NeoDynamics AB (publ.)
Half-year report 2019

01-01 2019 – 06-30-2019

neodynamics

The English text is an unofficial translation of the Swedish report

Approaching the market – registration in focus

Second quarter 2019

- No sales have taken place during the quarter. Revenue amounted to SEK 6.328 m (7.848 m). Capitalized costs of SEK 6.328 m (7.847 m) are incluced in the revenue.
- Loss after tax amounted to SEK-3.981 m (-3.101 m).
- Earnings per share amounted to SEK -0,26 (-0,45).

Half-year 2019

- Revenue amounted to SEK 11.748 m (12.125 m). No sales have taken place during the period.Capitalized costs of SEK 11.745 m (12.124 m) are included in the revenue.
- Loss after tax amounted to SEK -8.115 m (-5 634 m).
- Earnings per share amounted to SEK-0.53 (-0.82).
- Equity per share was SEK 4.34 (4.87).
- Equity ratio was 91 (90) per cent.

Significant events during the second quarter

- Market research conducted showing substantial potential in China.
- New partly owned company started with dermatologist for development of innovative skin biopsy instruments.

Significant events after the period

- Anna Forsberg appointed as Country Manager in the USA.
- Petra Lindholm appointed as Chief Compliance & Regulatory Affairs
- An EGM in to be held 16 September was called to make decision on a convertibles issue.

Invitation to Audiocast

The half year report 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 select:

https://financialhearings.com/event/11969

Approaching the market – registrations in focus

Our product development journey with NeoNavia is in the final phase and work on verification, validation and documentation for registration in the EU and the US are underway. We are approaching the market at rapid pace.

In Europe, the MDD (Medical Device Directive) has been replaced by the MDR (Medical Device Regulation) bringing registration requirements more in line with US FDA legislation. Consequently, all Notified Bodies must undergo a new authorization by authorities. We are well prepared to be among the first to have a product approved according to MDR requirements. Exactly when this will happen is not only dependent on us but also on when our Notified Body, Intertek, will be authorized by the Medical Products Agency. Our goal is to submit our CE-application to Intertek by the end of 2019.

In parallel work is underway to document our 510 (k) application with the US FDA (Food & Drug Administration).

In China, we are also getting closer to registration. We are ready to begin registration work during the first quarter of 2020. Since 2016, we have Boai NKY Medical as a shareholder. We have now deepened the relationship with Boai who has the right expertise and staff that match market requirements including departments for clinical programs, registration, marketing and sales.

Data from the recent market survey give an idea of the size of the Chinese market. In Beijing alone, about 100 large hospitals, of which many carry out as many biopsies per month as major European hospitals perform in a year. We have interviewed both radiologists and distributors and conclude that the market in China for tissue sampling by needle biopsy is large and growing. We note that the Chinese biopsy market is becoming more similar to the European market and that prices of imported biopsy needles are in line with prices in Europe, which is very positive for us.

During the summer we appointed a Country Manager for the US market, Anna Forsberg. She is highly qualified with many years of US experience where she has worked throughout her career. She will focus on our clinical work, the application for the FDA-registration and initiate our work in the US market. An important task for her will be to develop our network at the major cancer clinics to prepare the launch of NeoNavia in 2020.

In Germany, studies are underway at seven prominent cancer centres and recruitment is proceeding according to plan. NeoNavia was presented with two scientific posters at the Senology Congress in Berlin, the largest annual national breast radiology meeting of the year.

It is worth highlighting that we have added strong regulatory expertise through the recruitment of Petra Lindholm, PhD with experience from regulatory processes in different med tech companies. She has previously been responsible for managing both EU registration authorities as well as US FDA. She will be instrumental during the upcoming intensive registration work.

To further leverage our expertise in product development and clinical areas, we founded as minority owners however with potential to grow, a company together with a Swedish dermatologist at Karolinska Hospital to develop a new skin biopsy instrument for skin cancer. This is a promising project that has already been granted financial support by the Swedish Innovation Agency,

Through the capital injection announced in a separate press release today, the company is adequately financed until the beginning of 2020 after the planned submission of regulatory applications.

CEO Anna Eriksrud

Lidingö 2019-08-28

Financial overview

Second Quarter 2019

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

Revenue

During the quarter, the company had no product sales. Capitalized costs accounted for SEK 6.328 m (7.847 m) of the reported revenue of SEK 6.328 m (7.848 m).

Earnings/loss

Earnings before depreciation amounted to SEK -3.979 m (-3.001 m). External costs decreased to SEK -8.229 m (-9.451 m) and mainly comprised of costs relating to clinical studies and product development. Staff costs increased to SEK-1.921 m (-1 285 m), partly as a result of the number of employees increasing from four to five. Loss for the quarter before tax and after tax amounted to SEK-3.981 m (-3.101 m) .

Financial postition

At the end of June, the equity ratio was 91 percent, compared with 90 percent at year-end. Shareholders' equity amounted to SEK 66.448 m, compared with SEK 74.563 m at year-end. Cash and cash equivalents amounted to SEK 6.116 m (25.654 m at year-end). Total assets amounted to SEK 72.727 m (82.455 m at year-end).

Capital requirements

The working capital requirement for the remainder of 2019 and the beginning of 2020 will be met by the propoed issue of convertible loans directed to a number of major shareholders. The reason for deviating from the shareholders' preferential rights is the need for a capital injection and that the transaction costs of acquisition of this finance are limited. More details can be found in a separate press release published today, with an invitation to an Extraordinary General Meeting to be held on 16 September 2019.

Outlook

The company is in the final phase of the validation of the NeoNavia biopsy system ahead of regulatory applications (CE and FDA) which are planned to be submitted by the end of the year. Development costs are expected to decline in the second half of the year

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 June 30, 2019, the number of shares in NeoDynamics AB was 15,303,520 (unchanged from 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 June 2019..

