Neola Medical

Q3 report 2026

Published November 18, 2026

"FDA Breakthrough Device Designation marks a major milestone for Neola Medical, strengthening our U.S. regulatory pathway and positioning us to advance the next critical steps toward market authorization."

CEO Hanna Sjöström

FDA Breakthrough Device Designation strengthens U.S. regulatory pathway

Third quarter, July–September 2026

- Neola Medical received FDA Breakthrough Device Designation for Neola®, a major regulatory milestone enabling prioritized interactions with the FDA.
- Neola Medical was granted a U.S. design patent protecting the graphical user interface of Neola®, further strengthening its intellectual property portfolio.

Summary
Operating income: SEK 0k (0)
Operating result: SEK –3 332k (-2 833)
The period's cash flow: SEK 17 051k (-4 390)
Result per share: -0,03 SEK (-0,04)

January–September 2026

- Completed enrollment in the Swedish clinical pilot study with Neola® in preterm born babies.
- Reported positive safety results from the clinical pilot study, supporting continued development.
- Granted two U.S. patents, strengthening protection of Neola® technology and graphical user interface.
- Completed a rights issue in June providing approximately SEK 32.5 million before issue costs, registered in Q3.
- Received FDA Breakthrough Device Designation for Neola®, strengthening the U.S. regulatory pathway.

Summary
Operating income: SEK 0k (0)
Operating result: SEK -10 654k (-8 573)
The period's cash flow: SEK 10 883k (2 568)
Result per share: -0,12 SEK (-0,11)

CEO comments



Hanna Sjöström, CEO

FDA Breakthrough Device Designation marks a defining milestone

The third quarter marked a significant milestone for Neola Medical. In September, the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation to Neola®, recognizing its potential to address an important unmet need in neonatal intensive care. The designation is a major step in our U.S. regulatory journey and reinforces our strategy to focus on continuous, non-invasive monitoring to support timely detection of pneumothorax (lung collapse) in preterm born babies.

A stronger regulatory pathway

Breakthrough Device Designation provides opportunities for more frequent, prioritized interaction with the FDA as we develop the evidence required for market authorization. While it does not constitute market approval, it creates a valuable framework for early alignment on clinical study design and regulatory expectations. Following the quarter, Neola® was enrolled in the FDA's Total Product Life Cycle Advisory Program (TAP) Pilot, which provides earlier and more frequent strategic engagement with the agency.

Focused development and clinical preparations

During the quarter, we advanced our preclinical validation program with a sharpened focus on pneumothorax detection, building on earlier encouraging findings in preclinical models that Neola® can detect changes associated with pneumothorax in several types of animals. Ongoing work is focused on strengthening the robustness of the detection approach and generating preclinical data to inform the next development steps.

In parallel, we continued planning for the U.S. clinical program, engaging neonatologists, regulatory advisors and contract research organizations. Our aim is to establish an evidence-generation strategy that meets FDA requirements while remaining proportionate to the clinical need and supporting future adoption by neonatal intensive care units.

Investing in critical milestones

Our increased cash burn reflects a deliberate acceleration of targeted preclinical, regulatory and clinical planning activities, supported by specialist external expertise. These investments have been directed toward achieving key milestones and reducing uncertainty in the development pathway and the commercial opportunities. We remain disciplined in allocating capital to activities that can advance regulatory alignment, strengthen clinical evidence and support long-term value creation.

Priorities ahead

Our next priorities are to further validate pneumothorax detection, align with the FDA on an efficient clinical and regulatory strategy, and define the scope, timing and financing of the next development phase. The Breakthrough Device Designation strengthens Neola Medical's regulatory position and marks an important step toward the U.S. market. With a clearly defined clinical application and enhanced opportunities for FDA engagement, we are well positioned to advance our clinical and regulatory development. Our priority remains disciplined execution, capital efficiency and long-term value creation through progress toward market authorization and clinical adoption.

Hanna Sjöström

The Company

Neola Medical, founded in 2016, is based on years of research at Lund University. The Company addresses the global market for neonatal intensive care with an innovative medical device, Neola®, the Neonatal Lung Analyzer, built on patented technology for near-infrared light measurements in the lungs.

Neola® is being developed for continuous, non-invasive lung monitoring in preterm born babies to aid in the early detection of pneumothorax (lung collapse) and support timely clinical intervention.

