

## Initial coverage

### NEODYNAMICS AB

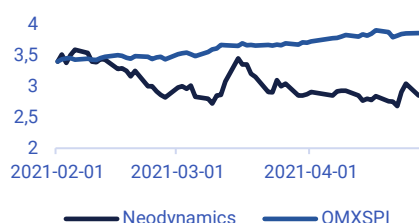
CEO: Anna Eriksrud  
 CoB: Ingrid Salén  
[www.neodynamics.com](http://www.neodynamics.com)

Bloomberg: NEOD:SS  
 Refinitiv Eikon: NEOD.ST

Listing: Spotlight Stock Market

Share, last: SEK 2.9  
 Market Cap: SEK 180m

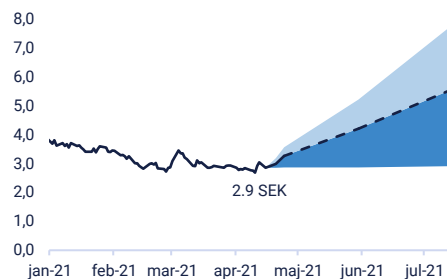
### SHARE PRICE DEVELOPMENT



|                 | 12M  | YTD | 6M  | 1M  |
|-----------------|------|-----|-----|-----|
| Share perf. (%) | -3.5 | -19 | -34 | 4.8 |

Source: Refinitiv Eikon

### VALUATION INTERVAL



|                 | BEAR | BASE | BULL |
|-----------------|------|------|------|
| Value per share | 2.90 | 5.55 | 7.76 |
| Up-/downside    | 0%   | 89%  | 165% |

Source: Carlsquare estimates

### CARLSQUARE EQUITY RESEARCH

Richard Ramanius  
 Equity Analyst

## The next generation of biopsy instruments

NeoDynamics is a MedTech company that has developed a new generation of breast biopsy instruments. Commercial introduction is underway. Clinical trials are used as traction. Read our investment case (pp. 3-8) and valuation (pp. 32-36) for a shorter overview of the case.

### New generation of breast biopsy instruments

NeoDynamics has invented NeoNavia, which is a powered biopsy instrument with three disposable needles that easily cuts through tissue and positions the needle in the correct location with no risk of overshooting the target. Its micro pulse technology is patented. The new proprietary needle type FlexiPulse gives 300 percent larger specimens in a tissue model. It is being evaluated in axillary (armpit) biopsy. Axillae are a sensitive part of the body, full of blood vessels and nerves, for which traditional biopsy instruments are not suited.

The product development is complete and NeoNavia has a CE certification. Commercialization is underway, with the first order having been received during the fourth quarter of 2020. The company is well prepared for the commercialization. Large sums are invested in two clinical trials with around 500 patients between them. The important FDA 510(k) application (for the US market) has been delayed but should be submitted by mid-year 2021. The company's largest shareholder, who is a Chinese company, will be responsible for clearance and sales in China.

### Investment thesis

In our opinion, the investment thesis for NeoDynamics boils down to the company succeeding on the American market. Clinical trials and sales to clinics in Europe will initially be important as testing grounds and for user references. We expect a clinical trial on the US market starting in 2022 together with a simultaneous market introduction. If successful, this could lead to a partnership with a large American company around 2023. This partner should be able to expand US sales quickly, which should lead to NeoDynamics becoming cash flow positive. Over time, the European and Chinese market should gradually catch up with the US market and contribute with growing positive cash flows. A sale of NeoDynamics to a larger MedTech company is likely if commercialization is successful in the USA.

### Valuation

We believe that the share is weighed down by the latest directed share issue of about SEK 90m from November last year. We value the company at SEK 5.55 in the base case scenario. Our bear scenario valuation is SEK 2.90, while our bull scenario valuation is SEK 7.76. Compared to a group of similar Swedish MedTech companies, NeoDynamics has a low market cap and enterprise value despite being in a more advanced stage.

### Key figures

|                     | 2019 | 2020 | 2021E | 2022E | 2023E |
|---------------------|------|------|-------|-------|-------|
| Net sales           | 0    | 0    | 6     | 16    | 57    |
| Adj. EBITDA         | -40  | -46  | -58   | -44   | 5     |
| Growth, net sales   | n.m. | n.m. | n.m.  | 157%  | 251%  |
| Growth, adj. EBITDA | n.m. | n.m. | n.m.  | 121%  | 63%   |
| Adj. EBITDA-margin  | n.m. | n.m. | -916% | -317% | 23%   |
| Adj. EBIT-margin    | n.m. | n.m. | -998% | -457% | -70%  |
| ROIC                | -39% | -33% | -56%  | -71%  | -12%  |
| EV/Sales            | n.m. | n.m. | 15,7x | 6,1x  | 1,7x  |
| EV/Adj. EBITDA      | n.m. | n.m. | n.m.  | n.m.  | 18,8x |
| P/BV                | 1,0x | 1,5x | 1,7x  | 1,8x  | 1,5x  |

Source: Carlsquare estimates.

## Table of contents

|  |    |
|--|----|
| Investment case .....                                  | 3  |
| Description of the company and share performance ..... | 9  |
| Technology and products.....                           | 13 |
| Medical background and regulatory development.....     | 16 |
| Market and comparable companies.....                   | 21 |
| Carlsquare estimates and financial history.....        | 27 |
| Valuation and valuation methods .....                  | 32 |
| Risks.....   | 37 |
| Accounts and key figures.....                          | 38 |
| Bibliography .....                                     | 41 |
| Disclaimer .....                                       | 42 |

## Investment case

This section gives an overview of NeoDynamics' business idea, share triggers, investment risks and a short valuation section (base case SEK 5.55).

### Business idea

#### Breast cancer is the most common type of cancer

About one in eight women will develop breast cancer during her lifetime. It is the most common type of cancer in the world with an incidence of about 2.3 million. In NeoDynamics's main markets, there are almost one million cases per year. It is the largest biopsy market. The instruments used are often simple and functional. There is room for more advanced devices with a better performance.

