



**NeoDynamics AB (publ)**  
**Q3 2022 Report**

1 January - 30 September 2022

# Gaining momentum in the US

## Third Quarter 2022

- Revenues amounted to SEK 151 (339) thousand, of which SEK 73 (24) thousand capitalized costs and SEK 32 (300) thousand net sales, i.e., sales of finished products.
- Net loss amounted to SEK -14,629 (-13,066) thousand.
- Loss per share amounted to SEK -0.12 (-0.22).
- Cash and cash equivalents amounted to SEK 37,607 (24,710 at year-end) thousand.

## First Nine Months of 2022

- Revenues amounted to SEK 462 (1,155) thousand, of which SEK 214 (785) thousand capitalized costs and SEK 135 (322) thousand net sales, i.e., sales of finished products.
- Net loss amounted to SEK -50,115 (-48,596) thousand.
- Loss per share amounted to SEK -0.53 (-0.81).
- Cash and cash equivalents amounted to SEK 37,607 (24,710 at year-end) thousand.

## Significant events during the quarter

- NeoDynamics received FDA clearance for its pulse biopsy system NeoNavia® without any conditions.
- In July, NeoDynamics received ethical committee approval for a German device registry trial. The registry will be used to gather and evaluate real world data from the use of NeoNavia.
- NeoDynamics appointed Decomplex as Swiss representative. The role of the representative is to be a point of contact with authorities, keep technical documentation at hand and support with vigilance inquires.

## Significant events after the end of the quarter

- A partnership with Diligent Health Solutions is announced, ensuring US hospitals, physicians, and patients get the best customer care and reimbursement support possible as part of the NeoNavia launch in the US.
- In November, Brendan Carney was hired as National Sales Director to lead commercial strategy and execution, including field sales and managed markets for the company.
- The company announced it will launch the NeoNavia biopsy system configured with its FlexiPulse probe in the United States to support the diagnosis of cancer. The launch is scheduled for January 2023.

## CEO COMMENT

# US approval paves way for growth

The hard work we put into preparing and submitting a strong file to the US Food and Drug Administration (FDA) for a US commercialization - paid off in the third quarter, with approval by the FDA of our innovative pulse biopsy system NeoNavia. The approval is a major milestone for NeoDynamics as it means we can now push forward quickly to begin introducing the system to a massive market. The US breast biopsy market is expected to reach \$830 million by 2025.

The company is working full speed to start introducing the NeoNavia biopsy system configured with its FlexiPulse probe to clinicians and potential partners in the US. The launch is scheduled for January 2023.

Our system helps clinicians address the critical issues they face in diagnosing and treating breast cancer. The FlexiPulse needle is unique – it gives control thanks to the pulses. It offers the possibility to go into difficult-to-reach places such as lymph nodes in the armpit where you have bloodvessels and nerves, or take biopsies in breasts with implants – areas where you are prepared to pay for a new technology.

NeoDynamics is dedicated to delivering technology for precise, high-quality tissue samples to support the critical early detection of cancer.

We will leverage the deep experience gained in Europe with our Flexipulse probe as we accelerate in the US. We plan to work with clinics to further document the product in clinical use to support the marketing and sales strategy.

As part of our US ramp up, we announced after the end of the period a partnership with Diligent Health Solutions, which will support NeoDynamics's US efforts with tasks such as managing medical information, reimbursement and coding services.

We also announced the hiring of Brendan Carney, who has more than 30 years' experience in life science, as our national sales director in the US.



## Europe

Our plan to launch in the US is supported by the hard work ongoing at leading clinics in Europe. In Europe we designed a study program to highlight the value of our biopsy technology in a clinical setting. The traction we built with independent advocates in Europe is crucial as we enter the US. We will continue to work hard in the key centers in the German-speaking regions as well as the UK, Ireland and Sweden.

