



NeoDynamics AB (publ)
Full year report 2020

2020-01-01 – 2020-12-31

Commercialization underway

Fourth quarter 2020

- Revenue amounted to SEK 3.382 (5.948) m, of which capitalized costs amounted to SEK 2.963 (5.574) m.
- Loss after tax amounted to SEK -11.524 (-6.823) m.
- Loss per share amounted to SEK -0.19 (-0.45).

Full year 2020

- Revenue amounted to SEK 18.557 (22.277) m, of which capitalized costs amounted to SEK 17.104 (21.787) m.
- Loss after tax amounted to SEK -31.006 (-19.415) m.
- Loss per share amounted to SEK -0.51 (-1.74).
- The equity ratio was 97 (60) percent at the end of the year.

Significant events during the quarter

- A share issue was directed at a limited group of investors, including Cardeon AB and its management team as well as Nyenburgh Holding BV, which raised a total of SEK 90 m.
- CFO Jörgen Vrenning left the company to retire. He 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.
- The company received its first order for the NeoNavia pulse biopsy system from the British Buckinghamshire Healthcare NHS Trust.

Significant events after the period

- The European Patent Office (EPO) issued a so-called Notice of Allowance intending to grant a European patent for NeoDynamics' pulse biopsy instrument that includes a multifunctional handset that can be used for several different types of biopsy needles.

CEO COMMENT

Commercialization underway

The commercialization of the pulse biopsy system NeoNavia has begun. Centers in Germany, UK and Sweden evaluate the system in their own environment, on their own patients and experience the difference to the systems they have used to date. The feedback is positive from both radiologists and pathologists evaluating the tissue samples.

First order for NeoNavia

During the fourth quarter, we received our first order for NeoNavia, thereby reaching an important milestone in the company's history. The order came from Buckinghamshire Healthcare NHS Trust, a reputable hospital in the UK. We expect to complete additional sales in the near future as a number of quotes are out for decisions and evaluation programs are ongoing.

Launch

The launch strategy in Europe involves a gradual introduction of NeoNavia to centers in the UK, Sweden and Germany with nearby German-speaking countries. We ensure that centers are confident in using the product, how the different needles work and suit different situations, and also in passing on this knowledge to all doctors at the clinic. This way, we build trust in the product and pave the way for broad use. With reference clinics in place that can convince others to follow their lead, we expect to get a boost in sales later in the year.

Pandemic slowdown

Unfortunately, the launch is being slowed down by the pandemic making it difficult to visit clinics and assist doctors in getting to know the new technology. Conferences are digital, a format that does not promote hands-on testing of NeoNavia. However, the team skillfully finds ways around challenges and centers participating in our clinical program will be our early users. Feedback from demonstrations, digital and physical outside of hospitals is positive.



Ready for 2021

During the fourth quarter, we completed a directed issue of SEK 90 million. This is also an important milestone giving us peace of mind to fully focus on what we are to achieve during the year.

Of course, the agenda includes a continued introduction of the system in our markets in Europe. We will show our medical results and we will pursue our plan for the US. Compiling the FDA documentation has also been affected by the pandemic as we have not been able to carry out user studies as planned. We expect to be able to complete these in order for the application to be submitted during the first half of this year. We will do is a 510(k) registration, which is a less complex procedure than a drug approval.

The United States is key

A US registration is a milestone for NeoDynamics and the product. It opens up a very large market and positions NeoDynamics completely differently towards potential partners. Moreover, a US registration also paves the way for an approval in China, the next country in line for NeoNavia.

Preparations for transferring the production of disposables to a manufacturer in Thailand are proceeding according to plan. Production is expected to start in mid-2021, and will enable us to achieve our long-term goals for manufacturing costs.

I look forward to an eventful 2021.

CEO Anna Eriksrud

Financial overview

NeoDynamics applies a policy of capitalizing development costs to intangible assets, but not of personnel costs.

Revenue and earnings/loss

The company had no product sales during the fourth quarter. The reported revenue amounted to SEK 3.382 (5.948) m, of which capitalized costs accounted for SEK 2.963 (5.574) m. Other revenue consisted mainly of re-invoiced material costs for product development. For the full year, the reported revenue amounted to SEK 18.557 (21.787) m, of which capitalized costs amounted to SEK 17.104 (22.277) m.

