NeoDynamics AB (publ)
Full-year report 2021

1 January – 31 December 2021

neodynamics

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

NeoNavia® is gaining ground

Fourth quarter October-December 2021

- Revenues amounted to SEK 930 (3,382) thousand, of which SEK 0 (2,963) thousand capitalized costs and SEK 839 (0) thousand net sales, ie sales of finished products.
- Loss after tax amounted to SEK -19,134 (-11,524) thousand.
- Loss per share amounted to SEK -0.32 (-0.28).
- Cash and cash equivalents amounted to SEK 24,710 (73,250) thousand.

Full year January-December 2021

- Revenues amounted to SEK 2,085 (18,558) thousand, of which SEK 785 (17,104) thousand capitalized costs.
- Loss after tax amounted to SEK -67,730 (-31,006) thousand.
- Loss per share amounted to SEK -1.12 (-1.00).

Significant events during the fourth quarter

- 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 of the PULSE study were presented at the prestigious British Society of Breast Radiology's (BSBR) annual scientific meeting. The study shows that NeoNavia can be successfully and widely used for sampling in the axilla with a low frequency of side effects. The data is unique and has aroused great interest.

Significant events after the end of the period

- 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, held May 16-19, 2022. The symposium is considered the most important annual meeting for breast radiologists in the U.S.
- Aaron Wong took over as CFO on February 1, 2022. Aaron Wong most recently came from a similar position at the medical technology company ADDvise Group AB.
- The Board decided on a new share issue to shareholders of approximately SEK 69.3 million, which is fully secured through subscription commitments and underwriting undertakings. The issue is conditional on the approval of an Extraordinary General Meeting.
- The Board has convened an Extraordinary General Meeting on February 25 to resolve on issues related to the rights issue and to decide on an incentive program and bonuses for employees.

CEO COMMENT

NeoNavia® is gaining ground step by step

Our introduction of NeoNavia in Germany and other German speaking countries, the United Kingdom and Sweden continues, and we are meeting a strong interest from radiologists and gynecologists.

Good impact on scientific meetings

The interest from the profession is also reflected in that we are being selected to present at prestigious radiologist meetings. In the fourth quarter, the first results from the PULSE study were presented at the British Society of Breast Radiologists' annual scientific meeting. The study shows that NeoNavia can successfully, and with a low occurrence of side effects, be used widely in both very difficult and more clear-cut sampling in the axilla - which is a strong argument for choosing NeoNavia over exisiting products on the market. As this data is unique in the scientific world and has great relevance to clinical practice, it has attracted a significant amount interest. At the beginning of the year, the results of a subgroup in the PULSE study with particularly challenging biopsy conditions was accepted for oral presentation at the most important U.S. breast radiologist meeting, SBI / ACR (Society of Breast Imaging / American College of Radiologists), and their Breast Imaging Symposium held in Savannah, Georgia, in early May. Oral presentation is an opportunity that is only offered to the few, and is usually meet with a great deal of interest from the conference participants.

The US introduction draws near

This presentation at SBI / ACR is expected to underpin the planned introduction of NeoNavia in the US. The registration application is planned to be submitted to the FDA within the next few weeks, and an approval of NeoNavia in the US may follow a few months after submission of the documentation. Together with specialist consultants, we have prepared a high quality registration application, which we expect will facilitate a smoother process with the authorites. The aim is to minimize the subsequent interaction with the authorities in order to reduce the risk of pandemic-related delays. Once the product is registered, it can start to be marketed within a reasonable preparation time since the product already has codes and compensation in place for similar products, unlike pharmaceuticals where you in practice need to wait for decisions on various insurance claims.

As the pandemic has flared up again we have encountered delayes our processes, both in the registration application in the USA and in the launch. However, this does not mean at all that the business is at a standstill.

NeoDynamics is undergoing a transformation

The study version of NeoNavia that was created in 2016, has been used in the clinical studies that are now published and gives us traction in the launch of the innovative biopsy technology. Late in 2019, a commercial version of NeoNavia with three needle types was CE approved. This version began to be presented to the market in the spring of 2020. After some intital fine-tuning, the system and needles can now be delivered in commercial form and in volume. A transfer of our needle production to Asia will be completed during the spring, lowering the production cost of these disposable needles.

We are currently working on the financing for the continued launch of NeoNavia in Europe, to prepare for the launch in the U.S. and to begin registration work in China, as well as to complete the clinical development program with NeoNavia. A small part of the planned fund raising will finance continued work with product development, both to strengthen our current offering with a tissue marker as well as to expand the use of NeoNavia from breast cancer to other cancers. We have good support from major shareholders in these efforts.