The team in Europe continued to fine tune the product over the past months, and we are on track to resume production of the CorePulse and VacuPulse needles by the end of the year. Flexipulse, which will now be sold in the US, has not had any production challenges and is ready to go. We still expect the CorePulse needle to remain in high demand in Europe, while the FlexiPulse and VacuPulse needles should garner more attention in the US.

Clinics in Europe remain very engaged in the product with dozens of clinics now using the system and many others running pilots. As always, the feedback we get from these clinics allows us to constantly ensure quality.

CEO Anna Eriksrud

# Financial overview

## Revenue and earnings

Revenues during the quarter amounted to SEK 151 (339) thousand, and for the first nine months of the year to SEK 462 (1,155) thousand, of which net sales were SEK 32 (300) thousand and SEK 135 (322) thousand respectively. Development costs for NeoNavia were capitalized with SEK 73 (24) thousand during the quarter. Sales and production have been temporarily paused, to include feedback from our customers ahead of the US launch. The incremental improvements are going according to schedule, and we expect sales to resume shortly.

Cost of goods were SEK 31 (-85) thousand during the quarter and SEK 144 (4,239) thousand for the first nine months of the year, due to a halt in production while fine-tuning products. Other external costs increased to SEK 8,497 (7,253) thousand for the quarter and SEK 31,069 (25,029) thousand for the first nine months of the year, mainly reflecting higher costs for the establishment of the German subsidiary coupled with preparations for the US market.

Personnel costs decreased to SEK 1,693 (1,745) thousand during the quarter and SEK 5,643 (7,026) thousand for the first nine months of the year, an effect of several employees being replaced by consultants.

Operating loss amounted to SEK -14,661 (-13,066) thousand for the quarter and SEK 50,168 (48,595) thousand for the first half year whereas EBITDA, i.e., operating profit excluding depreciation, amounted to SEK -10,106 (-8,612) thousand for the quarter and SEK -36,584 (-35,238) thousand for the first nine months of the year.

## Financial position

Cash and cash equivalents at the end of the period amounted to SEK 37,607 thousand (SEK 24,710 thousand at year-end).

Cash flow from operating activities before changes in working capital amounted to SEK -10,017 (-8,891) thousand and after changes in working capital to SEK -11,971 (-10,877) thousand. Receivables decreased by SEK 9 thousand. The total cash flow amounted to SEK -12,296 (-10,986) thousand.

At period-end, the equity to assets ratio was 93 (95) percent and equity amounted to SEK 108,325 (116,307) thousand.

## The share

NeoDynamic's share was listed on Spotlight Stock Market on December 7, 2018 and on May 2, 2022 the share started trading on Nasdaq First North Growth Market with Redeye as Certified Adviser. The share's ticker remains "NEOD" and the ISIN code is SE0011563410.

On June 30, 2022 the number of shares in NeoDynamics AB amounted to 120,501,184, up from 60,250,592, at year-end. A rights issue of 60,250,592 shares was completed during the second quarter, increasing the share capital by SEK 6,025,059 to SEK 12,050,119.

On September 30, 2022, the number of shares in the company was 120,501,184 and the last price paid in the period was SEK 0.488.

## Shareholders

On September 30, the company had a total of 2,309 shareholders, compared with 1,451 at year-end. The 10 largest shareholders on that date are listed in the table below.

<b>Name</b>	<b>Shareholding</b>	<b>Ownership</b>
Gryningskust Holding AB	16,844,360	14.0%
Fang, Huasheng	13,631,896	11.3%
NKY SwedenAB	4,922,544	4.1%
SIX SIS AG	4,346,554	3.6%
Avanza Pension	4,080,781	3.4%
SEB Life International9	3,406,500	2.8%
Nordnet Pensionsförsäkring AB	3,308,034	2.8%
Karkas Capital AB	3,275,478	2.7%
Cardeon	3,072,774	2.6%
Futur Pension	2,444,306	2.0%
Others	61,167,957	50.7%

### Financial calendar

Year-End Report 2022	2023-02-17
Interim Report Jan-Mar	2023-05-11
Annual General Meeting	2023-05-23
Interim Report Jan-Jun	2023-08-17
Interim Report Jan-Sep	2023-11-16

## 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. As of recent, we see an added uncertainty in our surrounding world, both as a result of Russia's invasion of Ukraine and through a financial instability with rising inflation and general macroeconomic uncertainty. The company now stands ready to commercialize its first main product. The board and company management are assessing alternatives to secure financing of the commercialization and the company's long-term capital requirements on an ongoing basis. For a detailed outline of the risks attributable to the company and its shares, please refer to the prospectus published by the Board in March 2022.