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.

Vision

The Company's vision is to improve the care of preterm born babies by making serious lung complications such as pneumothorax easier to detect early and for healthcare providers to act upon this information.

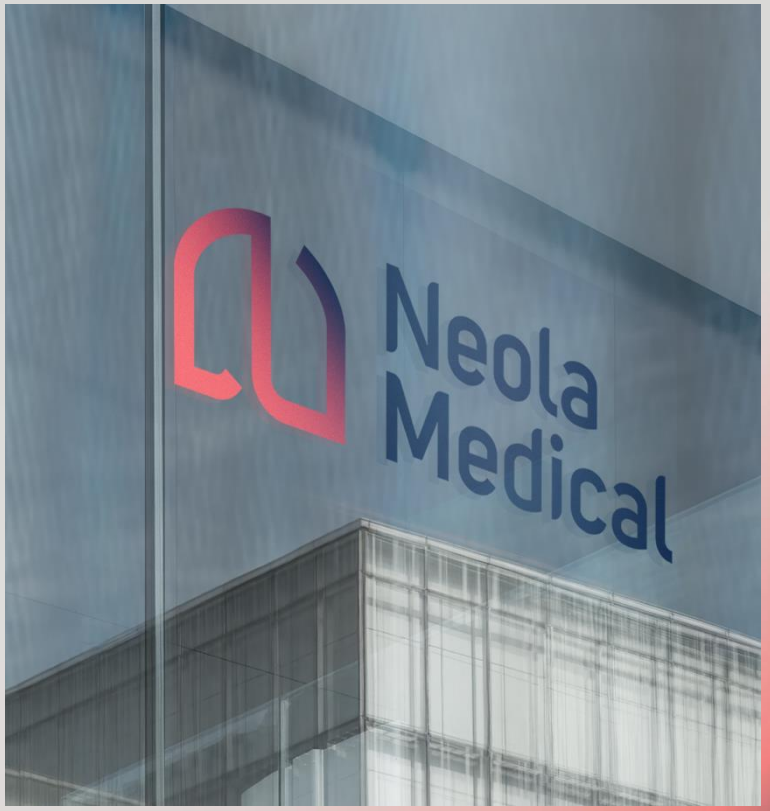
Goal

The Company's objective is to establish optical lung monitoring for the timely detection of pneumothorax as a new standard of care in neonatal intensive care units and to be present in leading hospitals globally. The Company's financial goal is to achieve a positive operating profit three years after commercial launch.

Business concept and model

Neola Medical's business concept is to commercialize Neola® in neonatal intensive care units globally, with a primary focus on the U.S. market.

The Company's business model is based on recurring revenue from disposable monitoring probes used with each Neola® device, generating consumable sales alongside the device.



Neola®

Designed to provide continuous non-invasive lung monitoring to aid in the early detection of pneumothorax

Lung collapse is a potentially life-threatening complication, and early detection can support timely intervention.



