



NeoDynamics AB (publ)
First half 2022

1 January – 30 June 2022

Focus shifting towards the US

Second Quarter 2022

- Revenues amounted to SEK 164 (411) thousand, of which SEK 141 (383) thousand capitalized costs and SEK 10 (0) thousand net sales, i.e., sales of finished products.
- Net loss amounted to SEK -18,294 (-18,263) thousand.
- Loss per share amounted to SEK -0.17 (-0.30).
- Cash and cash equivalents amounted to SEK 49,903 (24,710 at year-end) thousand.

First Half 2022

- Revenues amounted to SEK 311 (816) thousand, of which SEK 141 (762) thousand capitalized costs and SEK 103 (22) thousand net sales, i.e., sales of finished products.
- Net loss amounted to SEK -35,485 (-35,519) thousand.
- Loss per share amounted to SEK -0.42 (-0.59).
- Cash and cash equivalents amounted to SEK 49,903 (24,710 at year-end) thousand.

Significant events during the quarter

- NeoDynamics completed a rights issue raising approx. SEK 69.3 million before transaction costs, increasing the number of shares by 60,250,592 to 120,501,184, and the share capital by SEK 6,025,059 to SEK 12,050,118.
- NeoDynamics was approved for trading on Nasdaq First North Growth Market in Stockholm, where the share began trading on May 2, 2022.
- The annual general meeting held on May 12, reelected the Board of Directors.

Business highlights

- Professor Marc Thill presented new data from the PULSE study at the SBI/ACR Breast Imaging Symposium in Savannah, Georgia in May, showing a success rate of 96% for NeoNavia in very complex and risky axilla biopsies.
- Gryningskust Holding AB acquired 4,922,544 shares in NeoDynamics from Boai NKY Medical in June, thereby increasing its holding to 16,844,360 shares, representing 14 per cent of shares and votes in the company. Gryningskust thereby became the largest owner in NeoDynamics.
- In July, NeoDynamics received ethical committee approval for a German device registry trial. The registry will be used to gather and evaluate real world data from the use of NeoNavia.

Focus shifting towards the US

Preparations underway

The groundwork for the US commercialization and subsequent launch are in full swing. The team is working in parallel with the FDA approval process to ensure that there are no unnecessary delays, but the 510(k) application process is dependent on the FDA's internal processes. The dialogue with the authority has been constructive and we expect that the process will be concluded before long. I remain convinced that NeoDynamics will be able to take the first steps in commercialising the NeoNavia system in the US before the year-end.

Meanwhile, NeoDynamics has set up an agile, external organization that will allow us to swiftly initiate a launch for NeoNavia, while also taking care of administrative requirements. Once up and running, we will start to build-up internal resources to maintain an effective and cost efficient start. To help locate the sweet spots for NeoNavia, a market research report was commissioned which continues to build our knowledge and understanding of the market, including different aspects on reimbursement.

Europe paves the way

The efforts to enter the US market began when NeoDynamics started to engage with key clinics in Europe, designing a study program that would showcase the value of the products within a clinical setting. These activities have paved the way to where NeoDynamics 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 entering a large market such as the USA. We will ensure that this job on key centres in the German speaking part of Europe as well as the UK, Ireland and Sweden is continued. We are strengthening our product experience and confirm we are a reliable partner.



Fine-tuning the product

In Europe, the team has engaged in dialogue with key centers to further optimize the system ahead of the US launch. This has resulted in small, but necessary, fine-tuning of the needles that has led to a temporary pause in production and sales. Deliveries are expected to resume with the CorePulse needle, and the VacuPulse needle during the the last months of the year, both from our Asian supplier. This suits operations well, as the CorePulse needle is in high demand in Europe while the FlexiPulse needle and the VacuPulse needle are expected to become the center of attention in the US. The interruption in supply has not deterred interest in the product with over 35 clinics having introduced NeoNavia in their clinical practice, and some 30 running pilots. Their feedback continues to be very encouraging and I feel confident that we will have great support in our continued efforts.

Looking forward

I look forward to an eventful autumn, during which NeoDynamics will share important news. To stay up to date with development, you can register for our monthly newsletter on the website www.neodynamics.com.

