NeoDynamics AB (publ)
First quarter report 2021

01-01-2021 – 03-31-2021

neodynamics

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

Introduction underway

First Quarter 2021

- Revenue amounted to SEK 405 (6,269) thousand, of which SEK 378 (6,303) thousand were capitalized costs.
- Cash flow from operating activities amounted to SEK -10,510 (-9,534) thousand.
- Loss after tax amounted to SEK -17,261 (-7,235) thousand.
- Loss per share SEK -0.29 (-0.41).
- The equity / assets ratio was 94 (78) percent.

Significant events during the quarter

- The European Patent Office EPO issued a European patent for the company's pulse biopsy instrument, including a multifunctional handset that can be used for several different types of biopsy needles.
- In March, Dr. Stefan Paepke presented preclinical results with NeoDynamic's innovative biopsy system, which show that tissue samples taken with all of NeoNavia's three needle types provide significantly larger tissue samples than today's “gold standard” techniques achieve.
- The development work of NeoDynamics marker, the company's second project after NeoNavia, is increasing in scope.

Significant events after period-end

- NeoDynamics has received an approval for a scientific abstract, to be presented at the annual surgery conference ABS, Association of Breast Surgeons, in Birmingham, describing how the company's FlexiPulse needle surpasses standard biopsy in preclinical models by almost 300 percent in terms of volume.

CEO COMMENT

Introduction underway

The commercialization of the pulse biopsy system NeoNavia has begun. Clinics in Germany, England and Sweden are evaluating the system in their own environment, on their own patients and experience the difference compared to the systems they have used so far. The feedback we receive is positive from both the radiologist and the person evaluating the sample, i.e., the pathologist.

Step by step introduction and launch

The strategy NeoDynamics has chosen is to focus on the most important clinics in the UK, Sweden, and Germany. We make sure that these top clinics feel safe with how the product is to be used and that they are also willing to pass on this knowledge to all doctors at their own clinic as well as at other clinics. We are sensitive to the clinics' experiences of using the product in clinical everyday life and make minor adjustments. In this way, we build trust in the product and pave the way for wider use in the long run. Our goal is to have run workshops with NeoNavia at the most important clinics within ultrasound lead biopsy this spring and summer provided that the pandemic allows us. In parallel, we expect that the purchasing processes will be in place and first orders will follow. These well-known clinics will be our reference clinics that can convince others to follow their example and we expect sales to follow later in the year.

FDA registration

We continue the work with our documentation for the registration file in dialogue with the FDA. As we have said earlier, the work with our registration file has also been affected by the pandemic, among other things through the authority's focus on and allocation of resources to covid-related applications. We expect to submit the application to the FDA in the autumn of 2021. The submission date is important, but even more important is the quality of the file we submit.

This is where the dialogue with the authorities comes in to guide us so that what we submit is what the FDA expects to see. If we succeed in this, the processing time for the file

can be considerably shorter. What we do is a 510 (k) registration, which is a less complicated procedure than a drug approval.

The registration in the USA is a milestone for NeoDynamics and the product. It opens up a very large market and strengthens NeoDynamics' position in relation to potential partners. A US registration also lays a good foundation for an approval in China, which is the next country in line for NeoNavia.

A unique marker for ultrasound

In parallel with NeoNavia, we have also worked on developing a marker. Markers are inserted during biopsy to make it easier to follow how the tumor develops during treatment and are removed when the patient has completed treatment. It is a product that is well suited to sell together with NeoNavia. There are several different markers today, that can be seen on X-rays, but no commercially available marker that can be seen well enough on ultrasound. The idea to create the marker was born by one of the USA's foremost ultrasound specialists who also supports us in the development work. We expect to be able to complete the design phase at the end of the year.

I look forward to a continued eventful 2021.

CEO Anna Eriksrud

Financial overview

Revenue and earnings

The fact that the company has begun the commercialization of NeoNavia results in that development costs for this product no longer are capitalized but instead depreciated. This is reflected in lower revenues and higher depreciation, affecting operating earnings but not cash flow.

Net sales amounted to SEK 22 (0) thousand, which is attributable to the sale of needles to the initial customer. Capitalized costs for product development are attributed only to the marker and amounted to SEK 378 (6,303) thousand of the reported revenues of SEK 405 (6,269) thousand.