## 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 interim report has not been reviewed by the company's auditor.

## Interim report submitted

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

Lidingö on November 17, 2022

Anna Eriksrud  
CEO

Ingrid Salén  
Chairman of the Board

Jessie Bao  
Board member

Carina Bolin  
Board member

Matthew E. Colpoys Jr  
Board member

Claes Pettersson  
Board member

Xiao-Jun Xu  
Board member

NeoDynamics AB 559014-9117

**For further information, please contact**

CEO Anna Eriksrud, phone +46 (0)708 444 966, e-mail [anna.eriksrud@neodynamics.com](mailto:anna.eriksrud@neodynamics.com)

CFO Aaron Wong, phone +46 (0)79 010 1714, e-mail [aaron.wong@neodynamics.com](mailto:aaron.wong@neodynamics.com)

The company's Certified Adviser is Redeye AB.

## Income Statement

Amount in SEK thousands	2022 July-Sept	2021 July-Sept	2022 Jan-Sept	2021 Jan-Sept	2021 Jan-Dec
<b>Revenue</b>					
Net sales	32	300	135	322	1,162
Work performed by the Company for its own use and capitalized	73	24	214	785	785
Other operating income	46	15	113	47	138
	<b>151</b>	<b>339</b>	<b>462</b>	<b>1,155</b>	<b>2,085</b>
<b>Operating expenses</b>					
Cost of goods	-31	85	-144	-4,239	-5,772
Other external costs	-8,497	-7,253	-31,069	-25,029	-37,124
Personnel costs	-1,693	-1,745	-5,643	-7,026	-9,698
Depreciation/amortization of tangible and intangible assets	-4,555	-4,454	-13,584	-13,357	-17,841
Other operating expenses	-36	-39	-190	-99	-120
<b>OPERATING LOSS</b>	<b>-14,661</b>	<b>-13,066</b>	<b>-50,168</b>	<b>-48,595</b>	<b>-68,469</b>
<b>Financial items</b>					
Financial income	32	0	55	0	0
Financial costs	0	0	-2	0	0
<b>Net financial items</b>	<b>32</b>	<b>0</b>	<b>53</b>	<b>0</b>	<b>0</b>
<b>LOSS AFTER FINANCIAL ITEMS</b>	<b>-14,629</b>	<b>-13,066</b>	<b>-50,115</b>	<b>-48,596</b>	<b>-68,469</b>
<b>Loss before tax</b>	<b>-14,629</b>	<b>-13,066</b>	<b>-50,115</b>	<b>-48,596</b>	<b>-68,469</b>
Tax	0	0	0	0	0
<b>Net loss</b>	<b>-14,629</b>	<b>-13,066</b>	<b>-50,115</b>	<b>-48,596</b>	<b>-68,469</b>
<b>EARNINGS PER SHARE BEFORE DILUTION, SEK</b>					
(no dilution)	<b>-0.12</b>	<b>-0.22</b>	<b>-0.53</b>	<b>-0.81</b>	<b>-1.14</b>
Number of shares at end of period	120,501,184	60,250,592	120,501,184	60,250,592	60,250,592
Average number of shares	120,501,184	60,250,592	93,687,189	60,250,592	60,250,592

