



NeoDynamics AB (publ.)
First quarter report 2020

01-01-2020 - 03-31-2020

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

First Quarter 2020

Somewhat higher development cost, but mainly in line

First Quarter 2020

- There were no sales in the period. Revenue amounted to SEK 6.929 m (5.420 m) including capitalized costs of SEK 6.3030 m (5.418 m)
- Loss after tax amounted to SEK -7.235 m (-4.134 m)
- Loss per share amounted to SEK -0.41 (-0.27)
- The solvency ratio was 78 per cent

Significant events during the quarter

- The Extraordinary General Meeting on January 28, 2020 resolved on a rights issue of 15,303,520 shares, each share entitling to subscribe for a new share for SEK 3. The issue was oversubscribed and a large number of new shareholders were added. The Extraordinary General Meeting also resolved to change the conversion price per share for the Company's convertibles from SEK 4 to SEK 3, and authorized the Board to issue shares with or without preference for existing shareholders until the Annual General Meeting.
- The company received notice from the Chinese patent authority about the patent granted for biopsy instruments, which is an important component of the NeoNavia® biopsy system.
- An abstract from a clinical breast study conducted at the New Karolinska Hospital was approved for presentation at the American Breast Radiology, Congress Society of Breast Imagings (SBI) meeting in April in the United States. The congress was canceled due to the global pandemic, but the presentation of the study is planned to be carried out at a later date.
- The impact of the Corona pandemic has been relatively limited so far. International scientific meetings where the company should have had the chance to meet customers have been canceled. The pandemic has also caused minor delays in production and material supply, which has resulted in the company's inventory of launch products not coming into place until September. The sales process at key clinics will be commencing before that.

Significant events after period-end

- As a consequence of restrictions due to the pandemic, the company did not receive payment of approximately SEK 7.7 million for subscribed convertibles when the convertible bond issue, decided in the second half of 2019, was registered in March 2020. The investor instead subscribed for shares in a directed share issue with subscription price 3 SEK decided in April under mandate from the Extraordinary General Meeting.
- In April, the Board of Directors decided to convert all outstanding convertibles into shares.
- Following the resolutions on a directed issue and conversion, the share capital will, after the forthcoming registration of the directed issue and conversion, amount to SEK 3,600,695.10 divided into 36,006,951 shares.

NeoNavia closer to launch

As planned, NeoDynamics started the year by completing the development of the biopsy system NeoNavia. For the second half of the year, focus will shift to the launch of NeoNavia for use in breast cancer diagnostics.

The outbreak of covid-19 has negatively affected NeoDynamics alike many other companies, mainly by complicating the logistics of production, making visits to hospitals impossible and by delaying our ongoing clinical trials. Despite the prevailing situation, we have a clear advantage of having a very solid launch and sales strategy which is based on long-term contacts with study and reference clinics.

The most obvious consequence of the Corona pandemic is a minor delay in the production of our biopsy needles. We have now rectified this and currently assess that delivery of products will be possible straight after summer. In conjunction with the delay, the development costs have been somewhat higher than expected.

The second consequence is that studies conducted in Europe are delayed since there are fewer breast cancer patients in hospitals as clinics have been forced to prioritize resources and postpone planned studies. We are currently seeing a brightening with for example the British healthcare system, NHS, recently stating that cancer diagnostics and care should reopen at the end of June. The Swedish authorities followed suit with a similar message. An adequate diagnosis early in the course of the disease is commonly believed to save lives. Therefore, the cancer area is a priority when covid-19 closed activities are reopened.

Unlike studies in drug development, our clinical studies with NeoNavia are not necessary for the launch of the product. They are however important for building relationships and demonstrating the company's seriosity, as well as for creating customer knowledge and experience on how NeoNavia can be used in clinical practice.



Work on our US regulatory application is progressing, and the application will be submitted during the fall. As the US launch gets closer, work on the Chinese application is starting to take shape, and an FDA approval is likely to be a door opener with the Chinese regulatory authority.

