

# The proposed financing strengthens NeoDynamics ahead of pivotal period

## Third quarter 2020

- There were no sales during the period. Revenue amounted to SEK 2.643 m (4.581 m) including capitalized costs of SEK 2.051 m (4.469 m).
- Loss after tax amounted to SEK -6.731 m (-4.416 m).
- Loss per share amounted to SEK -0.19 (-0.29).

#### 9 months 2020

- There were no sales during the period. Revenue amounted to SEK 15.175 m (16.329 m), whereof capitalized costs SEK 14.140 m (16 214 m).
- Costs for product development contuned to be higher than expected.
- Loss after tax amounted to SEK -18.011 m (-12.498 m).
- Loss per share amounted to SEK -0.71 (-0.82).
- Equity per share was SEK 2.52 (3.63 at year-end).
- Equity ratio was 94 (60 per cent at year-end)

# Significant events during the third quarter

- Reference centers established in Germany to support the introduction of the new pulse biopsy system NeoNavia and optimize the diagnosis of breast cancer.
- An Extraordinary General Meeting on 13 August resolved on an incentive program for employees with a maximum of 1,021,900 warrants, where each warrant entitles to subscribe to one new share at SEK 4.71 per share during the period 1 Aug 30 Sep 2023.
- The directed share issue of 2,561,339 shares, SEK 7,684,017 announced in April, was registered with the Swedish Companies Registration Office in September. Hence, the share capital is SEK 3,600,695.10 distributed on 36,006,951 shares.
- In September, the NeoNavia biopsy system was very well received at the international senology congresses in Vienna and Lucerne, and for the first time, physicians gained practical experience of the finished product.

## Significant events after the period

- An Extraordinary General Meeting on November 19 will resolve on a directed share issue to a limited group of investors. The subscription price in the share issue is proposed to be SEK 3.71 per share and was determined through an accelerated bookbuilding procedure. The share issue can provide the company with close to SEK 90 million before transaction costs.
- On November 2, the company announced that its CFO, Jörgen Vrenning, has decided to leave the company after eight years to retire. Jörgen will continue in an advisory role until the end of May 2021 to ensure a smooth transition.
- The company joined a scientific partnership to evaluate the NeoNavia pulse biopsy system for knee and bone tissue sampling in a new potential indication, osteoarthritis.
- Neodynamics gets first order for the pulse biopsy system NeoNavia from the Buckinghamshire Healthcare NHS Trust, London.

#### CEO's comments

# Proposed new financing strengthens NeoDynamics ahead of pivotal period

During the autumn, the Board discussed various ways to strengthen the company's cash flow in order to be able to carry out the forthcoming market introduction of NeoNavia in a successful manner. These discussions, which have also involved the company's main owners, led to the Board's proposal for a directed issue of approximately SEK 90 million. The company's owners will decide on the matter at an extraordinary general meeting on 19 November. The share issue provides muchneeded room for manoeuvre to create value. The Board's assessment is that the funding benefits both old and new shareholders.

Through the proposed raising of capital, the ownership circle will be expanded with competence and experience in MedTech, a significant stamp of quality for a company such as NeoDynamics The Dutch investment firm Nyenburgh and Swedish Cardeon Futuring Finance have thoroughly analysed the company prior to investing in NeoDynamics. Both appreciate the solid preparation for the launch of NeoNavia, and state it as one of the most important reasons why they have chosen to invest in NeoDynamics.

#### First order

NeoNavia is now launched in the UK, Germany and Sweden, somewhat delayed compared to plan as the announced product development dragged on and the pandemic further delayed the project in the critical verification and validation phase. Covid-19 currently also limits the possibility of physical meetings on site with radiologists, but many activities are now underway thanks to our specialist sales staff in the UK, Germany and Sweden.

It is gratifying to note that after a short introduction, the first centre in the UK was able to place an order. A strong symbolism that we are now up and running. Other centres will want to follow suit.

The cancer area remains a priority in hospitals and there is a backlog when it comes to caring for breast cancer patients. Our studies have familiarized doctors with our product and built knowledge on how to use it. This provides benefits when NeoNavia now becomes commercially available.

Due to the pandemic, the study in the UK has not been able to be conducted normally and therefore we are expanding with more centres for faster results that can be used in sales work.