External costs increased during the quarter to SEK 10.502 (9.421) m, mainly due to increased marketing costs. Personnel costs increased to SEK 3.766 (2.715) m. For the full year, external costs amounted to SEK 34 641 (31.332) m, while personnel costs were SEK 12.381 (9.151) m.

Operating loss for the fourth quarter amounted to SEK -11.022 (-6.377) m and net loss amounted to SEK -11.524 (-6.823) m. For the full year, operating loss amounted to -29.032 (-18.875) m and net loss before tax to SEK -31.006 (-19.415) m.

Financial position

Cash and cash equivalents at the end of the year amounted to SEK 73.250 (6.258) m. Cash flow from operating activities in 2020 amounted to SEK -36.457 (-17.680) m. The financing operations generated a cash flow of SEK 120.911 (20.820) m during the year, where the new share issue provided the company with SEK 86.854 m during the fourth quarter. The cash flow for the year totaled SEK +66.991 (-19.395) m.

At the end of the year, the company's total assets amounted to SEK 171.292 (91.916) m. The equity ratio was 97 (60) percent. Equity increased during the year to SEK 165.554 (55.148) m.

Capital requirement

The company met its capital requirement until and including the beginning of 2022 after the private placement carried out during the fourth quarter.

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 during the first half of 2021 and then begin filing for registration in China. Development costs are expected to be significantly lower in 2021 than in 2020, while sales and marketing costs are expected to be significantly higher.

The business is affected by the pandemic in several ways, among other by complicating contacts with customers and thus the introduction of the product, and by complicating various types of studies. The company monitors developments closely and actively works to find ways to minimize this impact.

Owners

The 10 largest owners on 31 December 2020	Number of shares	Ownership
Huasheng Fang	6 815 948	11.3%
Boai NKY Medical Holdings Ltd, Kina	4 922 544	8.2%
Cardeon AB and its management team	4 690 023	7.8%
M2 Capital Management & M2 Asset Management	4 318 607	7.2%
Gryningskust Holding AB	3 873 169	6.4%
Sebastian Jahreskog	3 623 604	6.0%
Nyenburgh Holding BV	2 803 234	4.6%
Quiq Distribution Holding AB	895 245	2.2%
Rentability Sweden AB	895 245	1.5%
Humlan Fastighetsutveckling AB	869 715	1.4%

The 10 largest owners hold approximately 57 percent of outstanding shares. The number of shareholders increased during the year from just over 600 to scantily 1,300. The majority of the new shareholders were added in connection with the share issue in February.

The share

NeoDynamics share has been listed on Spotlight Stock Market since December 7, 2018. The share's trading symbol is "NEOD" and the ISIN code is SE0011563410. On December 31, 2020, the number of shares was 60,250,592. The share closed the year at a price of SEK 3.75, an increase of 22 percent from SEK 3.08 at previous year-end.

Financial calendar

Interim report Jan-March 2021	19 May, 2021
Annual General Meeting 2021	26 May, 2021
Interim report Jan-June 2021	19 Aug, 2021
Interim report Jan-Sept 2021	17 Nov, 2021

Risks and uncertainties

A number of risk factors could have a negative impact on NeoDynamics 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 in connection with the preferential share issue in February 2020.

Accounting principles

The full 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.

Auditors' review

This report has not been reviewed by the company's auditors.

