



NeoDynamics AB (publ)
First quarter 2022

1 January – 31 March 2022

European order activities growing, and ramping up for the US commercialization

First Quarter 2022

- Revenues amounted to SEK 147 (405) thousand, of which SEK 0 (378) thousand capitalized costs and SEK 92 (22) thousand net sales, i.e., sales of finished products.
- Loss after tax amounted to SEK -17,192 (-17,261) thousand.
- Loss per share amounted to SEK -0.29 (-0.29).
- Cash and cash equivalents amounted to SEK 8,301 (62,278) thousand.

Significant events during the quarter

- NeoDynamics filed a registration application of type 510(K) for its innovative pulse biopsy system NeoNavia® with the US Food and Drug Administration, FDA.
- On March 31, 2022 NeoDynamics announced the outcome of its fully guaranteed rights issue of approximately SEK 69.3 million before transaction costs, which is expected to increase the number of shares by 60,250,592 to 120,501,184, resulting in an increase in the share capital of SEK 6,025,059.20 to SEK 12,050,118.40. At the time of publication of the Q1 report a partial registration of the rights issue has been completed and a second partial registration is being processed. A payment of SEK 2 335 415,40 is outstanding from one guarantor, with whom the company is in dialogue with. It is the company's current assessment that the outstanding payment will be received shortly.
- Aaron Wong assumed the position as CFO on February 1, 2022. Aaron Wong most recently came from a similar position at the medical technology company ADDvise Group AB.
- As part of the preparations for launching NeoNavia in the US market, a subsidiary in the USA, NeoDynamics USA Inc., was started. The subsidiary facilitates the recruitment of employees and for the company to enter into various types of agreements which will directly support the launch.
- Data from the PULSE study showing the benefits of the NeoNavia biopsy system in particularly challenging axillary lymph nodes were accepted for presentation at the SBI / ACR Breast Imaging Symposium in Savannah, Georgia, to be held May 16-19, 2022. The symposium is considered the most important annual meeting for breast radiologists in the U.S.

Significant events after period-end

- NeoDynamics was approved for trading on Nasdaq First North Growth Market in Stockholm, where the share began trading on May 2, 2022.

European order activities growing, and ramping up for the US commercialization

During the quarter, we took several important initiatives towards the introduction of NeoNavia in the US. After careful preparatory work, the registration application for NeoNavia was submitted to the FDA, and we are now awaiting approval. Once approved, marketing of the product can start within a relatively short period of time, in comparison with the pharmaceutical industry which takes much longer. We count on the possibility to commercialise the NeoNavia system in the US before the end of this year.

In Germany and the UK, we are proceeding with the evaluation phase which is based on products delivered and invoiced during December 2021. It is a delicate and timeconsuming process when each hospital transitions through the “new product evaluation” and final decision making process. The first time is always unique. On an average it takes approximately 3 months, however, we are patiently waiting for the final go-ahead for each of the hospitals to include NeoNavia in their clinical practice.

We also started our US subsidiary, NeoDynamics Inc., which will house our highly specialised sales organization. Initially, we will employ a smaller number of specialist sales representatives to liaise with key university centers who are ready to get started with the system in their clinical practice. Adding to that, the change of our listing to the Nasdaq First North Growth Market signals our commitment toward the US and to our current and future shareholders.

Furthermore, we are looking forward to our presentation at the SBI / ACR (Society of Breast Imaging / American College of Radiologists) Breast Imaging Symposium in Savannah, Georgia, on the 16th of May. This is a great opportunity for us because this is the most important US meeting in our space and our study has been selected for oral presentation, offered to only a few companies with these study results. Here, we will present data from a subgroup in the PULSE study with particularly challenging biopsy conditions.

Setting out on a journey

Notwithstanding these recently intensified activities, our efforts to enter the US market began some time ago, as



we started to forge bonds with key clinics in Europe and designed a study program that would allow us to showcase our products’ value within a clinical setting. These activities have paved the way to where we stand today, presenting at important congresses and seeing the benefits of independent advocates with clinical experience using our product. This is an important point of reference when you enter a new market such as the USA.

