



NeoDynamics AB (publ.)
Full-year report 2019

01-01 2019 - 31-12-2019

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

Fourth quarter 2019

- Revenue amounted to SEK 6.381 (9.104) m whereof SEK 6.007 (9.019) m were capitalized costs.
- Profit after tax amounted to SEK -6.390 (-8.598) m.
- Earnings per share amounted to SEK -0.42 (-0.72).

Full-year 2019

- Revenue amounted to SEK 22.710 (24.978) m whereof SEK 22.220 (24.877) m were capitalized costs.
- Profit after tax amounted to SEK -18.982 (-18.200) m.
- Earnings per share amounted to SEK -1.24 (-2.08).
- Equity per share was SEK 3.63 (4.87).
- The equity/assets ratio was 60 (90) percent.

Significant events during the fourth quarter

- In October the company obtained regulatory approval in the EU for the NeoNavia biopsy system.
- The company signed an agreement to manufacture biopsy products with FDA-approved Asian companies.
- The Board of Directors proposed a rights issue of SEK 45.9 million, in which each share entitles to subscribe for a new share for SEK 3, and called for an Extraordinary General Meeting to make the necessary decisions.
- In December, the company signed a loan facility of a maximum of SEK 14 million.
- The warrants program 2018/19 TO was terminated without subscription..

Significant events after the end of the period

- An Extraordinary General Meeting on January 28 resolved on a rights issue of shares corresponding to SEK 45.9 million.
- NeoDynamics AB (publ) received notification of a granted patent on biopsy instruments in China.
- An abstract from a clinical breast study conducted at New Karolinska has been approved for presentation at the American Breast Radiology Congress Society of Breast Imaging (SBI) meeting in April in the United States.

Summing up a productive 2019

NeoDynamics has now closed the fiscal year 2019, a very productive year is summed up, which ended with the presentation of a fully guaranteed rights issue that will raise approximately SEK 46 million. Thereby, NeoDynamics is very well prepared for the launch of the Neonavia biopsy system in 2020.

At the end of October, an important piece of the puzzle came into place with the approval for marketing of NeoNavia with three micropulse-driven needle types in the EU. NeoDynamics can thus offer radiologists a complete range of precision needles for all types of ultrasound-guided biopsy.

It also stands clear that a so-called 510 (k) application is sufficient for the sale of NeoNavia in the US, which is a less complex procedure than an application for a completely new product. This reduces the risk of delays in the schedule. Compiling the file for a US approval with a submission in the middle of the year is proceeding as planned.

At the end of November, an agreement was signed for the production of the system's disposable biopsy needles. The agreement was signed with an FDA approved Asian manufacturer and means that the needles will be manufactured at competitive costs. This is of course also an important puzzle piece before the launch of NeoNavia in the middle of the year.

In December, NeoNavia was exhibited for the first time to American radiologists at the annual meeting of the Radiologic Society of North America (RSNA), which gathers over 50,000 participants from around the world. The meeting showed that there is a great interest in innovations that help doctors and patients to better diagnosis and treatment. It was also clear that there are many technologically interested radiologists, which may prove an advantage when NeoNavia becomes commercially available.

NeoDynamics established good contacts with several important US centres at the meeting and looks forward to continuing to develop these relationships during the year. The next important event in the United States is the Society of Breast Imaging (SBI) meeting in Denver in April which brings together thousands of breast radiologists, ie our target



audience. NeoDynamics will participate in the congress, including an abstract by Associate professor Edward Azavedo about the clinical experience of NeoNavia in breast cancer patients at Karolinska Hospital. The company also plans to participate in the most important congresses for the target group in 2020 in priority markets in Europe, i.e. in Sweden, Germany and the UK. Already today an active dialogue with many clinics are ongoing to prepare the launch.

In addition to the studies the company conducts in Germany and the United Kingdom, it is important to also develop good relationships with reference clinics, the centres in Europe that are pioneers in the use of the product. The centres help build knowledge, recommendations and experience around how Neonavia can be used in clinical practice. This way of approaching the market gives a cautious start where sales increase gradually as the clinical experience grows and spreads to other centres through peer to peer recommendations. The strategy reduces the risk of setbacks and paves the way for a successful introduction on a broad front.

