



NeoDynamics AB (publ)
Nine months 2021 report

2021-01-01 – 2021-09-30

The English text is an unofficial translation of the Swedish report.

Higher pace after relief in restrictions

Third quarter 2021

- Revenue amounted to SEK 339 (2 643) thousand, of which SEK 24 (2 051) thousand were capitalized costs and net sales SEK 300 (0) thousand.
- Loss after tax amounted to SEK -13 066 (-6 731) thousand.
- Loss per share SEK -0,22 (-0,19).
- Cash and cash equivalents amounted to SEK 37 352 (3 486) thousand

First nine months of 2021

- Revenues amounted to SEK 1 155 (15 175) thousand, of which SEK 785 (14 140) thousand capitalized costs.
- Profit after tax amounted to SEK -48 596 (-19 482) thousand.
- Earnings per share amounted to SEK -0,81 (-1,71).

Significant events during the third quarter

- Hermann-Josef-Hospital in Erkelenz, a university hospital within the University of Aachen, became the first German hospital to order the NeoNavia biopsy system. Additional high-profile clinics in Germany and Switzerland placed orders for needles.
- Patents were issued in the United States for the FlexiPulse needle.
- NeoNavia was demonstrated at scientific congresses in Austria and Switzerland. Doctors received the system very well at the congresses which marked a return to a more normal market.

Significant events after the end of the period

- NeoDynamics received orders from four high-profile clinics in Germany and Switzerland for the NeoNavia biopsy system. This shows that clinicians are moving to the next step in evaluating the system and are moving towards incorporating it into their clinical practice.
- NeoDynamics started a subsidiary in Germany, NeoDynamics GmbH, to grow in this important market for the company's innovative biopsy system NeoNavia
- The first results from the German PULSE study were presented at the prestigious British Society of Breast Radiology (BSBR) annual scientific meeting. The study shows that NeoNavia can be used successfully and with a low frequency of side effects for sampling in the axilla.

CEO COMMENT

Higher pace after relief in restrictions

The market has begun to return to normality as the pandemic restrictions have eased. This means that the team was recently able to participate in person at several congresses and in connection with this also conducted workshops with doctors from several different clinics. The launch of NeoNavia can thus begin to take place in the way we planned for before the pandemic, which means a faster rollout than has been possible so far. The introduction continues with 2-3 months of pilot evaluations, where the team initially supports the clinics so that the doctors can evaluate and feel confident in how the system should function. It is a model that is appreciated by customers.

The product has been well received. During the fourth quarter, NeoDynamics will deliver and invoice probes to about 20 clinics that participate in pilot studies and where several also use the biopsy system in parallel in patients not participating in studies. If a clinic chooses to include the system in their practice, they will also pay for base and hand units. The use of the system that has now been initiated will provide a fantastic platform for NeoNavia and further processing in 2022.

The interest in the system is also reflected in the fact that abstracts on studies with NeoNavia have been accepted at congresses, which provides good visibility and contributes to a broader acceptance of the new technology in hospitals. The studies show the product's high quality and clinical benefit. We are particularly pleased to present data from our first prospective multicenter study at the prestigious annual scientific congress of the BSBR (British Society of Breast Radiology). In this study, which we called our German PULSE study, NeoNavia was used to take tissue samples in axillary lymph nodes in over 100 breast cancer patients with very good results.

Approaching the US

The work of preparing an introduction to the United States is progressing but is slower than desired as the US FDA has re-prioritized resources during the covid-19 pandemic. The registration application is nearing, but the exact timing is dependent on the FDA and the



dialogue we have with them. A submission at the beginning of next year, but a faster processing because the file holds up well – can be a better option than a hasty submission before the turn of the year since questions from the authority risk to delay the process even further. Therefore, the team seeks to submit a high-quality application, thereby minimizing the interaction with the authority after submission. Once the product is registered, it can begin to be marketed immediately, in contrast to what is the case for medicines, where in practice you also need to wait for decisions in various insurance companies.