Product transfer underway

From our base in Sweden, we have also overseen the transfer of our needle production to Asia, to more effectively manage our cost base. Production and assembly in Asia, instead of Sweden, starts now with the first of three needles. Meanwhile we still maintain the NeoNavia base unit and driver production here in Sweden.

Good progress in Europe

In total, there are currently over 35 clinics that are using NeoNavia in their clinical practice, of which six are our customers, and 30 are running pilots. The feedback we are receiving from these clinics is very encouraging and I feel confident that we will have great support in our continued launch efforts.

Positioned for success

The pandemic is no longer hindering us to gain access to the hospitals or participate in “live” congresses. Last, but certainly not least, I am also very pleased that we managed to strengthen our finances through our most recent rights issue. This will mean that we can continue our efforts to bring NeoNavia to the market, both in Europe and in the US. We are well positioned for success.

CEO Anna Eriksrud

Financial overview

Revenue and earnings

Revenues during the quarter amounted to a total of SEK 147 (405) thousand, of which net sales were SEK 92 (22) thousand. Development costs for the marker project were capitalized with SEK 0 (378) thousand.

External costs amounted to SEK 10,612 (8,959) thousand consisting mainly of costs for sales, clinical studies, and product development. Personnel costs decreased to SEK 2,090 (2,655) thousand, an effect of several employees being replaced by consultants. Cost of goods amounted to SEK 48 (1,554) thousand. Depreciation increased to SEK 4,506 (4,449) thousand, relating essentially to development costs for NeoNavia.

Operating profit amounted to SEK -17,175 (-17,261) thousand. EBITDA, i.e., operating profit excluding depreciation, amounted to SEK -12,668 (-12,812) thousand.

Financial position

Cash and cash equivalents at the end of the period amounted to SEK 8,301 thousand (SEK 24,710 thousand at year-end). After period-end, funds from the rights issue have been received, strengthening the cash position.

Cash flow from operating activities before changes in working capital amounted to SEK -12,777 (-13,020) thousand and after changes in working capital to SEK -16,395 (-10,510) thousand. Cash flow from investing activities was SEK -242 (-461) thousand. The total cash flow amounted to SEK -16,409 (-10,972) thousand.

At period-end, the equity to assets ratio was 90 (94) percent and equity amounted to SEK 80,269 (148,085) thousand.

Effects of the pandemic

Operations are affected by the pandemic in several ways, partly due to differences in infection status and how different countries manage the pandemic. Contacts with customers and patients are more difficult in certain markets impacting the introduction of the product as well as different types of studies.

Due to Covid-19, the FDA has limited resources to handle matters other than those related to Covid-19 and there is therefore a risk that the FDA's handling of the company's matter will be time consuming. The preparatory work for the registration file in the USA has also taken longer than expected. The company follows developments closely and actively tries to find ways to minimize this impact.

Annual general meeting

The Annual General Meeting will take place on May 24, 2022, at 13.00 at the company's office at Lejonvägen 14 on Lidingö. All AGM documents, including the annual report, are available on the company's website. The documents are also available at the company's head office and can be sent by post to those shareholders who so request and state their postal address.

The share

NeoDynamic's share was listed on Spotlight Stock Market on December 7, 2018 and on May 2, 2022 the share started trading on Nasdaq First North Growth Market

with Redeye as Certified Adviser. The share's ticker remains "NEOD" and the ISIN code is SE0011563410.

On March 31, 2022 the number of shares in NeoDynamics AB amounted to 60,250,592, unchanged from year-end. The share closed the quarter at a share price of SEK 0.98, a decrease of 44 percent from SEK 1.76 at the turn of the year.

After period-end, a total of 50,427,557 were issued, raising the number of shares to 110,678,149, resulting in an increase in the share capital of SEK 5,042,755.70 to SEK 11,067,814.90.