As earlier mentioned, NeoDynamics is in very active dialogue with many clinics to prepare for the launch of NeoNavia in Europe during the fall. Despite not being able to visit them during the pandemic, we have several reference and training centers in place. These will serve as support for clinics that start using NeoNavia for the first time when the commercial product is launched. These reference clinics are already building up their knowledge about the product through participation in our study program. To become a reference center, they naturally also need our new biopsy system, which is why we initially will prioritize sales and deliveries to these clinics.

The financial position was strengthened during the quarter through a successful share issue raising SEK 45.9 million before issue costs. Since the issue was oversubscribed, the company did not need to call on the underwriters. We also increased the number of shareholders in connection with the share issue, which together with the oversubscription indicates a growing interest in the company.

We continue our work to commercialize the NeoNavia biopsy system and on our long-term objective to improve the diagnosis and treatment of breast cancer and other forms of cancer.

CEO Anna Eriksrud

Financial overview

First quarter 2020

During the period January - March 2020, the company has largely developed according to plan, where the main costs are attributable to product development, clinical studies and personnel. NeoDynamics applies a policy of activating development costs to intangible assets, but not staff costs. These intangible assets will start to be amortized when the sale of NeoNavia starts.

Revenue

During the quarter, the Company had no sales of products. Capitalized expenses accounted for SEK 6.303 m (5.418 m) of reported revenue of SEK 6.269 m (5.420 m).

Earnings/loss

The loss after depreciation amounted to SEK -5.580 m (-3.968 m). External costs increased to SEK -9.129 m (-6.963 m) mainly comprising costs related to clinical studies and product development. Personnel costs were SEK -2.692 m (-2.411 m), partly as a result of an increase in the number of employees. Loss for the quarter before and after tax amounted to SEK -7.235 m (-4.134 m) during the quarter.

Financial position

At the end of March, the equity ratio was 78 percent, compared with 60 percent at year-end. Shareholders' equity amounted to SEK 88.506 m, compared with SEK 55.581 m at year-end. Cash and cash equivalents amounted to SEK 23.048 m (6.258 m at year-end). The rights issue provided approximately SEK 40 m after issue costs and following the amortization of loans and expenses during the quarter, cash amounted to just over SEK 23 m at the end of March. Total assets were SEK 113.108 m (92.349 m at year-end).

Capital requirements

The working capital requirement in 2020, will be met by available liquid funds and the directed share issue decided in April. The Board of Directors has proposed the Annual General Meeting, to be held on May 28, to authorize the Board of Directors to carry out further directed issues.

Outlook

The company is finalizing verification and validation of the NeoNavia biopsy system and is preparing to launch the product in Europe during the second half of the year. The company plans to submit a regulatory application to the FDA in the US this fall. Development costs are expected to fall sharply in the second half of the year, while sales and marketing costs are expected to rise.

The share

NeoDynamics AB's share is listed on Spotlight Stock Market since December 7, 2018. The share's ticker code is "NEOD" and the ISIN code is SE0011563410. As of March 31, 2020, the number of shares in NeoDynamics AB was 30,607,040 (15,303,520 at year-end). Following a decision in April on conversion to shares of outstanding convertibles, the number of shares will increase to 33,445,612. The directed issue of shares will increase the total by an additional 2,561,339 shares to 36,006,951.

Owners

The table below shows the shareholdings and the share of votes and capital of the 10 largest shareholders in NeoDynamics AB at the end of March 2020.

1	NKY Sweden AB (Boai NKY Medical Holdings Ltd)	4 922 544	16.08%
2	Huasheng Fang	3 333 333	10.89%
3	M2 Capital Management AB	2 556 914	8.35%
4	Gryningskust Holding AB	1 829 800	5.98%
5	Rentability Sweden AB	687 442	2.25%
6	ADB Invest AB	631 497	2.06%
7	Humlan Fastighetsutveckling AB	620 082	2.03%
8	Jörgen Vrenning	611 764	2.00%
9	Claes Pettersson	485 668	1.59%
10	Salenterprise AB	462 320	1.51%

Annual general meeting

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

Dividend

The Board and CEO propose no dividend for the year 2020.

