Neola Medical

Q4 report 2024

Published February 12, 2025

"Having achieved key milestones in 2024, we now enter the clinical phase with approval to initiate the first clinical study with Neola® on preterm born babies in neonatal care."

CEO Hanna Sjöström

Received approval for initiation of first clinical pilot study on preterm born babies

Fourth quarter, October-December 2024

- Approval to initiate first clinical pilot study on preterm born babies received from the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten).
- Participating in largest European Neonatal Medicine Congress sponsoring lecture on the potential of GASMAS Technology, delivered by leading U.S. Professor in Neonatology.
- U.S. trademark registration of the Neola® logotype, featuring its symbolic lung design, strengthens the brand as a trusted symbol of safety, quality, and innovation in neonatal intensive care.

Summary
Operating income: SEK 0k (0)
Operating result: SEK -2 742k (-2 139)
The period's cash flow: SEK -4 606k (-5 036)
Result per share: -0,04 SEK (-0,04)

Yearly report, January-December 2024

- Advancing from the technical verification phase to the clinical phase preparing for the first clinical pilot study on preterm born babies, following approval by Swedish authorities.
- The Human Factors Validation Study with Neola®, was successfully concluded in the U.S., laying foundation for the upcoming FDA application for market launch in the U.S.
- Neola® obtained a CB certificate according to high international standards, meeting partial regulatory requirements for market approval in the U.S.
- Increased IP protection highlighted by patent grants in both U.S. and Europe reinforcing the innovation pipeline.

Summary
Operating income: SEK 0k (0)
Operating result: SEK -10 797k (-9 621)
The period's cash flow: SEK -2 022k (-18 512)
Result per share: -0,14 SEK (-0,17)

CEO comments

Hanna Sjöström, CEO

We are pleased to share the progress we have made during 2024 on our mission to improve neonatal care. This year has been marked by significant milestones in our journey toward FDA approval and commercialization, while also preparing for the critical next steps in our clinical validation.

A key focus has been laying the groundwork for our pivotal clinical study in the U.S. We successfully obtained the CB certificate for Neola® and completed the Human Factors Validation study in the U.S., meeting partial regulatory requirements for market approval. These achievements mark our transition from the technical verification phase to clinical validation.

Following approval from Swedish authorities, we will initiate our first clinical pilot study on preterm born babies at a neonatal intensive care unit in Sweden, marking the very first clinical study with Neola® on its target patient population. As preterm born babies differ significantly from full-term newborns, insights from this study can guide us in optimizing and refining Neola® to meet the specific needs of this vulnerable 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. As we move forward, we remain committed to navigating the complexities of clinical studies with diligence.

U.S. market preparations continue to be a key focus area, with recognition from Stanford's international industry experts as one of the world's leading innovators in pediatric medical technology, we were honored to win the silver medal at the prestigious Stanford PDC Accelerator Pitch Competition 2024, partially funded by the FDA to promote pediatric innovation. The award provides mentorship from Stanford's top medical technology experts, offering tailored guidance and support to fast-track our development and market entry.

In October we sponsored a keynote lecture by Professor Vineet Bhandari at Europe's leading neonatology conference. His presentation, "GASMAS Transit to the NICU – Are We There Yet?", highlighted GASMAS technology's potential to improve neonatal care. Engaging with international key opinion leaders is a strategic priority as we strengthen Neola®'s clinical and commercial positioning. By actively participating in high-profile scientific forums, we enhance awareness, credibility, and long-term adoption of our technology in neonatal intensive care, a key to driving market acceptance and future business growth.

During the year, we strengthened our competitive position with both U.S. and European patent grants, securing our innovation pipeline. The year ended on a high note with the U.S. trademark registration of the Neola® logotype, reinforcing our IP protection and elevating Neola® as a trusted symbol of innovation in neonatal intensive care.

Thank you for your continued trust and confidence in our mission. Your support is invaluable as we work toward providing preterm born babies worldwide with a safer start in life.