#### The evolution of breast biopsy

There are two generations of needle instruments used in the diagnosis of breast cancer, three if we include fine needles, which might be called generation 0. The first generation consists of spring-loaded core needles (core needle biopsy, CNB). They enabled the sampling of histologic specimens (cut out tissue) from a small needle as a minimally invasive intervention instead of traditional surgical biopsy (opening of the skin followed by excision). The second generation followed just a few years later and consists of vacuum assisted biopsy (VAB) instruments. Whereas only one sample can be acquired at a time with a spring-loaded core needle, this generation enables the sampling of several histologic specimens at the same time. It also enables the extraction of a larger amounts of tissue since the needle is thicker. The vacuum aspirates tissue samples through the side of the needle which are cut off and collected in a small container. VAB is mainly used for cases where a volume of tissue is calcified or where the lesion or tumour cannot be felt.

NeoDynamics has invented what we would define as the third generation of biopsy instruments. Whereas the other instruments consist of ordinary needles that have to be pushed through the tissue to the tumour by hand, the needles from NeoDynamics cut through the tissue by means of a pneumatic mechanism that transfers pulses to it. The needle uses a hammering action that has a stroke length of 1-2.5mm. This means that insertion through the tissue can be performed without force and that the tumour can be penetrated by the same method. In the first and second generation, the tumour itself cannot be penetrated by simple needle insertion (since it is very dense), rather the spring and vacuum mechanisms are needed for this. Furthermore, the manual insertion means that tissue is torn, while NeoNavia cuts through tissue, leading to less tissue damage. It is particularly an advantage when inserting the needle through dense rather than fatty breast tissue (around half of all women have mainly dense rather than non-dense breast tissue). Using traditional biopsy instruments requires experience. NeoNavia's easier handling should be of use to younger physicians who are entering the field. They might require less tutelage from experienced physicians when using NeoNavia compared to traditional CNB.

NeoDynamics has also invented a new generation of needles, the FlexiPulse, which is only compatible with NeoNavia. It enables a larger sample size with the same needle diameter with better control of the area being sampled. It is currently being evaluated in axilla biopsies where surgical biopsy is still the main method used. CNB is sometimes used, but the instrument is not ideal for this purpose, since the fire and forget principle risks damaging surrounding nerves and blood vessels.

NeoNavia and its three needle types can easily substitute standard needle biopsy as the handling is the same and needle sizes are the same. The devices it substitutes are already standard of care in western countries. This means that the users will not encounter any problems regarding reimbursement for the biopsy procedure, as it is already in place. The vacuum assisted biopsy needle could also replace some minor surgery procedures.

The large majority of the revenue will come from disposable needles, which are only used once. The main unit will last for about 5000 biopsies, which should be at least ten years for a normal clinic. Having recurring revenues from disposable products that are used once for every procedure is an attractive sales model with predictable revenue streams.

## Better and larger samples sizes with NeoNavia

CNB is dependent on a spring to position the needle in and then cut through a lesion. Some VAB also use mechanisms (typically also a spring) to place the needle inside the lesion. In both cases, the high force employed can fracture and displace tissue inside the lesion. The large acceleration and small stroke length of NeoNavia minimizes these issues and should provide samples with cleaner cuts. This makes it easier to perform the histological analysis necessary for a correct diagnosis.

NeoNavia's three needle types also provide significantly larger tissue samples than today's gold standard. According to recent results from a pre-clinical trial, NeoNavia's needles provide 299 percent larger samples sizes with the FlexiPulse, 37 percent higher with CorePulse and 12 percent higher with VacuPulse.

Axillary biopsies with CNB are in general not as reliable as when used for breasts. They have a somewhat lower sensitivity when used in the axilla. This could likely be improved by using FlexiPulse, which gives much larger samples. There is an ongoing trial that investigates this, among other things, in the UK, the COMPULSE trial.

## Avoiding surgical biopsies

The lymph node that drains the breast is always removed when cancer is detected in the breast. Core needle biopsies of the axilla are somewhat rare today due to the risk of complications. If core needle biopsies could become standard of care in this area, money could be saved and discomfort for the patient reduced. If a surgical biopsy of the axilla is performed and cancer detected, typically a second surgery will have to be performed to remove all lymph nodes in the axilla (axillary node clearance). It is better to perform a needle biopsy which is a minimally invasive intervention, and then the axillary node clearance if cancer is detected since this entails just one procedure. Surgical biopsies are expensive and entail a risk for the patient while a needle biopsy typically just costs a few thousand SEK (or a few hundred dollars) and can be performed at a breast imaging center. NeoNavia has the potential to decrease the number of surgical interventions in the axilla, which saves money for society and suffering and complications for patients.

## Share value drivers

The most important upcoming trigger is the FDA 510(k) submission. FDA promises to handle a submission within 90 days, but it can be paused while for example additional documentation is asked for. Therefore, it should take longer. On average it takes 10 months. We assume that the first sale in the US occurs during the first half of 2022. A clinical trial is planned for the American market and should start at the same time. A trial is not necessary for approval, rather it is used as a marketing tool, through which clinics get to try NeoNavia and key opinion leaders connected to the trial can start recommending NeoNavia through their personal networks.

Further important upcoming triggers are topline results of the clinical trials in Germany (PULSE), which should be available by mid-year, and the UK (COMPULSE), which should be available at the beginning of 2022. The results from these trials are crucial for a fast uptake of NeoNavia. Positive results should incentivize the participating clinics to start utilizing NeoNavia in axilla biopsies, for which there are no satisfactory minimally invasive instruments available. From there use of NeoNavia should spread to the more difficult cases of breast biopsy (for example dense tissue or small and deep lesions), and in the end the product should find a more general use in the more advanced breast cancer and screening clinics, such as university hospitals. Positive results from clinical trials are also important as leverage when negotiating deals with larger partners.

