



NeoDynamics AB
First Quarter report 2019

01-01-2019 - 03-31-2019

Quarterly report January–March 2019

[First quarter developed according to plan](#)
[Started development of a biopsy marker](#)

First quarter 2019

- Revenue amounted to SEK 5.420 m (4.277 m). No sales have taken place during the period. Capitalized costs of SEK 5.418 m (4.277 m) are included in the revenue.
- Profit after tax amounted to SEK -4.134 m (-2.533 m).
- Earnings per share amounted to SEK -0.27 (-0.37).
- Equity ratio was 94 procent (65).

Significant events during the period

- On April 8-9 in Berlin, Dr. Marc Thill (Priv.-Doz. Dr. med.), Agaplesion Markus-Krankenhaus, presented the plans for the German multicenter study ("PULSE") for the biopsy of lymph nodes to 150 specialists. The study is being conducted by the German association for research in radiological gynecology, AWOGyn.
- The Breast Center at Karolinska University Hospital has evaluated NeoNavia and has been granted permission by the Swedish Ethical Review Authority to collect data on biopsies.
- The audit of our quality system has been completed and a new certificate according to the ISO 13485:2016 standard has been received.

Significant events after the end of the period

- Advance notice of a granted patent on our biopsy device was obtained from the US Patent and Trademark Office.
- Concept development of a biopsy clip/marker started with an American specialist to broaden the range of biopsy products to our target group.

Invitation to audiocast

The report will be presented in an audiocast today at 10.15 (CET). The audiocast is presented by CEO Anna Eriksrud and CFO Jörgen Vrenning. The audiocast may be followed::

Sound and pictures: <https://tv.streamfabriken.com/neodynamics-q1-2019>

Sound: Sverige: +46 8 566 427 06, UK +44 333 300 9030 USA +1 833 526 8383

Studies pave the way for successful launch

NeoDynamics' strategy is to take our biopsy system NeoNavia for a commercial proof of concept by launching the new version in the Nordic countries, Germany and the UK. Later on, we will out license the product to a medical technology company with global sales or make a tech trade sell.

In the medical technology domain, it is possible to provide clear evidence of a product's potential with a relatively small number of talented key account managers. If there is support from leading "KOL", Key Opinion Leader centers from the very beginning, the impression made will be greater and the launch faster.

Our priorities are clear:

- We will document our new product for CE approval and submit the application in the second half of 2019.
- We will submit a 510(k) application to the FDA.
- We will complete our clinical studies in 2020.
- We prepare ourselves for Chinese FDA

The focus during the first quarter has been on our clinical studies in Sweden, Germany and the UK, the aim of these being to support the launch of NeoNavia during 2020. The documentation of the product's applications will allow doctors to become familiar with the technology, and enable us to establish a presence at leading clinics. This will strengthen our brand, and meanwhile we will become known to both the healthcare system and the compensation system used by the healthcare system. We will hereby increase our chances of getting recommendations from the leading clinics.

The design for our German multicenter study ("PULSE"), which involves taking biopsies of the axillary lymph nodes, was presented to approximately 150 specialists at the German association for research in radiological gynecology AWOgyn's meeting in Berlin in April. Our principal investigator Dr Marc Thill (Priv.-Doz. Dr. Med.) from Agaplesion Markus-Krankenhaus predicted during the presentation that the study will influence and simplify the biopsy procedure for German doctors and their breast cancer patients.



The Breast Center at Karolinska University Hospital got permission from the Ethics Review Board to collect data from its evaluation of NeoNavia in order to be able to publish the results of completed breast biopsies in a scientific journal. This will be a door opener for us and will confirm that the biopsy needle that we have developed works in the axilla and in the breast.

We recently started developing the concept for a "clip", a biopsy marker, to be used by doctors in conjunction with biopsies to mark the site of the tumor. The use of a clip is standard in the US, and is becoming more common in Europe. The aim is to produce a product that is more visible during ultrasound than existing products on the market. In collaboration with a US specialist, we will develop a new biopsy marker that will complement our biopsy product portfolio.

The business is currently operating at a fast pace, with intriguing new features, and we are essentially following the plan that has been established. The feedback we receive from our customers is positive and encouraging. In the second half of this year, our development costs will decrease and there will be more focus on market preparations with NeoNavia. In this context, we are pleased to have received advance notice of the approved biopsy device patent from the US Patent and Trademark Office, since the market in the US is twice as large as that in Europe.

We are working actively to ensure that more people within the stock market get to know us and come to appreciate the company's potential.