I look forward to an eventful 2022!

CEO Anna Eriksrud

Financial overview

Revenue and earnings

Revenues during the quarter amounted to a total of SEK 930 (3,382) thousand and for the full year to SEK 2,085 (18,558) thousand, of which net sales amounted to SEK 839 (0) thousand and SEK 1,162 (0) thousand, respectively. In 2021, all current costs for the NeoNavia system have been taken directly via the income statement, which is why only development costs for the marker project have been capitalized. Capitalized costs for product development during the quarter amounted to SEK 0 (2,963) thousand and for the full year to SEK 785 (17,104) thousand.

External costs during the quarter amounted to SEK 11,355 (10,502) thousand and for the full year to SEK 36,385 (34,641) thousand and consisted mainly of costs for sales, clinical studies, and product development. Personnel costs decreased during the quarter to SEK 2,672 (3,766) thousand and for the full year to SEK 9,698 (12,381) thousand, an effect of several employees being replaced by consultants.

Cost of goods during the quarter amounted to SEK 1,533 (0) thousand and for the full year to SEK 5,772 (0). Depreciation increased during the quarter to SEK 4,484 (98) thousand and during the full year to SEK 17,841 (454) thousand and relates essentially to the development costs for NeoNavia that have been accumulated up to and including 2020.

Operating profit during the quarter amounted to SEK -19,134 (-11,022) thousand and for the full year to SEK -67,730 (-29,032) thousand. EBITDA, ie operating profit excluding depreciation, amounted to SEK -14,650 (-10,924) thousand for the quarter and to SEK -49,889 (-28,578) thousand for the full year.

Financial position

Cash and cash equivalents at the turn of the year amounted to SEK 24,710 (73,250) thousand. Cash flow from operating activities before changes in working capital during the full year amounted to SEK -50,388 (-30,552) thousand and summed after changes in working capital to SEK -46,846 (-36,457) thousand. Cash flow from investing activities was SEK -1,694 (-17,462) thousand. The total cash flow amounted to SEK -48,540 (66,991) thousand.

At the turn of the year, the equity to assets ratio was 90 (97) percent and equity amounted to SEK 97,553 (165,554) thousand.

Capital requirement

The Board assesses that the company's capital needs is met up to and including the first quarter of 2022, after which the company needs additional funding to complete its business plan. The Board has therefore decided on a rights issue of approximately SEK 69.3 million, which is fully secured through subscription commitments and underwriting undertakings. The rights issue is subject to approval by the Extraordinary General Meeting.

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. Among other things, in certain markets, contacts with customers and thus the introduction of the product are made more difficult, but also the opportunity to recruit and start 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.

Dividend

The Board proposes that no dividend be paid for 2021.

Annual general meeting and annual report

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.

The share

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

On December 30, 2021, the number of shares in NeoDynamics AB amounted to 60,250,592. The share closed the year at a price of SEK 1.76, a decrease of 53 percent from SEK 3.75 at the previous turn of the year.

Owners

The 10 largest owners at 31 Dec 2021	Number of shares	Ownership
Huasheng Fang	6 815 948	11.3%
NKY Sweden AB (Boai)	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	2 925 079	4.9%
Cardeon AB	2 803 234	4.7%
Avanza Pension, Försäkringsbolaget	2 516 035	4.2%
Quiq Holding AB	1 347 708	2.2%
Rentability Sweden AB	1 008 245	1.7%
Others	26 994 127	44.8%

Financial calendar

Interim report Jan-Mar	2022-05-12
Annual General Meeting	2022-05-19
Half-year report Jan-June	2022-08-18
Interim report Jan-Sept	2022-11-17

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 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 February 16, 2022

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

NeoDynamics AB 559014–9117

For further information, please contact

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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 February 16, 2022, at 8.30 CET.