The SEK 45.9 million rights issue with subscription period February 7-21, will provide NeoDynamics the financial strength to continue the work of bringing Neonavia to hospitals and thus help many women with breast cancer to better diagnosis and treatment. Almost half of the issue is covered by subscription undertakings from major shareholders while the remainder is guaranteed. The fact that financing is thus secured further reduces the risk in the company, which – everything else alike – should make it more attractive for shareholders to exercise their rights to subscribe for new shares at SEK 3 each. At the same time, the company welcomes new shareholders to participate in the share issue and thereby become involved in an important period in the company's history.

Anna Eriksrud, CEO, Lidingö, 5 February 2020

Financial overview

Fourth Quarter 2019

During the fourth quarter 2019, the company developed according to plan, with the main costs being associated with product development, clinical studies, marketing and personnel. NeoDynamics applies a policy of capitalizing development costs to intangible assets, however not personnel costs.

Revenue

Capitalized costs accounted for SEK 6.007 (9.019) m of the reported revenue of SEK 6.381 (9.104 m). The Company had no sales in the period.

Earnings/loss

The loss after depreciation amounted to SEK -5.944 (-7.372) m in the fourth quarter. External costs decreased to SEK -9.421 (-12.580) m, mainly comprising costs related to clinical studies, product development and marketing. Personnel costs decreased to SEK -2.715 (-3.598) m. The loss for the quarter before and after tax amounted to SEK -6.930 (-8.598) m during the quarter.

Financial position

At the end of 2019, the equity ratio was 60 percent, compared with 90 percent at previous year-end. Shareholders' equity amounted to SEK 55.581 m, compared with SEK 74.563 m one year ago. Cash and cash equivalents at the end of December amounted to SEK 6,195 (25.654 m at year-end 2018). In December 2019, the company signed a loan facility of a maximum of SEK 14 million. Total assets amounted to SEK 92.286 m (82.455 m at year-end).

Capital requirements

The working capital requirement for the the next 12 months has been met by a rights issue of SEK 45.9 million with preferential rights for shareholders. The Board continuously reviews the company's financial position to ensure that the company has sufficient funding based on the established strategic plan.

Dividend

No dividend is proposed.

Annual report

The complete annual report will be available at least three weeks before the Annual meeting.

Outlook

During the fourth quarter, the company received regulatory approval for NeoNavia (EC), entered the final phase of verification and validation and begun planning for the production of CE marked products for delivery during the first half of 2020. Development costs are expected to decrease sharply in 2020 and onwards.

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 December 31, 2019, the number of shares in NeoDynamics AB was 15,303,520 (unchanged from year-end).

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 December 31, 2019.

1	Boai NKY Medical Holdings Ltd, Kina	4 922 544	32.2%
2	M2 Capital Management AB	1 278 457	8.4%
3	Gryningskust Holding AB	914 900	6.0%
4	Huasheng Fang	768 290	5.0%
5	ADB Invest AB	360 700	2.4%
6	Jörgen Vrenning	356 054	2.3%
7	Humlan Fastighetsutveckling AB	390 041	2.0%
8	Rentability Sweden AB	290 694	1.9%
9	Claes Pettersson	242 834	1,6%
10	Lignin Invest	183 520	1.2%

Financial calendar

Interim Report Jan-Mar	26 May, 2020
Half Year Report Jan-Jun	21 Aug, 2020
Interim Report Jan-Sep	11 Nov, 2020

Annual general meeting

The annual general meeting will be held at the Company's offices, Lidingö, May 28, 2020 at 15:00.

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 October 2018 and the annual report 2018.

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.

Full-year report submitted

The Board of Directors and the CEO hereby certify that the full-year-report 2019 provides a true and fair view of NeoDynamics' operations.

Lidingö, February 5, 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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This information is information that NeoDynamics AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication by the contact person above on February 5, 2020..