Hanna Sjöström

Significant events

During the quarter

- Neola Medical participated at the largest European Neonatal Medicine Congress in Wurzburg, October 12-14, showcasing GASMAS technology with keynote lecture delivered by leading U.S. Professor in Neonatology, MD DM Professor Vineet Bhandari, Division Head in Neonatology at The Children's Regional Hospital at Cooper, Camden, USA

- Neola Medical received U.S. trademark registration of Neola® logo ahead of market launch

After the quarter

- Neola Medical receives approval by Swedish Authorities to initiate Clinical Pilot Study on Preterm Born Babies in Sweden

The Company

Neola Medical, founded in 2016, is based on years of research at Lund University and addresses the global market for neonatal intensive care with an innovative medical device called Neola®, the Neonatal Lung Analyzer. This device is based on patented technology for the continuous monitoring of the lungs in preterm born infants.

Neola Medical's headquarters is located at IDEON Gateway, Scheelevägen 27 in Lund, Sweden. In addition to the headquarters in Lund, the Company has a U.S. office at Nordic Innovation House in Palo Alto, Silicon Valley, USA.

Business concept

Neola Medical's business concept is to develop and sell the Company's product for continuous lung monitoring, providing instant detection of respiratory complications to neonatal intensive care units globally, with a primary focus on the U.S. market.

Vision

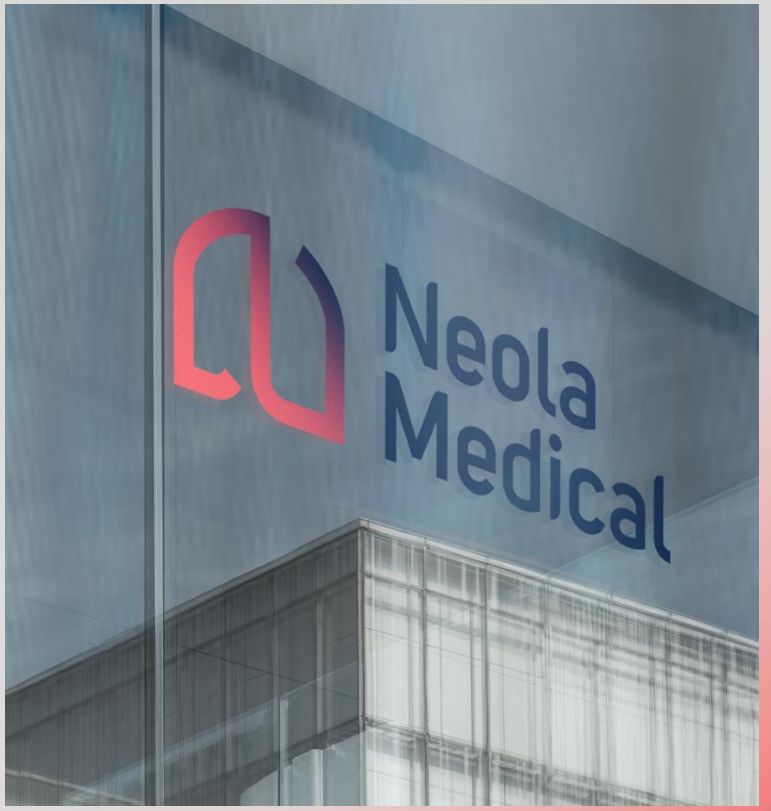
The Company's vision is for preterm born infants to have a better start in life. By providing neonatal intensive care units with the medical device Neola®, which enables continuous monitoring of the lungs of preterm born infants with direct detection of complications, the Company aims to enhance the care of these vulnerable children and potentially save lives.

Goal

The Company's overarching objective is to create a new market for non-invasive continuous lung monitoring in neonatal intensive care and to be present in the leading neonatal intensive care units globally. The Company's financial goal is to achieve a positive operating profit three years after commercial launch.

