

INVESTOR LETTER AUTUMN 2024

As autumn arrives in Lund, we are pleased to share that this seasonal transition mirrors our strategic advancements toward securing market approval in the USA for our continuous lung monitoring device, Neola®. We are making significant strides as we enter the clinical validation phase, a critical step in the forthcoming FDA application for market approval of Neola® in the USA. Neola Medical's commitment to long-term shareholder value is evident as we attract new strategic investors and gain stronger support from existing shareholders as they continue to strengthen their ownership positions in the company this year.

Neola® has recently achieved key milestones that align with FDA regulatory requirements, positioning us favorably in our approval journey for the U.S. market. The successful completion of the Human Factors Validation study in the USA, coupled with the newly acquired CB certification, affirms the safety and essential performance of Neola®. These accomplishments mark our transition from technical verification to clinical validation phase, preparing for clinical studies with our continuous lung monitoring device, Neola®.

Alongside our progress to clinical validation, we are advancing our commercialization strategy for Neola®. Recognizing the value of U.S. expertise at this pivotal stage, we are proud to welcome our first American board member as a strategic advisor. Her insights will be invaluable as we navigate this critical phase toward market launch.



Our competitive position continues to strengthen, highlighted by the recent patent grants in both the USA and Europe. These expansions in intellectual property protection ensure that Neola® remains at the forefront of modern neonatal care, safeguarding our innovations and market leadership.

The months ahead are set to be both intense and exhilarating as we prepare for the pivotal clinical study on preterm born babies in the USA, a cornerstone in our journey toward securing FDA market approval. To streamline preparations, we are conducting a pilot clinical study on preterm born babies at a neonatal intensive care unit in Sweden, gathering crucial insights to optimize conditions for success. We anticipate a productive and dynamic autumn and look forward to sharing our progress with you. Enjoy your reading!

Hanna Sjöström

NEWS NEOLA MEDICAL

Neola Medical granted patent in the USA. Read the press release here and more below.



Neola Medical prepares for pivotal clinical study on preterm born babies in the USA. Read the press release here and more below.



Neola Medical granted patent in Europe, Expands protection for medical device Neola®. Read the press release here and more below.



Neola Medical published the Q2 report of 2024. Read the press release and the Q2 report of 2024 here.



Watch the Q2 report 2024 commentary in BioStock studio with CEO Hanna Sjöström and CTO Sara Bergsten here.



Q2 report 2024 presentation at Finwire TV

Neola Medical presented the Q2 report of 2024 at Finwire TV. In the presentation CEO Hanna Sjöström outlined the critical milestones that will lay a foundation for the upcoming FDA application for market approval in the U.S. Clinical trials are now on the horizon, with further updates expected in the fall.

"In summary, the first half of 2024 has been focused on fulfilling key achievements for our upcoming FDA application for market approval in the USA. Concluding our technical verification phase and a successful Human Factors Validation Study, we now advance to the clinical validation phase and intensify planning for the clinical study in the USA on preterm born infants.", says CEO Hanna Sjöström



Neola Medical technology lecture at prestigious neonatal medicine congress

Neola Medical announced its prominent role at the upcoming Xth RECENT ADVANCES IN NEONATAL MEDICINE Congress, October 12-14 in Wurzburg, Germany. The congress is one of the largest and most prestigious scientific gatherings outside the U.S. Neola Medical is proud to sponsor a special lecture on its GASMAS technology, delivered by the esteemed MD DM Professor Vineet Bhandari. Read more [here](#).

"The potential of GASMAS technology in modern neonatal care is an exciting step forward in neonatal medicine, and I look forward to sharing its potential future with healthcare professionals from around the world.", Professor Vineet Bhandari



 Cooper Medical School of Rowan University

Professor Vineet Bhandari, Division Head of Neonatology at The Children's Regional Hospital at Cooper



Neola Medical showcases breakthrough GASMAS Technology at prestigious Neonatal Medicine Congress with lecture by leading U.S. Professor in Neonatology. Read more [here](#).



Neola Medical interviewed the new member of board of directors, Monica Alfaro Welling and BioStock published article with the new CFO at Neola Medical. Read more [below](#).



CEO Hanna Sjöström presented at the Medicon Valley Alliance MedTech Network meeting in Lund. Read the press release [here](#) and more [below](#).



Västra Hamnen Möter invited CEO Hanna Sjöström to discuss the company's promising study data and next steps toward the upcoming FDA application in the USA. Watch [here](#).



A bold new beginning made room for the heart in a top career - Exclusive article by Chefakademin with CEO Hanna Sjöström. Read more [below](#).