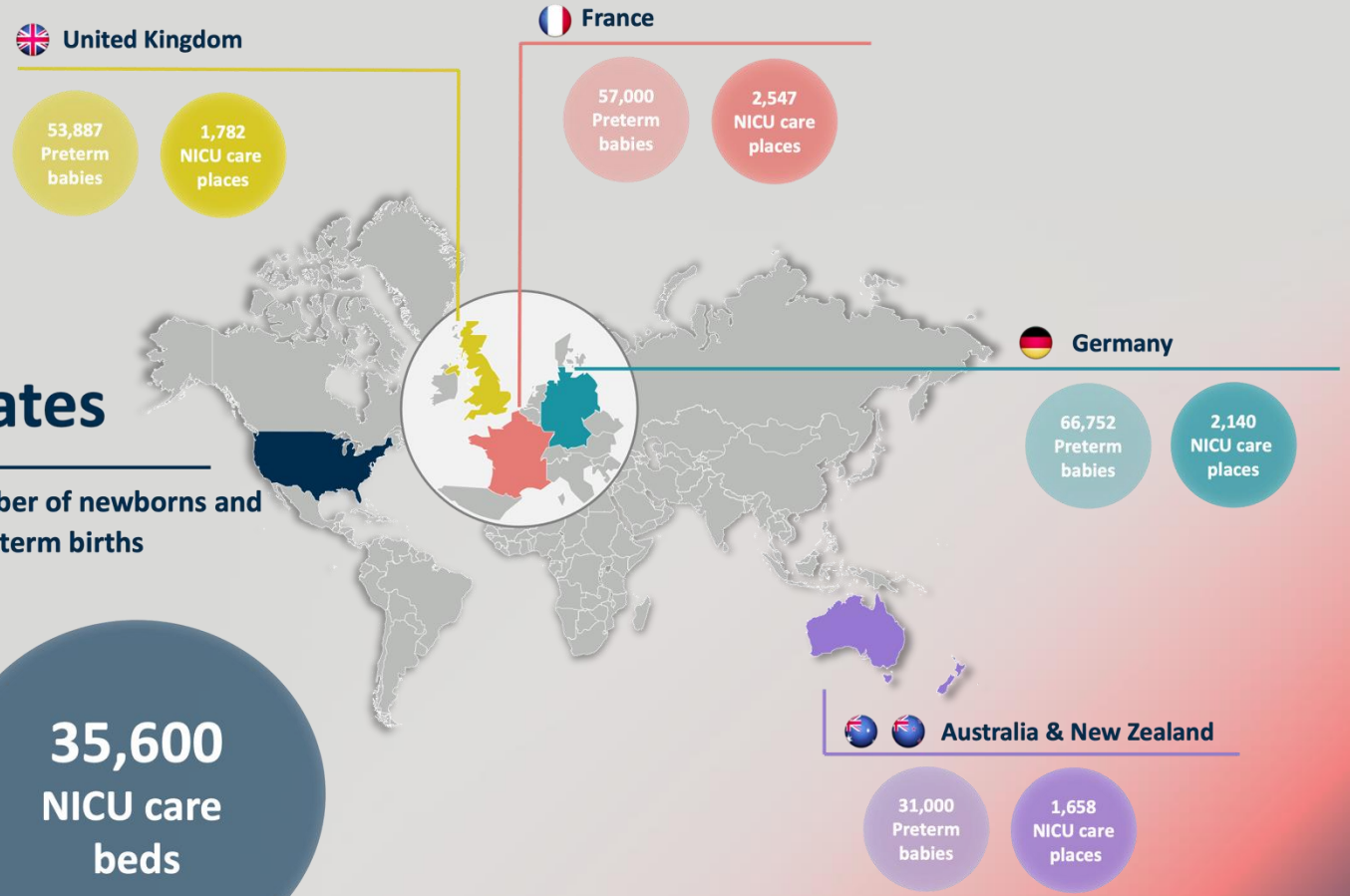


Neola® is an investigational device and is not available for sale in the United States.

Market

A specialized market with significant potential

Neola® aims to be introduced to the global market for respiratory equipment focused on neonatal intensive care, which was valued above USD 1.5 billion in 2025. The market is projected to expand with a compound annual growth rate (CAGR) of 4.9% from 2025 to 2032.



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, more than 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 often detected only after severe physical symptoms have appeared. Neola® addresses a clear and significant clinical need for a continuous monitoring method to detect pneumothorax (lung collapse). By enabling earlier detection, Neola® is designed to support timely intervention in the care of preterm born babies.



Addressing an unmet need in neonatal intensive care

Neola® aims to offer:



1. Potential for earlier detection of lung collapse to support timely intervention.
2. Potential to support clinical decision-making in neonatal intensive care.
3. Potential benefits for NICU workflows and resource utilization, subject to clinical validation.

Financial information



Financial summary

Neola Medical, summary	2026-07-01 -2026-09-30 3 mos	2025-07-01 -2025-09-30 3 mos	2026-01-01 -2026-09-30 9 mos	2025-01-01 -2025-09-30 9 mos	2025-01-01 2025-12-31 12 mos
Operating revenue (SEK k)	3 593	1 807	9 786	6 188	8 328
EBIT (SEK k)	-3 332	-2 833	-10 654	-8 573	-11 093
Cashflow for the period (SEK k)	17 051	-4 390	10 883	2 568	-3 432
Cash and cash equivalents (SEK k)	27 006	22 123	27 006	22 123	16 123
Equity per share before dilution (SEK)	0,85	1,01	0,85	1,01	0,97
Equity ratio (%)	95	95	95	95	96
Total assets (SEK k)	98 839	82 614	98 839	82 614	78 802
Quick ratio (%)	612	561	612	561	575
Average amount of shares before dilution (no.)*	110 476 933	77 950 234	88 792 467	76 216 901	76 650 234
Result per share before dilution (SEK)	-0,03	-0,04	-0,12	-0,11	-0,13
Amount of shares by the end of the period (no.)	110 476 933	77 950 234	110 476 933	77 950 234	77 950 234