Work should commence on a Chinese cFDA application as soon as NeoNavia receives the FDA 510(k) clearance. This is a somewhat lengthy process that might require a clinical trial in China. We assume that the process starts at the beginning of 2022 and ends by mid-2023, after which the first product sale occurs during the second half of 2023.

## Summary regulatory and sales events

|                   | 2021 H1 | 2021 H2 | 2022 H1 | 2022 H2 | 2023 H1 | 2023 H2 |
|-------------------|---------|---------|---------|---------|---------|---------|
| FDA 510(k)        |         |         |         |         |         |         |
| US Clinical trial |         |         |         |         |         |         |
| DE Clinical Trial |         |         |         |         |         |         |
| UK Clinical Trial |         |         |         |         |         |         |
| cFDA              |         |         |         |         |         |         |
| Sales Start EU-UK |         |         |         |         |         |         |
| Sales Start US    |         |         |         |         |         |         |
| Sales Start China |         |         |         |         |         |         |

Source: Carlsquare

There is a healthy M&A activity in breast biopsy instruments among international and American companies. If NeoNavia manages to establish itself on the US market, we deem it likely that the company will be sold. In our opinion, this could be relevant from around 2024.

Below we summarize factors that could drive the share price higher in the short to long term in order of chronological importance.

### Low valuation compared to developmental spending

Around SEK 127m was invested in the company before the IPO in 2018. A further SEK 190m has been raised on the capital markets during and after the IPO. In other words, more than SEK 300m has been invested to the company. This is far higher than the current market cap of SEK 180m. The average cost of developing and getting a medical device approved in the USA is USD 31m. NeoNavia is almost in this position.

NeoDynamics has a low market cap and enterprise value compared to similar Swedish MedTech companies. For example, BIBBInstruments has about the same market cap even though NeoDynamics is two years ahead in development and has received around four times more money in capital issues.

If the market realizes the comparatively low valuation of NeoDynamics, there might be a revaluation of the company, particularly after an FDA clearance.

### New biopsy marker clip

NeoDynamics is developing a biopsy marker clip that is visible on ultrasound, and not just on mammography. It is standard procedure in the US (and on its way to become this in Europe) to leave a tissue marker clip after a breast biopsy to be able to identify the location of the lesion for later treatment or monitoring. It could constitute an even interesting package together with NeoNavia for a US partner. More details about this project could be a trigger.

### FDA filing and US market introduction

The American market is crucial for NeoDynamics. We estimate that around 40-50 percent of the global value of breast biopsy instruments is concentrated in the US market. Higher quality instruments are used, more biopsies per breast cancer case are performed and the revenue per biopsy is higher.

If NeoDynamics is to be a success story, a partnership on the US market is essential. A large company that has sales personnel in contact with most radiology departments can push NeoNavia into many clinics simultaneously, which would speed up the sales expansion significantly, though at the cost of lower margins in the long term. In our estimate, the signing of a distribution agreement or license deal could occur in 2023. A logical partner would be producers of ultrasound equipment, which is practically always used in combination with NeoNavia. It should be a major trigger for the share.

### Unique opportunity in China

Boai NKY Medical Holdings is a Chinese corporation that owns almost 20 percent of NeoDynamics and has been a major shareholder for several years. The market opportunity in China is interesting since the sales of advanced breast biopsy instruments is still in its infancy. In our estimate, there are around 300 000 breast cancer cases per year in China, which is a similar number compared to the USA or Europe. NeoDynamics has the potential

to be among the first companies to introduce modern western breast biopsy instruments to China. First sales in China should therefore be a trigger for the share.

### Potential to become golden standard in axillary biopsy

In Neodynamics' main markets, there are around 940 000 new breast cancer cases per year. At least a quarter of them, or 235 000 patients, also need to have the axilla (armpit) examined. They could benefit from a non-invasive axillary needle biopsy. Assuming a price of SEK 2000 for the FlexiPulse, this equates to a market potential of SEK 470m. There is little competition in this segment. If the clinical trials in Germany and the UK show better results than expected, there is a potential to reach a large proportion of this group in the long term. This would offer an upside to our valuation, since we have assumed that only a small proportion of the total group (15 percent) will be treated with FlexiPulse.

### Expansion to new indications, new products

The total biopsy instrument market is worth around USD 2bn today. Breast cancer constitutes around one third of this. NeoNavia could also be used for prostate, kidney, liver or lung biopsies. In particular, around 1 million prostate biopsies are taken per year in the USA, compared to 1.6 million breast biopsies. An expansion to new indications would increase top sales and lead to a higher company valuation.

### Investment risks

Investing in pre-revenue Life Science companies entails a much higher risk compared to investing in mature companies. Below we list some risks that can result in a negative share price performance in the future.

#### Indifference from radiologists and doctors

The perhaps main difficulty for NeoDynamics will be to convince radiologists and doctors to try NeoNavia. Traditional core needle devices function well and get the job done in most situations. They already have very good sensitivity and specificity when used by an experienced physician. The healthcare sector can be conservative and traditional, especially if the existing solutions work well. The key will be to introduce NeoNavia in axillary core needle biopsies, where there are no good solutions today, and expand into the much larger breast biopsy market from there.

#### Slow sales roll-out

Our investment case is based on a quick market uptake of NeoNavia. If sales expansion is slower than we have foreseen, the valuation based on future discounted cash flow decreases, which should be reflected in the share price. Neodynamics itself has a limited sales force. Sales growth is, among other things, a function of the number of salespeople working for the company. Sales roll-out in Europe might be slower than expected. For this reason as well, finding an American partner will be crucial (in addition to being the largest market). Distributor agreements with certain European countries could also reduce the risk.