Income statement

(SEK thousands)	2019 Oct-Dec	2018 Oct-Dec	2019 Jan-Dec	2018 Jan-Dec
Revenue				
Net sales	-84	0	0	0
Work performed by the Company for its own use and capitalized	6 007	9 019	22 220	24 877
Other operating income	458	84	490	101
	6 381	9 104	22 710	24 978
Operating expenses				
Other external cost	-9 421	-12 580	-31 332	-32 421
Personnel cost	-2 715	-3 598	-9 151	-7 454
Depreciation/amortization and impairment of tangible and intangible assets	-162	-246	-600	-560
Other operating expenses	-28	-51	-67	-161
	-12 325	-16 476	-41 152	-40 596
OPERATING INCOME/LOSS	-5 944	-7 372	-18 442	-15 619
Financial items				
Financial income	0	134	0	134
Financial costs	-446	-1 359	-540	-2 715
Net financial items	-446	-1 226	-540	-2 581
	-6 390	-8 598	-18 982	-18 200
Profit/loss after financial items				
Profit/loss before tax	-6 390	-8 598	-18 982	-18 200
Tax	0	0	0	0
Net profit/loss	-6 390	-8 598	-18 982	-18 200
Earnings/loss per share before dilution, SEK (no dilution)	-0.42	-0.72	-1.24	-2.08
Number of shares at end of period	15 303 520	15 303 520	15 303 520	15 303 520
Average number of shares	15 303 520	11 955 694	15 303 520	8 741 198

Balance sheet

(SEK thousands)	30-Dec-19	31-Dec-18
ASSETS		
Fixed assets		
Intangible assets	70 974	48 827
Tangible assets	1 346	1 242
Financial assets	112	0
	72 433	50 069
Current assets		
Inventory, etc	361	2 632
Receivables	13 297	4 101
Cash and cash equivalents	6 195	25 654
	19 854	32 387
TOTAL ASSETS	92 286	82 455
EQUITY AND LIABILITIES		
Restricted Equity		
Share capital	-1 530	-1 530
Fund for development expenditure	-65 789	-43 569
	-67 320	-45 099
Unrestricted Equity		
Share premium reserve	-111 261	-111 261
Profit/loss brought forward	104 018	63 598
Profit/loss for the year	18 982	18 200
	11 739	-29 464
TOTAL EQUITY	-55 581	-74 563
Long term liabilities		
Convertible loans and similar	-14 620	0
Other long-term liabilities	-476	-476
	-15 096	-475
Short term liabilities		
Accounts payable	-2 164	-3 788
Other current liabilities	-16 520	-1 205
Accrued expenses and deferred income	-2 925	-2 423
	-21 609	-7 416
TOTAL LIABILITIES	-36 705	-7 891
TOTAL EQUITY AND LIABILITIES	-92 286	-82 455

Cash flow statement

(SEK thousands)	2019	2018
Operating activities		
Profit/loss after financial items	-18 892	-18 200
Adjustments for items not included in cash flow, etc	554	304
Cash flow from operating activities before changes in working capital	-18 428	-17 896
<i>Cash flow from changes in working capital</i>		
Increase (-) /Decrease (+) in inventories	0	531
Increase (-) /Decrease (+) in operating receivables	-6 925	-1 628
Increase (+) /Decrease (-) in operating liabilities	14 193	-1 836
Cash flow from operating activities	-11 160	-20 829
Investment activities		
Acquisition of intangible assets	-22 293	-24 653
Acquisition of tangible assets	-512	-970
Acquisition of financial assets	-112	0
Disposal of intangible assets	0	389
Cash flow from investment activities	-22 918	-25 458
Financing activities		
New share issue	0	66 056
Borrowings	14 620	358
Cash flow from financing activities	14 620	66 415
Cash flow for the year	-19 538	20 128
Cash and cash equivalents at the beginning of the period	25 654	5 525
Cash and cash equivalents at the end of the period	6 195	25 654

Key ratios

	31-dec-19	31-dec-18
Sales, SEK thousand	0	0
Operating income, SEK thousand	-18 882	-15 619
Operating margin %	neg	neg
Balance total, SEK thousand	-92 286	82 455
Equity ratio %	60%	90%
Cash, SEK thousands	6 195	25 654
Earnings/loss per share, SEK	-1.24	-2.08
Equity per share, SEK	3.63	4.87

Warrant program – 2018/21

The company has issued 550,000 warrants to senior executives in the company. Each warrant entitles the holder to subscribe for one (1) share in the Company at a subscription price of SEK 10.50 during the period October 1-31, 2021. The warrants entail a dilution of ownership when the price of share exceeds the exercise price of the warrants. There was no dilution effect during the period.

Warrant program – 2018/19 TO 1

The warrant program was terminated without subscription.

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 micropulse 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 micropulse 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. The patent will run for a great number of years ahead.

Clinically tested in key markets

More than 400 patients have undergone breast and axillary lymph node biopsy with the new 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

Our vision is that our micropulse 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>