Shareholders

On March 31, the company had a total of 1,689 shareholders, compared with 1,451 at year-end. The 10 largest shareholders on that date are listed in the table below, these include their BTA subscriptions.

Name	Shareholding	Ownership
Huasheng Fang	13 631 896	15.7%
Gryningskust Holding AB	8 646 338	9.9%
NKY Sweden AB (Boai)	4 922 544	5.6%
SIX SIS AG	4 359 346	5.0%
Alandsbanken ABP	4 226 530	4.8%
Nordnet Pensionsförsäkring AB	3 667 182	4.2%
Cardeon AB	3 142 875	3.6%
Avanza Pension, Försäkringsbolaget	2 240 032	2.5%
Rentability Sweden AB	2 016 490	2.3%
Humlan Fastighetsutveckling AB	1 739 430	2.0%
Others	38 151 533	44.4%

Financial calendar

Annual General Meeting	2022-05-24
Half-year report Jan-June	2022-08-18
Interim report Jan-Sept	2022-11-17
Year-End Report 2022	2023-02-17

Risks and uncertainties

A number of risk factors could have a negative impact on NeoDynamics AB's operations. It is therefore important to consider any relevant risks in addition to the company's growth opportunities. For a detailed outline of the risks attributable to the company and its shares, please refer to the prospectus published by the Board in March 2022.

Accounting principles

This report has been prepared in accordance with the Annual Accounts Act and in accordance with the Swedish Accounting Standards Board's general advice BFNAR 2012:1 Annual Report and Consolidated Financial Statements (K3). For intangible assets, the activation model in the general council has been applied. The company's assets and liabilities are stated at cost and nominal value, unless otherwise stated.

Review of the report

This interim report has not been reviewed by the company's auditor.

Interim report submitted

The Board of Directors and the CEO hereby certify that this interim report provides a true and fair view of NeoDynamics' operations.

Lidingö on May 12, 2022

Anna Eriksrud
CEO

Ingrid Salén
Chairman of the Board

Jessie Bao
Board member

Carina Bolin
Board member

Matthey E. Colpoys Jr
Board member

Claes Pettersson
Board member

Xiao-Jun Xu
Board member

NeoDynamics AB 559014-9117

For further information, please contact

CEO Anna Eriksrud, phone +46 (0)708 444 966, e-mail anna.eriksrud@neodynamics.com

CFO Aaron Wong, phone +46 (0)79 010 1714, e-mail aaron.wong@neodynamics.com

The company's Certified Adviser is Redeye AB, e-mail address: certifiedadviser@redeye.se and telephone number +46 8 121 576 90.

Income Statement

Amounts in SEK thousands	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Revenue			
Net sales	92	22	1,162
Work performed by the Company for its own use and capitalized	0	378	785
Other operating income	54	5	138
	147	405	2,085
Operating expenses			
Cost of goods	-48	-1,554	-5,772
Other external costs	-10,612	-8,959	-37,124
Personnel costs	-2,090	-2,655	-9,698
Depreciation/amortization of tangible and intangible assets	-4,506	-4,449	-17,841
Other operating expenses	-64	-49	-120
	-17,175	-17,261	-68,469
OPERATING LOSS			
Financial items			
Financial income	0	0	0
Financial costs	-17	0	0
Net financial items	-17	0	0
LOSS AFTER FINANCIAL ITEMS			
	-17,192	-17,261	-68,469
Loss before tax			
	-17,192	-17,261	-68,469
Tax	0	0	0
Net loss	-17,192	-17,261	-68,469
EARNINGS PER SHARE BEFORE DILUTION, SEK			
(no dilution)	-0.29	-0.29	-1.14
Number of shares at end of period	60,250,592	60,250,592	60,250,592
Average number of shares	60,250,592	60,250,592	60,250,592

