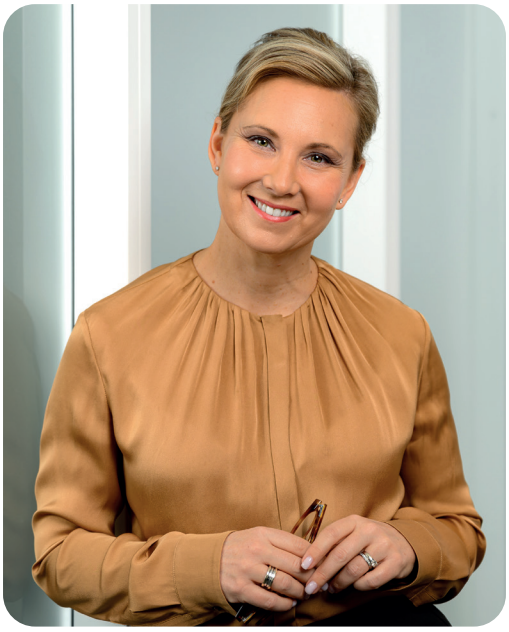
Neola Medical

INVESTOR LETTER SUMMER 2024

Summer's light shines brightly over our flourishing company. We're thrilled to report that in the first half of 2024, we've achieved several critical milestones in line with our business strategy. The successful Human Factors Validation Study of Neola® in Boston, USA, concluded with successful results confirming that Neola® is safe is safe for its intended use by healthcare professionals in neonatal intensive care. In addition to the formal results, we also received positive feedback from participating neonatal nurses highlighting its clinical benefits of lung monitoring in neonatal intesive care. This provides Neola® with excellent prospects for seamless integration into neonatal intensive care.

Additionally, Neola® has obtained a CB certificate signifying that the product has undergone a rigorous and comprehensive testing and evaluation process with particularly high demands on safety, essential performance, and electromagnetic compatibility by the accredited and independent IECEE testing house, FORCE Technology. The CB certificate underscores Neola®'s compliance with stringent international standards, affirming its safety and performance in neonatal intesive care units.

These both achievements lay a strong foundation for our upcoming FDA application for market approval in the USA. We now advance to the clinical validation phase and intensify planning for the clinical study in the USA on preterm born infants.



Our market preparation in the USA has also gained momentum. Recognized by Stanford's international industry experts as one of the world's top medical technology innovation companies that can improve pediatric care. We were honored by winning the silver medal at the prestigious international competition, Stanford PDC Accelerator Pitch Competition 2024, partially funded by the U.S. FDA to promote innovation in pediatric medical technology. Awarded with $25,000 and mentorship from Stanford's world-leading medical technology experts we receive tailored advice and full support to accelerate the development and increase the availability of advanced medichal technology innovation to reach the vulnerable pediatric patient group as quickly as possible.

I extend heartfelt thanks to our shareholders for your support at the annual general meeting. Together, we are reaching significant milestones and making great strides towards our launch. Wishing you all a wonderful summer and happy reading!

Hanna Sjöström

NEWS NEOLA MEDICAL

Successful results in completed Human Factors Validation Study with Neola® in USA, for FDA market approval. Read the press release here and the article by BioStock here.

BioStock studio - read exclusive details about the Humans Factors Validation Study in the Q1 report commentary with CEO Hanna Sjöström and Director QA & RA Magnus Johnsson below.

Silver medal for Neola Medical and 25 000 USD in Stanford's PDC Accelerator Award after final in Stanford PDS Pitch Accelerator Competition 2024 in the USA. Read more below.

Neola Medical releases the Annual Yearly report of 2023. Read the Annual report 2023 here.

May 22 Neola Medical published the Q1 report of 2024 and the communique from the Annual General Assembly. Read the Q1 report 2024 here and the communique here.

Annual General Assembly in Neola Medical

The attendance amongst shareholders was high, and votes represented more than 62% of the company's shares. Attending shareholders expressed great satisfaction with the event.

Chairman Märta Lewander Xu, Urban Ottosson, Tommy Hedberg and Mattias Lundin were re-elected as members of the board. Monica Alfaro Welling was elected to the board of directors as the company's first American board member, signaling the importance of U.S. experience as the company is progressing towards a market launch in the U.S.

Development Engineer Jasila Prabahar, who was on site for the Human Factors Validation Study in Boston, USA, last month conducted a product demonstration of Neola®. This presentation sparked significant enthusiasm among shareholders about Neola's groundbreaking technological capabilities and its potential to revolutionize clinical practice and enhance patient outcomes.