Business model

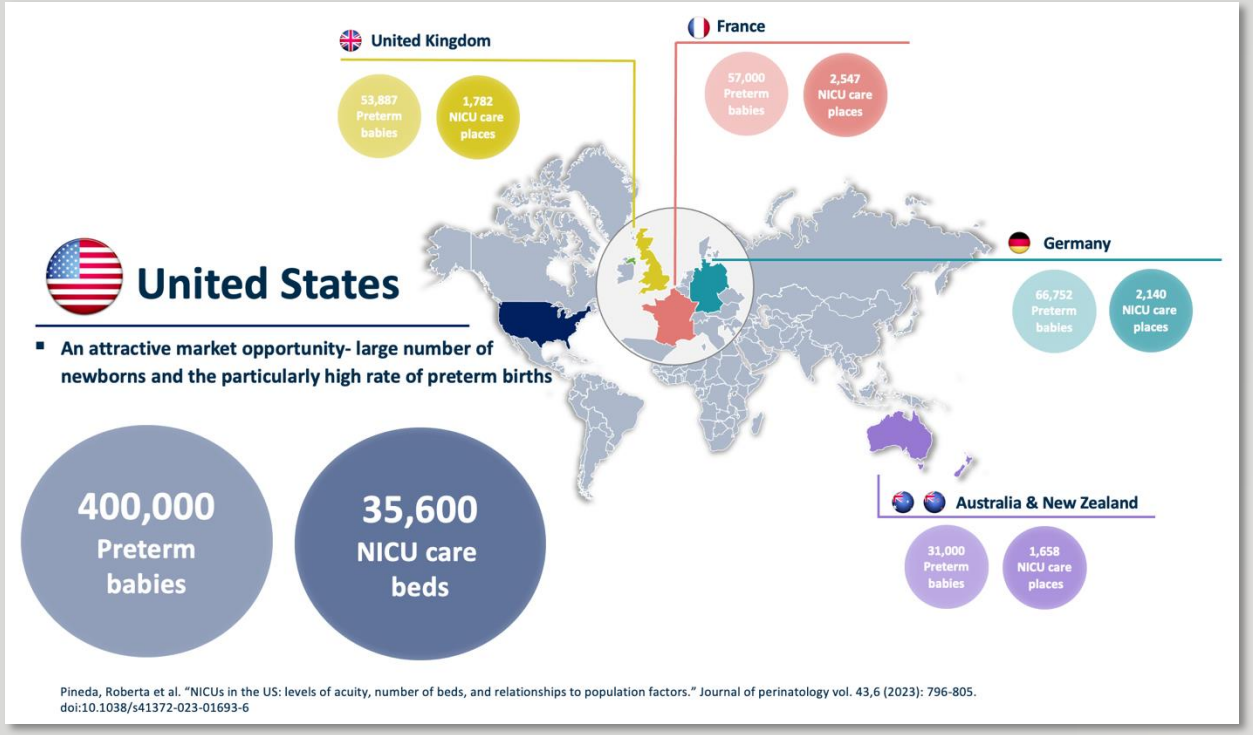
The Company's business model ensures recurring revenue by requiring a Neola® device for a significant proportion of the beds in the neonatal intensive care clinic, with the probes used for monitoring being disposables that are replaced daily on the infant.



Market

A highly significant and growing global market

Neola® will be introduced to the global market for respiratory equipment focused on neonatal intensive care, which was valued at USD 1.7 billion in 2022. The market is projected to expand with a compound annual growth rate (CAGR) of 5.9% from 2022 to 2032, reaching USD 3 billion by 2030.



The patients

Today, one in ten babies is born preterm, many of whom require intensive care to survive the first days due to underdeveloped lungs. Current methods for monitoring preterm born infants only provide a snapshot of their condition, and complications are detected only after severe physical symptoms have appeared. Neola® addresses a clear and significant clinical need for a continuous monitoring method. Neola® may result in better care, fewer days in intensive care, and ultimately, reduced morbidity and mortality in preterm born infants.

