Neola Medical

Q2 report 2025

Published August 25, 2025

"Advancing preparations for our pivotal U.S. clinical study with the signing of an agreement at a key site, a milestone that strengthens our regulatory pathway toward FDA market authorization."

CEO Hanna Sjöström

First U.S. Clinical Study Site Agreement Signed – Key Step in Regulatory Path to Market Authorization

Second quarter, April-June 2025

- The first patient was enrolled in the first clinical pilot study with Neola® on preterm born babies in Sweden.
- The company signed an agreement with Children's Regional Hospital at Cooper and received approval by the hospital's Institutional Review Board (IRB). This enables the initiation of the pivotal clinical study on preterm born babies in the U.S. under the leadership of Dr. Vineet Bhandari as principal investigator. The pivotal study is planned to start after the clinical pilot study results have been evaluated.
- A European patent was granted for an innovation related to continuous lung monitoring, the second validation within a new patent family, following the Chinese patent granted during the first quarter.

Summary

Operating income: SEK 0k (0)
Operating result: SEK –3 028k (-3 011)
The period's cash flow: SEK –6 152k (-6 034)
Result per share: -0,04 SEK (-0,04)

Half year report, January-June 2025

- The company's first clinical pilot study on preterm born babies was initiated at Södra Älvsborgs Sjukhus in Borås, Sweden, followed by a regulatory approval from the Swedish Medical Products Agency (Läkemedelsverket) and the Swedish Ethical Review Authority (Etikprövningsmyndigheten).
- A directed share issue was completed of approximately SEK 20 million before rights issue costs, welcoming two new institutional investors complementing a strong shareholder base.
- The IP portfolio was further strengthened with a patent granted both in China and Europe, marking a new patent family that reinforce the protection of our core medical technology for non-invasive lung monitoring and detection of pulmonary complications.

Summary

Operating income: SEK 0k (0)
Operating result: SEK -5 740k (-5 579)
The period's cash flow: SEK 6 958k (7 533)
Result per share: -0,07 SEK (-0,08)

CEO comments

Hanna Sjöström, CEO

During the first half of 2025, Neola Medical reached a significant clinical milestone with the initiation of our first clinical pilot study on preterm born babies in Sweden. In May, the first baby was successfully enrolled, marking the first real-world use of Neola® to continuously monitor the lungs of a preterm born baby in neonatal intensive care. This milestone represented the culmination of years of dedicated development and marked the beginning of an important phase in validating the safety and performance of Neola® in its target patient group. This is particularly important as preterm born babies' lung physiology and medical needs differ substantially from those of full-term newborns.

The insights gained from the clinical pilot study in Sweden, estimated to conclude during fall, may offer valuable input as we continue to refine Neola®. In parallel, we are preparing for the next step in our clinical development, the pivotal clinical study in the U.S., which will form part of the clinical evidence base for our planned FDA application for market authorization.

As part of these preparations, we have signed an agreement with the neonatal intensive care unit (NICU) at Children's Regional Hospital at Cooper in Camden, New Jersey. Institutional Review Board (IRB) approval was received, a key regulatory milestone, enabling the initiation of the pivotal clinical study on preterm born babies. We are honored to collaborate with Dr. Vineet Bhandari, serving as principal investigator of the study and recognized globally as one of the world's most respected key opinion leaders in neonatology. His clinical leadership at Cooper's NICU brings significant credibility and momentum to this strategically important study site, which will play a central role in our U.S. regulatory pathway.

This quarter also brought important recognition of our innovation, with a new European patent strengthening our IP position in a key market and our nomination for Sweden's global Pioneer Prize bringing international visibility and new opportunities for collaboration and growth.

As we move forward with the clinical pilot study in Sweden and continued progress in preparing for the pivotal clinical study in the U.S., we stay committed to our mission of giving preterm born babies a safer, stronger start in life.

