Neola Medical

Q3 report 2024

Published November 6, 2024

”As we advance to clinical validation, we are intensifying our preparations for the pivotal clinical study on preterm born babies in the U.S., a cornerstone in our forthcoming FDA application and journey toward securing approval for the U.S. market.”

CEO Hanna Sjöström

Intensifying preparations for the first pivotal clinical study on preterm born babies in the U.S. to secure market approval by the FDA

Third quarter, July-September 2024

- Advancing from the technical verification to the clinical validation phase.
- Intensifying preparations for the first pivotal clinical study on preterm born infants in the U.S. for Neola®.
- The clinical protocol for the pivotal study in the U.S. was aligned during a pre-submission meeting with the FDA.
- To streamline preparations for the U.S. pivotal clinical study, a clinical pilot study on preterm born infants is planned in Sweden.
- Expansions in intellectual property protection, highlighted by the patent grants in both the U.S. and Europe, reinforcing the protection of the company's innovation pipeline and safeguarding market leadership.

Summary
Operating income: SEK 0k (0)
Operating result: SEK -2 476k (-2 540)
The period's cash flow: SEK -4 950k (-3 565)
Result per share: -0,04 SEK (-0,05)

Interim report, January-September 2024

- Advancing from the technical verification to the clinical validation phase.
- The Human Factors Validation Study with Neola®, was successfully concluded with neonatal nurses in the U.S., and will lay a foundation for the upcoming market grant application to the FDA.
- Neola® obtained a CB certificate according to high international standards, highlighting its safe design and essential performance, meeting partial regulatory requirements for market approval in the U.S.
- Expansions in intellectual property protection, highlighted by the patent grants in both the U.S. and Europe, reinforcing the protection of the company's innovation pipeline and safeguarding market leadership.

Summary
Operating income: SEK 0k (0)
Operating result: SEK -8 055k (-7 482)
The period's cash flow: SEK 2 583k (-13 476)
Result per share: -0,11 SEK (-0,13)

CEO comments

Hanna Sjöström, CEO

During the third quarter of 2024, we have entered the clinical validation phase and are progressing our preparations for clinical studies, making advancements toward securing market approval in the U.S., for our continuous lung monitoring device, Neola®. With CB certificate and Human Factors Validation study completed during the first half year of 2024, we now advance to the next key milestone for the company, conducting our first pivotal clinical study on preterm born babies in the U.S.

The U.S. study, which will lay the foundation to our upcoming FDA application, is planned to start in 2025. During a pre-submission meeting with the FDA, we aligned on the clinical protocol for the pivotal clinical study and the clinical need of our medical device for continuous lung monitoring of preterm born babies was noted. To streamline preparations for the U.S. pivotal clinical study, we are also preparing a clinical pilot study on preterm born babies at a neonatal intensive care unit in Sweden.

Building on our progress to clinical studies we are continuing to strengthen our competitive position, highlighted by the recent patent grants in both the U.S. and Europe. These expansions in intellectual property protection reinforce the protection of the company's innovation pipeline for continuous lung monitoring and ensure that Neola® remains at the forefront of modern neonatal care, safeguarding our innovations and market leadership.

In summary, we have taken significant steps toward securing market approval in the U.S., as we advance to clinical validation phase, and intensify our preparations for the pivotal clinical study on preterm born babies in the U.S.

We look forward to the dynamic and productive months ahead, remaining steadfast in our commitment to improving care for preterm born infants. Our mission is clear: to not only save more babies but also to give them the best chance to thrive, living healthy lives with fewer severe disabilities.

Significant events

During the quarter

- Neola Medical was granted patent in Europe, Expands protection for medical device Neola®
- Neola Medical published the Q2 Report 2024 – Key milestones meet partial regulatory requirements for FDA approval
- Neola Medical announced preparations for pivotal clinical study on preterm born babies in the USA
- Neola Medical was granted patent in the USA
- Neola Medical presented at Medicon Valley Alliance MedTech Network Meeting
- Neola Medical announced its participation at largest European Neonatal Medicine Congress on October 12-14 in Wurzburg, sponsoring special lecture on the poteintal of GASMAS Technology, 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

