Neola Medical

Q2 report 2024

Publiched August 15 2024

”In the second quarter we are reaching several key milestones meeting partial regulatory requirements for FDA approval. Our successful Human Factors Validation Study in the USA coupled with obtaining a CB certificate for Neola®, highlights its safe design and essential performance.”

CEO Hanna Sjöström

Key achievements meets partial regulatory requirements for FDA approval

Second quarter, April-June 2024

Neola Medical reached several critical milestones aligned with its business strategy, aimed at market approval by the FDA. The Human Factors Validation Study with Neola®, was successfully concluded with neonatal nurses in the USA, and will lay a foundation for the upcoming market grant application to FDA. Additionally, Neola® obtained a CB certificate according to high international standards, meeting partial regulatory requirements for market approval in the USA. Increased interest and ownership positions in the company from existing shareholders.

Summary

Operating income: SEK 0k (0)
Operating result: SEK -3 011k (-2 586)
The period's cash flow: SEK -6 034k (-4 508)
Result per share: -0,04 SEK (-0,05)

Half year report, January-June 2024

- Intensified market preparations in the USA, meeting investors and industry partners at J.P. Morgan Healthcare Conference, regulatory experts at Stanford and visiting Stanford Children's Hospital in Palo Alto
- Honored winning the silver medal at the prestigious international competition, Stanford PDC Accelerator Pitch Competition 2024
- Advancing to the clinical validation phase and intensify planning for the clinical study in the USA on preterm born infants after concluded technical verification phase, by obtaining CB certificate, and completed Human Factors Validation Study

Summary

Operating income: SEK 0k (0)
Operating result: SEK -5 579k (-4 941)
The period's cash flow: SEK 7 533k (-9 911)
Result per share: -0,08 SEK (-0,09)

CEO comments

Hanna Sjöström, CEO

During the second quarter of 2024, we've achieved several critical milestones in line with our business strategy, that lay a strong foundation for our upcoming FDA application for market approval in the USA.

The successful Human Factors Validation Study of Neola® in Boston, USA, concluded with successful results confirming that Neola® is safe for its intended use by healthcare professionals in neonatal intensive care. In addition to the formal results, we also received positive feedback from participating neonatal nurses highlighting its clinical benefits of lung monitoring in neonatal intensive care. This provides Neola® with excellent prospects for seamless integration into neonatal intensive care.

Additionally, Neola® has obtained a CB certificate, according to high international standards, affirming its safety and essential performance in neonatal intensive care units. The CB certificate signifies that the product has undergone a rigorous and comprehensive testing and evaluation process with particularly high demands on safety, essential performance, and electromagnetic compatibility by the accredited and independent IECEE testing house, FORCE Technology. This is a strong testament to the effectiveness of our structured product development process.

Our market preparation in the USA has also gained momentum. Recognized by Stanford's international industry experts as one of the world's top medical technology innovation companies that can improve pediatric care. We were honored by winning the silver medal at the prestigious international competition, Stanford PDC Accelerator Pitch Competition 2024, partially funded by the FDA, to promote innovation in pediatric medical technology. Awarded with $25.000 and mentorship from Stanford's world-leading medical technology experts we receive tailored advice and full support to accelerate the development and increase the availability of advanced medical technology innovation to reach the vulnerable pediatric patient group as quickly as possible.

Ahead of our market launch in the USA, we are especially glad to have our first American board member as a strategic advisor.

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.

Hanna Sjöström

Significant events

During the quarter

- Annual report 2023 was published.
- The Company called to Annual General Assembly 2024.
- Neola Medical completed the Human Factors Validation Study with Neola® and achieved successful results, which will be submitted as part of the company's application to the FDA for market approval in the U.S.
- Neola Medical announced that all 2,358,805 shares of Neola Medical held by Cardeon AB were acquired by the company's existing major shareholders ANMIRO AB, Conspargo Capital (Pär Josefsson), LMK, Brodvik AB, and Bengt Nevsten, as well as by new shareholder Daniel Oelker.
- Neola Medical published the Q1 report of 2024
- Neola Medical published the communique from the Annual General Assembly that was held at the Company’s premises in Lund May 22, 2024. Chairman Märta Lewander Xu, Urban Ottosson, Tommy Hedberg and Mattias Lundin were re-elected as members of the board. Monica Alfaro Welling was elected to the board of directors as the company’s first American board member, signaling the importance of U.S. experience as the company is progressing towards a market launch in the U.S.
- Neola Medical announced the appointment of David Folkesson as Chief Financial Officer, effective August 26, 2024, ahead of market launch in the U.S.
- Neola® obtained CB certification according to high international standards, meeting partial regulatory requirements for market approval in the U.S.