New CFO at Neola Medical ahead of market launch in the USA.

Neola Medical announced the appointment of David Folkesson as Chief Financial Officer, effective August 26, 2024.

David Folkesson brings extensive experience as a CFO in both public and private companies. He has previously worked as an auditor at Deloitte and as a financial advisor at Pragati. With his expertise in financial reporting, accounting, financial management, and business development, David will enhance Neola Medical's financial operations and contribute to building a profitable business.

With David Folkessons business- and results-oriented experience, he will be a key player in the compnay's growth journey and commercialization phase, particularly as market launch in the USA is approaching.

Neola® obtains CB certification and meets partial regulatory requirements for market approval in the USA. Read more below and the entire press relese here.

CEO Hanna Sjöström appointed Chairman for MedTech task force in SwedenBio's new expert network and attended SwedenBio's Annual Meeting. Read more below.

Cardeon's entire shareholding in Neola Medical acquired by major shareholders. Read more below and the press release here.

New CFO at Neola Medical ahead of market launch in the U.S. Read the press release here.

SUCCESSFUL HUMAN FACTORS VALIDATION STUDY

In March 2024 Neola Medical completed the Human Factors Validation Study with Neola®, the company's medical device for continuous lung monitoring of preterm born infants. The study was conducted in Boston, USA, to validate the usability of the medical device Neola®, and the successful results of the study will be included in Neola Medical's application to the FDA for market approval ahead of the market launch in the USA. Watch CEO Hanna Sjöström and Magnus Johnsson, Director Quality Assurance & Regulatory Afffairs, discuss the results, the company's financials, and the next steps towards clinical trials in the BioStock studio here.

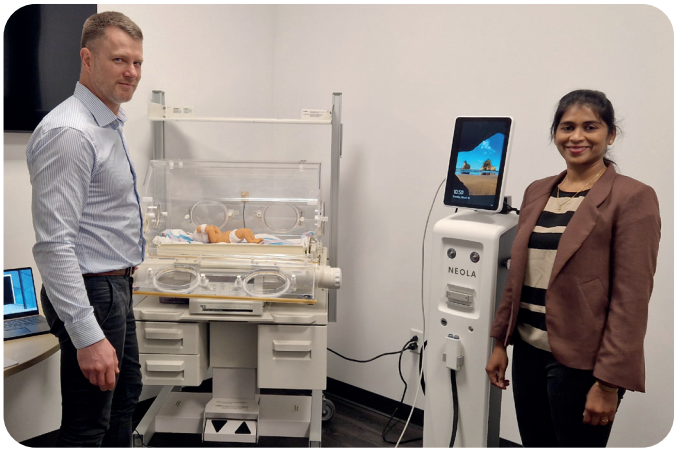
CEO Hanna Sjöström and Director Quality Assurance & Regulatory Affairs, Magnus Johnsson at BioStock studios.

"We are very pleased with the results, and it has been valuable to be on-site and observe the execution of the usability study at the testing center in Boston. We have had the opportunity to meet and train the participating neonatal nurses and have received their positive response regarding the potential of Neola®. They found Neola® easy to use and immediately understood its clinical utility, which provides favorable conditions for Neola® to be integrated effortlessly into neonatal intensive care.", says Magnus Johnsson, Director of Quality Assurance and Regulatory Affairs at Neola Medical.

"It is gratifying that the final results of the Human Factors Validation Study with Neola® in Boston, USA, confirm that our medical device is safe for its intended use by healthcare professionals. We have achieved an important milestone in line with the company's strategy and continue to reach our goals and milestones as planned. Successful results from the study are of great significance as we will use them as part of our forthcoming FDA application for market approval in the USA, which is an important step towards the market launch of Neola®.", says CEO Hanna Sjöström.

Evaluation of usability is a regulatory requirement from the FDA, and the goal of the study is to assess how well participants interact with Neola® and demonstrate that it is safe for its intended use by healthcare professionals in neonatal intensive care units. The collected results have been evaluated after the completion of the study in March 2024, and the report clearly indicates a usable and safe design. The report will be part of the forthcoming FDA application for market approval of Neola® in the USA.