CEO Anna Eriksrud

Financial overview

Revenue and earnings

Revenues during the quarter amounted to SEK 164 (411) thousand, and for the first half of the year to SEK 311 (816) thousand, of which net sales were SEK 10 (0) thousand and SEK 103 (22) thousand respectively. Development costs for NeoNavia were capitalized with SEK 141 (383) thousand during the quarter. Sales and production have been temporarily paused, to include feedback from our customers ahead of the US launch.

Cost of goods were SEK 64 (2,770) thousand during the quarter and SEK 113 (4,324) thousand for the first half year, due to a halt in production while fine-tuning products. Other external costs increased to SEK 11,960 (8,847) thousand for the quarter and SEK 22,572 (17,801) thousand for the first half year, mainly reflecting higher costs for the establishment of the German subsidiary coupled with preparations for the US market.

Personnel costs decreased to SEK 1,859 (2,591) thousand during the quarter and SEK 3,949 (5,246) thousand for the first half year, an effect of several employees being replaced by consultants.

Operating loss amounted to SEK -18,333 (-18,263) thousand for the quarter and SEK 35,507 (35,519) thousand for the first half year whereas EBITDA, i.e., operating profit excluding depreciation, amounted to SEK -13,810 (-13,809) thousand for the quarter and SEK -26,477 (-26,616) thousand for the half year.

Financial position

Cash and cash equivalents at the end of the period amounted to SEK 49,903 thousand (SEK 24,710 thousand at year-end). During the second quarter, funds from the rights issue were received, strengthening the cash position with SEK 69,126 (0) thousand.

Cash flow from operating activities before changes in working capital amounted to SEK -27,152 (-26,988) thousand and after changes in working capital to SEK -33,446 (-23,999) thousand. Receivables increased by SEK 4,091 thousand. The total cash flow amounted to SEK 25,169 (-24,911) thousand.

At period-end, the equity to assets ratio was 93 (95) percent and equity amounted to SEK 123,003 (129,663) 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 had 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. We are now though in the end of the process.

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 June 30, 2022 the number of shares in NeoDynamics AB amounted to 120,501,184, up from 60,250,592, at year-end. A rights issue of 60,250,592 shares was completed during the second quarter, increasing the share capital by SEK 6,025,059 to SEK 12,050,119.

The share closed the second quarter at a share price of SEK 0.828, a decrease of 53 percent from SEK 1.76 at the turn of the year.

Shareholders

On June 30, the company had a total of 1,861 shareholders, compared with 1,451 at year-end. The 10 largest shareholders on that date are listed in the table below.

Name	Shareholding	Ownership
Gryningskust Holding AB	16,844,360	14.0%
Fang, Huasheng	13,631,896	11.3%
NKY SwedenAB	4,922,544	4.1%
SIX SIS AG	4,782,296	4.0%
Alandsbanken ABP	4,217,130	3.5%
Hosseinian, Dariush	3,634,337	3.0%
Nordnet Pensionsförsäkring AB	3,422,859	2.8%
SEB Life International	3,406,500	2.8%
Karkas Capital AB	3,275,478	2.7%
Avanza Pension	2,884,836	2.4%
Others	59,478,948	49.4%

Financial calendar

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 August 18, 2022

Anna Eriksrud CEO	Ingrid Salén Chairman of the Board	Jessie Bao Board member	Carina Bolin Board member
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Matthey E. Colpoys Jr Board member	Claes Pettersson Board member	Xiao-Jun Xu Board member
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NeoDynamics AB 559014–9117

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The company's Certified Adviser is Redeye AB.

Income Statement

Amounts in SEK thousands	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Revenue					
Net sales	10	0	103	22	1,162
Work performed by the Company for its own use and capitalized	141	383	141	762	785
Other operating income	12	28	67	33	138
	164	411	311	816	2,085
Operating expenses					
Cost of goods	-64	-2,770	-113	-4,324	-5,772
Other external costs	-11,960	-8,847	-22,572	-17,801	-37,124
Personnel costs	-1,859	-2,591	-3,949	-5,246	-9,698
Depreciation/amortization of tangible and intangible assets	-4,523	-4,454	-9,030	-8,903	-17,841
Other operating expenses	-90	-12	-154	-61	-120
	-18,333	-18,263	-35,507	-35,519	-68,469
Financial items					
Financial income	41	0	24	0	0
Financial costs	-2	0	-2	0	0
Net financial items	39	0	22	0	0
	-18,294	-18,263	-35,485	-35,519	-68,469
LOSS AFTER FINANCIAL ITEMS					
	-18,294	-18,263	-35,485	-35,519	-68,469
Loss before tax					
	-18,294	-18,263	-35,485	-35,519	-68,469
Tax	0	0	0	0	0
Net loss	-18,294	-18,263	-35,485	-35,519	-68,469
EARNINGS PER SHARE BEFORE DILUTION, SEK					
(no dilution)	-0.17	-0.30	-0.42	-0.59	-1.14
Number of shares at end of period	120,501,184	60,250,592	120,501,184	60,250,592	60,250,592
Average number of shares	108,399,077	60,250,592	84,457,841	60,250,592	60,250,592