1	Boai NKY Medical Holdings Ltd, Kina	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	Humlan Fastighetsutveckling AB	290 000	1,89%
9	Claes Pettersson	242 834	1,59%
10	Mats Espander	200 242	1,31%

Financial calendar

Interim Report Jan-Sep	21 Nov, 2019
Year-end report Jan-Dec	21 Feb, 2020
Interim Report Jan-Mar	26 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

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.

Half-year 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, August 28, 2019

Anna Eriksrud	Ingrid Salén	Ulf Boberg
CEO	Chairman of the board	Board member
Carina Bolin	Claes Pettersson	Xiaojun Xu
Board member	Board member	Board member

NeoDynamics AB, 559014-9117

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Income statement

(SEK thousands)	2019 apr-jun	2018 apr-jun	2019 jan-jun	2018 jan-jun	2019 jan-dec
Revenue					
Net sales	0	0	0	0	0
Work performed by the Company for its own use and capitalized	6 328	7 847	11 745	12 124	24 877
Other operating income	1	1	3	2	101
	6 328	**7 848**	**11 748**	**12 125**	**24 978**
Operating expenses					
Other external cost	-8 229	-9 451	-15 193	-14 870	-32 426
Personnel cost	-1 921	-1 285	-4 332	-2 568	-7 454
Depreciation/amortization and impairment of tangible and intangible assets	-145	-105	-279	-209	-560
Other operating expenses	-12	-9	-26	-11	-156
OPERATING INCOME	**-3 979**	**-3 001**	**-8 082**	**-5 534**	**-15 619**
Financial items					
Financial income	0	0	0	0	134
Financial costs	-1	-100	-33	-100	-2 715
Net financial items	**-2**	**-100**	**-33**	**-100**	**-2 581**
Profit after financial items	**-3 981**	**-3 101**	**-8 115**	**-5 634**	**-18 200**
Profit before tax	**-3 981**	**-3 101**	**-8 115**	**-5 634**	**-18 200**
Tax	0	0	0	0	0
Net profit	**-3 981**	**-3 101**	**-8 115**	**-5 634**	**-18 200**
Earnings per share before dilution, SEK (no dilution)	**-0,26**	**-0,45**	**-0,53**	**-0,82**	**-2,08**
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-jun-19	31-dec-18
ASSSETS		
Fixed assets		
Intangible assets	60 500	48 827
Tangible assets	1 498	1 498
	61 998	**50 324**
Current assets		
Inventory, etc	715	2 632
Receivables	3 898	4 101
Cash and cash equivalents	6 116	25 654
TOTAL ASSETS	**72 727**	**82 455**
EQUITY AND LIABILITIES		
Restricted Equity		
Share capital	-1 530	-1 530
Fund for development expenditure	-55 314	-43 569
	-56 844	**-45 099**
Unrestricted Equity		
Share premium reserve	-111 261	-111 261
Profit/loss brought forward	93 543	63 598
Profit/loss for the year	8 115	18 200
TOTAL EQUITY	**-66 448**	**-74 563**
Long term liabilities		
Other long-term liabilities	-476	-476
Short term liabilities		
Accounts payable	-3 392	-3 788
Other current liabilities	-249	-1 205
Accrued expenses and deferred income	-2 161	-2 423
TOTAL LIABILITIES	**-6 279**	**-7 892**
TOTAL EQUITY AND LIABILITIES	**-72 727**	**-82 455**

Cash flow statement

(SEK thousands)	2019 jan-jun	2018 jan-jun	2018 jan-dec
Operating activities			
Profit/loss after financial items	-8 115	-5 634	-18 200
Adjustments for items not included in cash flow, etc	279	209	304
Cash flow from operating activities before changes in working capital	**-7 835**	**-5 424**	**-17 896**
Cash flow from changes in working capital			
Increase (-) /Decrease (+) in inventories	0	-379	531
Increase (-) /Decrease (+) in operating receivables	2 120	-1 709	-1 628
Increase (+) /Decrease (-) in operating liabilities	-1 614	16 253	-1 836
Cash flow from operating activities	**-7 330**	**8 741**	**-20 829**
Investment activities			
Acquisition of intangible assets	-11 745	-12 124	-24 877
Acquisition of iangible assets	-463	0	-970
Disposal of intangible assets	0	0	389
Cash flow from investment activities	**-12 208**	**-12 124**	**-25 458**
Financing activities			
New share issue	0	0	66 056
Borrowings	0	0	358
Cash flow from financing activities	**0**	**0**	**66 415**
Cash flow for the year	**-19 538**	**-3 383**	**20 128**
Cash and cash equivalents at the beginning of the period	**25 654**	**5 525**	**5 525**
Cash and cash equivalents at the end of the period	**6 116**	**2 142**	**25 654**

Key figures

	2019 jan-jun	2018 jan-dec
Sales, SEK thousands	0	0
Operating income, SEK thousands	-8 082	-15 619
Operating margin %	neg	Neg
Balance total, SEK thousands	-72 727	-82 455
Equity ratio %	91%	90%
Cash, SEK thousands	6 116	25 654
Earnings/share, SEK	-0.53	-2.08
Equity/share, SEK	4.34	4.87

WarrantsWarrant program – 2018/21

The company has issued 550,000 warrants to senior executives in the company. TheEach warrant holders haveentitle the rightholder 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 sharesthe share exceeds the exercise price of the warrants. There iswas no dilution effect during the period.

WarrantsWarrant 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 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."

[1] Source: NeoDynamics prospectus: https://spotlightstockmarket.com/media/5584/neodynamics-ab-publ-prospekt-2.pdf