Corona has obviously been a hindrance for the sales roll-out. The company has not been able to meet potential customers for hands-on demonstrations. We expected restrictions to decrease from this point in time. If Corona restrictions are prolonged still further, it will be detrimental for NeoDynamics and might have an impact on our forecasts.

#### Dilution through future share issues

If the company's sales strategy does not succeed, sales expansion might be too slow to fund operations and more share issues be necessary leading to dilution and a negative return on investment from the investors point of view. Any delays in regulatory or commercial development could lead to more or larger share issues than expected. Historically, the company has exceeded its development budget. In our DCF valuation, we have forecast one further share issue of SEK 50m.

#### Clinical trials

Neodynamics' strategy is to introduce NeoNavia through clinical trials. The hospitals that take part in the clinical trials have the option to purchase NeoNavia after the trial is completed. Bad results in the clinical trials would have a large negative impact for the company. The outcome of the clinical trials should thus be either a positive or negative trigger for the company (assuming clear-cut results).

**FDA and cFDA**

FDA has low reliability according to the most recent surveys. While it is unlikely that a level one medical device that is similar to existing products, such as NeoNavia, should not be cleared at all, there is the risk that clearance might be delayed and more documentation required. As the USA is the most important market for NeoDynamics, any delay that leads to a postponement of sales and cash flows will impact the valuation of the company negatively. It might also lead to a need for more share issues.

To sell a medical product in China, an approval from cFDA is necessary. It will be based on the American FDA clearance and should take at least one year. A local clinical trial might have to be performed. It is as yet unclear whether a clinical trial will have to be performed and whether NeoDynamics will have to pay for it. A quick cFDA clearance would be a positive trigger while a slow clearance would be a negative one.

**Funding and sales forecast**

As NeoDynamics is some years from being cash flow neutral, funding is important. Historically, most of the costs have been due to product development and related activities. From 2021 and onwards, sales and marketing costs will be the main expenses together with the clinical trials. The directed share issue during the fourth quarter of 2020 was intended to finance the company’s activities until early 2022.

On of the most significant expense the company will incur going forward is starting up clinics and recruiting patients for COMPULSE clinical trial in the UK that will include up to 400 patients, which is included in Other external charges. A new trial with up to 100 patients should be initiated in the US after the 510 (k) approval and at the same time as the market introduction. Further costs are capex investments for the serial production of core needles in Thailand (tooling etc.) and costs related to the FDA application and other IP charges.

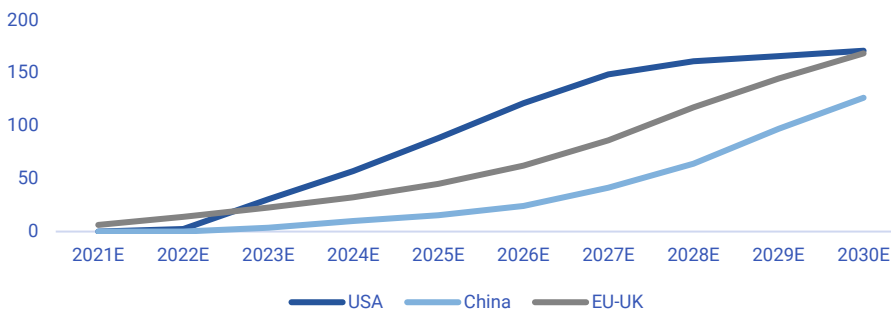
In our forecast of cash flows, we have estimated one new share issue in 2022 of SEK 50m.

In order to value NeoDynamics, we have made a top-down estimate of market share in the three main markets in 2030 and connected this with a bottom-up sales forecast for the first one or two years (depending on market). We model the sales growth with a sales curve. To this we add a forecast of costs and other components necessary for a discounted cash flow valuation. As can be seen in the graph below, we forecast the highest sales growth in the USA, where a full market share is reached before the other markets.

According to the prospectus from the first quarter of 2020, the funds from the share issue were to be distributed accordingly:

- Personnel 30%
- Administration 11%
- Product development, patent and regulatory 16%
- Clinical trials and sales 30%
- CAPEX 13%

**Sales forecast, 2021-2030**

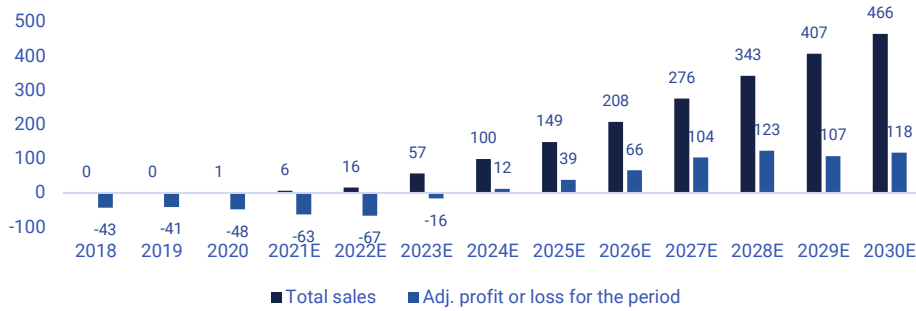


Source: Carlsquare Estimates.

Total sales and profit or loss is illustrated in the graph below. We forecast positive results (and cash flow) from 2023. This is dependent on finding an American partner by then. Due to carry forward losses, we estimate that taxes will have to be paid from 2029.



**Sales and profit forecast, 2018-2030**

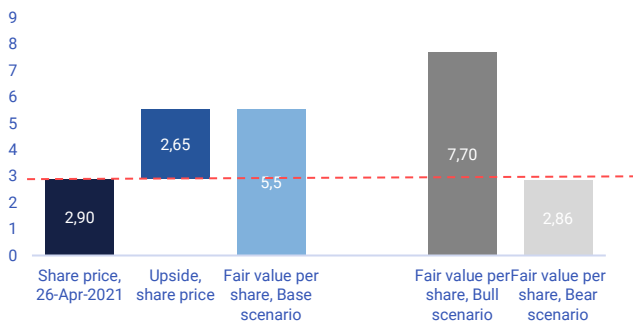


Source: Carlsquare Estimates.