Hanna Sjöström

Significant events

During the quarter

- Neola Medical was named finalist for Sweden's new global innovation award "Pioneer Prize" and participated as part of the Swedish business delegation at World Expo 2025 in Osaka, Japan.
- Neola Medical was granted a European patent for continuous lung monitoring, the second validation within the new patent family, following the Chinese patent granted during the first quarter.
- The first patient was enrolled in clinical pilot study with Neola® on preterm born babies.
- Neola Medical signed an agreement with a prominent neonatal intensive care unit (NICU) in the U.S., located at Children's Regional Hospital at Cooper in Camden, New Jersey, USA, to enable the initiation of the pivotal clinical study on preterm born babies in the U.S.

After the quarter

- No significant events to report.

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 babies.

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 commercialize 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

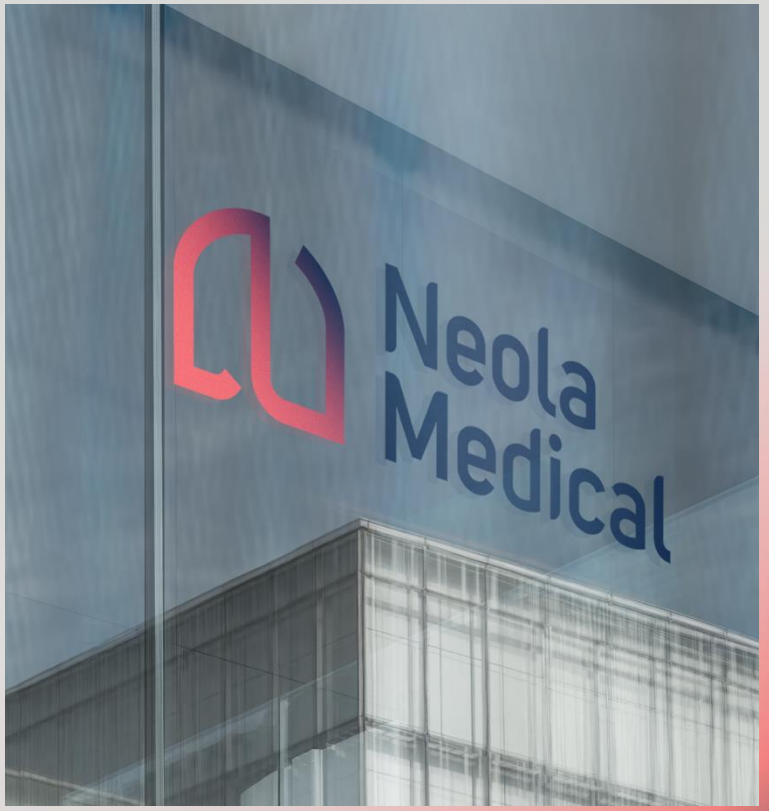
The Company's vision is for preterm born babies to have a better start in life. By providing neonatal intensive care units with the medical device Neola®, which enables continuous monitoring of the lungs of preterm born babies with direct detection of complications, the Company aims to enhance the care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