After the quarter

- Neola Medical Granted Patent in Europe, Expands Protection for Medical Device Neola®

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 is located at IDEON Gateway, Scheelevägen 27 in Lund, Sweden.

Business concept

Neola Medical's business concept is to develop and sell the company's product for continuous lung monitoring with direct detection of respiratory complications to neonatal intensive care units globally.

Vision

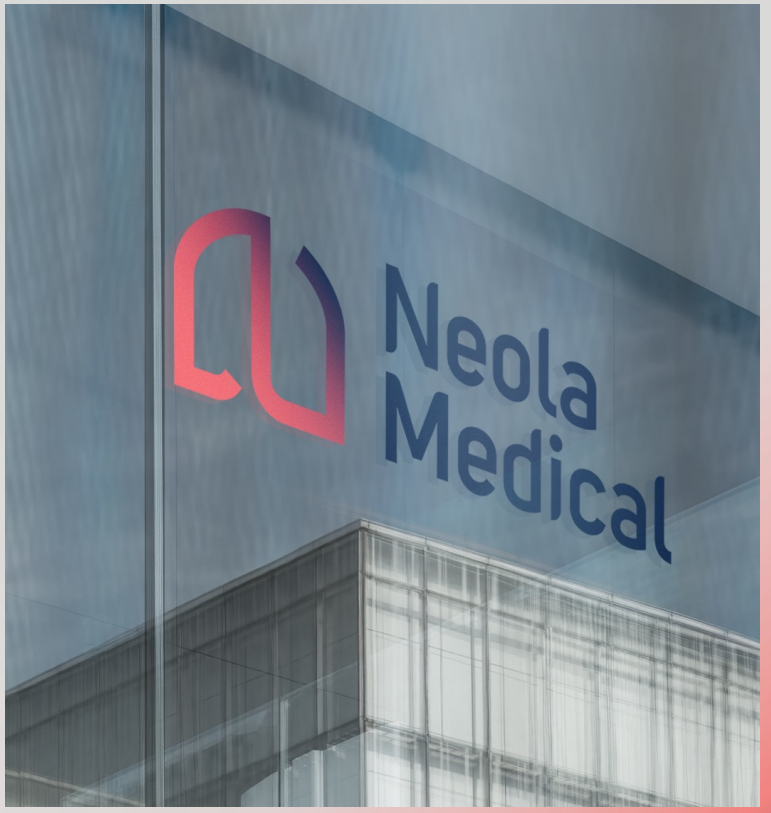
The company's vision is for preterm born infants to have a better start in life. By providing neonatal intensive care units with the medical device Neola®, which enables continuous monitoring of the lungs of preterm born infants with direct detection of complications, the company aims to enhance the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