REINFORCING COMPETITIVE POSITION

Neola Medical's intellectual property portfolio is one of the company's most significant assets. The patent portfolio encompasses seven different patent families, covering all major assets in three main areas related to medical patents including both the core technology for measuring gas within body cavities and product- and disposables specific applications. The company's patent portfolio has been continuously strengthened, and in 2024, it was expanded with two new patent grantifications, one in the USA and one in Europe. By continuously expanding the IP-portfolio, the company is reinforcing the opportunity to scale to other patient groups, secure future innovation, competitiveness and leverage.

In addition to patents, the Neola® trademark is registered in Europe, China, Australia, and the United States. Furthermore, trademark protection for the Neola® logo has been registered in Europe and China, with applications submitted in the USA and Australia.



Neola Medical AB has recently been granted a patent in the USA that strengthens the protection of the company's innovation pipeline of medical device for continuous lung monitoring. The granted patent is for a technical method which opens opportunities for lung monitoring of more patient groups than preterm born infants, and part of a patent family related to positioning the light source inside the body when measuring gas in the lungs. The approved patent is crucial for future measurements on larger patients, such as children and adults. The patent is pending in Europe and in China.



"The approval of this patent not only solidifies our competitive position in the American market but also protects a critical aspect of our technology pipeline. This patent is a cornerstone in our strategy to innovate and deliver next-generation lung monitoring solutions for patients in intensive care, including both children and adults.", says CEO Hanna Sjöström.

Neola Medical AB has been granted a patent in Europe for a technical method and equipment that enhance the accuracy of continuous measurements performed by the company's medical device for lung monitoring, Neola®. This patent extends the protection for Neola® and strengthens the product's competitiveness. The patent application is pending in the USA and China.

"The granting of this patent is a milestone in our intellectual property strategy, reinforcing our competitive edge in the market. By continuously expanding the protection of our product, we ensure that Neola® remains at the forefront of medical technology for neonatal care.", says CEO Hanna Sjöström



TOWARD MARKET LAUNCH

Building on progress in the clinical and FDA processes, the company's efforts in the U.S. market are gaining momentum with significant developments in launch preparations. As part of Neola®'s commercialization strategy in the American market, the company has established a U.S. subsidiary, Neola Medical, Inc. and appointed Monica Alfaro Welling, as its first American board member. Read the full interview [here](#).



Monica Alfaro Welling, board member at Neola Medical

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As I learned more about Neola®, I was impressed by Hanna Sjöström's leadership, the cutting-edge technology, and the company's dedication to neonatology—an area that is often underserved but closely aligned with the early focus of my career.

How do you think your experience will best be used to achieve the vision for the company?

– With over three decades of experience in the life sciences sector, I have successfully prepared and launched both established organizations and start-ups with high-impact brands in competitive environments. My strategic insight spans both the U.S. and international markets, where I've led efforts in navigating regulatory landscapes, developing risk mitigation strategies, scaling operations, and ensuring successful market entry. As a board member, I will leverage my experience and network to provide strategic oversight, helping Neola® drive sustainable growth, expand its market footprint, and solidify its leadership in the life sciences industry.

How do you think Neola Medical can make a significant impact in the global MedTech market, especially in the U.S.?

– I believe Neola Medical has the potential to make a significant impact, particularly in the U.S. market, by addressing a critical unmet need in neonatal care. The strong interest and support from key stakeholders, including the FDA and leading academic institutions, is a positive indicator of Neola®'s value and growing influence. By leveraging these relationships, Neola® has the opportunity to set new standards in neonatal care and establish itself as a leader in a niche, but highly impactful, segment of the MedTech industry.

Neola Medical has also strengthened its management team by appointing David Folkesson as the new CFO. With strong business acumen and a results-driven approach, David will be pivotal in the company's growth and commercialization efforts, enhancing financial operations and steering Neola Medical toward profitability. BioStock reached out to David to learn more about his background and the journey ahead. Read the entire article by clicking the BioStock logo!

What attracted you to Neola?

– The CFO assignment at Neola Medical felt inspiring and attractive by having the opportunity to combine the development of an incredibly important medical device that has the potential to improve neonatal care from day one at the clinic and at the same time working with a very inspiring team led by CEO Hanna Sjöström. The company has an exciting development and is in a significant phase where I look forward to both working with the operational part of the business and being an important part of the company's growth journey.

It has been quite a struggle financially for many life science companies in recent years. How do you see the financing landscape today?