Depreciation increased to SEK 4,449 (158) thousand and is essentially attributable to development costs for NeoNavia. External costs decreased to SEK 8,959 (9,129) thousand and consisted mainly of costs for sales, clinical studies and product development. Personnel costs were marginally lower than the previous year, SEK 2,655 (2,692) thousand.

Operating loss amounted to SEK -17,261 (-5,738) thousand. EBITDA, ie operating loss excluding depreciation, amounted to SEK -12,812 (-5,580) thousand. Loss for the period amounted to SEK -17,261 (-7,235) thousand and earnings per share to SEK -0.29 (-0.41).

Financial standing

Cash and cash equivalents amounted to SEK 62,278 thousand (SEK 73,250 thousand at the turn of the year).

Cash flow from operating activities before changes in working capital amounted to SEK -13,020 (-12,829) thousand, while changes in working capital was SEK -10,510 (-9,534) thousand. The difference mainly consists of a planned increase in inventories of SEK 1,651 (0) thousand prior to the relocation of production to Asia during the second part of 2021. Cash flow for the period totaled SEK -10,972 (16,790) thousand.

At the end of the period, the equity / assets ratio was 94 percent, compared with 97 percent at the turn of the year. Equity amounted to SEK 148,085 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 is currently launching the NeoNavia biopsy system in the UK, Sweden and Germany. The company plans to file a regulatory application with the FDA in the United States in the fall of 2021 and then begin filing for registration in China. Development costs are expected to be significantly lower in 2021 than in 2020, while sales and marketing costs are expected to be significantly higher.

Effects of Corona Pandemic

The business is affected by the pandemic in several ways, among other things by making contacts with customers more difficult and thus the introduction of the product, and by delaying various types of studies. The company follows the development 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 ticker is “NEOD” and ISIN code is SE0011563410. On March 31, 2021, the number of shares in NeoDynamics AB amounted to 60,250,592. The share closed at the end of the quarter at a price of SEK 2.87, a decrease of 23 percent from SEK 3.75 at the turn of the year.

Owners

The 10 largest owners March 31, 2021

	Number of shares	Ownership
Huasheng Fang	6 815 948	11,3%
Boai NKY Medical Holdings (Kina), via NKY Sweden AB	4 922 544	8,2%
Cardeon AB and its management	4 070 077	6,8%
Gryningskust Holding AB	3 873 169	6,4%
Sebastian Jahreskog	3 623 604	6,0%
M2 Capital Management & M2 Asset Management	3 010 882	5,0%
Nordnet Pensionsförsäkring AB	3 009 901	5,0%
Försäkringsbolaget Avanza Pension	2 509 501	4,2%
Quiq Distribution Holding AB	1 347 708	2,2%
Rentability Sweden AB	970 245	1,6%
Others	26 097 013	43,3%

Annual general meeting

The annual general meeting will be held on 28 May, 2021. The annual report for 2020 is available for download at the company's website www.neodynamics.com.

Financial calendar

Half Year Report Jan-Jun	Aug 19, 2021
Interim Report Jan-Sep	Nov 17, 2021

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.

First quarter report submitted

The Board of Directors and the CEO hereby certify that the first quarter report 2021 provides a true and fair view of NeoDynamics' operations.

Lidingö, May 19, 2021

Anna Eriksrud	Ingrid Salén	Jessie Bao	Ulf Boberg
CEO	Chairman of the Board	Board member	Board member
Carina Bolin	Claes Pettersson	Xiaojun Xu	
Board member	Board member	Board member	

NeoDynamics AB 559014–9117

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Income statement

(SEK thousand)	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Revenue			
Net sales	22	0	0
Work performed by the Company for its own use and capitalized	378	6 303	17 104
Other operating income	5	-34	1 454
	405	**6 269**	**18 557**
Operating expenses			
Cost of goods	-1 554	0	0
Other external costs	-8 959	-9 129	-64 641
Personnel costs	-2 655	-2 692	-12 381
Depreciation/amortization of tangible and intangible assets	-4 449	-158	-454
Other operating expenses	-49	-28	-114
OPERATING LOSS	**-17 261**	**-5 738**	**-29 032**
Financial items			
Financial income	0	0	0
Financial costs	0	-1 496	-1 974
Net financial items	**0**	**-1 496**	**-1 974**
Loss after financial items	**-17 261**	**-7 235**	**-31 006**
Loss before tax	**-17 261**	**-7 235**	**-31 006**
Tax	0	0	0
Net loss	**-17 261**	**-7 235**	**-31 006**
EARNINGS PER SHARE BEFORE DILUTION, SEK (no dilution)	**-0.29**	**-0.41**	**-0.51**
Number of shares at end of period	60 250 592	30 607 040	60 250 592
Average number of shares	60 250 592	17 489 737	30 958 542