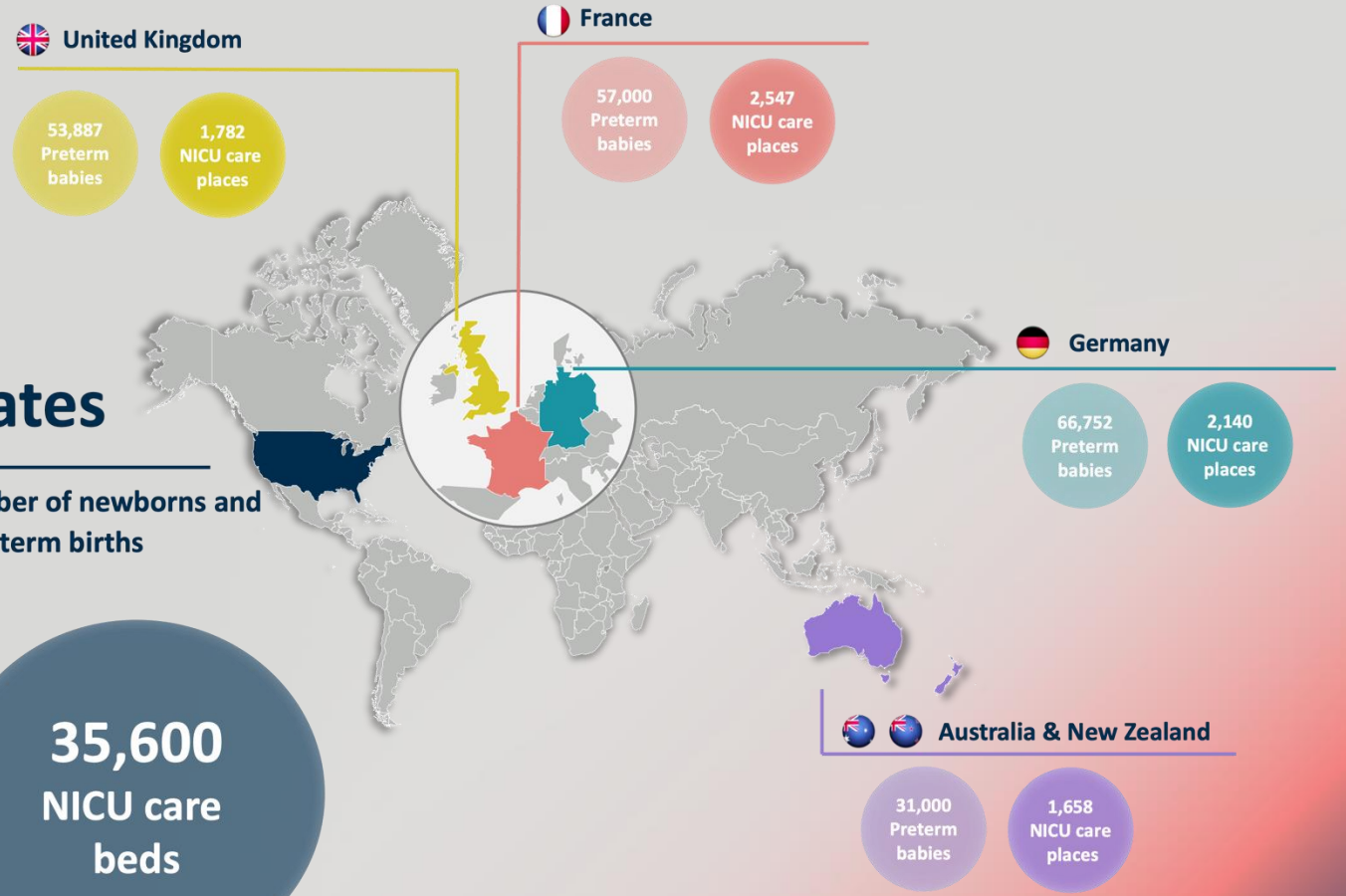
Neola®

Designed to enable continuous lung monitoring and instant detection of potentially life-threatening pulmonary complications for proactive care, reduced morbidity and improved quality of life.

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.



United States

- **Focus market due to large number of newborns and the particularly high rate of preterm births**

400,000 Preterm babies

35,600 NICU care beds

- Pineda, Roberta et al. "NICUs in the US: levels of acuity, number of beds, and relationships to population factors." Journal of perinatology vol. 43,6 (2023): 796-805. doi:10.1038/s41372-023-01693-6

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 babies 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 babies.

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	2025-04-01 -2025-06-30 3 mos	2024-04-01 -2024-06-30 3 mos	2025-01-01 -2025-06-30 6 mos	2024-01-01 -2024-06-30 6 mos	2024-01-01 2024-12-31 12 mos
Operating revenue (SEK k)	2 219	2 760	4 381	6 208	10 392
EBIT (SEK k)	-3 028	-3 011	-5 740	-5 579	-10 797
Cashflow for the period (SEK k)	-6 152	-6 034	6 958	7 533	-2 022
Cash and cash equivalents (SEK k)	26 513	29 111	26 513	29 111	19 555
Equity per share before dilution (SEK)	1,04	1,05	1,04	1,05	0,98
Equity ratio (%)	95	93	95	93	94
Total assets (SEK k)	85 298	79 799	85 298	79 799	73 612
Quick ratio (%)	681	547	681	547	453
Average amount of shares before dilution (no.)*	77 950 234	70 150 234	75 350 234	70 150 234	70 150 234
Result per share before dilution (SEK)	-0,04	-0,04	-0,07	-0,08	-0,14
Amount of shares by the end of the period (no.)	77 950 234	70 150 234	77 950 234	70 150 234	70 150 234