The study was led by Custom Medical, global experts in usability studies, and conducted at a testing center in Boston during March 2024. The study's design has been aligned during a pre-submission meeting with the FDA, and the study has been executed entirely according to plan. The participants in the study consisted of 15 neonatal nurses, with varying levels of experience in the field, from several neonatal intensive care units in the USA. Neola Medical's staff were present in Boston to train the study participants in the use of Neola®.

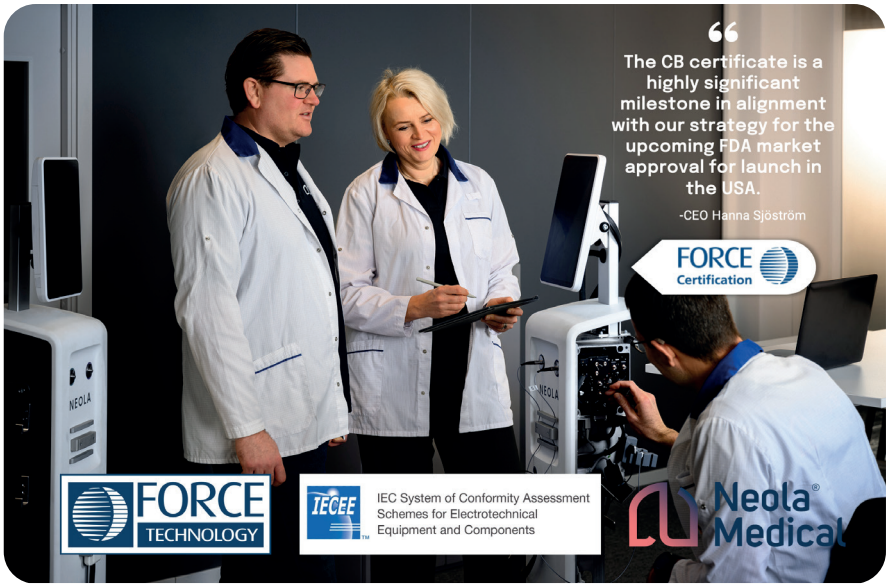


Magnus Johnsson, Director Quality Assurance & Regulatory Affairs with Jasila Prabahar, Development Engineer, at the testing center in Boston, USA.

SAFETY AND PERFORMANCE CERTIFICATION

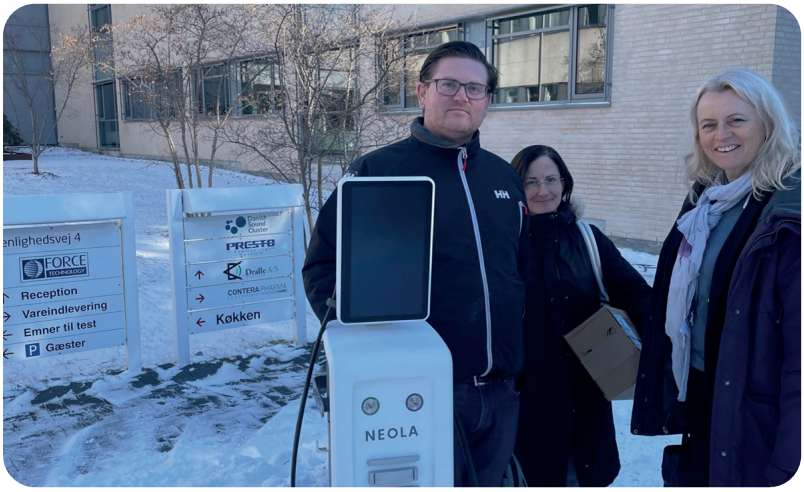
Neola® has successfully passed the comprehensive and stringent testing against IEC 60601-1 and IEC 60601-1-2 standards. This has resulted in the issuance of an IECEE CB Scheme certificate, which is recognized proof of Neola®'s safety and essential performance, issued by the accredited testing body FORCE Technology. The certificate is internationally recognized in about 50 countries and will form the basis for meeting the FDA's regulatory requirements.

"We are achieving a highly significant milestone in line with our plan for the upcoming market launch in the USA. The CB certificate demonstrates the company's ability to meet extensive and stringent international medical device standards and means that we have a crucial component in place for the forthcoming market approval by the U.S. Food and Drug Administration (FDA).", says CEO Hanna Sjöström.