After the quarter

- Neola Medical published the Investor Letter Autumn 2024

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

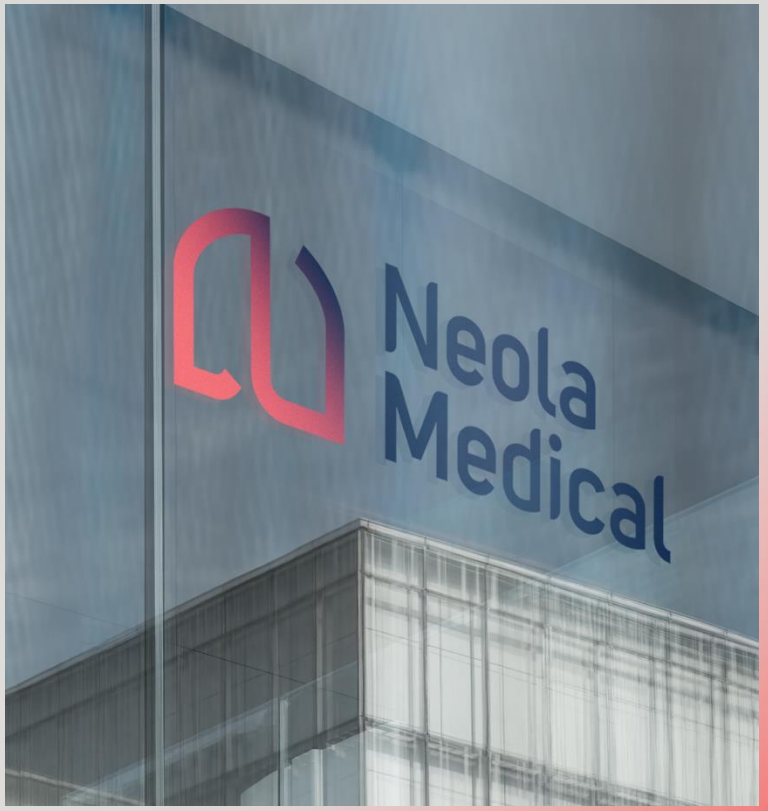
The Company's vision is for preterm born infants to have a better start in life. By providing neonatal intensive care units with the medical device Neola®, which enables continuous monitoring of the lungs of preterm born infants with direct detection of complications, the Company aims to enhance the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

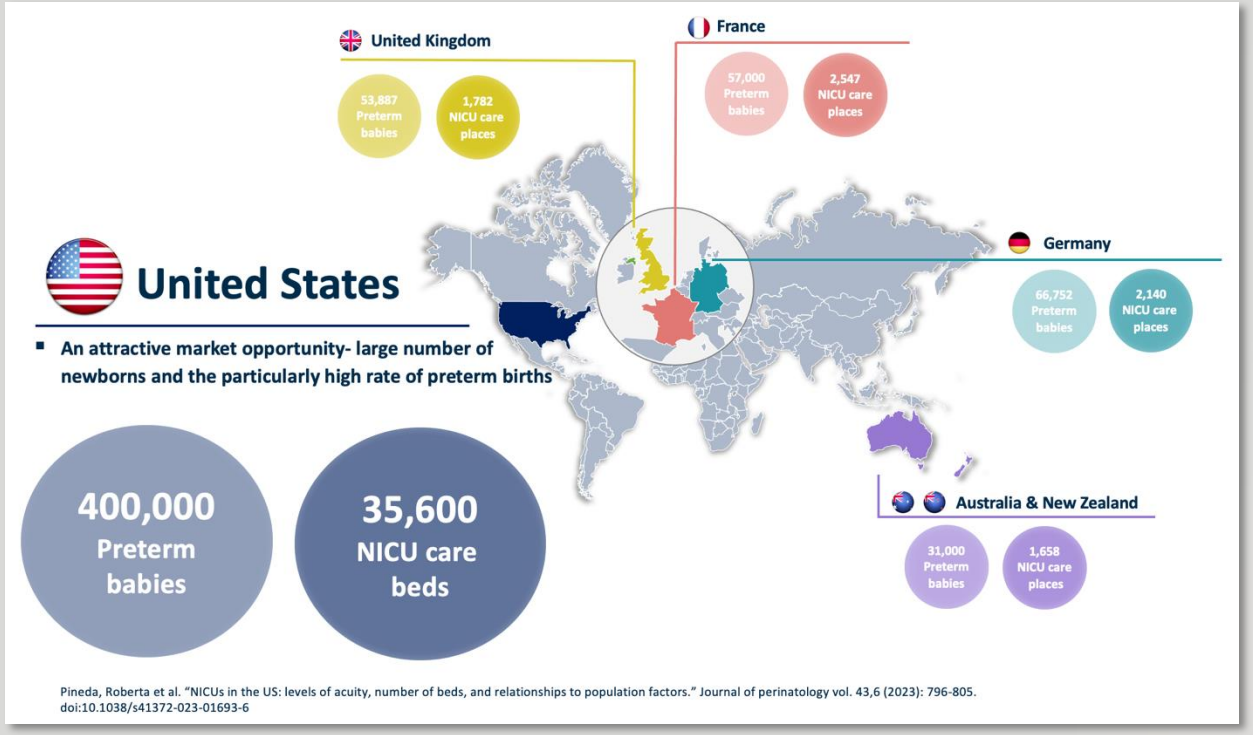
The Company's business model ensures recurring revenue by requiring a Neola® device for a significant proportion of the beds in the neonatal intensive care clinic, with the probes used for monitoring being disposables that are replaced daily on the infant.