CEO Anna Eriksrud

Financial overview

First quarter 2019

During the period January-March 2019, the company developed according to plan, the main costs beings associated with product development, clinical studies and personnel. NeoDynamics applies a policy of capitalization of development costs to intangible assets, but not of personnel costs.

Revenue

During the period, the Company had no product sales. Capitalized costs accounted for SEK 5.418 m (4.277 m) of the reported revenues of SEK 5.420 m (4.277 m).

Earnings

Earnings before depreciation for the period amounted to SEK -4.031 m (-2.428 m). External costs increased to SEK 6,963 (5,412) and consisted mainly of costs relating to clinical studies and product development. Staff costs increased to SEK 2.411 m (1.283 m), partly as a result of the number of employees increasing from four to five. Profit for the year before tax and after tax amounted to SEK -4.134 m (-2.533 m).

Financial position

At the end of the period, the equity ratio was 94 percent, compared with 90 percent at year-end. Shareholders' equity amounted to SEK 70 429 m compared with SEK 26.706 m at year-end. Cash and cash equivalents amounted to SEK 15.329 m (SEK 25.654 m at year-end). Total assets amounted to SEK 74.750 m (SEK 82.639 m at year-end).

Capital requirements

The Board's assessment is that the working capital requirement in 2019 will be met by using available cash and net proceeds from a planned new issue through a warrant program that may raise approximately SEK 24 m in new equity at the end of the year.

Seasonal variations

The company is in a period during which significant funds are being invested in the development of the NeoNavia biopsy system. In the second half of 2019 the CE submission of file will take place. Development costs are expected to decline during the second half of the year.

NeoDynamics shares

NeoDynamics shares have been listed on the Spotlight Stock Market since December 7, 2018. The short name of the share is "NEOD" and the ISIN code is SE0011563410. As of December 31, 2018, the total number of shares in issue was 15,303,520 (6,908,000).

Ownership

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

| | | | |
|----|--------------------------------------|-----------|--------|
| 1 | Boai NKY Medical Holdings Ltd, China | 4,922,544 | 32.17% |
| 2 | M2 Capital Management AB | 1,278,457 | 8.35% |
| 3 | Gryningskust Holding AB | 914,900 | 5.98% |
| 4 | Huasheng Fang | 768,290 | 5.02% |
| 5 | ADB Invest AB | 360,700 | 2.36% |
| 6 | Jörgen Vrenning | 356,054 | 2.33% |
| 7 | Rentability Sweden AB | 290,694 | 1.90% |
| 8 | Claes Petterson | 242,834 | 1.59% |
| 9 | Humlan Fastighetsutveckling AB | 240,000 | 1.57% |
| 10 | Espander Life Science Partner AB | 200,000 | 1.31% |

Annual shareholder meeting

NeoDynamics' Annual General Meeting will be held on May 23, 2019, at Scandic Foresta/Vinterträdgården, Lidingö, Sweden. The annual report is available on the company's website (www.neodynamics.se).

Dividend

The Board of Directors and the CEO propose no dividend for the financial year 2018.

Financial calendar

| | |
|---------------------------|--------------|
| Annual General Meeting | May 23, 2019 |
| Interim report (Jan-Jun) | Aug 21, 2019 |
| Interim report (Jan-Sept) | Nov 21, 2019 |

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.

Accounting principles

The year-end 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 quarterly report provides a true and fair view of NeoDynamics' operations.

Lidingö May 21, 2019

Anna Eriksrud
CEO

Ingrid Salén
Chairman of the board

Carina Bolin
Board member

Claes Pettersson
Board member

Jörgen Vrenning
Board member

Xiaojun Xu
Board member

NeoDynamics AB, 559014-9117

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www.neodynamics.se

Income statement

| (SEK thousand) | 2019 Jan-Mar | 2018 Jan-Mar | 2018 |
|----------------------------------------------------------------------------|-------------------|------------------|-------------------|
| Revenue | 5 420 | 4 277 | 24 978 |
| Net sales | 0 | 0 | - |
| Work performed by the Company for its own use and capitalized | 5 418 | 4 277 | 24 877 |
| Other operating income | 2 | 0 | 101 |
| Operating expenses | | | |
| Other external costs | -6 963 | -5 412 | -32 426 |
| Personnel costs | -2 411 | -1 283 | -7 454 |
| Depreciation/amortization and impairment of tangible and intangible assets | -134 | -105 | -560 |
| Other operating expenses | -14 | -2 | -156 |
| OPERATING INCOME | -4 165 | -2 533 | -15 619 |
| Financial items | | | |
| Financial income | 0 | 0 | 134 |
| Financial costs | -31 | 0 | -2 715 |
| Net financial items | -31 | 0 | -2 581 |
| Profit after financial items | -4 134 | -2 533 | -18 200 |
| Profit before tax | -4 134 | -2 533 | -18 200 |
| Tax | 0 | 0 | 0 |
| Net profit | -4 134 | -2 533 | -18 200 |
| Earnings per share before dilution, SEK (no dilution) | -0.27 | -0.37 | -2.08 |
| Number of shares at end of period | 15 303 520 | 6 908 000 | 15 303 520 |
| Average number of shares | 15 303 520 | 6 908 000 | 8 741 198 |