**Fair share value 5.55 SEK**

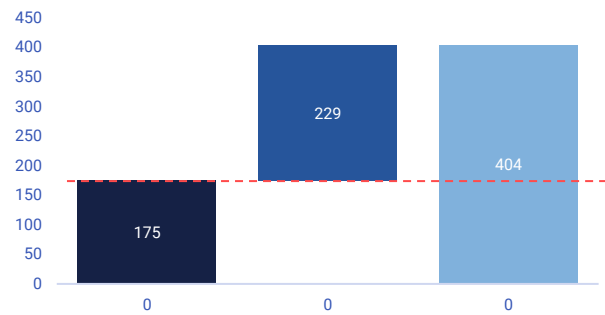
By discounting the cash flows with a rate of 14.7 percent, adding net cash at hands (SEK 73.3m) and dividing the resulting equity with the full number of shares after a further share issue (72.8 million shares), we obtain a fair value per share of SEK 5.55.

**Visualization fair value per share, Base scenario (SEK)**



Source: Carlsquare estimates

**Visualization market value, Base scenario (mSEK)**



Source: Carlsquare Estimates

**Bull Scenario**

In the bull scenario, we assume 30 percent higher sales figures for the final year, 2030. We also assume much higher sales growth rates in Europe and China. **This leads to a fully diluted fair value per share of SEK 7.76.**

**Bear Scenario**

In the bear scenario, we assume 30 percent lower sales figures for the final year, 2030. We also assume slower growth rates across all markets. Due to the slower sales growth, the company will need to raise more money, SEK 60m instead of the SEK 50m in the base case scenario. We also assume that the share price for the capital raise is lower, at SEK 3 per share. **This leads to a fully diluted fair share value of SEK 2.90.**



## Description of the company and share performance

Neodynamics has invented the new breast biopsy instrument NeoNavia, which can use three different needles, one of them proprietary and suitable for axillary biopsies and other types of biopsies in sensitive areas. NeoNavia operates through micro pulses. The company has a solid institutional ownership exceeding 50 percent. The company has raised large sums of money compared to its market cap. The share performance has been stagnant since the IPO in late 2018.

## Introduction to NeoDynamics

### History and goals

The first company that developed Neonavia was founded in 2004 by Professor Hans Wiksell but went bankrupt in 2015. In the same year it was re-founded as Neodynamics. The technology behind Neonavia is based on research from the Karolinska Institute. The validation version of NeoNavia was CE approved in 2016. The company was listed on Spotlight Stock Market in 2018. The money raised was intended for the completion of the commercial version of Neonavia and the initiation of clinical trials in Germany and the UK. The improved version consequently accepted by the notified body as an improvement of the validation version in October 2019 and given CE certification. In 2021 production is being relocated to Thailand. The process should be complete by mid-year. This will enable large scale serial production at a lower cost compared to the previous facilities in Örnköldsvik. Companies commercial phase started in the fourth quarter of 2020, as the first order for NeoNavia was received from Buckinghamshire NHS Trust.

In the short term, the company's goal is now to introduce NeoNavia to the clinics that have participated in clinical trials or the development of the commercial version, which are generally university clinics or top clinics. In our estimate, there are six clinics in Sweden, seven clinics in Germany and eight clinics in the UK. Neodynamics goal is to reach a 50 percent market share in these clinics after two years. Additional clinics will be added through peer-to-peer sales and collaboration with key opinion leaders, assuming a positive outcome in the clinical trials.

Entry on the US market is expected during the first half of 2021. This should occur simultaneously with a US clinical trial, comprising around 100 patients in at least five centers. Sales during the first year is expected to be slow. Assuming that a distributor or partner can be found, they should speed up substantially from 2023 onwards.

The Chinese application will be based on the FDA application. An additional local trial in China will be undertaken. This should lead to sales initiation at the end of 2023.

Long-term, the goal is to limit sales costs and maximize reach through the use of distributors, except for Europe where we expect direct sales (distributors might be used on some markets). The company expects a 60-80 percent gross margin from pulse biopsy probes. Distributors will obviously buy the product at a lower price compared to direct sales, so the overall gross margins should be even lower, particularly for products sold in China compared to the US.

## Key personnel and organization

Neodynamics has been run on a virtual business model, whereby most services are purchased from service providers, which is typical for small developmental companies. This can be seen in the income statement, where other external charges make up the largest part of costs. Capitalized development work is another post that is mainly related to the purchase of external services. An example of the virtual business model is the development of the commercial version of Neonavia, which was done by Etteplan.

The company has eight employees. Five people are members of the board. The previous CFO, Jörgen Vrenning, has retired and is not part of the work force but will continue as a consultant until May 2021.



**Anna Eriksrud** is CEO since 2016. She has a background as entrepreneur in health care, most recently from Apoteksamariten AB (2009-2015). She has international experience from Q-Med and Pharmacia, having worked with product launches in Europe as well as in the USA. She has 141 905 shares (verified 2020-12-09) and warrants from series 2020/23 and 2018/21.



**Ingrid Salén** is chairman of the board. She founded Rentability AB. She has experience from Scania CV AB (1995-2009), where she became procurement manager in 2003, and Maquet Critical Care AB (2012-2014). She owns 290 694 shares through Rentability Sweden AB and warrants from series 2020/23 and 2018/21.



**Magnus Olsen** is Chief Development and Operations Officer and has worked at Neodynamics since 2012 as responsible for responsible for product development. He has 15 years of previous experience in medical product development, including 12 years from St. Jude Medical AB. He has 130 000 shares (verified 2020-12-31) and warrants from series 2020/23 and 2018/21.