## Balance Sheet

Amount in SEK thousands	30 Sept 2022	30 Sept 2021	31 Dec 2021
<b>ASSETS</b>			
<b>Fixed Assets</b>			
Intangible assets	58,779	75,343	70,997
Tangible assets	1,789	1,207	1,494
Financial assets	2,398	123	370
	<b>62,966</b>	<b>76,673</b>	<b>72,861</b>
<b>Current Assets</b>			
Inventories	3,728	2,092	2,545
Accounts receivables	690	339	1,020
Receivables from group companies	782	0	0
Current tax assets	0	0	159
Other receivables	9,503	5,308	6,031
Prepaid expenses and accrued income	1,078	479	714
Cash and cash equivalents	37,607	37,352	24,710
	<b>53,389</b>	<b>45,570</b>	<b>35,179</b>
<b>TOTAL ASSETS</b>	<b>116,354</b>	<b>122,242</b>	<b>108,040</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Restricted Equity</b>			
Share capital	12,050	6,025	6,025
Fund for development expenditure	53,667	75,298	65,875
	<b>65,718</b>	<b>81,323</b>	<b>71,900</b>
<b>Non-restricted Equity</b>			
Share premium reserve	303,041	247,528	248,179
Retained earnings	-210,319	-163,948	-154,057
Profit/loss for the year	-50,115	-48,596	-68,469
	<b>42,607</b>	<b>34,984</b>	<b>25,653</b>
<b>TOTAL EQUITY</b>	<b>108,325</b>	<b>116,307</b>	<b>97,553</b>
<b>Provisions</b>			
Provisions for guarantee	240	0	240
<b>Long-term liabilities</b>			
Other long-term liabilities	665	327	327
<b>Current liabilities</b>			
Accounts payable	3,275	2,489	4,789
Current tax liability	0	201	0
Income tax payable	37	603	353
Accrued expenses	3,812	2,315	4,778
	<b>8,030</b>	<b>5,935</b>	<b>10,487</b>
<b>TOTAL LIABILITIES</b>	<b>8,030</b>	<b>5,935</b>	<b>10,487</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>116,354</b>	<b>122,242</b>	<b>108,040</b>



## Cash Flow Statement

Amounts in SEK thousands	2022 July- Sept	2021 July- Sept	2022 Jan- Sept	2021 Jan- Sept	2021 Jan-Dec
<b>Operating activities</b>					
Loss after financial items	-14,629	-13,066	-50,115	-48,596	-68,469
Adjustments for items not included in cash flow	4,612	4,175	13,618	12,706	18,081
<b>Cash provided by operating activities before changes in working capital</b>	<b>-10,017</b>	<b>-8,891</b>	<b>-36,497</b>	<b>-35,890</b>	<b>-50,388</b>
<i>Cash from changes in working capital</i>					
Increase (-) / decrease (+) in inventories	-302	-391	-1,263	-282	-736
Increase (-) / Decrease (+) in receivables	9	-73	-4,081	1,099	-884
Increase (+) / decrease (-) in operating liabilities	-1,661	-1,521	-2,903	197	5,162
<b>Cash provided by operating activities</b>	<b>-11,971</b>	<b>-10,877</b>	<b>-44,744</b>	<b>-34,876</b>	<b>-46,846</b>
<b>Investing activities</b>					
Investment in intangible assets	-148	-109	-820	-785	-785
Investment in tangible assets	-129	0	-760	-226	-651
Investment in financial assets	0	0	-2,027	-10	-258
<b>Cash used in investing activities</b>	<b>-276</b>	<b>-109</b>	<b>-3,607</b>	<b>-1,021</b>	<b>-1,694</b>
<b>Financing activities</b>					
Rights issue	-49	0	60,887	0	0
Issuance of share options	0	0	338	0	0
<b>Cash used in financing activities</b>	<b>-49</b>	<b>0</b>	<b>61,225</b>	<b>0</b>	<b>0</b>
<b>Net change in cash and cash equivalents</b>	<b>-12,296</b>	<b>-10,986</b>	<b>12,873</b>	<b>-35,898</b>	<b>-48,540</b>
Cash and cash equivalents, opening balance	49,903	48,339	24,710	73,250	73,250
Foreign exchange differences in cash	0	0	24	0	0
Cash and cash equivalents, ending balance	37,607	37,352	37,607	37,352	24,710