New precision care upgrading current standard of care

Neola® aims to offer:

01 Faster detection of pulmonary complications preventing further major morbidities

02 Decreased number of days in the expensive neonatal intensive care unit

03 Decreased time for visual observation by nurses

Financial information

Financial summary

Neola Medical, summary	2024-10-01 -2024-12-31 3 mos	2023-10-01 -2023-12-31 3 mos	2024-01-01 -2024-12-31 12 mos	2023-01-01 -2023-12-31 12 mos
Operating revenue (SEK k)	2 442	3 115	10 392	9 830
EBIT (SEK k)	-2 742	-2 139	-10 797	-9 621
Cashflow for the period (SEK k)	-4 606	-5 036	-2 022	-18 512
Cash and cash equivalents (SEK k)	19 555	21 578	19 555	21 578
Equity per share before dilution (SEK)	0,98	1,13	0,98	1,13
Equity ratio (%)	94	92	94	92
Total assets (SEK k)	73 612	86 018	73 612	86 018
Quick ratio (%)	453	700	453	700
Average amount of shares before dilution (no.)*	70 150 234	56 000 737	70 150 234	55 765 558
Result per share before dilution (SEK)	-0,04	-0,04	-0,14	-0,17
Amount of shares by the end of the period (no.)	70 150 234	70 150 234	70 150 234	70 150 234

* 2 605 000 warrants in ongoing programs may give a total dilution of 3.7%

Financial progress January – December 2024

Revenues and results of operations

For the period January to December, operating revenues amounted to SEK 10.392 thousand (SEK 9.830 thousand). As in previous periods, the Company's revenues primarily consisted of capitalized own work. Neola Medical capitalizes expenses for its development projects, as well as for patents, licenses, and similar intangible assets. The capitalization of development work amounted to SEK 10.065 thousand (SEK 9.784 thousand).

Operating expenses for the period January to December amounted to SEK 19 600 thousand (SEK 17.858 thousand). In addition to costs directly attributable to the Company's product development, expenses also included financial and legal advisory services related to legal agreements, stock exchange costs, public reporting, as well as investor relations activities and communication.

The Human Factor validation study that was conducted in Q1 and preparations for upcoming studies has increased costs compared to the corresponding period last year, all according to plan. Neola Medical has strengthened the team during the year which has increased the personnel cost compared to last year.

The operating result amounted to SEK –10.797 thousand (SEK –9.621 thousand). The Company maintains stability on the cost side with a burn rate according to plan. Neola Medical continues its work focusing on preparation for clinical studies, and other activities aimed at the certification and market approval of Neola®.

The Company's burn rate averaged SEK –1.805 thousand (SEK –1.543 thousand) per month during the period and is expected to increase with the acceleration of product development, especially clinical validation, over the next year.

Preparations for a commercial structure are also expected to impact the cost base going forward. The result after tax amounted to SEK –10.081 thousand (SEK –9.009 thousand), and the earnings per share were SEK -0,14 (SEK -0,17) for the period January to December.

Cash flow and investments

The total cash flow for the period January to December amounted to SEK –2.022 thousand (SEK –18.512 thousand). The cash flow from investing activities alone amounted to SEK –11.459 thousand (SEK -12 305 thousand) and consisted of investments in intangible assets such as capitalized development work, concessions, patents, and similar rights. The inflow of proceeds from new share issues at the beginning of the period increased the cash balance by SEK 19,931 thousand after deducting issuance costs. Cash and cash equivalents at the end of the period amounted to SEK 19.555 thousand (SEK 21 578 thousand).

Financial position and balance sheet

As of December 31, 2024, the equity ratio was 94% (92%), and own capital amounted to SEK 68.963 thousand (SEK 79.028 thousand). The Company was free from interest-bearing debt as of the balance sheet date. Intangible assets amounted to SEK 52.368 thousand (SEK 42.776 thousand).

Risks and uncertainties

Macroeconomic and Geopolitical Risks

The geopolitical developments currently have no direct impact on the Company's operations. However, the Company closely monitors the global situation and continuously analyzes potential risks and consequences that may affect the operations.

Clinical trials and regulatory approvals

All medical devices developed for market release must undergo a comprehensive registration process with the relevant authority in each individual market. This process includes, where applicable, requirements for preclinical development, clinical trials, registration, approval, marketing, manufacturing, and distribution of new medical devices. Changes in the regulatory landscape for each individual market may affect the company’s regulatory process. Clinical studies may necessitate further optimization and refinement of Neola®, which could impact the overall timeline. Failure to meet existing or future requirements may necessitate additional clinical studies, product recalls, and may prevent registration approval.