* 2 830 000 warrants in ongoing programs may give a total dilution of 3.5%

Financial progress January – June 2025

Revenues and results of operations

For the period January to June, operating revenues amounted to SEK 4.381 thousand (SEK 6.208 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 4.914 thousand (SEK 6.181 thousand).

Operating expenses for the period January to June amounted to SEK 9.431 thousand (SEK 10.988 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 operating result amounted to SEK –5.740 thousand (SEK –5.579 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 further clinical studies, and other activities aimed at the certification and market approval of Neola®.
The Company's burn rate averaged SEK –1.841 thousand (SEK –2.078 thousand) per month during the period and is expected to increase with the acceleration of clinical validation over the coming years.

Preparations for a commercial structure are also expected to impact the cost base going forward. The result after tax amounted to SEK –5.602 thousand (SEK – 5.150 thousand), and the earnings per share were SEK -0,07 (SEK -0,08) for the period January to June.

Cash flow and investments

The total cash flow for the period January to June amounted to SEK 6.958 thousand (SEK 7.533 thousand). The cash flow from investing activities alone amounted to SEK –5.300 thousand (SEK –7.386 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 17.861 thousand after deducting issuance costs. Cash and cash equivalents at the end of the period amounted to SEK 26.513 thousand (SEK 29.111 thousand).

Financial position and balance sheet

As of June 30, 2025, the equity ratio was 95% (93%), and own capital amounted to SEK 81.222 thousand (SEK 73.877 thousand). The Company was free from interest-bearing debt as of the balance sheet date. Intangible assets amounted to SEK 56.947 thousand (SEK 48.797 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, refinement or development 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 2024. For further information, refer to the Group's Annual report of 2024.

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)	2025-04-01 -2025-06-30 3 mos	2024-04-01 -2024-06-30 3 mos	2025-01-01 -2025-06-30 6 mos	2024-01-01 -2024-06-30 6 mos	2024-01-01 2024-12-31 12 mos
Operating income	0	0	0	0	0
Capitalized own work	2 199	2 744	4 346	6 181	10 065
Other operating income	20	16	35	27	327
Operating revenue	**2 219**	**2 760**	**4 381**	**6 208**	**10 392**
Raw materials and consumables	-56	-368	-154	-1 130	-1 369
Other external costs	-1 975	-2 289	-3 934	-4 852	-8 883
Personnel costs	-2 870	-2 655	-5 343	-4 941	-9 348
Depreciation	-346	-399	-690	-799	-1 527
Other operating expenses	0	-59	0	-65	-62
Operating result	**-3 028**	**-3 011**	**-5 740**	**-5 579**	**-10 797**
Financial income and expenses	67	183	138	429	733
Result before tax	**-2 961**	**-2 829**	**-5 602**	**-5 150**	**-10 064**
Tax on result for the period	0	0	0	0	0
Result for the period	**-2 961**	**-2 829**	**-5 602**	**-5 150**	**-10 064**

Financial reports in summary

Balance sheet, (SEK k)			
Assets			
Non-current assets	**2025-06-30**	**2024-06-30**	**2024-12-31**
Intangible assets	56 947	48 797	52 368
Tangible assets	241	94	202
Financial assets	336	53	0
Sum non-current assets	**57 524**	**48 944**	**52 570**
Current assets			
Inventory	0	0	83
Short-term receivables	1 261	1 744	1 404
Cash and bank balances	26 513	29 111	19 555
Sum current assets	**27 774**	**30 855**	**21 042**
Sum assets	**85 298**	**79 799**	**73 612**