# The United States is the next step

Work on our registration application to the Federal Drug Administration (FDA) is ongoing, as is the dialogue with the authority. We expect to submit the documentation at the beginning of 2021, in order to get the go-ahead to start selling NeoNavia in the USA during the year as well. Covid-19 has led to the closure of several states where we have planned user tests with American physicians

The work in the USA also lays the foundation for the regulative application in China, which is next on the agenda. We will also perform a local study in China to get a strong basis, both in the dialogue with the authority and with future customers in the Chinese market.

## Scale up of production

The company works continuously to optimize its production processes to keep manufacturing costs at a level that enables a long-term good profit margin. We have been collaborating for just over a year with a well-established FDA-approved Thai manufacturer who, together with us, is preparing the transfer of our disposable probes (needles) to serial / commercial production. The first delivery is expected to take place in mid-2021. Until then, the company's Swedish partner Sanmina in Örnsköldsvik will be used, which will continue to manufacture the reusable system parts (base unit and driver) which are built with a significantly larger technical content.

Finally, we have recently started an international research collaboration to evaluate the NeoNavia pulse biopsy system for knee and bone tissue sampling in osteoarthritis, which is also a large indication. Here we collaborate with William Hunter Revisited, a research consortium consisting of six universities as well as academic hospitals, which specialize in osteoarthritis. We know that our pulse technology is attractive to develop in other indications as well, which we have confirmed by being approached by this research team

NeoDynamics is finally on its way to the market. We look forward to in-depth relationships with cancer clinics in Europe, to roll out NeoNavia in the US and to receive feedback on how the products will be received by doctors and patients.

#### CEO Anna Eriksrud

# Financial overview

## Third quarter 2020

The main costs are attributable to product development, clinical trials, marketing and personnel. The costs for product development were higher than expected. NeoDynamics applies a policy on capitalization of development costs to intangible assets, but not of costs for personnel.

# Renevue and Earnings/Loss

During the quarter, the company had no product sales. Capitalized costs accunted for SEK 2.051 m (4.469) of the reported revenue of SEK 2.643 m (4.581).

External costs were SEK 6.681 m (6.719) and mainly comprised of costs relating to product development, clinical studies and sales and marketing. Personnel costs increased to SEK 2.566 m (2.105). The loss after depreciation amounted to SEK -6.690 m (-4.402). The loss before tax and after tax amounted to SEK 6.731 m (-4.416).

#### Financial position

Cash and cash equivalents at the end of the period amounted to SEK 3.486 m (6.258 m at year-end). Equity increased to SEK 90.630 m, compared with SEK 55.581 m at the turn of the year. Total assets amounted to SEK 95.581 m (92.349 m at year-end). At the end of the period, the equity/assets ratio was 94 percent, compared with 60 percent at the ene of 2019.

#### Capital requirement

The working capital requirement for the remaining part of 2020 has increased due to higher costs than expected for product development. The need for capital up to and including the beginning of 2022 will be met by the proposed new share issue to the Extra General Meeting 19 November.

#### 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 early 2021 and then begin filing for registration in China. Development costs are expected to decrease sharply during the rest of this and the coming years. Sales and marketing costs are expected to rise.

## The share

NeoDynamics AB's share is been listed on Spotlight Stock Market since December 7, 2018. The share's short name is "NEOD" and the ISIN code is SE0011563410. As of September 30, 2020, the number of shares in NeoDynamics AB was 36,006,951 (15,303,520 at year-end).

#### **Owners**

The table below shows shareholdings and the share of votes and capital for the 10 largest shareholders in NeoDynamics AB at the end of September 2020. The 10 largest shareholders controls close to 60 per cent of total shares outstanding.

1	Huasheng Fang	6 815 948	18,93%
2	NKY Sweden (Boai NKY Medical Holdings Ltd)	4 922 544	13,67%
3	M2 Capital Management AB	2 970 899	8,25%
4	Gryningskust Holding AB	2 245 407	6,24%
5	Sebastian Jahreskog	930 187	2,58%
6	Rentability Sweden AB	895 245	2,49%

7	Avanza Pension	828 979	2,30%
8	ADB Invest AB	631 497	1,75%
9	Humlan Fastighetsutveckling AB	620 082	1,72%
10	Claes Pettersson	485 668	1,35%

The number of shareholders increased from just over 600 at the turn of the year to just over 1,000 at the end of the third quarter. The majority of these were added in connection with the new share issue in February.