Neola Medical plans to submit documentation for FDA approval and CE marking for Neola® by 2026, respectively, with approvals expected in 2026/2027. The Company relies on these approvals for commercial launch. Therefore, the Company needs a functioning capital market to finance product development until this milestone is reached.

Dependence on expertise and key personnel

The Company depends on specialist expertise and key personnel. Loss of such expertise and key individuals could impede the Company's development.

Intellectual property rights

The Company's intellectual property rights are protected through patents, patent applications, agreements, and legislation safeguarding trade secrets. Infringement of the Company's intellectual property rights could harm its operations. Furthermore, patent protection for biomedical and biotechnological companies is uncertain and involves complex legal and technical issues. There is a risk that patents will not be granted for patent-pending inventions and that granted patents will not provide sufficient protection. Additionally, not all developments and technologies can be patented.

Financing and conditions for continued operations

The Company conducts capital-intensive research and development activities. To date, the Company has financed its operations through equity via new share issues and shareholder contributions. The Company's activities may require additional external financing before generating revenue, and it cannot be guaranteed that the Company will secure the necessary capital. If, for any reason, the Company is unable to continue its operations, this could affect the Company's ability to realize the reported values of its assets, particularly concerning capitalized development costs and patents, which are based on and dependent upon the conditions for continued operations.

Accounting principles and judgements

Accounting Principles

Neola Medical applies the Annual Accounts Act and the Swedish Accounting Standards Board's general guidelines BFNAR 2012:1 (K3) in the preparation of its financial reports. The applied accounting principles remain unchanged from those used in the Annual report of 2023. For further information, refer to the Group's Annual report of 2023.

Estimates and Judgments

In preparing the financial reports, the Board of Directors and management make judgments and assumptions that affect the Group's results and financial position, as well as the information provided otherwise. Estimates and judgments are continuously evaluated and are based on historical experience and other factors, including expectations of future events deemed reasonable under current circumstances. Actual outcomes may differ from these estimates. The areas where estimates and assumptions could involve significant risks of adjustments to the reported values of results and financial positions in future reporting periods mainly pertain to judgments about market conditions and, consequently, the value of the Group's fixed assets.

Since the operations of the subsidiary Neola Medical, Inc. in Delaware USA, is considered to be insignificant in scope, no consolidated financial statements are prepared.

Financial reports in summary

Profit and loss statement, (SEK k)	2024-10-01 -2024-12-31 3 mos	2023-10-01 -2023-12-31 3 mos	2024-01-01 -2024-12-31 12 mos	2023-01-01 -2023-12-31 12 mos
Operating income	0	0	0	0
Capitalized own work	2 153	3 084	10 065	9 784
Other operating income	289	32	327	46
Operating revenue	**2 442**	**3 115**	**10 392**	**9 830**
Raw materials and consumables	-153	-676	-1 369	-1 765
Other external costs	-2 405	-2 448	-8 883	-7 986
Personnel costs	-2 314	-1 728	-9 348	-8 107
Depreciation	-327	-403	-1 527	-1 593
Other operating expenses	15	0	-62	0
Operating result	**-2 742**	**-2 139**	**-10 797**	**-9 621**
Financial income and expenses	116	185	733	612
Result before tax	**-2 626**	**-1 954**	**-10 064**	**-9 009**
Tax on result for the period	0	0	0	0
Result for the period	**-2 626**	**-1 954**	**-10 064**	**-9 009**

Financial reports in summary

Balance sheet, (SEK k)		
Assets		
Non-current assets	**2024-12-31**	**2023-12-31**
Intangible assets	52 368	42 776
Tangible assets	202	137
Financial assets	0	0
Sum non-current assets	**52 570**	**42 913**
Current assets		
Inventory	83	180
Short-term receivables	1 404	21 348
Cash and bank balances	19 555	21 578
Sum current assets	**21 042**	**43 105**
Sum assets	**73 612**	**86 018**