NeoDynamics has a small but very competent organization for the US market. Country Manager Anna Forsberg, who is heading the FDA registration, has more than 30 years of relevant experience in the US market. Magnus Precht is equally experienced in US commercial operations and will be sure to recruit highly skilled and well-established salespeople. To their aid, they have strong support from Matt Colpoys, who was elected to NeoDynamics' board of directors this spring.

Preparations for China

During the autumn, the team also started preparations for registering NeoNavia in China. The work has good guidance from the company's largest owner Huasheng Fang, who is strongly connected to local breast centers, as well as board members Jie Bao and Xiao-Jun Xu.

A few weeks ago, NeoDynamics appointed a legal advisor for the work in the Chinese market. The next step is to appoint a regulatory advisor. During this process, the company will have good help from the work done in other markets, not least in the United States.

I look forward to an intense end to 2021, and a successful 2022!

CEO Anna Eriksrud

Financial overview

Revenue and earnings

Revenues during the quarter amounted to a total of SEK 339 (2,643) thousand and for the entire period to SEK 1,155 (15,175) thousand. Capitalized costs for product development in 2021 are only attributable to the marker project and during the quarter amounted to SEK 24 (2,051) thousand and for the entire period to SEK 785 (14,140) thousand.

External costs increased during the quarter to SEK 7,253 (6,681) thousand and for the entire period to SEK 25,029 (24,139) thousand and mainly consisted of costs for sales, clinical studies, and product development. Personnel costs decreased during the quarter and amounted to SEK 1,745 (2,566) thousand and for the entire period to SEK 7,026 (8,615) thousand, which is due to fewer employees which were replaced by consultants.

Depreciation increased during the quarter to SEK 4,454 (86) thousand and during the entire period to SEK 13,357 (356) thousand and relates essentially to development costs for NeoNavia.

Operating profit during the quarter amounted to SEK -13,066 (-6,731) thousand and for the entire period to SEK -48,595 (-18,011) thousand. EBITDA, i.e., operating profit excluding depreciation, amounted to SEK -8,612 (-6,645) thousand for the quarter and to SEK -35,238 (-17,655) thousand for the entire period.

Financial position

Cash and cash equivalents at the end of the period amounted to SEK 37,352 thousand (SEK 73,250 thousand at year-end).

Cash flow during the entire period from operating activities before change in working capital amounted to SEK -35,890 (-25,364) thousand and summed after change in working capital to SEK -34,876 (-35,100) thousand. The total cash flow for the entire period amounted to SEK -35,898 (-2,773) thousand. Cash flow excluding financing activities is just over SEK 13 million better for the entire period this year than in the corresponding period last year.

At the end of the period, the equity / assets ratio was 95 percent, compared with 97 percent at the turn of the year. Equity amounted to SEK 116,307 thousand, compared with SEK 165,554 thousand at the turn of the year.

Capital requirement

The Board assesses that the company's capital requirement is being met until the beginning of 2022, after which the company needs additional financing to complete its business plan.

Outlook

NeoDynamics has begun launching the NeoNavia biopsy system in the UK, Germany and Sweden, a launch that will continue through 2022. The company plans to file a regulatory application with the FDA in the United States around the turn of the year and thereafter initiate a registration application in China.

Effects of Corona Pandemic

Operations were affected by the pandemic during the first half of 2021 in several ways, among others by making contacts with customers more difficult and thus the introduction of the product, and by delaying various types of studies. The FDA's processing times in the ongoing dialogue have also delayed work on the

registration file. The company follows developments closely and actively tries to find ways to minimize this impact.

The share

NeoDynamic's share has been listed on Spotlight Stock Market since December 7, 2018. The share's ticker is "NEOD" and ISIN code is SE0011563410.

On September 30, 2021, the number of shares in NeoDynamics AB amounted to 60,250,592. The share closed the third quarter at a price of SEK 2.78, a decrease of 26 percent from SEK 3.75 at year-end.