* 14 270 000 warrants in ongoing programs may give a total dilution of 11,4%

Financial progress January – September 2026

Revenues and results of operations

For the period January to September operating revenues amounted to SEK 9.786 thousand (SEK 6.188 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 10.274 thousand (SEK 6.143 thousand).

Operating expenses for the period January to September amounted to SEK 19.414 thousand (SEK 13.723 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 –10.654 thousand (SEK –8.573 thousand). The increased costs reflect intensified preclinical development, regulatory activities and specialized external expertise supporting the achievement of key development milestones. Neola Medical continues its preparations for further studies and activities aimed at regulatory approval and future market introduction of Neola®.

The Company's burn rate averaged SEK –2.020 thousand (SEK –1.699 thousand) per month during the period, reflecting increased investments in prioritized development activities. The Company continues to focus on disciplined resource allocation and capital efficiency as it advances toward its next milestones.

Cash flow and investments

The total cash flow for the period January to September amounted to SEK 10.883 thousand (SEK 2.568 thousand). The cash flow from investing activities alone amounted to SEK –10.285 thousand (SEK –7.117 thousand) and consisted of investments in intangible assets such as capitalized development work, concessions, patents, and similar rights. Cash and cash equivalents at the end of the period amounted to SEK 27.006 thousand (SEK 22.123 thousand).

Financial position and market value

As of September 30, 2026, the equity ratio was 95% (95%), and own capital amounted to SEK 94.258 thousand (SEK 78.462 thousand). The Company was free from interest-bearing debt as of the balance sheet date. Intangible assets amounted to SEK 70.505 thousand (SEK 58.781 thousand).

At the end of the reporting period, the company’s market capitalization was below its reported equity. An evaluation of the assets' recoverable amount, calculated based on value in use in accordance with established business plans, confirms that the recoverable amount continues to exceed the carrying amount and that no impairment is required. Nevertheless, both operational earnings performance and market valuation are monitored continuously.

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, regulatory approvals and market adoption

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®. 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.

Successful commercialization of Neola® will depend on clinical adoption and healthcare providers’ willingness to pay for the technology. There is a risk that the perceived clinical and health economic value may not be sufficient to support broad market adoption at commercially viable pricing levels.

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 2025. For further information, refer to the Group's Annual report of 2025.

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)	2026-07-01 -2026-09-30 3 mos	2025-07-01 -2025-09-30 3 mos	2026-01-01 -2026-09-30 9 mos	2025-01-01 -2025-09-30 9 mos	2025-01-01 2025-12-31 12 mos
Operating income	0	0	0	0	0
Capitalized own work	3 593	1 797	9 786	6 143	8 283
Other operating income	0	10	0	45	45
Operating revenue	**3 593**	**1 807**	**9 786**	**6 188**	**8 328**
Raw materials and consumables	-177	-92	-229	-246	-274
Other external costs	-4 085	-1 945	-10 161	-5 879	-7 707
Personnel costs	-2 345	-2 255	-9 024	-7 598	-10 055
Depreciation	-318	-348	-1 026	-1 038	-1 385
Other operating expenses	0	0	0	0	0
Operating result	**-3 332**	**-2 833**	**-10 654**	**-8 573**	**-11 093**
Financial income and expenses	1	72	44	210	71
Result before tax	**-3 331**	**-2 761**	**-10 610**	**-8 363**	**-11 022**
Tax on result for the period	0	0	0	0	0
Result for the period	**-3 331**	**-2 761**	**-10 610**	**-8 363**	**-11 022**

Financial reports in summary

Balance sheet, (SEK k)