**Kai-Uwe Schässburger** is Director of Clinical Development and Medical Affairs since 2011. He has been involved with NeoNavia since an early stage, having written a PhD. on it which was awarded in 2018. He has 40 000 shares (verified 2020-12-31) and warrants from series 2020/23 and 2018/21.



**Gunilla Almqvist** is Sales and marketing manager since 2018. She has around 20 years' experience from the pharmaceutical and medical device industry including in sales.

Source: Company information

In addition to the above, there is one manager responsible for quality and regulatory development (who worked with the CE and works with the FDA approval) and three additional country sales managers, one for Germany, one for the UK and one for the US.

## Capital raised and share performance

In order to reach its goals in product and regulatory development as well as sales, the company has had to rely on raising capital. As a public company, Neodynamics has raised almost SEK 190m. Before the IPO, the company had received investments of in total SEK 137m since 2012. This can be compared to the present market cap of around SEK 180m.

- November 2018, IPO with capital raise of SEK 50.5m at SEK 8.20 per share, total number of shares increases to 15.3 million.
- February 2020 preferential sights issue of SEK 45.9m at SEK 3.0 per share, total number of shares increases to 30.6 million.
- November 2020 directed share issue of SEK 90m at 3.72 SEK per share, total number of shares increases to 60.25 million.

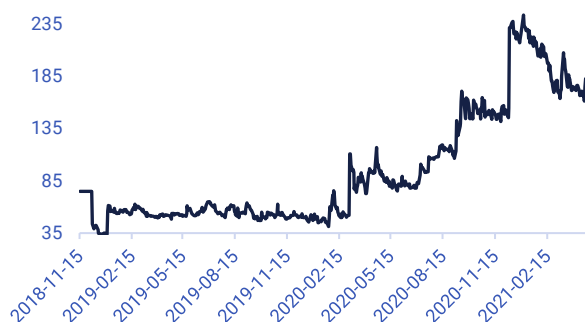
Warrants, TO1, were annexed to the units of the IPO. Strike price was SEK 8.20 and last subscription date 29 November 2019. 0 percent were subscribed for.

The number of shares has increased from 9.1 million before the IPO to 60.25 million today. The pre-money valuation of the company before the IPO was almost SEK 75m. We expect another share issue before the company becomes cash flow neutral.

The share has traded in the range between 2.5 and 5 SEK since the IPO. The market cap on the other hand has increased substantially from a minimum of SEK 41m in 2019-2020

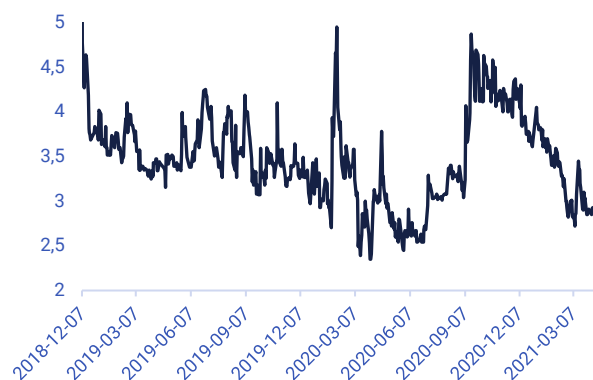
to a maximum of SEK 263m in 2020. The expansion in market cap is not surprising as the company has raised a lot of money in relation to its market cap, which entailed issuing a large number of shares. During most of the period on the stock market, the share has traded at a very low market cap compared to the money invested in the company. On a positive note, the share has not decreased in value in proportion to the share dilution. This implies that the market has at least adjusted the valuation upwards as more money has been invested in the company.

### Evolution of market cap



Source: Refinitiv Eikon & Carlsquare Estimates

### Evolution of the share price



Source: Refinitiv Eikon

The market cap of Neodynamics is in fact lower than the cost to develop a medical device in the USA. According to the survey "FDA Impact on US Medical Technology Innovation – A Survey of Over 200 Medical Technology Companies" from 2020, the average cost to bring a medical device from concept through a 510(k) clearance is USD 31m, of which USD 24m are related to FDA-related aspects such as clinical trials, and a smaller amount on product development. The survey includes class II products. Neonavia is a Class I product. Nevertheless, NeoNavia is a complex system and comparable in terms of development costs. It is undergoing two large clinical trials, which makes it somewhat comparable in clinical development. Some money has also been invested into sales and marketing, but this is a small percentage of the total. Therefore, we believe that a comparison with the average of USD 31m is meaningful.

### Ownership

Since the company will rely on at least one further share issues, the ownership base is important. The ten largest owners are listed below.

#### 10 largest owners

| Owner                          | Share | Verified   |
|--------------------------------|-------|------------|
| Huasheng Fang                  | 11,3% | 2020-12-31 |
| Boai NKY Medical Holdings Ltd  | 8,2%  | 2020-12-31 |
| Cardeon och ledningsgrupp      | 7,8%  | 2020-12-31 |
| Rutger Arnhult                 | 7,2%  | 2020-12-31 |
| Johan Thorell                  | 6,4%  | 2020-12-31 |
| Sebastian Jahreskog            | 6,0%  | 2020-12-31 |
| Nyenburgh Holding BV           | 4,6%  | 2020-12-31 |
| Daniel Johnsson                | 2,2%  | 2020-12-31 |
| Ingrid Salén                   | 1,4%  | 2020-12-31 |
| Humlan Fastighetsutveckling AB | 1,4%  | 2020-12-31 |
|                                | 56,6% |            |

Source: Company Information

#### Boai NKY Medical Holdings

Chinese Boai NKY owns 19.5 percent of the company. The company's chairman of the board is registered as the largest owner, but presumably the subsidiary NKY Sweden AB is intended.

Boai NKY Medical Holdings is a large Chinese corporation. Hua Sheng Fang is chairman of the board to Boai NKY Medical Holdings with an ownership of around 2 percent. Market cap is around CNY 3.5bn. He owns 30 percent of the subsidiary BOAI NKY

Pharmaceuticals. Boai NKY owns 19.5 percent of Neodynamics. They control one of five board members.

