NeoDynamics AB (publ) Full Year Report

1 January - 31 December 2022

neodynamics

Pre-Launch Activities in the US underway

Group consolidated accounts have been prepared for the fourth quarter, and full year, which includes the consolidation of NeoDynamics AB, NeoDynamics GmbH and NeoDynamics Inc. These are represented in the financial statements as adjusted numbers, and are the comparative figures used for last year.

Fourth Quarter 2022

- Revenues amounted to SEK 130 (931) thousand, of which SEK 0 (1,039) thousand were net sales
- Net loss amounted to SEK -26,857 (-19,957) thousand.
- Loss per share amounted to SEK -0.22 (-0.33).
- Cash and cash equivalents amounted to SEK 20,067 (24,960 at year-end) thousand.

Full Year 2022

- Revenues amounted to SEK 903 (2,086) thousand, of which SEK 135 (1,162) thousand were net sales
- Net loss amounted to SEK -74,514 (-68,553) thousand.
- Loss per share amounted to SEK -0.73 (-1.14).
- Cash and cash equivalents amounted to SEK 20,067 (24,960 at year-end) thousand.

Significant events during the quarter

- In early November, NeoDynamics hired National Sales Director in the USA, Brendan Carney, for the launch of its NeoNavia® Biopsy System. Brendan has more than 20 years of experience including Genentech and Pharmacia, leading teams and product launches in oncology, infectious diseases, endocrinology, and medical devices
- In late November, NeoDynamics geared up for the US launch by partnering with Diligent Health Solutions. Diligent will assist NeoDynamics in communicating with patients, caregivers, and health care professionals, from initial consultation to strategic implementation and daily operations. Their specialists will support the company's efforts to manage medical information, reimbursement and coding services.
- In December, NeoDynamics appointed Matthew Colpoys, to lead US operations. Matt will remain on the board and reports to CEO Anna Eriksrud.

Significant events after the end of the quarter

- In January, NeoDynamics Partnered with Uniphar for US Distribution and Logistics support. Uniphar is a global distribution and logistics giant and will help to ensure a successful US launch of NeoNavia®
- In February NeoDynamics' largest owner secures the launch of NeoNavia in the US. Gryningskust Holding AB, offered the company a loan of SEK 14 million, with a fixed interest rate of 8%, which is within the market price range considering other similar financing. The loan maturity date is August 15th, 2023. The loan is intended to be converted into shares if the company issues new shares in the future, subject to shareholder approval.
- NeoDynamics announed that Jie Bao and Xiaojun Xu will step down from the Board of Directors as of 2023-02-14 based on a mutual agreement. They will instead focus on supporting the company and its plans for the Chinese market.

CEO COMMENT

Ready for commercialisation in the US

In September 2022, we reached an essential milestone with the FDA clearance of NeoNavia®. The US approval is a cornerstone in our strategic way forward and path to profitability.

The covid pandemic delayed all FDA applications and made the timing of approvals unpredictable. Thus, it was prudent for a small company such as NeoDynamics to wait for the go-ahead from the FDA before starting to build the US organization.

The recently deployed management team is preparing for fullscale commercialization of Neonavia in 2023. This includes identifying and hiring personnel, locking in attendance at key scientific congresses and building the infrastructure to support sales activities in the field. The first product to market is FlexiPulse. The FlexiPulse needle is unique in its design and allows insertion into challenging locations. Checking lymph nodes in the axilla (armpit) is critical to assessing whether cancer has spread. The introduction of FlexiPulse will allow physicians to safely and effectively simplify biopsy of the lymph nodes in the axilla in a minimally invasive fashion. Shortcomings of existing biopsy systems result in most axillary nodes being removed surgically. A common side effect of surgical removal of axilla lymph nodes is persistent swelling (edema) of the arm, and a FlexiPulse biopsy minimizes this risk. Further, the design of the FlexiPulse makes it ideal for tissue sampling in suspected lesions in the proximity of breast implants, which is an increasingly common problem, especially in the United States.

An ever more critical stakeholder in breast cancer treatment is the patient themselves and related patient advocacy groups. Patient empowerment is an increasingly important aspect of delivering breast cancer care. For this reason, NeoDynamics' hired a US management team with significant backgrounds working with specialty products and associated patient associations. Another advantage of the organization's special markets background is working with key-opinion-leading physicians at the most prestigious treatment centers in the United States.

To ensure cost-effectiveness, NeoDynamics Inc. outsources customer care and logistics functions



to its partners Diligent Health Solutions and Uniphar Logistics, both divisions of Uniphar Group of Ireland.