Neola®

Neola® has obtained a CB certificate, signifying that the product has undergone a rigorous and comprehensive testing and evaluation process at an accredited and independent IECEE testing house, FORCE Technology. The certification for IEC 60601-1 and IEC 60601-1-2 indicates that the product meets specific quality requirements and international standards for medical devices in healthcare, with particularly high demands on safety, essential performance, and electromagnetic compatibility. In practical terms, this means that Neola® has been tested and verified to be safe for use according to the requirements for its application in neonatal intensive care units. This is a crucial piece that the company has secured in preparation for the market approval of Neola® in the USA.



System architect Martin Hansson, Consultant Regulatory Affairs Ceciila Larsson and CTO Sara Bergsten

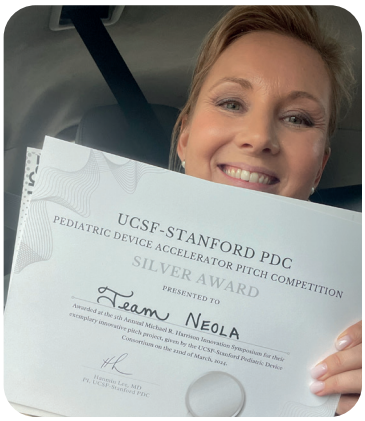
"The acquisition of the CB certificate for Neola® is a testament to the effectiveness of our structured product development process, as it indicates that the product meets the IEC 60601-1 family of medical device standards and our risk management process according to ISO 14971. Furthermore, FORCE has reviewed our product development to ensure it adheres to standards for usability evaluation and software development. That our medical device, Neola®, has met these rigorous requirements underscores our commitment to quality and patient safety.", says CTO Sara Bergsten.

FORCE TECHNOLOGY

FORCE Certification

STANFORD SILVER MEDAL AWARD

Neola Medical's product for lung monitoring of preterm born infants, Neola®, was selected by Stanford as one of the top ten most promising medical technology products in the world that can improve care for children. On Friday, March 22, 2024, Neola Medical, as one of the finalists for the PDC Accelerator Award in the Stanford Pediatric Device Consortium (PDC) Accelerator Pitch Competition 2024, had the opportunity to present the company's innovation at the Michael R Harrison Innovation Symposium at the University of California, San Francisco (UCSF), USA. CEO Hanna Sjöström was present and pitched Neola® to win the silver medal, receiving a 25 000 USD PDC Accelerator Award as well as mentorship and tailored guidance from Stanford's team of world-leading experts in medical technology.



"This recognition is especially meaningful as we approach the commercial launch of Neola®

The first part of the competition began with a pitch in front of a large audience, followed by questions from a panel of international industry experts. During the final part of the competition, a prize ceremony was held where the panel selected the best innovations to receive the PDC Accelerator Award based on the level of innovation, marketability, and clinical utility of the medical technology product. Thanks to funding from the U.S. Food and Drug Administration (FDA) through the Pediatric Device Consortia Grants Program, and generous support from the Frederick Gardner Cottrell Foundation and The Hooper Family, a total of 250 000 USD was awarded in grants.

CEO Hanna Sjöström on site in the USA to recieve the Stanford PDC Accelerator Award

"I am honored that Neola Medical has been awarded the silver medal and 25 000 USD in the PDC Accelerator Award in such a prestigious international competition for advanced medical technology in the USA. The competition has been tough, and it is a privilege to be recognized among the best innovative companies that can improve healthcare for children by Stanford's own international industry experts. This recognition is especially meaningful as we approach the commercial launch of Neola®, our medical technology product for non-invasive, continuous monitoring of lung function in preterm born infants, in the USA." , says Hanna Sjöström, CEO Neola Medical

About the UCSF-Stanford Pediatric Device Consortium (PDC)

The UCSF-Stanford Pediatric Device Consortium (PDC) Accelerator is a direct funding program targeting companies, innovators, and academic institutions based in the USA with a promising idea for a pediatric healthcare medical technology product that can enhance care for children. The program is offered once a year, and participants are selected through the PDC Accelerator Pitch Competition in March, with participation lasting for one year for accepted applicants who meet the FDA's definition of a medical technology product. Opportunities are provided to collaborate with UCSF-Stanford PDC's pediatric team and its advisors to develop the idea into a marketable product and to expedite its market availability for the benefit of patients. A few selected participants will also be given the opportunity to be part of and work closely with the world-leading medical technology incubator, Fogarty Innovation Accelerator in the USA, with the aim of advancing their pediatric innovations and contributing to the promotion of pediatric healthcare.