NKY's main activity is the production of PVP, which is a water-soluble polymer. It is used as an ingredient in various medical and technical products. Among other things, NKY focuses on excipients for the pharmaceutical industry. The holding company owns several daughter companies, including one focused on precision medicine. They have also established a subsidiary for female health and oncology, whose goal is to market NeoNavia as soon as it is approved in China.

#### **Other owners**

The second largest owner is the investment company Cardeon with management team. Masoud Khayyami is the founder of it. He is an entrepreneur and investor in life science, perhaps best known as the previous CEO of Spectracore. Johan Thorell and Rutger Arnhult are two well-known investors from the real estate industry and can be considered institutional investors. Sebastian Jahreskog is one of the main owners of Infant Bacterial Therapeutics. Nyenburgh Holding is a Dutch privately held proprietary trading firm that also invests long-term in Life Science companies. Ingrid Salén is chairman of Neodynamics' board.

Overall, Neodynamics has a very strong ownership base since the latest share issue. The ten largest owners own 56,6 percent of the shares and most of them can be described as institutional investors. This is important if more share issues are called for in the future. Weak ownership together with frequent share issuing has the risk of leading to a gradual sell-off in a share over time.

## Technology and products

Neodynamics is a single-product company, which is described in this section. The product is called Neonavia and is used for breast and axillary biopsies. It consists of a base unit, with a dual vacuum function, a handheld device and three disposable needles: a spring-loaded core needle, a vacuum assisted biopsy needle and a proprietary newly developed needle (FlexiPulse) with superior handling and larger specimen size.

### Neonavia

Neodynamics has developed a new biopsy system called Neonavia for breast cancer biopsy. It consists of a driver unit, a tethered handheld device and three types of needles. It is intended to be used in conjunction with ultrasound. The needles are used once per patient and then discarded.

#### Base unit



Source: Company information.

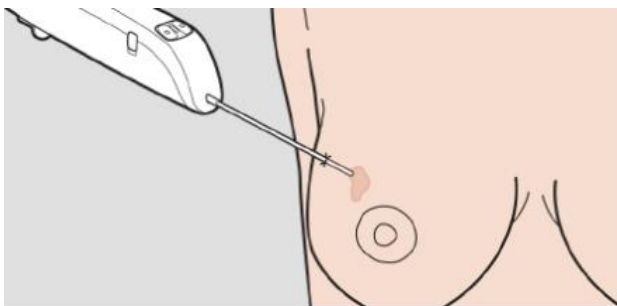
#### Handheld device and needles



Source: Company information.

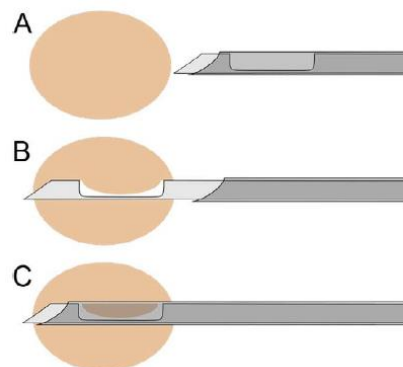
Biopsy samples can be obtained surgically or from needle devices. Today, breast biopsy with a needle device is standard treatment when lesions that could be cancer are detected. In order to understand the novelty of Neonavia, it is necessary to describe the present standard of care.

#### Breast biopsy with needle



Source: Company information.

#### Spring-loaded core needle biopsy



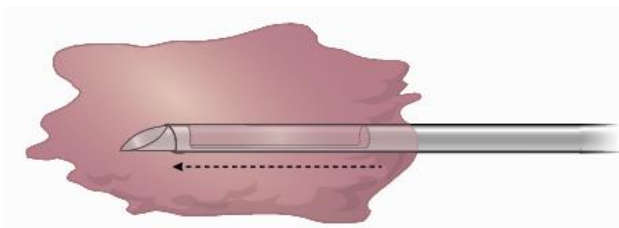
Source: Schässburger et al., 2018.

Standard of care employs either spring-loaded core needle biopsy (CNB) or vacuum assisted breast biopsy (VAB). Core needle biopsy became common in the 90s. A core needle has a simple design: it consists of a handheld device and a needle (as in the picture above to the left). The needle itself consists of two parts, an outer cutting cannula and inner stylet, both of which are spring loaded. When a biopsy specimen is taken, the needle is inserted in the breast and positioned in front of the suspected tumour (or lesion). When the spring is released, the needle penetrates the lesion and a small tubular specimen is cut out (see above to the right). The needle then has to be removed from the breast so that the specimen can be culled. If more specimens are needed, the procedure has to be repeated. The standard needle diameter is 14G.

The first VAB device, Mammotome from Johnson & Johnson, came out in 1995. It is essentially a development of the spring-loaded core needle and it works in a similar manner. It

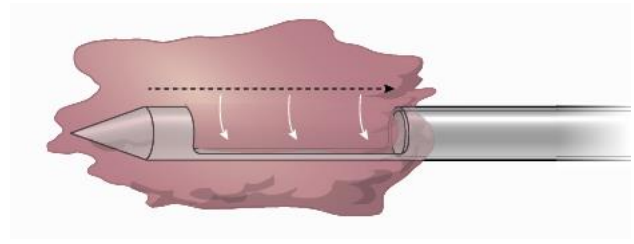
consists of an additional drive unit that is connected to the handheld device. The needle used for VAB is different compared to CNB, see the image below to the right. It is normally not positioned in front of the lesion and then fired through it. Rather, it is placed beside it. The opening in the needle aspirates tissue into the aperture (it “sucks it in”) which is then sliced and aspirated through the needle into a collector in the drive unit. Consequently, several samples can be taken simultaneously with this method. Standard procedure is to rotate the needle and cut off samples around the needle. The standard needle diameter is 11G, which is larger than the standard 14G of CNBs.