Of course, the deep experience gained in Europe is vital for success in the USA. In more than 30 cancer research centres in Germany, the UK and Sweden, we continue our work and collaboration with key opinion leaders. From this ongoing experience we can conclude that clinics in Europe remain very engaged. We have fine-tuned two needles during 2022, which has resulted in better products, but also in postponed deliveries. It is our firm commitment to make no compromise on product quality.

Also, we continue to run our clinical study program to document the pulse technology and our different needles in clinical practice. The clinical program has resulted in several presentations at congresses during 2022 including the prestigious SBI congress in Savannah in May.

Organisational development

In 2022, we added several senior and experienced members to our team. On December 1, 2022, Matthew E. Colpoys, Jr. (member of the Board of Directors) assumed the position of US CEO for NeoDynamics Inc. We also welcomed Brendan Carney, our national sales director in the US. In February 2022, we also onboarded Aaron Wong as our Group CFO of NeoDynamics AB. We now have an organization that is capable of executing the strategy in both the short and long term.

Our performance in 2022

Our revenue is still modest while we continue to deploy resources in a controlled fashion to develop our products in Europe and the US. We are pleased to have secured short-term funding for the launch in the US.

CEO Anna Eriksrud

Financial overview

Revenue and earnings

Revenues during the quarter amounted to SEK 130 (931) thousand, and for the full year SEK 903 (2,086) thousand, of which net sales were SEK 0 (1,039) thousand and SEK 135 (1,162) thousand respectively. Development costs for NeoNavia, related to personnel costs, were capitalized with SEK 0 (0) thousand during the quarter. Deliveries 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 deliveries to resume shortly.

Cost of goods were SEK 752 (1,533) thousand during the quarter and SEK 947 (5,772) thousand for the full year, due to a halt in production while fine-tuning our products. Other external costs increased to SEK 14,755 (12,179) thousand for the quarter and SEK 38,239 (37,209) thousand for the full year, mainly reflecting higher costs for the preparation of the commercialisation in the US market.

Personnel costs increased to SEK 5,355 (2,672) thousand during the quarter and SEK 16,321 (9,698) thousand for the full year, an effect of several new employees joining the business during 2022.

Operating loss amounted to SEK 25,459 (19,957) thousand for the quarter and SEK 73,231 (68,552) thousand for the full year, whereas EBITDA, i.e., operating profit excluding depreciation, amounted to SEK -20,900 (-15,473) thousand for the quarter and SEK -55,087 (-50,712) thousand for the full year.

Financial position

Cash and cash equivalents at the end of the period amounted to SEK 20,067 thousand (SEK 24,960 thousand at year-end). The loan from our largest shareholder, Gryningskust Holding AB, positively impacts our work capital and further secures the immediate financing needs of the business.

We started to report the consolidated Group numbers on the 29th October 2021, and the figures referenced in the below cash flow from 2021, are from this point up until 31st December 2021.

Group Cash flow from operating activities before changes in working capital amounted to SEK -19,893 (-10,530) thousand and after changes in working capital to SEK -19,575 (-7,789) thousand. Receivables decreased by SEK 34 thousand. The total cash flow amounted to SEK -19,856 (-8,215) thousand.

At the end of the reporting period, the equity to assets ratio was 90 (90) percent and equity amounted to SEK 84,571 (97,476) 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 December 31, 2022 the number of shares in NeoDynamics AB amounted to 120,501,184, up from 60,250,592, at year-end 2021. A rights issue of 60,250,592 shares was completed during the second quarter of 2022, increasing the share capital by SEK 6,025,059 to SEK 12,050,118.

On December 31, 2022, the number of shares in the company was 120,501,184 and the last price paid in the period was SEK 0.47.

Shareholders

On December 31, the company had a total of 3,105 shareholders, compared with 1,451 the year before. The 10 largest shareholders on that date are listed in the table below.

Name	Shareholding	Ownership
Gryningskust Holding AB	16,844,360	14.0%
Fang, Huasheng	13,631,896	11.3%
Avanza Pension	5,606,903	4.7%
Boai NKY Medical Holdings Ltd	4,922,544	4.1%
SIX SIS AG	4,146,554	3,1%
Nordnet Pensionsförsäkring AB	3,548,290	2.9%
Alandsbanken ABP	3,462,242	2.9%
Rentability Sweden AB	2,804,134	2.3%
Cardeon AB (Publ)	2,803,234	2.3%
Futur Pension Försäkring	1,634,285	2,0%
Others	61,096,742	55.5%
Financial Calendar 2023/24		
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	
Annual Accounts 2023	2024-02-16	

All reports are available at the company's website: https://www.neodynamics.com/en-gb/reports

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 February 17, 2023

Anna Eriksrud	Ingrid Salén	Jessie Bao	Carina Bolin
CEO	Chairman of the Board	Board member	Board member
Matthew E. Colpoys Jr	Claes Pettersson	Xiao-Jun Xu	
Board member	Board member	Board member	

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The company's Certified Adviser is Redeye AB.