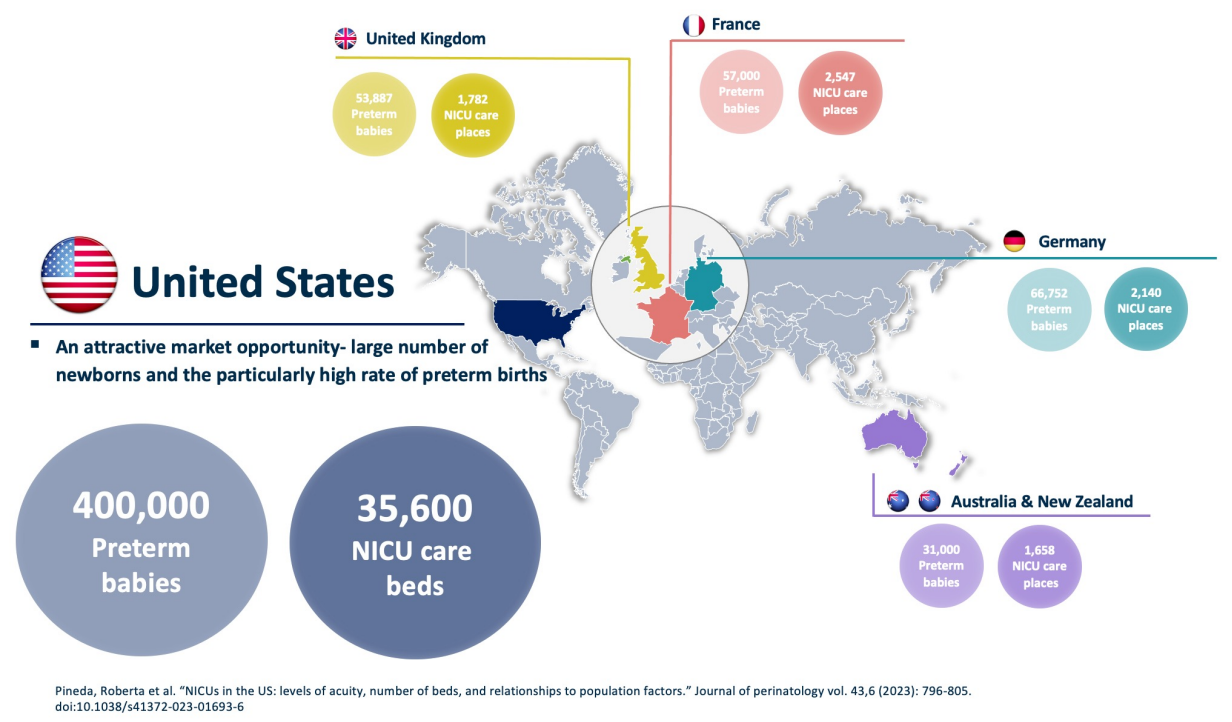
The company's business model ensures recurring revenue by requiring a Neola® device for a significant proportion of the beds in the clinic, with the probes used for monitoring being disposables that are replaced daily on the infant.



Market

A highly significant and growing global market

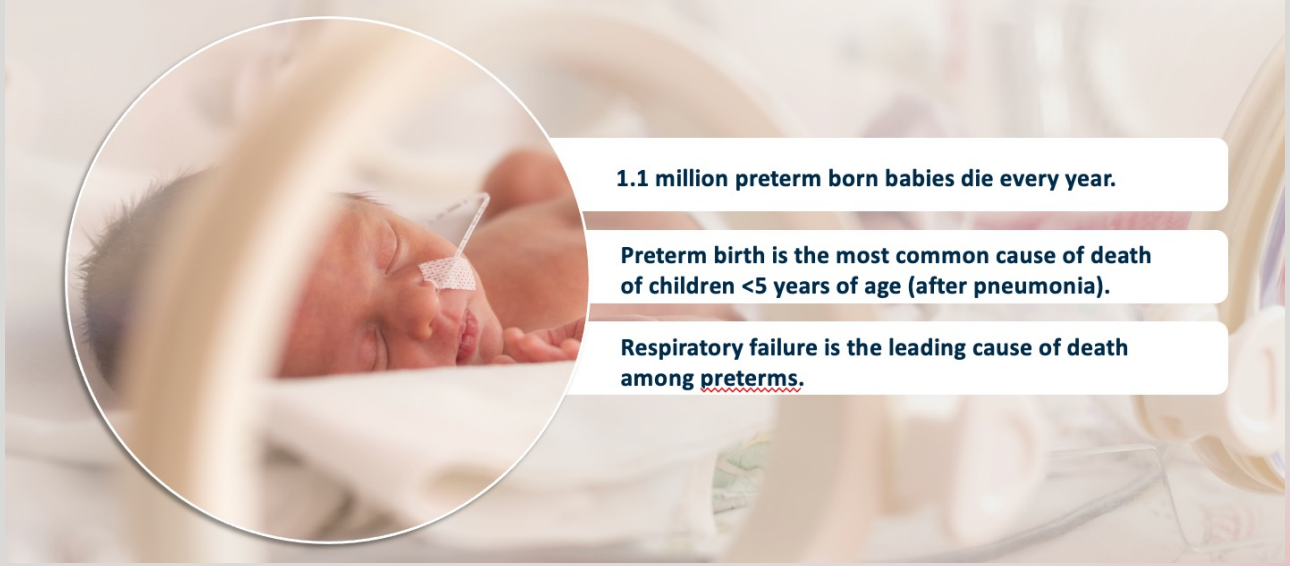
Neola® will be introduced to the global market for respiratory equipment focused on neonatal intensive care, which was valued at USD 1.7 billion in 2022. The market is projected to expand with a compound annual growth rate (CAGR) of 5.9% from 2022 to 2032, reaching USD 3 billion by 2030.