Balance sheet

Amounts in SEK thousands	31 Mar 2022	31 Mar 2021	31 Dec 2021
ASSETS			
Fixed Assets			
Intangible assets	66,651	83,629	70,997
Tangible assets	1,576	1,269	1,494
Financial assets	370	123	370
	68,597	85,020	72,861
Current Assets			
Inventories	3,449	3,460	2,545
Accounts receivables	737	0	1,020
Receivables from group companies	1,819	0	0
Current tax assets	0	0	159
Other receivables	5,587	5,533	6,031
Prepaid expenses and accrued income	764	594	714
Cash and cash equivalents	8,301	62,278	24,710
	20,657	71,866	35,179
TOTAL ASSETS	89,253	156,886	108,040
EQUITY AND LIABILITIES			
Restricted Equity			
Share capital	6,025	6,025	6,025
Fund for development expenditure	61,532	78,496	65,875
	67,557	84,521	71,900
Non-restricted Equity			
Share premium reserve	248,088	247,971	248,179
Retained earnings	-218,184	-167,146	-154,057
Profit/loss for the year	-17,192	-17,261	-68,469
	12,712	63,564	25,653
TOTAL EQUITY	80,269	148,085	97,553
Provisions			
Provisions for guarantee	240	0	240
Long-term liabilities			
Other long-term liabilities	665	327	327
Current liabilities			
Accounts payable	3,230	4,072	4,789
Current tax liability	0	109	0
Income tax payable	103	646	353
Accrued expenses	4,746	3,647	4,778
TOTAL LIABILITIES	8,984	8,801	10,487
TOTAL EQUITY AND LIABILITIES	89,253	156,886	108,040

Cash Flow Statement

Amounts in SEK thousands	2022 Jan- Mar	2021 Jan- Mar	2021 Jan- Dec
Operating activities			
Loss after financial items	-17,192	-17,261	-68,469
Adjustments for items not included in cash flow	4,415	4,241	17,342
Cash flow from Operating Activities before changes in working capital	-12,777	-13,020	-51,127
<i>Cash from changes in working capital</i>			
Increase (-) / decrease (+) in inventories	-904	-1,651	-736
Increase (-) / decrease (+) in receivables	-1,142	957	-884
Increase (+) / decrease (-) in operating liabilities	-1,573	3,203	5,162
Cash Flow from Operating Activities	-16,395	-10,510	-47,585
Investing activities			
Acquisition of intangible assets	0	-378	-785
Acquisition of tangible assets	-242	-73	-651
Acquisition of financial assets	0	-10	-258
Cash Flow from Investing Activities	-242	-461	-1,694
Financing activities			
Rights issue	0	0	0
Issuance of share options	228	0	0
Cash Flow from Financing Activities	228	0	0
Net change in cash and cash equivalents	-16,409	-10,972	-49,279
Cash and cash equivalents, opening balance	24,710	73,250	73,250
Cash and cash equivalents, ending balance	8,301	62,278	24,710

Key Figures

	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022
Net sales, SEK thousands	0	0	0	22	0	300	839	92
Operating loss, SEK thousands	-5,541	-6,731	-11,022	-17,261	-18,263	-13,066	-19,134	-17,175
Operating margin %	neg	neg	neg	neg	neg	neg	neg	neg
Balance sheet total, SEK thousands	95,321	95,981	171,292	156,886	136,981	122,242	107,881	89,253
Equity ratio %	94%	94%	97%	94%	95%	95%	90%	90%
Cash, SEK thousands	7,177	3,486	73,250	62,278	48,339	37,352	24,710	8,301
Earnings/loss per share, SEK	-0.18	-0.19	-0.28	-0.29	-0.30	-0.22	-0.32	-0.29
Equity per share, SEK	2.68	2.52	2.75	2.46	2.15	1.93	1.62	1.33

Definitions

Equity per share	Equity at the end of the reporting period / average number of shares
Earnings/Loss per share	Earnings/loss for the period / average number of shares
Operating margin	Operating profit / net sales
Equity / assets ratio	Total equity / total assets

Warrant program – 2020/2023 and 2022/2025

The company has implemented two incentive programs aimed at senior executives in the company. In 2020, 1,021,900 warrants were issued with the right for holders to for each option subscribe for one (1) share with a subscription price of SEK 4.71 during the period August 1, 2023 – September 30, 2023.