MEDTECH EXPERT AT SWEDENBIO

”When political processes take time, we are the catalyst that makes things happen.” - SwedenBio is forming a new expert network to develop the MedTech industry in Sweden, which has long faced challenges with political and bureaucratic processes that impeding advancement and the integration of Swedish medical innovations into the country’s healthcare system.

CEO Hanna Sjöström has been appointed Chairman of the MedTech task force at SwedenBio, comprising Senior Executives representing diverse Medtech companies. Leveraging her expertise in pioneering cutting-edge medical devices aimed at addressing unmet clinical needs and enhancing patient outcomes, she champions the integration of technology into healthcare. With a keen focus on the transformative power of technology in healthcare, the MedTech task force at Sweden Bio drives forward the agenda to propel Swedish healthcare into a new era. Central to the mission is the empowerment of Swedish MedTech companies to ascend as global frontrunners in the industry.

The expert network at Sweden Bio consists of working groups and task forces in various areas, comprising CEOs and senior employees from small to large companies within industry. These constitute the engine of SwedenBIO’s specific way of working to translate words into action – with the help of the network’s expertise – identify, analyze, and address the challenges facing the industry. The goal is to influence decision-makers and accelerate change that improves people’s health in Sweden and the world through medical innovations.

”The MedTech industry plays a crucial role in Sweden’s landscape, marrying the realms of medicine and technology to enhance healthcare outcomes. Leading the MedTech task force at SwedenBio is a privilege, as we collaborate to fortify Sweden’s position in this field, both in Sweden and globally. Our mission encompasses pivotal issues for Swedish MedTech companies, including global competitiveness, talent acquisition in medicine and technology, fostering an innovation-friendly environment, and reinstating Swedish hospitals as pioneers in technology integration, thereby ensuring our citizens have access to cutting-edge advancements in healthcare.”
– Hanna Sjöström, CEO Neola Medical

From words to action - identify, analyze and adress

SwedenBio Annual Meeting 2024 in Stockholm
On May 14th, the SwedenBio Annual Meeting and CEO Summit 2024, a pivotal gathering for life science industry leaders, was held at Münchenbryggeriet in Stockholm. CEO Hanna Sjöström attended SwedenBIO’s Executive dinner at the event, which centered on cultivating competent boards.

”In the Life Science sector, board competence is not just a valuable asset but a critical necessity. As we navigate the complexities of rapid advancements and stringent regulatory landscapes, the strategic diversity and specialized knowledge within our boards empower us to make informed decisions that drive innovation and compliance. The evolving demands of medical technology, digital health, and sustainability require a deep understanding and comprehensive expertise that we are committed to fostering.”
– Hanna Sjöström, CEO Neola Medical

NEOLA MEDICAL IN MEDIA

Neola Medical - the first listed company at Lejonkulan

”With great potential for the youngest” - reads the title as CEO Hanna Sjöström joins venture capitalist Jan Dahlqvist in Lejonkulan, the new podcast of Rapidus, which for the first time hosted a listed company.

In the interview CEO Hanna Sjöström elaborated on Neola® and the company’s business model. Jan Dahlqvist shared his opinions about the company’s business strategy, product development and investment potential. Listen to the episode here.

CEO Hanna Sjöström and host Jan Dahlqvist, Lejonkulan.

Life Science Sweden about the strengthen ownership positions in Neola Medical

The largest shareholders of the Lund-based company Neola Medical are strengthening their positions through an off-market share transaction. One of the company’s owners, Cardeon, decided to sell his shares and relinquish his ownership in the company through an off-market share transaction. The shares are acquired by existing major shareholders - Anmiro, Conspargo Capital, LMK, Brodvik, and Bengt Nevsten - as well as a new shareholder, Daniel Oelker, according to a company press release.

”It is significant for Neola Medical that existing major shareholders are once again strengthening their ownership positions in the company while we also welcome another major shareholder. We appreciate the confidence and long-term commitment demonstrated by our larger shareholders through this transaction, and we view them as strategic partners for the company’s growth journey ahead, with a focus on market launch in the USA,” says Neola’s CEO, Hanna Sjöström, in a statement.

Read the full article by Life Science Sweden here.

FINANCIAL CALENDAR

15 Augusti 2024	6 November 2024	12 Februari 2025	9 April 2025
Q2 report 2024	Q3 report 2024	Year End Financial Statement 2024	Annual report 2024

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

The next investor letter will come in the autumn of 2024!

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