The patients

Today, one in ten babies is born prematurely, 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 physical symptoms have appeared. Neola® addresses a clear and significant clinical need for a continuous monitoring method. Neola® can result in better care, fewer days in intensive care, and ultimately, reduced morbidity and mortality in preterm born infants.

One in ten babies is born too soon and may depend on neonatal intensive care for their survival



1.1 million preterm born babies die every year.

Preterm birth is the most common cause of death of children <5 years of age (after pneumonia).

Respiratory failure is the leading cause of death among preterms.

New precision care upgrading current standard of care

Neola® offers:

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

National, regional, and worldwide estimates of preterm birth rates in the year 2010 with time trends since 1990 for selected countries: a systematic analysis and implications Blencowe et al. The Lancet 2012

Financial information

Financial summary

Neola Medical, summary	2024-04-01 -2024-06-30 3 mos	2023-04-01 -2023-06-30 3 mos	2024-01-01 -2024-06-30 6 mos	2023-01-01 -2023-06-30 6 mos	2023-01-01 -2023-12-31 12 mos
Operating revenue (SEK k)	2 760	2 595	6 208	4 935	9 830
EBIT (SEK k)	-3 011	-2 586	-5 579	-4 941	-9 621
Cashflow for the period (SEK k)	-6 034	-4 508	7 533	-9 911	-18 512
Cash and cash equivalents (SEK k)	29 111	30 178	29 111	30 178	21 578
Equity per share before dilution (SEK)	1,05	1,14	1,05	1,14	1,13
Equity ratio (%)	93	90	93	90	92
Total assets (SEK k)	79 799	70 170	79 799	70 170	86 018
Quick ratio (%)	547	646	547	646	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	-0,08	-0,09	-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 – June 2024

Revenues and results of operations

For the period January to June, operating revenues amounted to SEK 6.208 thousand (SEK 4.935 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 6.181 thousand (SEK 4.918 thousand).

Operating expenses for the period January to June amounted to SEK 10.988 thousand (SEK 9.083 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 -5.579 thousand (SEK -4.941 thousand). The Company maintains stability on the cost side with a burn rate according to plan and continues its work focusing on product development with technical verification, preparation for clinical studies, and other activities aimed at the certification of Neola®.

The Company's burn rate averaged SEK -2,078 thousand (SEK -1,736 thousand) per month during the period and is expected to increase with the acceleration of product development over the next year, also influenced by the current inflation situation.

Preparations for a commercial structure are also expected to impact the cost base going forward. The result after tax amounted to SEK -5.150 thousand (SEK -4.689 thousand), and the earnings per share were SEK -0.08 (SEK -0.09) for the period January to June.

Cash flow and investments

The total cash flow for the period January to June amounted to SEK 7.533 thousand (SEK -9.911 thousand). The cash flow from investing activities alone amounted to SEK -7.386 thousand (SEK -5.978 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 29.111 thousand (SEK 30.178 thousand).

Financial position and balance sheet

As of June 30, 2024, the equity ratio was 93% (90%), and own capital amounted to SEK 73.877 thousand (SEK 63.301 thousand). The Company was free from interest-bearing debt as of the balance sheet date. Intangible assets amounted to SEK 48.797 thousand (SEK 38.178 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® in 2025. 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 2021 annual report. For further information, refer to the Group's 2021 annual report. 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 Company'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)	2024-04-01 -2024-06-30 3 mos	2023-04-01 -2023-06-30 3 mos	2024-01-01 -2024-06-30 6 mos	2023-01-01 -2023-06-30 6 mos	2023-01-01 -2023-12-31 12 mos
Operating income	0	0	0	0	0
Capitalized own work	2 744	2 581	6 181	4 918	9 784
Other operating income	16	14	27	17	45
Operating revenue	**2 760**	**2 595**	**6 208**	**4 935**	**9 830**
Raw materials and consumables	-368	-506	-1 130	-881	-1 765
Other external costs	-2 289	-1 913	-4 852	-3 715	-7 986
Personnel costs	-2 655	-2 361	-4 941	-4 481	-8 107
Depreciation	-399	-397	-799	-793	-1 593
Other operating expenses	-59	-3	-65	-5	0
Operating result	**-3 011**	**-2 586**	**-5 579**	**-4 941**	**-9 621**
Financial income and expenses	183	186	429	253	612
Result before tax	**-2 829**	**-2 400**	**-5 150**	**-4 689**	**-9 010**
Tax on result for the period	0	0	0	0	0
Result for the period	**-2 829**	**-2 400**	**-5 150**	**-4 689**	**-9 010**