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	3 mos	3 mos	9 mos	9 mos	12 mos
Operating revenue (SEK k)	1 742	1 794	7 950	6 729	9 830
EBIT (SEK k)	-2 476	-2 540	-8 055	-7 482	-9 621
Cashflow for the period (SEK k)	-4 950	-3 565	2 583	-13 476	-18 512
Cash and cash equivalents (SEK k)	24 161	26 613	24 161	26 613	21 578
Equity per share before dilution (SEK)	1,02	1,10	1,02	1,10	1,13
Equity ratio (%)	93	89	93	89	92
Total assets (SEK k)	76 587	68 357	76 587	68 357	86 018
Quick ratio (%)	515	504	515	504	700
Average number of shares before dilution	70 150 234	55 686 304	70 150 234	55 686 304	55 765 558
Result per share before dilution (SEK)	-0,04	-0,05	-0,11	-0,13	-0,17
Number of shares at end of period	70 150 234	55 686 304	70 150 234	55 686 304	70 150 234

Financial progress January – September 2024

Revenues and results of operations

For the period January to September, operating revenues amounted to SEK 7.950 thousand (SEK 6.729 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 7.912 thousand (SEK 6.701 thousand).

Operating expenses for the period January to June amounted to SEK 14.805 thousand (SEK 13.021 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 usability 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.

The operating result amounted to SEK -8.055 thousand (SEK -7.482 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 -1,911 thousand (SEK -1,497 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 -7.4388 thousand (SEK -7.055 thousand), and the earnings per share were SEK -0.11 (SEK -0.13) for the period January to September.

Cash flow and investments

The total cash flow for the period January to September amounted to SEK 2.583 thousand (SEK -13.476 thousand). The cash flow from investing activities alone amounted to SEK -9.113 thousand (SEK -8.377 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 24.161 thousand (SEK 26.613 thousand).

Financial position and balance sheet

As of September 30, 2024, the equity ratio was 93% (89%), and own capital amounted to SEK 71.589 thousand (SEK 61.078 thousand). The Company was free from interest-bearing debt as of the balance sheet date. Intangible assets amounted to SEK 50.457 thousand (SEK 39.923 thousand).

Risks and uncertainties

The war in Ukraine

At present, the war has had no direct impact on the Company's operations. The Company is closely monitoring the situation and continuously analyzing potential impacts.

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. Failure to meet these 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 late 2025 and mid of 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 2021. For further information, refer to the Group's Annual report of 2021. Interim reports are prepared in accordance with BFNAR 2007:1.

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 are considered to be insignificant in scope, no consolidated financial statements are prepared.

Financial reports in summary

Profit and loss statement, (SEK k)	2024-07-01 -2024-09-30 3 mos	2023-07-01 -2023-09-30 3 mos	2024-01-01 -2024-09-30 9 mos	2023-01-01 -2023-09-30 9 mos	2023-01-01 2023-12-31 12 mos
Operating income	0	0	0	0	0
Capitalized own work	1 731	1 783	7 912	6 701	9 784
Other operating income	11	11	38	28	45
Operating revenue	**1 742**	**1 794**	**7 950**	**6 729**	**9 830**
Raw materials and consumables	-86	-207	-1 216	-1 089	-1 765
Other external costs	-1 626	-1 823	-6 478	-5 538	-7 986
Personell costs	-2 093	-1 898	-7 034	-6 379	-8 107
Depreciation	-401	-397	-1 200	-1 190	-1 593
Other operating expenses	-12	-9	-77	-14	0
Operating result	**-2 476**	**-2 540**	**-8 055**	**-7 482**	**-9 621**
Financial income and expenses	187	174	617	427	612
Result before tax	**-2 289**	**-2 366**	**-7 438**	**-7 055**	**-9 009**
Tax on result for the period	0	0	0	0	0

