



NeoDynamics AB (publ.)  
Third quarter report 2019

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

## Regulatory approval!

### Third quarter 2019

- Revenue amounted to SEK 4.581 m (3.749 m), including capitalized costs of SEK 4.469 m (3.734 m). During the quarter, the company had minor sales of materials.
- Loss after tax amounted to SEK -4.477 m (-3.968 m).
- Loss per share amounted to SEK -0.29 (-0.57).

### Nine months 2019

- Revenue amounted to SEK 16.329 m (15.874 m), including capitalized costs of SEK 16.214 m (15.858 m). During the quarter, the company had minor sales of materials.
- Loss after tax amounted to SEK 12.592 m (-9.602 m).
- Loss per share amounted to SEK -0.82 (-1.39).
- Equity per share was SEK 4.05 (4.70).
- The equity ratio was 75 (86) per cent.

### Significant events during the second quarter

- US Country Manager took up her position
- Chief Compliance & Regulatory Affairs Officer recruited.
- The EGM on September 16 resolved on a directed issue of a convertible loan.
- Country Manager for Germany recruited.

### Significant events after period-end

- The new version of NeoDynamics biopsy system NeoNavia received regulatory approval in the EU.
- NeoNavia attracted great interest at the British radiology congress in Bristol, BSBR.
- The convertible loan was subscribed to with SEK 14.6 million.
- The Company's warrant program with subscription period 5-29 November 2019 is set to end without subscription.

### Invitation to Audiocast

The report for the third quarter will be presented in an audiocast today at 10.15 (CET) by CEO Anna Eriksrud and CFO Jörgen Vrenning. To participate in the Audiocast, please use the following link:  
<https://financialhearings.com/event/11969>

## EU approval increases the temperature

On October 29, NeoDynamics received clearance to increase the number of products under our existing certificate to accommodate our new improved version of the biopsy system with more features and new needles.

NeoDynamics have thus obtained regulatory approval to CE-mark our products as soon as our process for verification and validation is completed and we are thereafter entitled to market the new products.

This is a fantastic piece of news that means NeoDynamics save time and resources. We can thus put all uncertainty around the regulatory issue aside and fully focus on preparing for a strong launch in prioritized markets in Europe by mid-2020.

The launch is being prepared by highly qualified Country Managers in our key markets. Already today, the system is being used and evaluated at leading cancer clinics in Germany, England and Sweden, and these clinics will act as reference hospitals when sales of the product start.

During the summer we recruited a Country Manager in the US and in Germany we added a Country Manager to the organisation, Renate Reiss. Renate is a senior person with solid experience of introducing medtech and pharmaceutical products in the market. We are convinced that she is the right woman for NeoDynamics in Germany.

The positive regulatory news means that NeoDynamics have moved closer to a registration in China. Chinese authorities require that an EU certification in order to grant go-ahead for the study program in China. An early move into China is part of our strategy and our Chinese partners are active in women's health, enabling a faster launch on this large market.

In the US, we continue to document our 510 (k) application with the US FDA (Food & Drug Administration).



In September, we strengthened the company's cash position by issuing a convertible loan of about SEK 15 million, which secured the short-term capital requirement.

In November, NeoDynamics were represented as one of the main sponsors of the annual British Breast Sonography Meeting, BSBR (British Society of Breast Radiology), gathering around 300 breast radiologists in Bristol. NeoDynamics dominated the conference with very popular Neonavia workshops where participants were offered to try out the micropulse technology using the study version of NeoNavia as well as an opportunity to see our new probes/needles. The centres trained will be among the first to use NeoNavia in a clinical setting.

In December, NeoDynamics will for the first time have meetings to show the new NeoNavia to American physicians. These meetings will take place in Chicago at the major annual radiologist meeting in the United States, RSNA, the North American Society of Radiologists.

These are just some of the activities that the company currently is undertaking to be ready for launch in the second quarter of 2020.

Clearly this is an exciting time for NeoDynamics!

Anna Eriksrud, CEO  
Lidingö, 21 November 2019

# Financial overview

## Third Quarter 2019

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

### Revenue

Capitalized costs accounted for SEK 4.469 m (3.734 m) of the reported revenue of SEK 4.581 m (3.749 m). During the quarter, the company had minor sales of materials.

### Earnings/loss

The loss after depreciation amounted to SEK -4.416 m (-2.713 m). External costs increased to SEK -6.719 m (-4.976 m) mainly comprising costs related to clinical studies and product development. Personnel costs increased to SEK -2.105 m (-1 287 m), partly as a result of the number of employees increasing from four to five. Loss for the quarter before and after tax amounted to SEK -4.477 m (-3.968 m) during the quarter.

### Financial position

At the end of September, the equity ratio was 75 percent, compared with 90 percent at year-end. Shareholders' equity amounted to SEK 61.971 m, compared with SEK 74.563 m at year-end. Cash and cash equivalents amounted to SEK 1.153 m (25.654 m at year-end). After the end of the reporting period, the company issued a convertible loan of SEK 14.6 m, strengthening liquid funds. Total assets amounted to SEK 82.321 m (82.455 m at year-end).

### Capital requirements

The working capital requirement for the remainder of 2019 and the beginning of 2020 has been met by a convertible loan of SEK 14.6 million, which was directed to a number of the major shareholders. The Board continuously reviews the company's financial position to ensure that the company has sufficient funding based on the established strategic plan.