Balance sheet, (SEK k)			
Equity and liabilities			
Equity	**2025-06-30**	**2024-06-30**	**2024-12-31**
Equity	81 222	73 877	68 963
Sum equity	**81 222**	**73 877**	**68 963**
Liabilities			
Long-term liabilities	0	278	0
Accrued expenses and deferred income	2 081	1 909	1 997
Other current liabilities	1 995	3 735	2 652
Sum liabilities	**4 076**	**5 922**	**4 649**
Sum equity and liabilities	**85 298**	**79 799**	**73 612**

Financial reports in summary

Changes in own capital, (SEK k)	2025-04-01 -2025-06-30 3 mos	2024-04-01 -2024-06-30 3 mos	2025-01-01 -2025-06-30 6 mos	2024-01-01 -2024-06-30 6 mos	2024-01-01 2024-12-31 12 mos
Own capital at beginning of period	84 207	76 637	68 963	79 028	79 028
New share issues and subscribed share capital	0	0	19 500	0	0
Issuance costs	-68	0	-1 684	-69	-69
Issued subscription warrants	44	68	44	68	68
Other adjustments and provisions	0	0	0	0	0
Result for the period	-2 961	-2 829	-5 602	-5 150	-10 064
Own capital at end of period	**81 222**	**73 877**	**81 222**	**73 877**	**68 963**

Cash flow, (SEK k)	2025-04-01 -2025-06-30 3 mos	2024-04-01 -2024-06-30 3 mos	2025-01-01 -2025-06-30 6 mos	2024-01-01 -2024-06-30 6 mos	2024-04-01 2024-12-31 12 mos
Cash flow from operating activities before changes in working capital	-2 959	-2 461	-5 256	-4 457	-8 538
Changes in working capital	-539	-145	-347	-623	-2 300
Cash flow from operating activities	**-3 498**	**-2 606**	**-5 603**	**-5 080**	**-10 837**
Cash flow from investing activities	-2 629	-3 497	-5 300	-7 386	-11 184
Cash flow from financing activities	-25	68	17 861	19 999	19 999
Cash flow for the period	**-6 152**	**-6 034**	**6 958**	**7 533**	**-2 022**
Cash and cash equivalents at the beginning of the period	32 665	35 145	19 555	21 578	21 578
Cash and cash equivalents at the end of the period	**26 513**	**29 111**	**26 513**	**29 111**	**19 555**

About the share

Share capital, shareholders and the share 2025-06-30

As of June 30th, 2025, Neola Medical's share capital was 5 567 896,30 SEK with a total of 77 950 234 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 had 1 567 owners by the end of the quarter.

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

Shareholders 2025-06-30 (Top 10)	Amount of shares	Percentage of capital	Percentage of votes
ANMIRO AB	18 447 246	23,7%	23,7%
Pär Josefsson	16 737 411	21,5%	17,5%
Brodvik AB	8 576 566	11,0%	11,0%
LMK-bolagen & Stiftelse	8 300 360	10,6%	10,6%
Cicero Fonder (Aktiespararna småbolag Edge)	3 700 000	4,7%	4,7%
Bengt Nevsten	2 362 914	3,0%	3,0%
Adrigo Small & Midcap	1 200 000	1,5%	1,5%
Avanza Pension	950 943	1,2%	1,2%
Hans Ove Sven Åhlén	632 866	0,8%	0,8%
Magnus Kenneby	627 049	0,8%	0,8%
Other shareholders	16 414 879	21,1%	25,0%
Total	**77 950 234**	**100,0%**	**100,0%**

* SEB Life International have 3,9% voting rights through Pär Josefssons shares

Financial calendar and contact

5 Nov 2025	12 Feb 2026	14 Apr 2026	19 May 2026
Q3 report 2025	Q4 report 2025	Annual report 2025	Q1 report 2026

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

Lund August 25, 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 core technology
5. Highly experienced team

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