Financial reports in summary

Balance sheet, (SEK k)	2024-06-30	2023-06-30
Assets		
Non-current assets		
Intangible assets	48 797	38 178
Tangible assets	94	180
Financial assets	53	0
Sum non-current assets	**48 944**	**38 358**
Current assets		
Short-term receivables	1 744	1 634
Cash and bank balances	29 111	30 178
Sum current assets	**30 855**	**31 812**
Sum assets	**79 799**	**70 170**
Equity and liabilities		
Equity		
Equity	73 877	63 301
Sum equity	**73 877**	**63 301**
Liabilities		
Long-term liabilities	278	1 944
Accrued expenses and deferred income	1 909	2 035
Other current liabilities	3 736	2 890
Sum liabilities	**5 923**	**6 869**
Sum equity and liabilities	**79 799**	**70 170**

Financial reports in summary

Changes in own capital, (SEK k)	2024-04-01 -2024-06-30 3 mos	2023-04-01 -2023-06-30 3 mos	2024-01-01 -2024-06-30 6 mos	2023-01-01 -2023-06-30 6 mos	2023-01-01 -2023-12-31 12 mos
Own capital at beginning of period	76 637	65 197	79 028	67 485	67 485
New share issues and subscribed share capital	0	0	0	0	20 000
Issuance costs	0	0	-69	0	-168
Issued subscription warrants	68	504	68	504	720
Other adjustments and provisions	0	0	0	0	0
Result for the period	-2 829	-2 400	-5 150	-4 689	-9 010
Own capital at end of period	**73 877**	**63 301**	**73 877**	**63 301**	**79 028**

Cash flow, (SEK k)	2024-04-01 -2024-06-30 3 mos	2023-04-01 -2023-06-30 3 mos	2024-01-01 -2024-06-30 6 mos	2023-01-01 -2023-06-30 6 mos	2023-01-01 -2023-12-31 12 mos
Cash flow from operaiting activities before changes in working capital	-2 461	-2 027	-4 457	-3 966	-7 183
Changes in working capital	-145	-94	-623	-471	641
Cash flow from operating activities	**-2 606**	**-2 121**	**-5 080**	**-4 437**	**-6 542**
Cash flow from investing activities	-3 497	-2 891	-7 386	-5 978	-12 305
Cash flow from financing activities	68	504	19 999	504	336
Cash flow for the period	**-6 034**	**-4 508**	**7 533**	**-9 911**	**-18 512**
Cash and cash equivalents at the beginning of the period	35 145	34 686	21 578	40 089	40 089
Cash and cash equivalents at the end of the period	**29 111**	**30 178**	**29 111**	**30 178**	**21 578**

About the share

Share capital, shareholders and the share 2024-06-30

As of June 30th 2024 Neola Medical's share capital was 5 010 751 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 2024-06-30 (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 & Stiftelsen	7 350 360	10.5%	10.5%
Cardeon AB (Publ)	2 362 914	3.4%	3.4%
Bengt Nevsten	981 581	1.4%	1.4%
Nordnet Pensionsförsäkring	625 000	0.9%	0.9%
Avanza Pension	613 153	0.9%	0.9%
Magnus Kenneby	584 240	0.8%	0.8%
Urban Ottosson	546 600	0.8%	0.8%
Övriga aktieägare	15 275 163	21.8%	21.8%
Totalt	**70 150 234**	**100.0%**	**100,0%**

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

Financial calendar and contact

6 Nov 2024	12 Feb 2025	9 April 2025	21 May 2025
Q3 report 2024	Year End Financial Statement 2024	Annual report 2024	Q1 report 2025 and Annual General Assembly

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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Questions about the report is answered by:
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Christian Gyllenberg, CFO
E-mail: christian.gyllenberg@neolamedical.com

Lund August 15 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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