Owners

The 10 largest owners at Sept 30	Number of shares	Ownership
Huasheng Fang	6 815 948	11.3%
NKY Sweden AB	4 922 544	8.2%
Gryningskust Holding AB	4 323 169	7.2%
Sebastian Jahreskog	3 623 604	6.0%
M2 Capital Management AB	2 970 899	4.9%
Nordnet Pensionsförsäkring AB	2 969 153	4.9%
Cardeon AB	2 803 234	4.7%
Avanza Pension, Försäkringsbolaget	2 653 932	4.4%
Quiq Holding AB	1 347 708	2.2%
Rentability Sweden AB	1 008 245	1.7%
Others	26 812 156	44.5%

Financial calendar

Year-end report	2022-02-16
Interim report Jan-Mar	2022-05-12
Annual General Meeting	2022-05-19

Annual General Meeting

The Annual General Meeting will take place on May 19, 2022, at 16.00 at the company's office at Lejonvägen 14 on Lidingö. Shareholders who wish to have a matter considered at the meeting are asked to contact the board at the following email address: info@neodynamics.com. All AGM documents, including the annual report, will be available on the company's website no later than three weeks before the AGM. The documents will also be available at the company's head office and can be sent by post to those shareholders who so request and state their postal address.

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 February 2020.

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 November 17, 2021

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

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

This is information that NeoDynamics AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, on November 17, 2021, at 8.30 CET.

Income statement

Amounts in SEK thousands	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Full year
Revenue					
Net sales	300	0	322	0	0
Work performed by the Company for its own use and capitalized	24	2 051	785	14 140	17 104
Other operating income	15	593	47	1 034	1 454
	339	2 643	1 155	15 175	18 557
Operating expenses					
Cost of goods	85	0	-4 239	0	0
Other external costs	-7 253	-6 681	-25 029	-24 139	-34 641
Personnel costs	-1 745	-2 566	-7 026	-8 615	-12 381
Depreciation/amortization of tangible and intangible assets	-4 454	-86	-13 357	-356	-454
Other operating expenses	-39	-42	-99	-76	-114
OPERATING LOSS	-13 066	-6 731	-48 595	-18 011	-29 032
Financial items					
Financial income	0	0	0	0	0
Financial costs	0	0	0	-1 472	-1 974
Net financial items	0	0	0	-1 472	-1 974
Loss after financial items	-13 066	-6 731	-48 596	-19 482	-31 006
Loss before tax	-13 066	-6 731	-48 596	-19 482	-31 006
Tax	0	0	0	0	0
Net loss	-13 066	-6 731	-48 596	-19 482	-31 006
EARNINGS PER SHARE BEFORE DILUTION, SEK (no dilution)					
	-0,22	-0,19	-0,81	-1,71	-0,51
Number of shares at end of period	60 250 592	36 006 951	60 250 592	36 006 951	60 250 592
Average number of shares	60 250 592	35 109 912	60 250 592	27 259 806	30 958 542

Balance sheet

Amounts in SEK thousands

30 Sep 2021

30 Sep 2020

31 Dec 2020

ASSETS

Fixed assets

Intangible assets	75 343	85 070	87 597
Tangible assets	1 207	1 035	1 299
Financial assets	123	112	112
	76 673	86 217	89 008

Current assets

Inventory, etc	2 092	162	1 810
Receivables	6 126	6 117	7 225
Cash and cash equivalents	37 352	3 486	73 250
	45 570	9 764	82 285

TOTAL ASSETS	122 242	95 981	171 292
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EQUITY AND LIABILITIES

Restricted Equity

Share capital	-6 025	-3 601	-6 025
Fund for development expenditure	-75 298	-79 930	-82 460
	-81 323	-83 531	-88 485

Unrestricted Equity

Share premium reserve	-247 528	-163 723	-248 179
Profit/loss brought forward	163 948	137 140	140 104
Profit/loss for the year	48 596	19 482	31 006
	-34 984	-7 100	-77 069
TOTAL EQUITY	-116 307	-90 631	-165 554

Long term debt

Other long-term liabilities	-327	-327	-327
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Short term liabilities