Income statement

Amounts in SEK thousands	2021 Oct-Dec	2020 Oct-Dec	2021 Full year	2020 Full year
Revenue				
Net sales	839	0	1 162	0
Work performed by the Company for its own use and capitalized	0	2 963	785	17 104
Other operating income	91	419	138	1 454
	930	**3 382**	**2 085**	**18 557**
Operating expenses				
Cost of goods	-1 533	0	-5 772	0
Other external costs	-11 355	-10 502	-36 385	-34 641
Personnel costs	-2 672	-3 766	-9 698	-12 381
Depreciation/amortization of tangible and intangible assets	-4 484	-98	-17 841	-454
Other operating expenses	-20	-38	-120	-114
OPERATING LOSS	**-19 134**	**-11 022**	**-67 730**	**-29 032**
Financial items				
Financial income	0	0	0	0
Financial costs	0	-502	0	-1 974
Net financial items	**0**	**-502**	**0**	**-1 974**
Loss after financial items	**-19 134**	**-11 524**	**-67 730**	**-31 006**
Loss before tax	**-19 134**	**-11 524**	**-67 730**	-31 006
Tax	0	0	0	0
Net loss	**-19 134**	**-11 524**	**-67 730**	**-31 006**
EARNINGS PER SHARE BEFORE DILUTION, SEK (no dilution)	**-0.32**	**-0.28**	**-1.12**	-0.51
Number of shares at end of period	60 250 592	36 006 951	60 250 592	60 250 592
Average number of shares	60 250 592	60 250 592	60 250 592	30 958 542
	60 250 592	41 868 051	60 250 592	

Balance sheet

Amounts in SEK thousands	31 Dec 2021	31 Dec 2020
ASSETS		
Fixed assets		
Intangible assets	70 997	87 597
Tangible assets	1 494	1 299
Financial assets	370	112
	72 861	**89 008**
Current assets		
Inventory, etc	2 545	1 810
Receivables	7 765	7 225
Cash and cash equivalents	24 710	73 250
	35 020	**82 285**
TOTAL ASSETS	**107 881**	**171 292**
EQUITY AND LIABILITIES		
Restricted Equity		
Share capital	6 025	6 025
Fund for development expenditure	70 956	82 460
	76 981	**88 485**
Unrestricted Equity		
Share premium reserve	247 440	248 179
Profit/loss brought forward	-159 138	-140 104
Profit/loss for the year	-67 730	-31 006
	20 572	**77 069**
TOTAL EQUITY	**97 553**	**165 554**
Long term debt		
Other long-term liabilities	240	0
Short term liabilities		
Accounts payable	327	327
Current tax liabilities	4 789	1 275
Other current liabilities	194	1 075
Accrued expenses and deferred income	4 778	3 061
TOTAL LIABILITIES	**10 328**	**5 738**
TOTAL EQUITY AND LIABILITIES	**107 881**	**171 292**

Cash flow analysis

Amounts in SEK thousands	2021 Oct-Dec	2020 Oct-Dec	2021 Full year	2020 Full year
Operating activities				
Loss after financial items	-19 134	-11 524	-67 730	-31 006
Adjustments for items not included in cash flow	4 636	98	17 342	454
Cash flow from operating activities before changes in working capital	**-14 498**	**-11 426**	**-50 388**	**-30 552**
Cash flow from changes in operating capital				
Increase (-) /decrease (+) in inventory	-453	-1 810	-736	-1 810
Increase (-) /decrease (+) in receivables	-2 214	-947	-884	-3 567
Increase (-) /decrease (+) in operating liabilities	5 196	388	5 162	-528
CASH FLOW FROM OPERATING ACTIVITIES	**-11 970**	**-13 795**	**-46 846**	**-36 457**
Investing activities				
Acquisition of intangible assets	0	-2 963	-785	-17 103
Acquisition of tangible assets	-425	-359	-651	-359
Acquisition of financial assets	-247	0	-258	0
Cash flow from investing activities	**-673**	**-3 322**	**-1 694**	**-17 462**
Financing activities				
Share issue	0	86 881	0	141 412
Changes in loans	0	0	0	-20 502
Cash flow from financing activities	**0**	**86 881**	**0**	**120 911**
CASH FLOW	**-12 642**	**69 764**	**-48 540**	**66 991**
Cash at the beginning of the year	37 352	3 486	73 250	6 258
Cash at the end of the year	24 710	73 250	24 710	73 250

Key figures

	Q1 2020	Q2 2020	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021
Sales, SEK thousands	0	0	0	0	22	0	300	839
Operating loss, SEK thousands	-5 738	-5 541	-6 731	-11 022	-17 261	-18 263	-13 066	-19 134
Operating margin, %	neg	neg	neg	neg	neg	neg	neg	Neg
Balance sheet total, SEK thousands	113 108	95 321	95 981	171 292	156 886	136 981	122 242	107 881
Equity ratio, %	78%	94%	94%	97%	94%	95%	95%	90%
Cash, SEK thousands	23 048	7 177	3 486	73 250	62 278	48 339	37 352	24 710
Earnings/loss per share, SEK	-0.41	-0.18	-0.19	-0.28	-0.29	-0.30	-0.22	-0.32
Equity per share, SEK	2.89	2.68	2.52	2.75	2.46	2.15	1.93	1.62

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

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. 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.

Immaterial 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 400 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. P086. 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.