### Outlook

During the 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 June 30, 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 September 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	290 000	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

Year-end report Jan-Dec	21 Feb, 2020
Interim Report Jan-Mar	26 May, 2020
Half Year Report Jan-Jun	21 Aug, 2020

### Annual general meeting

The annual general meeting will be held at Lidingö on 28 May, 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 October 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.

## Third quarter report submitted

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

*Lidingö, November 21, 2019*

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

### For further information please contact

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## Income statement

(SEK thousands)	2019 July-Sept	2018 July-Sept	2019 Jan-Sept	2018 Jan-Sept	2019 Full year
<b>Revenue</b>					
Net sales	84	0	84	0	0
Work performed by the Company for its own use and capitalized	4 469	3 734	16 214	15 858	24 877
Other operating income	28	15	31	16	101
	<b>4 581</b>	<b>3 749</b>	<b>16 329</b>	<b>15 874</b>	<b>24 978</b>
<b>Operating expenses</b>					
Other external cost	-6 719	-4 976	-21 912	-19 846	-32 426
Personnel cost	-2 105	-1 287	-6 437	-3 855	-7 454
Depreciation/amortization and impairment of tangible and intangible assets	-159	-105	-439	-314	-560
Other operating expenses	-13	-94	-39	-105	-156
	<b>-4 416</b>	<b>-2 713</b>	<b>-12 498</b>	<b>-8 247</b>	<b>-15 619</b>
<b>Financial items</b>					
Financial income	0	0	0	0	134
Financial costs	-61	-1 255	-94	-1 356	-2 715
<b>Net financial items</b>	<b>-61</b>	<b>-1 255</b>	<b>-94</b>	<b>-1 356</b>	<b>-2 581</b>
	<b>-4 417</b>	<b>-3 968</b>	<b>-12 595</b>	<b>-9 602</b>	<b>-18 200</b>
<b>Profit/loss after financial items</b>	<b>-4 417</b>	<b>-3 968</b>	<b>-12 595</b>	<b>-9 602</b>	<b>-18 200</b>
	<b>-4 477</b>	<b>-3 968</b>	<b>-12 592</b>	<b>-9 602</b>	<b>-18 200</b>
<b>Profit/loss before tax</b>	<b>-4 477</b>	<b>-3 968</b>	<b>-12 592</b>	<b>-9 602</b>	<b>-18 200</b>
Tax	0	0	0	0	0
<b>Net profit/loss</b>	<b>-4 477</b>	<b>-3 968</b>	<b>-12 592</b>	<b>-9 602</b>	<b>-18 200</b>
<b>Earnings/loss per share before dilution, SEK (no dilution)</b>					
	<b>-0.29</b>	<b>-0.57</b>	<b>-0.82</b>	<b>-1.39</b>	<b>-2.08</b>
Number of shares at end of period	15 303 520	6 908 000	15 303 520	6 908 000	15 303 520
Average number of shares	15 303 520	6 908 000	15 303 520	6 908 000	8 741 198

## Balance sheet

(SEK thousands)	30-Sept-19	31-Dec-18
<b>ASSETS</b>		
<b>Fixed assets</b>		
Intangible assets	64 933	48 827
Tangible assets	1 474	1 242
Financial assets	112	0
	<b>66 519</b>	<b>50 069</b>
<b>Current assets</b>		
Inventory, etc	783	2 632
Receivables	13 866	4 101
Cash and cash equivalents	1 153	25 654
	<b>15 802</b>	<b>32 387</b>
<b>TOTAL ASSETS</b>	<b>82 321</b>	<b>82 455</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Restricted Equity</b>		
Share capital	-1 530	-1 530
Fund for development expenditure	-59 783	-43 569
	<b>-61 313</b>	<b>-45 099</b>
<b>Unrestricted Equity</b>		
Share premium reserve	-111 261	-111 261
Profit/loss brought forward	98 012	63 598
Profit/loss for the year	12 592	18 200
	<b>-658</b>	<b>-29 464</b>
<b>TOTAL EQUITY</b>	<b>-61 971</b>	<b>-74 563</b>
<b>Long term liabilities</b>		
Convertible loans and similar	-14 620	0
Other long-term liabilities	-476	-476
	<b>-15 096</b>	<b>-476</b>
<b>Short term liabilities</b>		
Accounts payable	-2 980	-3 788
Other current liabilities	-44	-1 043
Accrued expenses and deferred income	-2 230	-2 585
	<b>-5 254</b>	<b>-7 416</b>
<b>TOTAL LIABILITIES</b>	<b>-20 350</b>	<b>-7 892</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>-82 321</b>	<b>-82 455</b>

## Key figures

	2019 Jan-Sept	2018 Jan-Sept	2018
Sales, SEK thousands	84	0	0
Operating income, SEK thousands	-12 498	-8 247	-15 619
Operating margin %	neg	neg	neg
Balance total, SEK thousands	82 321	49 717	82 455
Equity ratio %	75	86	90
Cash, SEK thousands	1 153	29	25 654
Earnings/loss per share, SEK	-0.82	1.39	-2.08
Equity per share, SEK	4.05	4.70	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

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. The warrant program is expected to be terminated without subscription.

## NeoDynamics in brief

## 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®, which is in the late stages of development. 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.<sup>1</sup>

### 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. 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 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.”**

<sup>1</sup> Source: NeoDynamics prospectus: <https://spotlightstockmarket.com/media/5584/neodynamics-ab-publ-prospekt-2.pdf>