In 2022, 2,640,000 warrants were issued with the right for holders to for each option subscribe for one (1) share with a subscription price of SEK 1.74 during the period February 17, 2025 – May 17, 2025.

The Board's ambition is to propose the issuance of warrants or equivalent up to a maximum total dilution of 5%.

There are no dilution effects during the period. The warrant terms are available on the company's website.

NeoDynamics in brief

NeoDynamics AB (publ) is a Swedish medical technology company dedicated to advancing the diagnosis and care of cancer. The company has an innovative biopsy system, NeoNavia®. The biopsy system is based on patented pulse technology, developed from research carried out at the Karolinska Institute in Sweden. The system is designed to offer clinicians and patients accurate lesion targeting and high tissue yield for accurate diagnosis and individualized treatment. The launch of NeoNavia® has been initiated in the UK, Germany and Sweden.

A growing breast biopsy market

At least 6 million breast biopsies are performed every year in order to detect suspected cancer. Every year, about 2.1 million women are diagnosed with breast cancer, a number that increases by 5 percent annually. The market for breast cancer diagnostics is growing and was estimated in 2020 at 725 million dollars. The proportion of non-surgical biopsies is increasing at the expense of the surgical ones. Extended screening programs and new screening techniques enable more and more tumors to be detected earlier. New therapies are increasing the need for biopsies to confirm diagnoses but also to follow up on treatment results.

NeoNavia® – a unique biopsy system

NeoNavia consists of a base unit, a handheld driver and three different types of biopsy needles. Each needle type is driven by pulses, enabling high precision and control when inserting and positioning the biopsy needle in a suspicious lesion. The system is designed to offer accurate lesion targeting and high tissue yield for accurate diagnosis and individualized treatment.

New innovative technology

The patented pulse technology is based on a pneumatically driven mechanism that enables high precision and control when inserting and positioning the biopsy needle, regardless of tissue type. The pneumatic driver that generates pulses is placed in a handheld instrument. Powered by the base unit, the driver accelerates the needle with great control even over a short distance, enabling its distinct stepwise insertion without risking to destroy surrounding tissue. This

facilitates ease of access and flexibility in sampling, even in very small lesions in delicate and difficult locations as well as in dense tissue.

Intellectual Property

The technology is protected in Europe's larger countries as well as in China and the USA. Patents for technology in the proprietary needle have been approved in Europe, the USA and China. The company's various patents run until 2034 and additional patent applications have been filed.

Good results in clinical studies

More than 500 patients have undergone biopsy of the breast and axillary lymph nodes with NeoDynamic's new biopsy technology. The PULSE study (ClinicalTrials.gov ID: NCT03975855) shows that the system performs well when used in axillary lymph nodes. The patented pulse technology was considered to stabilize the target organ lymph node and improve needle control during insertion, and it was possible to obtain multiple samples with a single needle insertion.

Tomorrow's breast cancer biopsy

NeoDynamics' vision is that our pulse technology will become the new standard for all ultrasound-guided breast cancer biopsies, and that precision and reliability will be improved, thereby helping to save lives and improve the quality of life of all women with breast cancer.

“The NeoNavia® biopsy system can safely increase the precision of ultrasound-led, technically difficult biopsies such as in the axillary lymph nodes.”

Ref 1, Markets and Markets, September 2020 <https://www.marketsandmarkets.com/Market-Reports/biopsy-devices-breast-biopsy-market-189011805.html> Schässburger K, Paepke S. Po86. Novel pulse biopsy platform incorporating adaptive open-tip sampling needle increases sampling yield and needle control. European Journal of Surgical Oncology. 2021;47(5). doi:10.1016/j.ejso.2021.03.090.