Financial reports in summary

Balance sheet, (SEK k)	2024-09-30	2023-09-30	2023-12-31
Assets			
Non-current assets			
Intangible assets	50 457	39 923	42 776
Tangible assets	217	159	137
Financial assets	152	0	0
Sum non-current assets	**50 826**	**40 082**	**42 913**
Current assets			
Short-term receivables	1 600	1 661	21 528
Cash and bank balances	24 161	26 613	21 578
Sum current assets	**25 761**	**28 275**	**43 105**
Sum assets	**76 587**	**68 357**	**86 018**
Equity and liabilities			
Equity			
Equity	71 589	61 078	79 028
Sum equity	**71 589**	**61 078**	**79 028**
Liabilities			
Long-term liabilities	0	1 667	833
Accrued expenses and deferred income	1 934	1 802	1 620
Other current liabilities	3 064	3 810	4 537
Sum liabilities	**4 998**	**7 279**	**6 990**
Sum equity and liabilities	**76 587**	**68 357**	**86 018**

Financial reports in summary

Changes in own capital, (SEK k)	2024-07-01 -2024-09-30 3 mos	2023-07-01 -2023-09-30 3 mos	2024-01-01 -2024-09-30 9 mos	2023-01-01 -2023-09-30 9 mos	2023-01-01 2023-12-31 12 mos
Own capital at beginning of period	73 877	63 300	79 028	67 485	67 485
New share issues and subscribed share capital	0	144	0	0	20 000
Issuance costs	0	0	-69	0	-168
Issued subscription warrants	0	0	68	648	720
Other adjustments and provisions	0	0	0	0	0
Result for the period	-2 289	-2 366	-7 438	-7 055	-9 010
Own capital at end of period	**71 589**	**61 078**	**71 589**	**61 078**	**79 028**

Cash flow, (SEK k)	2024-07-01 -2024-09-30 3 mos	2023-07-01 -2023-09-30 3 mos	2024-01-01 -2024-09-30 9 mos	2023-01-01 -2023-09-30 9 mos	2023-01-01 2023-12-31 12 mos
Cash flow from operaiting activities before changes in working capital	-1 782	-1 994	-6 239	-5 960	-7 183
Changes in working capital	-1 440	684	-2 063	213	641
Cash flow from operating activities	**-3 222**	**-1 310**	**-8 302**	**-5 747**	**-6 542**
Cash flow from investing activities	-1 727	-2 399	-9 113	-8 377	-12 305
Cash flow from financing activities	0	144	19 999	648	336
Cash flow for the period	**-4 950**	**-3 565**	**2 583**	**-13 476**	**-18 512**
Cash and cash equivalents at the beginning of the period	29 111	30 178	21 578	40 089	40 089
Cash and cash equivalents at the end of the period	**24 161**	**26 613**	**24 161**	**26 613**	**21 578**

About the share

Share capital, shareholders and the share 2024-09-30

As of September 30th 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 2024-09-30 (Top 10)	Number of shares	Percentage of capital	Percentage of votes
ANMIRO AB	17 647 246	25,2%	25,2%
Pär Josefsson*	16 537 411	23,6%	23,6%
Brodvik AB	7 626 566	10,9%	10,9%
LMK-bolagen & Stiftelse	7 350 360	10,5%	10,5%
Bengt Nevsten	2 362 914	3,4%	3,4%
Avanza Pension	968 513	1,4%	1,4%
Nordnet Pensionsförsäkring	589 899	0,8%	0,8%
Magnus Kenneby	625 000	0,9%	0,9%
Urban Ottosson	584 240	0,8%	0,8%
Swedbank Försäkring	549 500	0,8%	0,8%
Övriga aktieägare	15 308 585	21,8%	21,8%
Totalt	70 150 234	100%	100%

* SEB Life International have 4,4% voting rights through Pär Josefsson's shares.

Financial calendar and contact

12 Feb 2025	9 April 2025	21 May 2025	22 Aug 2025
Year End Financial Statement 2024	Annual report 2024	Q1 report 2025 and Annual General Assembly in Lund	Q2 report 2025

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

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

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David Folkesson, CFO
E-mail: david.folkesson@neolamedical.com

Lund November 6 2024
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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