#### Financial calendar

 Year-end report 2020
 17 Feb,2020

 Interim report Jan-Mar 2021
 19 May 2021

 Annual meeting 2021
 25 May, 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 IPO-prospectus published by the Board in October 2018 and the prospectus published in connection with the preferential share issue in February 2020.

#### Accounting principles

The half year 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 half yearly report provides a true and fair view of NeoDynamics' operations.

Lidingö, November 19, 2020

Anna Eriksrud Ingrid Salén Jie 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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#### www.neodynamics.com

# Income statement

(SEK thousands)	2020	2019	2020	2019	2019
(02.11.0000.100)	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Ded
Revenue					
Net sales	0	0	0	0	(
Work performed by the Company for its own use and capitalized	2 051	4 469	14 140	16 214	22 220
Other operating income	593	112	1034	115	490
Revenue	2 643	4 581	15 175	16 329	22 710
Operating expenses					
Other external cost	-6 681	-6 719	-24 139	-21 912	-31 332
Personnel cost	-2 566	-2 105	-8 615	-6 437	-9 151
Depreciation/amortization and impairment of tangible and	-86	-159	-356	-439	-600
intangible assets Other operating expenses					
Other operating expenses	-42	-13	-76	-39	-67
OPERATING INCOME	-6 731	-4 416	-18 011	-12 498	-18 442
Financial items					
Financial income	0	0	0	0	(
Financial costs	0	-61	-1 472	-94	-540
Net financial items	0	-61	-1 472	-94	-540
Profit after financial items	-6 731	-4 477	-19 482	-12 592	-18 982
Profit before tax	-6 731	-4 477	-19 482	-12 592	-18 982
Тах	0	0	0	0	(
Net profit	-6 731	-4 477	-19 482	-12 592	-18 982
Earnings per share before dilution, SEK					
(no dilution):	-0.19	-0-29	-0.71	-0.82	-1.24
Number of shares at end of period:	36 006 951	15 303 520	36 006 951	15 303 520	15 303 520
Average number of shares:	35 109 912	15 303 520	27 259 806	15 303 520	15 303 520

# Balance sheet

(SEK thousands)	30-sep-20	31-dec-19
ASSETS		
Fixed assets		
Intangible assets	85 070	70 974
Tangible assets	1 035	1 346
Financial assets	112	112
	86 217	72 433
Current assets		
Inventory, etc	162	36 <sup>-</sup>
Receivables	6 117	13 29
Cash and cash equivalents	3 486	6 258
	9 764	19 917
TOTAL ASSETS	95 981	92 34
EQUITY AND LIABILITES		
Restricted Equity		
Share capital	-3 601	-1 530
Fund for development expenditure	-79 930	-65 78
	-83 531	-67 32
Unrestricted Equity		
Share premium reserve	-163 723	-111 26
Profit/loss brought forward	137 140	104 018
Profit and loss for the year	19 482	18 982
	-7 100	11 73
TOTAL EQUITY	-90 630	-55 58 <sup>-</sup>
Long term liabilities		
Other long-term liabilities	-327	(
Short term liabilities		
Accounts payable	-1 893	-2 17
Other current liabilities	-875	-31 666
Accrued expenses and deferred income	-2 256	-2 92
TOTAL LIABILITIES	-5 350	-36 76

# Key figures

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	2020	2019	2019
	Jan-Sep	Jan-Sep	
Sales, SEK thousands	0	0	0
Operating income, SEK thousands	-6 731	-4 416	-18 442
Operating margin %	Neg	neg	neg
Balance total, SEK thousands	95 981	82 321	92 349
Equity ratio %	94	75	60
Cash, SEK thousands	3 486	1 153	6 258
Earnings/share, SEK	-0.71	-0.82	-1.24
Equity/share, SEK	2.52	4.05	3.63

# Warrant program - 2018/21

The company has issued 550,000 warrants to senior executives in the company. Each warrant entitle the rightholder to subscribe 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 the NeoDynamics share exceeds the exercise price of the warrants. There was no dilution effect during the period.

# Warrant program - 2020/23

An Extraordinary General Meeting on 13 August resolved on an incentive program for employees with a maximum of 1,021,900 warrants. Each warrant entitle the rightholder to subscribe one (1) share in the Company at a subscription price of SEK 4.71 during August 1 – September 30, 2023.

# 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.

## 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 ultrasoundled, 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