Balance sheet

Amounts in SEK thousands	30 June 2022	30 June 2021	31 Dec 2021
ASSETS			
Fixed Assets			
Intangible assets	62,977	79,666	70,997
Tangible assets	1,788	1,228	1,494
Financial assets	2,398	123	370
	67,162	81,017	72,861
Current Assets			
Inventories	3,506	1,701	2,545
Accounts receivables	748	243	1,020
Receivables from group companies	875	0	0
Current tax assets	0	0	159
Other receivables	9,259	5,082	6,031
Prepaid expenses and accrued income	1,133	600	714
Cash and cash equivalents	49,903	48,339	24,710
	65,424	55,965	35,179
TOTAL ASSETS	132,586	136,981	108,040
EQUITY AND LIABILITIES			
Restricted Equity			
Share capital	12,050	6,025	6,025
Fund for development expenditure	57,862	75,984	65,875
	69,913	82,009	71,900
Non-restricted Equity			
Share premium reserve	303,090	247,807	248,179
Retained earnings	-214,514	-164,634	-154,057
Profit/loss for the year	-35,485	-35,519	-68,469
	53,090	47,654	25,653
TOTAL EQUITY	123,003	129,663	97,553
Provisions			
Provisions for guarantee	240	0	240
Long-term liabilities			
Other long-term liabilities	665	327	327
Current liabilities			
Accounts payable	1,875	2,787	4,789
Current tax liability	0	79	0
Income tax payable	386	963	353
Accrued expenses	6,417	3,163	4,778
	9,584	7,319	10,487
TOTAL LIABILITIES	9,584	7,319	10,487
TOTAL EQUITY AND LIABILITIES	132,586	136,981	108,040

Cash Flow Statement

Amounts in SEK thousands	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Operating activities			
Loss after financial items	-35,485	-35,519	-68,469
Adjustments for items not included in cash flow	9,006	8,531	18,081
Cash provided by operating activities before changes in working capital	-26,479	-26,988	-50,388
<i>Cash from changes in working capital</i>			
Increase (-) / decrease (+) in inventories	-961	109	-736
Increase (-) / Decrease (+) in receivables	-4,091	1,300	-884
Increase (+) / decrease (-) in operating liabilities	-1,242	1,580	5,162
Cash provided by operating activities	-32,773	-23,999	-46,846
Investing activities			
Investment in intangible assets	-673	-762	-785
Investment in tangible assets	-631	-140	-651
Investment in financial assets	-2,027	-10	-258
Cash used in investing activities	-3,331	-912	-1,694
Financing activities			
Rights issue	60,936	0	0
Issuance of share options	338	0	0
Cash used in financing activities	61,274	0	0
Net change in cash and cash equivalents	25,170	-24,911	-48,540
Cash and cash equivalents, opening balance	24,710	73,250	73,250
Foreign exchange differences in cash	24	0	0
Cash and cash equivalents, ending balance	49,903	48,339	24,710

Key Figures

	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022
Net sales, SEK thousands	0	0	0	22	0	300	839	92	10
Operating loss, SEK thousands	-5,541	-6,731	-11,022	-17,261	-18,263	-13,066	-19,134	-	-18,333
Operating margin %	neg	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	132,586
Equity ratio %	94%	94%	97%	94%	95%	95%	90%	90%	93%
Cash, SEK thousands	7,177	3,486	73,250	62,278	48,339	37,352	24,710	8,301	49,903
Earnings/loss per share, SEK	-0.18	-0.19	-0.28	-0.29	-0.30	-0.22	-0.32	-0.29	-0.17
Equity per share, SEK	2.68	2.52	2.75	2.46	2.15	1.93	1.62	1.33	1.02

Definitions

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

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-guided, 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.