## Key Figures

	Q3 2020	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022
Net sales, SEK thousands	0	0	22	0	300	839	92	10	32
Operating loss, SEK thousands	-6,731	-11,022	-17,261	-18,263	-13,066	-19,134	17,175	-18,333	-14,661
Operating margin %	neg	neg	neg	neg	neg	neg	neg	neg	neg
Balance sheet total, SEK thousands	95,981	171,292	156,886	136,981	122,242	107,881	89,253	132,586	116,354
Equity ratio %	94%	97%	94%	95%	95%	90%	90%	93%	93%
Cash, SEK thousands	3,486	73,250	62,278	48,339	37,352	24,710	8,301	49,903	37,607
Earnings/loss per share, SEK	-0.19	-0.28	-0.29	-0.30	-0.22	-0.32	-0.29	-0.17	-0.12
Equity per share, SEK	2.52	2.75	2.46	2.15	1.93	1.62	1.33	1.02	0.90

## Statements of change in equity in summary

Amount in SEK thousands	July - Sept		Jan-Sept		Full year
	2022	2021	2022	2021	2021
Balance at the beginning of the period	123,003	129,663	97,553	165,554	165,554
Warrant Premium	0	-289	0	-651	467
New share issue (net of issue costs)	-49	0	60,887	0	0
Profit(-loss) for the period	-14,629	-13,066	-50,115	-48,596	-68,469
Balance at the end of the period	<b>108,325</b>	<b>116,307</b>	<b>108,325</b>	<b>116,307</b>	<b>97,553</b>
Average number of shares during the period	120,501,184	60,250,592	120,501,184	60,250,592	60,250,592
Shares outstanding at the end of the period	120,501,184	60,250,592	93,687,189	60,250,592	60,250,592

## Definitions

<b>Earnings/Loss per share</b>	Earnings/loss for the period / average number of shares
<b>Equity / assets ratio</b>	Total equity / total assets
<b>Equity per share</b>	Equity at the end of the reporting period / average number of shares
<b>Operating margin</b>	Operating profit / net sales

## Warrant program – 2020/2023 and 2022/2025

The company has implemented two incentive programs aimed at senior executives in the company. In 2020, 1,021,900 warrants were issued with the right for holders to for each option subscribe for one (1) share with a subscription price of SEK 4.71 during the period August 1, 2023 – September 30, 2023.

In 2022, 2,640,000 warrants were issued with the right for holders to for each option subscribe for one (1) share with a subscription price of SEK 1.74 during the period February 17, 2025 – May 17, 2025.

The Board's ambition is to propose the issuance of warrants or equivalent up to a maximum total dilution of 5%.

There are no dilution effects during the period. The warrant terms are available on the company's website.

## 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. Every year, about 2.1 million women are diagnosed with breast cancer, a number that increases by 5 percent annually. The market for breast cancer diagnostics is growing and was estimated in 2025 to reach 830 million US dollars. The proportion of non-surgical biopsies is increasing at the expense of the surgical ones. Extended screening programs and new screening techniques enable more and more tumors to be detected earlier. 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 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. The product has CE approval since 2016 and received FDA clearance in 2022

### New innovative technology

The patented 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 as well as in dense tissue.

### Intellectual Property

The technology is protected in Europe's larger countries as well as in China and the USA. Patents for technology in the proprietary needle have been approved in Europe, the USA and China. The company's various patents run until 2034 and additional patent applications have been filed.

### Good results in clinical studies

The PULSE study (ClinicalTrials.gov ID: NCT03975855) shows that the system performs well when used in axillary lymph nodes. The patented pulse technology was considered to stabilize the target organ lymph node and improve needle control during insertion, and it was possible to obtain multiple samples with a single needle insertion.

### 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-guided, technically difficult biopsies such as in the axillary lymph nodes.”**