Consolidated Accounts

Income Statement

Amount in SEK thousands	2022 Oct-Dec	2021 Oct, 29 - Dec	2022 Jan-Dec	2021 Oct, 29 - Dec
Revenue				
Net sales	0	839	135	839
Work performed by the Company for its own use and capitalized	0	0	214	C
Other operating income	130	18	553	18
	130	858	903	858
Operating expenses				
Cost of goods	-752	-1,515	-947	-1,515
Other external costs	-14,755	-8,782	-38,239	-8,782
Personnel costs	-5,355	-1,959	-16,321	-1,959
Depreciation/amortization of tangible and intangible assets	-4,559	-3,000	-18,144	-3,00
Other operating expenses	-169	-14	-483	-14
OPERATING LOSS	-25,459	-14,412	-73,231	-14,412
Financial items				
Financial income	26	0	103	(
Financial costs	-1	0	-3	(
Net financial items	25	0	100	
LOSS AFTER FINANCIAL ITEMS	-25,434	-14,412	-73,130	-14,412
Loss before tax	-25,434	-14,412	-73,130	-14,412
Tax	-1,423	0	-1,384	(
Net loss	-26,857	-14,412	-74,514	-14,412

Consolidated Accounts

Balance sheet

Amount in SEK thousands

	31 Dec 2022	31 Dec 2021
ASSETS		
Fixed Assets		
Intangible assets	54,713	70,997
Tangible assets	1,575	1,494
Financial assets	138	123
	56,426	72,614
Current Assets		
Inventories	3,547	2,545
Accounts receivables	132	1,020
Receivables from group companies	0	0
Current tax assets	0	159
Other receivables	12,665	6,041
Prepaid expenses and accrued income	651	714
Cash and cash equivalents	20,067	24,960
	37,062	35,441
TOTAL ASSETS	93,488	108,054
EQUITY AND LIABILITIES		
Restricted Equity		
Share capital	12,050	6,025
	303,060	248,179
Other equity incl. profit/loss for the year	-230,539	-156,728
TOTAL EQUITY	84,571	
Provisions		
Provisions for guarantee	500	240
Long-term liabilities		
Other long-term liabilities	0	327
Current liabilities		
Accounts payable	1,742	4,865
Current tax liability	1,448	0
Other liabilities	162	354
Accrued expenses	5,065	4,793
	5,000	0
TOTAL LIADII ITIES AND DDOVICIONS	0 017	10,578
TOTAL LIABILITIES AND PROVISIONS	8,917	108,054
TOTAL EQUITY AND LIABILITIES	93,488	200,001

Consolidated Accounts

Cash Flow Statement				
	2022	2021	2022	2021
Amount in SEK thousands	Oct-Dec	Oct,29- Dec	Jan - Dec	Oct 29 -Dec
A				
Operating activities	25.450	14.412	50.004	44442
Operating profit/loss	-25,459	-14,412	-73,231	-14,412
Adjustments for items not included in cash flow	5,557	3,920	19,016	3,920
Financial Income	11	0	32	0
Financial Expenses	0	-37	0	-37
Cash provided by operating activities before changes in working capital	-19,893	-10,530	-54,186	-10,530
Cash from changes in working capital				
Increase (-) / decrease (+) in inventories	-334	-456	-1,593	-456
Increase (-) / decrease (+) in receivables	34	-958	-5,469	-958
Increase (+) / decrease (-) in operating liabilities	618	4,154	-3,246	4,154
Cash provided by operating activities	-19,575	-7,789	-64,495	-7,789
Investing activities				
Investment in intangible assets	-281	-425	-887	-425
Investment in tangible assets	0	0	-760	C
Investment in financial assets	0	0	-14	C
Cash used in investing activities	-281	-425	-1,660	-425
Financing activities				
Rights issue	0	0	60,887	C
Issuance of share options	0	0	338	C
Cash used in financing activities	0	0	61,225	0
Net change in cash and cash equivalents	-19,856	-8,215	-4,930	-8,215
Cash and cash equivalents, opening balance	39,966	33,191	24,960	33,191
Foreign exchange differences in cash	-44	-16	37	-16
Cash and cash equivalents, ending balance	20,067	24,960	20,067	24,960