– It has been a difficult time for many. I believe it is important that companies continue to create high confidence and interest from shareholders, which Neola Medical has succeeded in doing by starting 2024 with strengthened cash position and an expanded shareholder base after a directed share issue at the end of 2023. It was also impressive that, during the harsh climate in the capital market, the company was able to do a cost-effective capital raise that was made at a premium to the share price at the time.



David Folkesson, CFO at Neola Medical

PREPARING FOR CLINICAL STUDIES

Neola Medical AB is advancing to the clinical validation phase with its medical device for continuous lung monitoring, Neola®. In preparation for a pivotal clinical study on preterm born babies in the USA, scheduled for 2025, Neola Medical will launch a clinical pilot study at a Swedish hospital. The pivotal clinical study, along with the successful Human Factors study results and the recently obtained CB certificate, will be instrumental in supporting Neola Medical's forthcoming FDA application for market approval in the USA.

“*Exciting months lay ahead, as we advance into the clinical validation phase and gear up for the pivotal clinical study on preterm born babies in the USA. This study will be a cornerstone in our journey toward securing FDA market approval.*”



Neola Medical takes significant steps toward market approval in the USA. The company's lung monitoring device has achieved critical milestones that meet key regulatory requirements for FDA approval. The successful Human Factors Validation study conducted in the USA, along with the recently acquired CB certification, underscores the product's safe design and essential performance. As a result, Neola Medical is transitioning from the technical verification phase to the clinical validation phase, preparing for clinical studies.



Neola Medical initiate clinical studies on preterm born infants, preparing for clinical pilot study in Sweden and clinical study in the USA.

The company is now in detailed planning for a pivotal clinical study on preterm born babies in the USA, scheduled to begin in 2025. In preparation for this, Neola Medical will conduct a clinical pilot study on preterm born babies at a neonatal intensive care unit in Sweden. The clinical protocol for the Swedish study has been finalized, and the company is currently in contract negotiations with a Swedish hospital.

NEOLA MEDICAL IN MEDIA



CEO Hanna Sjöström presents at MVA Medtech Network

In the presentation CEO Hanna Sjöström outlined pivotal experiences that have propelled the company's progress and the strategic approaches taken to navigate and overcome industry challenges.

The event featured presentations from innovative companies at various stages of their growth journey to provide an in-depth look into the strategies, groundbreaking innovations, and critical experiences that have fueled their success.

"MVA has been instrumental in fostering collaboration and innovation within the life science community, and I am honored to share Neola Medical's journey and our team's ability to overcome industry challenges to shape the future of neonatal care.", says CEO Hanna Sjöström



The event offers investors a valuable opportunity to gain insights from real-world examples of how industry challenges have been overcome. It also serves as a platform to network with key players in the MedTech sector and explore avenues for collaboration and growth within this dynamic community. Read more [here](#).

Västra Hamnen Möter hosts Neola Medical

The company's product for continuous lung monitoring of preterm born infants is attracting significant international interest.

CEO Hanna Sjöström and CEO Oscar Ahlgren at Västra Hamnen TV discussed Neola Medical's promising study data and what remains before submitting a regulatory application to the FDA. Watch [here](#).



CEO Oscar Ahlgren at Västra Hamnen Corporate Finance and CEO Hanna Sjöström discussed pivotal milestones toward market approval in the USA at Västra Hamnen Möter.

NEOLA MEDICAL IN MEDIA



Exclusive interview by Chefakademin with CEO Hanna Sjöström

A bold new beginning made room for the heart in a top career. - Hanna Sjöström's career trajectory is impressive: first an international top career at Coca-Cola and L'Oréal, now CEO of a life-saving startup. Chefakademin's Executive MBA is part of the recipe for success.

Hanna Sjöström's passion is unmistakable as she talks about the company. She has reached this point through an international top-tier career and bold decision-making.

Hanna Sjöström became Neola Medical's first full-time CEO in 2019. The primary focus was on taking the company public, leading to the decision to put her Executive MBA studies on hold. When the listing on Nasdaq First North was completed in 2020, a U.S. launch strategy became necessary. Hanna Sjöström recognized the need to further enhance her knowledge in strategy, particularly international strategy.

“ *We developed the American launch strategy for Neola Medical during the course. It was absolutely invaluable. It was like having my own little McKinsey team.* ”

Hanna Sjöström views pursuing an Executive MBA alongside her career as a key to success. The flexibility of Chefakademin's program, which can be completed in three stages with breaks in between, allows for personal and professional development, making it highly relevant even for those with demanding careers. Read the full article (in Swedish) [here](#).

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

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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 winter of 2024!

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