Balance sheet

Amounts in SEK thousands	31 Mar 2021	31 Mar 2020	31 Dec 2020
ASSETS			
Fixed assets			
Intangible assets	83 629	77 240	87 597
Tangible assets	1 269	1 225	1 299
Financial assets	123	112	112
	85 020	**78 577**	**89 008**
Current assets			
Inventory, etc	3 460	213	1 810
Receivables	6 127	11 269	7 225
Cash and cash equivalents	62 278	23 048	73 250
	71 866	**34 530**	**82 285**
TOTAL ASSETS	**156 886**	**113 108**	**171 292**
EQUITY AND LIABILITIES			
Restricted Equity			
Share capital	-6 025	-3 061	-6 025
Fund for development expenditure	-78 496	-72 092	-82 460
	-84 521	**-75 153**	**-88 485**
Unrestricted Equity			
Share premium reserve	-247 971	-149 890	-248 179
Profit/loss brought forward	167 146	129 303	140 104
Profit/loss for the year	17 261	7 235	31 006
	-63 564	**-13 353**	**-77 069**
TOTAL EQUITY	**-148 085**	**-88 506**	**-165 554**
Long term debt			
Other long-term liabilities	-327	0	-327
Short term liabilities			
Accounts payable	-4 072	-5 689	-1 275
Current tax liabilities	-109	-59	-62
Other current liabilities	-646	-16 111	-1 013
Accrued expenses and deferred income	-3 647	-2 744	-3 061
TOTAL LIABILITIES	**-8 801**	**-24 602**	**-5 738**
TOTAL EQUITY AND LIABILITIES	**-156 886**	**-113 108**	**-171 292**

Cash flow analysis

SEK thousands	2021 Jan-Mar	2020 Jan-Mar	2020 Jan-Dec
Operating activities			
Loss after financial items	-17 261	-7 235	-31 006
Adjustments for items not included in cash flow	4 241	-5 594	454
Cash flow from operating activities before changes in working capital	**-13 020**	**-12 829**	**-30 552**
Cash flow from changes in operating capital			
Increase (-) /decrease (+) in inventory	-1 651	0	-1 810
Increase (-) /decrease (+) in receivables	957	-140	-3 567
Increase (-) /decrease (+) in operating liabilities	3 203	3 434	-528
CASH FLOW FROM OPERATING ACTIVITIES	**-10 510**	**-9 534**	**-36 457**
Investing activities			
Acquisition of intangible assets	-378	-6 303	-17 104
Acquisition of tangible assets	-73	0	-359
Acquisition of financial assets	-10	0	0
Cash flow from investing activities	**-461**	**-6 303**	**-17 462**
Financing activities			
Share issue	0	45 911	141 412
Changes in loans	0	-13 284	-20 502
Cash flow from financing activities	**0**	**32 627**	**120 911**
CASH FLOW	**-10 972**	**16 790**	**66 991**
Cash at the beginning of the year	**73 250**	**6 258**	**6 258**
Cash at the end of the year	**62 278**	**23 048**	**73 250**

Key figures

	2021 Jan-Mar	2020 Jan-Mar	2020
Sales, SEK thousands	22	0	0
Operating loss, SEK thousands	-17 261	-5 738	-29 032
Operating margin, %	neg	neg	neg
Balance sheet total, SEK thousands	156 886	113 108	171 292
Equity ratio, %	94	78	97
Cash, SEK thousands	62 278	23 048	73 250
Earnings/loss per share, SEK	-0.29	-0.41	-0.51
Equity per share, SEK	2.46	2.89	2.75

Warrant programs – 2018/2021 and 2020/2023

The company has implemented two incentive programs aimed at senior executives in the company. The Board's ambition is to propose the issuance of warrants or equivalent up to a maximum total dilution of 5%.

In 2018, 550,000 warrants were issued with the right for holders to for each option subscribe for one (1) share with a subscription price of SEK 10.50 during the period October 1-31, 2021. 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.

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. Design-specific patents for the needle designed by NeoDynamics have already been approved in Europe, the US and China. The patent is 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