Assets

Non-current assets	**2026-09-30**	**2025-09-30**	**2025-12-31**
Intangible assets	70 505	58 781	61 216
Tangible assets	174	228	215
Financial assets	145	330	134
Sum non-current assets	**70 824**	**59 339**	**61 565**
Current assets			
Inventory	0	0	0
Short-term receivables	1 009	1 152	1 114
Cash and bank balances	27 006	22 123	16 123
Sum current assets	**28 015**	**23 275**	**17 237**
Sum assets	**98 839**	**82 614**	**78 802**

Balance sheet, (SEK k)

Equity and liabilities

Equity	**2026-09-30**	**2025-09-30**	**2025-12-31**
Equity	94 258	78 462	75 803
Sum equity	**94 258**	**78 462**	**75 803**
Liabilities			
Long-term liabilities	0	0	0
Accrued expenses and deferred income	2 544	1 479	1 556
Other current liabilities	2 037	2 673	1 443
Sum liabilities	**4 581**	**4 152**	**2 999**
Sum equity and liabilities	**98 839**	**82 614**	**78 802**

Financial reports in summary

Changes in own capital, (SEK k)	2026-07-01 -2026-09-30 3 mos	2025-07-01 -2025-09-30 3 mos	2026-01-01 -2026-09-30 9 mos	2025-01-01 -2025-09-30 9 mos	2025-01-01 2025-12-31 12 mos
Own capital at beginning of period	97 589	81 222	75 803	68 963	68 963
New share issues and subscribed share capital	0	0	32 526	19 500	19 500
Issuance costs	0	0	-3 461	-1 683	-1 683
Issued subscription warrants	0	0	0	44	44
Other adjustments and provisions	0	0	0	0	0
Result for the period	-3 331	-2 761	-10 610	-8 363	-11 022
Own capital at end of period	**94 258**	**78 462**	**94 258**	**78 462**	**75 803**

Cash flow, (SEK k)	2026-07-01 -2026-09-30 3 mos	2025-07-01 -2025-09-30 3 mos	2026-01-01 -2026-09-30 9 mos	2025-01-01 -2025-09-30 9 mos	2025-01-01 2025-12-31 12 mos
Cash flow from operating activities before changes in working capital	-6 387	-2 413	-9 584	-8 015	-10 675
Changes in working capital	1 661	186	1 687	-162	-1 277
Cash flow from operating activities	**-4 726**	**-2 227**	**-7 897**	**-8 177**	**-11 952**
Cash flow from investing activities	-7 288	-2 163	-10 285	-7 117	-9 342
Cash flow from financing activities	29 065	0	29 065	17 862	17 862
Cash flow for the period	**17 051**	**-4 390**	**10 883**	**2 568**	**-3 432**
Cash and cash equivalents at the beginning of the period	9 955	26 513	16 123	19 555	19 555
Cash and cash equivalents at the end of the period	**27 006**	**22 123**	**27 006**	**22 123**	**16 123**

About the share

Share capital, shareholders and the share 2026-09-30

As of September 30th, 2026, Neola Medical's share capital amounted to 7 891 241,31 SEK with a total of 110 476 933 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 1 508 shareholders at the end of the quarter. The updated shareholder structure following the latest rights issue is available on the company's website, neolamedical.com.

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

Shareholders 2026-09-30 (Top 10)	Amount of shares	Percentage of capital	Percentage of votes
ANMIRO AB	25 447 248	23,03%	23,03%
Pär Josefsson	17 237 411	15,60%	12,38%
Brodvik AB	13 722 505	12,42%	12,42%
LMK-bolagen & Stiftelse	13 280 576	12,02%	12,02%
Cicero Fonder (Aktiespararna småbolag Edge)	5 920 000	5,36%	5,36%
Bengt Nevsten	2 362 914	2,14%	2,14%
Nordnet Pensionsförsäkring	1 943 712	1,76%	1,76%
Avanza Pension	1 806 800	1,60%	1,60%
Olle Olsson	1 766 693	1,64%	1,64%
Urban Ottosson	933 993	0,85%	0,85%
Other shareholders	26 055 081	23,58%	26,81%
Total	**110 476 933**	**100,0%**	**100,0%**

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

Financial calendar and contact

16 Feb 2027	19 May 2027	27 May 2027
Q4 report 2026	Q1 report 2027	Annual General Meeting in Lund

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

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Lund November 18, 2026
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. Unmet clinical need
2. Innovative technology
3. Strong market potential
4. Scalable business model
5. Proven team and network



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