Financial calendar

Annual general meeting	28 May, 2020
Half Year Report Jan-Jun	21 Aug, 2020
Interim Report Jan-Sep	19 Nov, 2020

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 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 2020 provides a true and fair view of NeoDynamics' operations.

Lidingö, May 26, 2020

Anna Eriksrud
CEO

Ingrid Salén
Chairman of the board

Ulf Boberg
Board member

Carina Bolin
Board member

Claes Pettersson
Board member

Xiaojun Xu
Board member

NeoDynamics AB, 559014-9117

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Income statement

(SEK thousand)	2020 Jan-Mar	2019 Jan-Mar	2019
Revenue	-44	0	0
Net sales	6 303	5 418	22 220
Work performed by the Company for its own use and capitalized	10	2	490
Other operating income	6 269	5 420	22 710
Operating expenses			
Other external costs	-6 963	-5 412	-32 426
Personnel costs	-9 129	-6 963	-31 332
Depreciation/amortization and impairment of tangible and intangible assets	-2 692	-2 411	-9 151
Other operating expenses	-158	-134	-600
	-28	-14	-67
OPERATING INCOME	-5 738	-4 102	-18 442
Financial items			
Financial income	0	0	0
Financial costs	-1 496	-31	-540
Net financial items	-1 496	-31	-540
Profit after financial items	-7 235	-4 134	-18 982
Profit before tax	-7 235	-4 134	-18 982
Tax	0	0	0
Net profit	-7 235	-4 134	-18 892
Earnings per share before dilution, SEK (no dilution)	-0.41	-0.27	-1.23
Number of shares at end of period	15 303 520	6 908 000	8 741 198
Average number of shares	17 489 737	15 303 520	15 303 520

Balance sheet

(SEK thousands)	31-Mar-20	31-Dec-19
ASSETS		
Fixed assets		
Intangible assets	77 240	70 974
Tangible assets	1 225	1 346
Financial assets	112	112
	78 577	72 433
Current assets		
Inventory, etc	213	361
Receivables	11 269	13 297
Cash and cash equivalents	23 048	6 258
	34 530	19 917
TOTAL ASSETS	113 108	92 349
EQUITY AND LIABILITIES		
Restricted Equity		
Share capital	-3 061	-1 530
Fund for development expenditure	-72 092	-65 789
	-75 153	-67 320
Unrestricted Equity		
Share premium reserve	-149 890	-111 261
Profit/loss brought forward	129 303	104 018
Profit/loss for the year	7 235	18 982
	-13 353	11 739
TOTAL EQUITY	-88 506	-55 581
Short term liabilities		
Accounts payable	-5 689	-2 177
Other current liabilities	-16 169	-31 666
Accrued expenses and deferred income	-2 744	-2 925
TOTAL LIABILITIES	-24 602	-36 768
TOTAL EQUITY AND LIABILITIES	-113 108	-92 349

Key figures

	2020 Jan-Mar	2019 Jan-Mar	2019
Sales, SEK thousands	-44	0	0
Operating income, SEK thousands	-5 738	-4 102	-18 442
Operating margin, %	neg	neg	Neg
Balance total, SEK thousands	113 108	74 750	92 349
Equity ratio, %	78	94	60
Cash, SEK thousands	23 048	15 329	6 258
Earnings/loss per share, SEK	-0.41	-0.27	-1.23
Equity per share, SEK	2.89	4.60	3.63

Warrant program – 2018/21

In 2018, the company issued 550,000 warrants to senior executives in the company with the right for the holders to subscribe for one share for each warrant, at a price per share with the original subscription price of SEK 10.50, no later than October 31, 2021. Both the number of shares and the subscription price for outstanding warrants are subject to conversion according to terms and conditions, available at 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 micro-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. NeoNavia® is being evaluated at leading clinics in the UK, Germany and Sweden. A commercial launch is expected in 2020.

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.¹

NeoNavia – a unique biopsy system

NeoNavia is the brand name 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 micro-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 micro-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.

Patent rights

NeoNavia's micro-pulse technology has received a 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 will run 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 new 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 micro-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>