Full-year report submitted

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

Lidingö, February 17, 2021

Anna Eriksrud
CEO

Ingrid Salén
Chairman of the Board

Jessie Bao
Board member

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

Anna Eriksrud, phone +46 0708 444 966, anna.eriksrud@neodynamics.com

Income statement

SEK thousands	2020 Oct-Dec	2019 Oct-Dec	2020 Jan-Dec	2019 Jan-Dec
Net sales	0	0	0	0
Work performed by the Company for its own use and capitalized	2 963	5 574	17 104	21 787
Other operating income	419	375	1 454	490
Revenue	3 382	5 948	18 557	22 277
Operating expenses				
Other external cost	-10 502	-9 421	-34 641	-31 332
Personnel cost	-3 766	-2 715	-12 381	-9 151
Depreciation/amortization and impairment of tangible and intangible assets	-98	-162	-454	-600
Other operating expenses	-38	-28	-114	-67
OPERATING INCOME	-11 022	-6 377	-29 032	-18 875
Financial items				
Financial income	0	0	0	0
Financial costs	-502	-446	-1 974	-540
Net financial items	-502	-446	-1 974	-540
Profit after financial items	-11 524	-6 823	-31 006	-18 415
Profit before tax	-11 524	-6 823	-31 006	-18 415
Tax	0	0	0	0
Net profit	-11 524	-6 823	-31 006	-18 415
Earnings per share, SEK				
(no dilution)	-0.19	-0.45	-0.52	-1.27
Number of shares at end of period	60 250 592	15 303 520	60 250 592	15 303 520
Average number of shares	41 868 051	15 303 520	30 958 542	15 303 520

Balance sheet

SEK thousands	31-Dec-20	31-Dec-19
ASSETS		
Fixed Assets		
Intangible assets	87 596	70 541
Tangible assets	1 299	1 346
Financial assets	112	112
	89 007	72 433
Current assets		
Inventory, etc.	1 810	361
Receivables	7 226	13 297
Cash and cash equivalents	73 250	6 258
	82 285	19 917
TOTAL ASSETS	171 292	91 916
EQUITY AND LIABILITIES		
Restricted Equity		
Share capital	-6 025	-1 530
Fund for development expenditure	-82 460	-65 356
	-88 485	-66 887
Unrestricted Equity		
Share premium reserve	-248 179	-111 261
Profit/loss brought forward	140 104	103 585
Profit and loss for the year	31 006	19 415
	-77 069	11 739
TOTAL EQUITY	-165 554	-55 148
Long term liabilities		
Other long-term liabilities	-327	0
Short term liabilities		
Accounts payable	-1 275	-2 177
Other current liabilities	-62	0
Accrued expenses and deferred income	-1 013	-31 666
	-3 061	-2 925
TOTAL LIABILITIES	-5 738	-36 768
TOTAL EQUITY AND LIABILITIES	-171 292	-91 916

Cash flow analysis

SEK thousands	2020	2019
Operating activities		
Loss after financial items	-31 006	-19 415
Adjustments for items not included in cash flow	454	604
Cash flow from operating activities before changes in working capital	-30 552	-18 810
Increase (-) /decrease (+) in inventory	-1 810	0
Increase (-) /decrease (+) in receivables	-3 567	3 075
Increase (-) /decrease (+) in operating liabilities	-528	-1 944
Cash flow from operating activities after changes in working capital	-5 905	1 130
CASH FLOW FROM OPERATING ACTIVITIES	-36 457	-17 680
Investing activities		
Acquisition of intangible assets	-17 103	-22 860
Acquisition of tangible assets	-359	-563
Acquisition of financial assets	0	-112
Cash flow from investing activities	-17 462	-22 535
Financing activities		
Share issue	141 412	0
Changes in loans	-20 502	20 820
Cash flow from financing activities	120 911	20 820
CASH FLOW	66 991	-19 395
Cash at the beginning of the year	6 258	25 654
Cash at the end of the year	73 250	6 258

Key figures

	2020	2019
Sales, SEK thousands	0	0
Operating loss, SEK thousands	-29 032	-18 875
Operating margin, %	neg	neg
Balance sheet total, SEK thousands	171 292	91 916
Equity ratio, %	97	60
Cash, SEK thousands	73 250	6 258
Loss/share, SEK	-0.51	-1.27
Equity/share, SEK	2.75	3.60

Warrant program – 2018/21

The company has issued 550,000 warrants to senior executives in the company. Each warrant entitle the holder 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

The company has issued 1,021,900 warrants to senior executives. The option holders have the right for each option to subscribe for a new share for SEK 4.71 during the period 1 August to 31 September 2023. 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 cancer. The company has an innovative biopsy system, NeoNavia®. The biopsy system is based on patented 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. The launch of NeoNavia® has been initiated in the UK, Germany and Sweden.

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 registered trade mark 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 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 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.

Immaterial property

NeoNavia's pulse technology has received 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 is granted 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 novel 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 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>