objective of the program is to meet the children's care needs by accelerating the development and increasing the availability of effective new technology in healthcare that has been developed specifically for children. The Food and Drug Administration (FDA) in the U.S. approves fewer and fewer medical device innovations for children each year. This means that pediatricians do not always have access to the advanced medical technology they need to meet the unique care needs of their small, vulnerable patients. The FDA is supporting Stanford's Impact1 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.



"It means a lot to us to be part of the exclusive network of technology companies partnering with Stanford to rapidly bring innovation that makes a real difference to children's hospitals in the U.S. and around the world. Neola Medical has the opportunity to be a game changer in the care of preterm born babies. Stanford and the American pharmaceutical agency FDA are determined to bring more medical technology innovation to the care of children, and the fact that we now get their full support will, I believe, be of great importance to our upcoming launch of Neola®, to hospitals in the United States."

- Hanna Sjöström, CEO Neola Medical

STANFORD IMPACT1 CEO SUMMIT 2023

In this year's Stanford Impact1 CEO Summit, CEOs from the exclusive network of leading healthtech companies in pediatrics gathered to discuss and share experiences on how advanced technology can get to market and patient in the U.S. faster. Neola Medical's CEO Hanna Sjöström participated in the conference on site in Palo Alto, Silicon Valley, USA, on October 12-13, 2023.

The conference has been an important step in the market preparation work before the launch of Neola® in the U.S. as it provided the opportunity to meet Stanford's leading doctors and experts and important American investors. Below are examples of some key opinion leaders together with CEO Hanna Sjöström.



Charlette Stallworth, Vice President of Business Development and Innovation at Stanford Medicine Children's Health and CEO Hanna Sjöström



Cheryl Cheng, Founder of Vive Collective, Wendy Sue Swanson, Doctor of Medicine, CEO Hanna Sjöström and Ashley Seehusen, CEO of Santé Accel

CLINICAL STUDY RESULTS PRESENTED

An important part of the market preparation work is the increase of Neola Medical's presence at major conferences in neonatology. At the end of September, CTO Sara Bergsten attended the jENS conference 2023 (Congress of joint European Neonatal Societies) in Rome, Italy. jENS is a well known international conference where experts and researchers from all over the world gather to take part in the latest research in neonatal care.



"It was a rewarding few days in Rome where I had the opportunity to meet researchers from all over the world and learn about the latest updates in neonatal research. It was particularly gratifying to hear the latest study results with Neola Medical's medical technology and to see the great interest that Neola® and GASMAS technology arouses among neonatologists."

- Sara Bergsten, CTO Neola Medical

During the jENS conference, clinical researcher and neonatologist Jurate Panaviene presented the new results and conclusions of the independent clinical trial NIOMI (Non-Invasive Lung Oxygen Monitoring in Term Infants) which was initiated in 2021 at the University Hospital in Cork, Ireland.

The study was led by Professor Eugene Dempsey, Horgan Chair in Neonatology from the INFANT Centre, University College Cork (UCC) to investigate the possibility of providing real-time information on lung function in newborn babies.



The results in brief



100% measured oxygen in all lungs

A non-invasive lung monitoring of newborn babies with Neola Medical's Neola®, Neonatal Lung Analyzer, intended for clinical studies, was used to evaluate oxygen measurements in 100 newborn babies. The newborn babies varied in different weight classes between 2.4 – 4.9 kg.



Safe and well tolerated technology

The final results show that Neola® measures oxygen in the lungs of 100% of the 100 participating newborns and the company's GASMAS technology is confirmed to be a safe and well tolerated technology for lung monitoring of preterm born babies.



Large space to place the probes

The influence of the placement of the probes on the signals was investigated and the results show that for each child there are many different placements that provide good measurement signals. In practice, this means that Neola® can be easily integrated into an existing workflow in the time-critical neonatal intensive care, as healthcare staff have a large space to place the probes on the child's chest.




Easily integrated in neonative intensive care

BACKGROUND TO THE NIOMI STUDY

Every day, one in ten babies are preterm born, many of them with underdeveloped lungs that can develop into life threatening conditions during their stay in the neonatal unit. They are likely to need breathing support due to respiratory distress syndrome (RDS), a serious lung condition whose complications can affect up to 80 percent of babies born extremely preterm. Rapid detection and diagnosis are critical in the neonatal intensive care unit to be able to administer treatment and prevent potential impairments later in life in preterm born babies.

The results from the NIOMI study provide information to guide the development of the GASMAS-based systems for future clinical adaptation in preterm born babies and to answer several technical questions regarding lung monitoring with Neola® as well as future clinical use in neonatal intensive care.


” Preterm born infants are at increased risk of requiring breathing support due to the underlying lung immaturity; this technology has the potential to change the way we manage these babies, help to avoid invasive mechanical ventilation and reduce longer-term lung problems. In the future, this system could improve the detection, diagnosis and treatment of newborn infants, particularly preterm born babies with reduced lung function ”



Professor Eugene Dempsey, Horgan Chair in Neonatology, INFANT Centre, UCC.

Quote Professor Eugene Dempsey, Professor in neonatology at University Collage Cork, Clinical leader for neonatal research and Principal investigator at INFANT Centre

” Implementing better methods of monitoring the lung function of preterm born infants is needed. Today, neonatal health care professionals treating children being born preterm must rely on manual observation with help from chest x-rays and blood samples predominantly ”



Research Fellow Jurate Panaviene, INFANT Centre, UCC and Cork University Maternity Hospital.

Quote Clinical researcher and Doctor Jurate Panaviene in neonatology at University Collage Cork, INFANT Center

FINANCIAL CALENDAR

9
November
2023
Rapport för tredje kvartalet 2023

14
Februari
2024
Bokslutskommuniké 2023

9
April
2024
Årsredovisning 2023

22
Maj
2024
Rapport för första kvartalet 2024 & Årsstämma 2024

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

The next investor letter is coming in winter 2023!

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