Balance sheet

| (SEK thousands) | 31-Mar-19 | 31-Dec-18 |
|--------------------------------------|----------------|----------------|
| ASSETS | | |
| Fixed assets | | |
| Intangible assets | 54 208 | 48 827 |
| Tangible assets | 1 144 | 1 242 |
| | 55 352 | 50 069 |
| Current assets | | |
| Inventory, etc | 704 | 2 632 |
| Receivables | 3 366 | 4 101 |
| Cash and bank | 15 329 | 25 654 |
| | 19 398 | 32 387 |
| TOTAL ASSETS | 74 750 | 82 455 |
| EQUITY AND LIABILITIES | | |
| Restricted equity | | |
| Share capital | -1 530 | -1 530 |
| Fund for development expenditure | -48 986 | -43 569 |
| | -50 517 | -45 099 |
| Unrestricted equity | | |
| Share premium reserve | -111 261 | -111 261 |
| Profit/loss brought forward | 87 215 | 63 598 |
| Profit/loss for the year | 4 134 | 18 200 |
| TOTAL EQUITY | -70 429 | -74 563 |
| Long-term liabilities | | |
| Other long-term liabilities | -476 | -476 |
| Short-term liabilities | | |
| Accounts payable | -1 133 | -3 788 |
| Other current liabilities | -52 | -1 205 |
| Accrued expenses and deferred income | -2 660 | -2 423 |
| TOTAL LIABILITIES | -4 321 | -7 892 |
| TOTAL EQUITY AND LIABILITIES | -74 750 | -82 455 |

Key figures

| | 2019 Jan-Mar | 2018 Jan-Mar | 2018 |
|---------------------------------|-----------------|-----------------|---------|
| Sales, SEK thousands | 0 | 0 | 0 |
| Operating income, SEK thousands | -4 165 | -2 533 | -15 619 |
| Operating margin % | neg | neg | neg |
| Balance total, SEK thousands | 74 750 | 39 425 | 82 455 |
| Equity ratio % | 94 | 65 | 90 |
| Cash, SEK thousands | 15 329 | 1 756 | 25 654 |
| Earnings/share, SEK | -0.27 | -0.37 | -2.08 |
| Equity/share, SEK | 4.60 | 4.87 | 3.50 |

Warrants program – 2018/21

The company has issued 550,000 warrants to senior executives in the company. The warrant holders have the right to apply for one (1) share in the Company at a subscription price of SEK 10.50 for each warrant during the period October 1-31, 2021. The warrants entail a dilution of ownership when the price of shares exceeds the exercise price of the warrants. There is no dilution effect during the period.

Warrants program – 2018/19 TO 1

In connection with the rights issue in November 2018, 3,080,000 warrants were issued, with each warrant entitling the holder to apply for one new share in the Company at a subscription price of SEK 8.20 during the period November 5-26, 2019. The warrants entail a dilution of the ownership when the share price exceeds the exercise price of the options. There is no dilution effect during the period.

NeoDynamics in brief

NeoDynamics AB (publ) is a Swedish medical technology company dedicated to advancing the diagnosis and care of breast cancer. The company has an innovative biopsy system, NeoNavia®, which is in the late stages of development. The precision biopsy system is built from a patented micro-pulse technology, based on 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 taken is increasing by 10 percent per year. Every year 2.1 million woman are diagnosed with breast cancer, a number that is increasing by 5 percent per year. The market for breast biopsy devices is worth USD 500 million/year. The proportion of non-surgical biopsies taken 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 the results of treatment.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. With power from the base unit, the driver accelerates the needle with great control even over a short distance, enabling its distinct stepwise insertion without the risk of destroying surrounding tissue. This facilitates ease of access and flexibility in sampling, even in very small lesions in delicate and difficult locations.

Global patent rights

NeoNavia's micro-pulse technology has global patent protection. 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 300 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 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>