NeoDynamics AB

Income Statement

Amount in SEK thousands	2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
Revenue				
Net sales	1,244	839	1,379	1,162
Work performed by the Company for its own use and capitalized	0	0	214	785
Other operating income	41	91	154	138
	1,285	930	1,747	2,085
Operating expenses				
Cost of goods	-751	-1,533	-895	-5,772
Other external costs	-17,581	-12,094	-48,650	-37,124
Personnel costs	-1,970	-2,672	-7,613	-9,698
Depreciation/amortization of tangible and intangible assets	-4,559	-4,484	-18,144	-17,841
Other operating expenses	-122	-20	-311	-120
OPERATING LOSS	-23,697	-19,873	-73,866	-68,469
Financial items				
Result from shares in group companies	-4,184	0	-4,184	(
Financial income	37	0	93	(
Financial costs	-1	0	-3	(
Net financial items	36	0	90	(
LOSS AFTER FINANCIAL ITEMS	-27,845	-19,873	-77,960	-68,469
Loss before tax	-27,845	-19,873	-77,960	-68,469
Tax	0	0	0	(
Net loss	-27,845	-19,873	-77,960	-68,469
EARNINGS PER SHARE BEFORE DILUTION, SEK				
(no dilution)	-0.23	-0.33	-0.76	-1.14
Number of shares at end of period	120,501,184	60,250,592	120,501,184	60,250,592
Average number of shares	120,501,184	60,250,592	102,627,636	60,250,592

	NeoDynamics AB			
Balance sheet				
Amount in SEK thousands	31 Dec 2022	31 Dec 2021		
ASSETS				
Fixed Assets				
Intangible assets	54,713	70,997		
Tangible assets	1,575	1,494		
Financial assets	371	370		
	56,660	72,861		
Current Assets				
Inventories	3,406	2,545		
Accounts receivables	132	1,020		
Receivables from group companies	1,385	0		
Current tax assets	0	159		
Other receivables	12,205	6,030		
Prepaid expenses and accrued income	531	714		
Cash and cash equivalents	16,534	24,710		
	34,193	35,179		
TOTAL ASSETS	90,853	108,040		
EQUITY AND LIABILITIES				
Restricted Equity				
Share capital	12,050	6,025		
Fund for development expenditure	49,461	65,875		
	61,511	71,900		
Non-restricted Equity				
Share premium reserve	303,060	248,179		
Retained earnings	-205,448	-154,057		
Profit/loss for the year	-77,960	-68,469		
	19,653	25,653		
TOTAL EQUITY	81,164	97,553		
Provisions				
Provisions for guarantee	500	240		
Long-term liabilities				
Other long-term liabilities	0	327		
Current liabilities				
Accounts payable	1,515	4,789		
Liabilities to group companies	3,526	0		
Current tax liability	0	0		
Income tax payable	29	354		
Accrued expenses	4,118	4,778		
TOTAL LIABILITIES AND PROVISIONS	9,689	10,488		
TOTAL EQUITY AND LIABILITIES	90,853	108,040		

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NeoDynamics AB

2022 Oct-Dec	2021 Oct-Dec	2022 Jan-Dec	2021 Jan-Dec
-27 845	-19 873	-77 960	-68,469
			18,081
-18,120	-14,498	-54,831	-50,388
-196	-453	-1,459	-736
-2,386	-2,214	-6,467	-884
2,064	5,196	-839	5,162
-18,638	-11,969	-63,596	-46,846
-281	0	-887	-785
0	-425	-760	-651
0	-247	0	-258
-2,437	-672	-5,831	-1,694
0	0	60,887	0
0	0	338	
0 0	0 0	338 61,225	0
			0 0 -48,540
0	0	61,225	0 0
0 -21,075	0 -12,641	61,225 -8,202	0 0 -48,540
	Oct-Dec -27,845 9,725 -18,120 -196 -2,386 2,064 -2,386 -2,386 -2,386 0 -2,386 0 -2,386 0 -2,386 0 -2,386 0 -2,386 0 -2,386 -2,387 -2,386 -2,437 -2,437 -2,437	Oct-Dec Oct-Dec -27,845 -19,873 9,725 5,375 9,725 5,375 -18,120 -14,498 -196 -453 -2,386 -2,214 2,064 5,196 -2,386 -2,214 -2,386 -2,214 -2,386 -2,214 -2,386 -11,969 -196 -4253 -2,064 5,196 -2,064 5,196 -2,064 0 -2,064 -2,214 0 -2,214 -2,064 -2,214 -2,064 -2,214 -2,064 -2,214 0 -2,247 -2,281 0 -2,2437 -6672	Oct-Dec Jan-Dec 0 -19.873 -19.873 -27,845 -19.873 23,129 9,725 5,375 23,129 9,725 5,375 23,129 -18,120 -14,498 -54,831 -196 -14,498 -54,831 -197 -2,386 -2,214 -6,467 -2,364 5,196 -839 -2,064 5,196 -839 -2,064 5,196 -839 -2,064 5,196 -839 -2,064 5,196 -839 -2,064 5,196 -839 -2,064 5,196 -63,596 -2,064 -1,969 -839 -2,064 -1,969 -839 -2,064 -1,969 -839 -2,17 0 -247 -2,281 -247 0 -2,437 -6472 -5,831