Balance sheet, (SEK k)		
Equity and liabilities		
Equity	**2024-12-31**	**2023-12-31**
Equity	68 963	79 028
Sum equity	**68 963**	**79 028**
Liabilities		
Long-term liabilities	0	833
Accrued expenses and deferred income	1 997	1 620
Other current liabilities	2 652	4 537
Sum liabilities	**4 649**	**6 991**
Sum equity and liabilities	**73 612**	**86 018**

Financial reports in summary

Changes in own capital, (SEK k)	2024-10-01 -2024-12-31 3 mos	2023-10-01 -2023-12-31 3 mos	2024-01-01 -2024-12-31 12 mos	2023-01-01 -2023-12-31 12 mos
Own capital at beginning of period	71 589	61 078	79 028	67 485
New share issues and subscribed share capital	0	20 072	0	20 000
Issuance costs	0	-168	-69	-168
Issued subscription warrants	0	0	68	720
Other adjustments and provisions	0	0	0	0
Result for the period	-2 626	-1 954	-10 064	-9 009
Own capital at end of period	**68 963**	**79 028**	**68 963**	**79 028**

Cash flow, (SEK k)	2024-10-01 -2024-12-31 3 mos	2023-10-01 -2023-12-31 3 mos	2024-01-01 -2024-12-31 12 mos	2023-01-01 -2023-12-31 12 mos
Cash flow from operating activities before changes in working capital	-2 299	-1 440	-8 538	-7 183
Changes in working capital	-236	333	-2 300	641
Cash flow from operating activities	**-2 535**	**-1 107**	**-10 837**	**-6 542**
Cash flow from investing activities	-2 071	-3 928	-11 184	-12 305
Cash flow from financing activities	0	0	19 999	336
Cash flow for the period	**-4 606**	**-5 036**	**-2 022**	**-18 512**
Cash and cash equivalents at the beginning of the period	24 161	26 613	21 578	40 089
Cash and cash equivalents at the end of the period	**19 555**	**21 578**	**19 555**	**21 578**

About the share

Share capital, shareholders and the share 2024-12-31

As of December 31st, 2024, Neola Medical's share capital was 5 010 751,19 SEK with a total of 70 150 234 shares. All shares are of the same type, have an equal right to a share in the Company's assets and profits and have the same voting value.

Neola Medical's share is listed at Nasdaq First North Growth Market Stockholm under the name NEOLA since October 2, 2020.

Shareholders 2024-12-31 (Top 10)	Amount of shares	Percentage of capital	Percentage of votes
ANMIRO AB	17 647 246	25,3%	25,3%
Pär Josefsson	16 537 411	23,7%	23,7%
Brodvik AB	7 626 566	10,9%	10,9%
LMK-bolagen & Stiftelse	7 350 360	10,6%	10,6%
Bengt Nevsten	2 362 914	3,4%	3,4%
Avanza Pension	990 060	1,4%	1,4%
Magnus Kenneby	625 000	0,9%	0,9%
Nordnet Pensionsförsäkring	590 851	0,8%	0,8%
Urban Ottosson	584 240	0,8%	0,8%
Swedbank Försäkring	557 500	0,8%	0,8%
Other shareholders	14 778 086	21,2%	21,2%
Total	**69 650 234**	**100,0%**	**100,0%**

* Out of Pär Josefsson's holdings 2 500 977 shares are placed in capital insurance. Holdings in capital insurance does not have the right to vote.

Financial calendar and contact

9 April 2025	21 May 2025	22 Aug 2025	6 Nov 2025
Annual report 2024	Q1 report 2025 and Annual General Assembly in Lund	Q2 report 2025	Q3 report 2025

Financial reports
Financial reports are available at www.neolamedical.com

Investor letter
Neola Medical publishes investor letters several times a year at www.neolamedical.com

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Questions about the report is answered by:
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David Folkesson, CFO
E-mail: david.folkesson@neolamedical.com

Lund February 12, 2025
The Board


Märta Lewander Xu


Tommy Hedberg


Urban Ottosson


Monica Alfaro Welling


Mattias Lundin

This report has not been subject to review by the company's auditors.

Investment highlights

1. Large and growing addressable market
2. Great clinical need and demand
3. Attractive business model
4. Proven technology
5. Highly experienced team

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