Accounts payable	-2 489	-1 893	-1 275
Current tax liabilities	-201	-41	-62
Other current liabilities	-603	-833	-1 013
Accrued expenses and deferred income	-2 315	-2 256	-3 061

TOTAL LIABILITIES	-5 935	-5 350	-5 738
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TOTAL EQUITY AND LIABILITIES	-122 242	-95 981	-171 292
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Cash flow statement

Amounts in SEK thousands	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Full year
Operating activities					
Loss after financial items	-13 066	-6 731	-48 596	-19 482	-31 006
Adjustments for items not included in cash flow	4 175	26	12 706	-5 882	454
Cash flow from operating activities before changes in working capital	-8 891	-6 705	-35 890	-25 364	-30 552
<i>Cash flow from changes in operating capital</i>					
Increase (-) /decrease (+) in inventory	-391	72	-282	200	-1 810
Increase (-) /decrease (+) in receivables	-73	-2 458	1 099	7 180	-3 567
Increase (-) /decrease (+) in operating liabilities	-1 521	-533	197	-17 116	-528
CASH FLOW FROM OPERATING ACTIVITIES	-10 877	-9 624	-34 876	-35 100	-36 457
Investing activities					
Acquisition of intangible assets	-109	-2 051	-785	-14 140	-17 104
Acquisition of tangible assets	0	0	-226	0	-359
Acquisition of financial assets	0	0	-10	0	0
Cash flow from investing activities	-109	-2 051	-1 021	-14 140	-17 462
Financing activities					
Share issue	0	7 657	0	60 769	141 412
Changes in loans	0	327	0	-14 302	-20 502
Cash flow from financing activities	0	7 984	0	46 468	120 911
CASH FLOW	-10 986	-3 691	-35 898	-2 773	66 991
Cash at the beginning of the year	48 339	7 177	73 250	6 258	6 258
Cash at the end of the year	37 352	3 486	37 352	3 486	73 250

Key Figures

	Q4 2019	Q1 2020	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021
Sales, SEK thousands	0	0	0	0	0	22	0	300
Operating loss, SEK thousands	-6 377	-5 738	-5 541	-6 731	-11 022	-17 261	-18 263	-13 066
Operating margin, %	neg	neg	neg	neg	neg	neg	neg	neg
Balance sheet total, SEK thousands	91 916	113 108	95 321	95 981	171 292	156 886	136 981	122 242
Equity ratio, %	60%	78%	94%	94%	97%	94%	95%	95%
Cash, SEK thousands	6 258	23 048	7 177	3 486	73 250	62 278	48 339	37 352
Earnings/loss per share, SEK	-0.45	-0.24	-0.16	-0.19	-0.19	-0.29	-0.30	-0.22
Equity per share, SEK	3.60	2.89	2.68	2.52	2.75	2.46	2.15	1.93

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 programs – 2018/2021 and 2020/2023

The company has implemented an 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.

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. The number of breast biopsies is increasing by 10 percent annually. Every year, 2.1 million women are diagnosed with breast cancer, a number that is increasing by 5 percent per year. The market for breast biopsy devices is valued at USD 500 million per year. The proportion of non-surgical biopsies is increasing at the expense of surgical biopsies. Expanded screening programs and new screening techniques are enabling an increasing number of tumors to be detected at an earlier stage. 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 is the registered trade mark for the entire biopsy system intended for use with ultrasound guidance. 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 micro-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.

Immaterial property

NeoNavia's pulse technology has received patent protection in many markets. The technology is patented in the larger European countries as well as in China and the US. Patent for the needle technology have been approved in Europe, the US and China. The company's patents are granted until 2034. Further patent applications have been made.

Clinically tested in key markets

More than 400 patients have undergone breast and axillary lymph node biopsy with NeoDynamics novel biopsy technique. Clinical studies are being conducted in Germany and are being planned in the UK for further evaluation of the technology.

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.”

1) Source: NeoDynamics prospectus:
<https://spotlightstockmarket.com/media/5584/neodynamics-ab-publ-prospekt-2.pdf>