Income Statement Adjusted for 2021*

Amount in SEK thousands	2021 NeoDynamics AB Oct 1st - Oct 28th	2021 Consolidated Accounts Oct 29 - Dec 31st	Q4 2021 Adjusted Income Statement	2021 NeoDynamics AB Jan 1st - Oct 28	2021 Consolidated Accounts Oct 29 - Dec 31st	2021 Total Adjusted Income Statement
Revenue						
Net sales	200	839	1,039	322	839	1,162
Work performed by the Company for its own use and capitalized	0	0	0	785	0	785
Other operating income	-127	18	-108	121	18	139
	73	858	931	1,228	858	2,086
Operating expenses						
Cost of goods	-18	-1,515	-1,533	-4,257	-1,515	-5,772
Other external costs	-3,397	-8,782	-12,179	-28,426	-8,782	-37,209
Personnel costs	-713	-1,959	-2,672	-7,739	-1,959	-9,698
Depreciation/amortization of tangible and intangible assets	-1,485	-3,000	-4,484	-14,841	-3,000	-17,841
Other operating expenses	-6	-14	-20	-106	-14	-120
OPERATING LOSS	-5,545	-14,412	-19,957	-54,140	-14,412	-68,552
Financial items						
Financial income	0	0	0	0	0	0
Financial costs	0	0	0	0	0	0
Net financial items	0	0	0	0	0	0
LOSS AFTER FINANCIAL ITEMS	-5,545	-14,412	-19,957	-54,140	-14,412	-68,553
Loss before tax	-5,545	-14,412	-19,957	-54,140	-14,412	-68,553
Tax	0	0	0	0	0	0
Net loss	-5,545	-14,412	-19,957	-54,140	-14,412	-68,553

* Consolidated Accounts for 2021 plus the result for the group mother, NeoDynamics AB, for the time before the group was created in 2021.

Key Figures

	Oct 29 - Dec 31 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022
Net sales, SEK thousands	839	92	10	32	0
Operating loss, SEK thousands	-14,412	-15,847	-17,487	-14,626	-25,459
Operating margin %	neg	neg	neg	neg	neg
Balance sheet total, SEK thousands	108,054	91,468	135,217	117,997	93,488
Equity ratio %	90%	89%	93%	94%	90%
Cash, SEK thousands	24,960	10,785	52,782	39,966	20,067

Consolidated Accounts

Statements of change in equity in summary			NeoDynamic	s Group
	Oct-Dec	Oct 29 -Dec	Jan-Dec	
Amounts in SEK thousands	2022	2021	2022	2021
Balance at the beginning of the period	110,699	110,758	97,476	110,758
Warrant premium	0	468	338	468
Reclass costs	20	680	0	680
Reclass warrant premium	665	0	327	0
New share issue (net of issue costs)	0	0	60,906	0
Translation difference	45	-17	38	-17
Profit(-loss) for the period	-26,857	-14,412	-74,514	-14,412
Balance at the end of the period	84,571	97,476	84,571	97,476

Definitions

Earnings/Loss per share	Earnings/loss for the period / average number of shares
Equity / assets ratio	Total equity / total assets
Equity per share	Equity at the end of the reporting period / average number of shares
Operating margin	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 aaproval 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."

Ref 1, Markets and Markets, September 2020 <u>https://www.marketsandmarkets.com/Market-Reports/biopsy-devices-breast-biopsy-market-189011805.html</u> Schässburger K, Paepke S. Po86. Novel pulse biopsy platform incorporating adaptive open-tip sampling needle increases sampling yield and needle control. European Journal of Surgical Oncology. 2021;47(5). doi:10.1016/j.ejs0.2021.03.090.