**Spring-loaded core needle**



Source: Company information.

**Vacuum needle**



Source: Company information.

Vacuum assisted breast biopsy is used when there are diffuse abnormalities, for example when there is a calcification in the breast, or when there are small lumps that cannot be felt or deep lumps that cannot be felt. When there is a clear lesion or tumour that can be felt, the preferred method is the spring-loaded core needle biopsy.

Both of the above methods are used freehanded with ultrasound guidance. They can be used with other imaging methods as well, mainly with stereotactic X-ray or MRI, though in these cases VAB is almost exclusively used, and the needle is guided mechanically (not freehanded) in a larger system. The main use of stereotactic imaging with VAB is when there are abnormal calcifications in the breast. It should be noted that NeoNavia cannot be used with stereotactic imaging or MRI today.

Calcification is the accumulation of calcium salts.

There are two issues with both of CNB and VAB: they are inexact and might easily remove tissue from places where it was not intended, and they have to be inserted through the tissue until they reach the lesion by pressure (which might damage the surrounding tissue). Neonavia solves these problems. It is a biopsy system with a pulse system that propels the needle through the tissue. The pulse system is driven by a pneumatic mechanism that propels the biopsy needle forward with a maximum stroke length of 2.5mm before returning to its original position. The stroke length can be configured to be only 1 mm. When activated from a hand piece, the operator can gradually advance the needle through the tissue without any resistance: the needle pulses into the tissue. The pulses enable an accurate positioning of the needle inside the lesion with good visibility of good needle on ultrasound. The pulses make the needle cut through the tissue instead of tearing through it as is the case with traditional biopsy needles. Therefore, there is less tissue damage with Neonavia.

It might be described as a development of vacuum needle biopsy and consequently represents the third generation of core needle biopsy instruments in our opinion. Neonavia can be used with spring-loaded core needles with the vacuum function turned off as well as with vacuum needles. Additionally, it has a proprietary needle developed specifically to be used with Neonavia’s pulse system, the FlexiPulse.

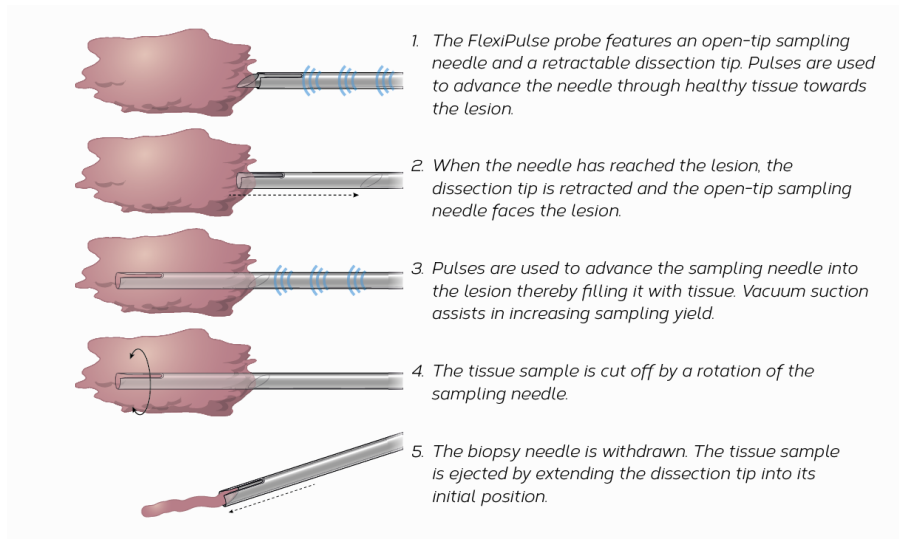
The spring-loaded core needle of Neonavia works in a different way compared to the standard version: by means of the pulse system, the needle can be placed inside the lesion, then the outer cannula is retracted, and the spring loaded and fired. See the illustration above to the left. This means that the spring mechanism does not have to shoot the cannula through the lesion, which might miss it or damage tissue behind it.

The Flexipulse needle is similar to the vacuum assisted needle. However, it directly penetrates the lesion at the point of contact and not from the side. Before entering the lesion, the vacuum function is engaged. When the needle enters the lesion, propelled pulses, a hole is cut through the lesion where the needle enters it, see the illustration below. Tissue enters the needle with the assistance of vacuum. This is a much more precise method



compared to CNB or VAB. Each sample is cut off by a rotation of the needle, which is performed automatically by a motor.

### FlexiPulse



Source: Company Information.

Neonavia's spring loaded needle and its Flexipulse needle are especially indicated for lesions which are located in sensitive areas where a small error might lead to damage on sensitive surrounding tissue, for example nerves or the wall of the lung (if the lesion is located close to the chest). The Flexipulse is the best option for challenging biopsies since it should be more accurate than the spring-loaded core needle.

The production version of Neonavia that is now being launched is specifically designed to enable one handed operation. With traditional spring-loaded core needles, two persons need to be present while the biopsy is performed, one who holds the ultrasound scanner and one who operates the biopsy device, which is operated by two hands. This means that time can be saved compared to older versions, though there are newer core needles that can be operated by one hand, such as Sertera from Hologic or Magnum from Bard (BD), so one-handed operation is to be expected from a modern product.

### IP

NeoNavia is protected by four patents. The micropulse technology, which is the core technology, is protected until 2029 in China, Germany, France, Sweden and Japan and until 2031 in the USA.

There are two patents for needle designs related to FlexiPulse in Europe, the USA and China valid until 2034 or 2035 (some granted, some patent-pending).

There is fourth patent application on the handheld driver unit, whose period of validity is not yet defined, in the USA and China. The patent was granted in Europe in January 2021. It should also provide a long protection to an integral component, the handheld driver, of NeoNavia.

In summary, NeoNavia is well protected until 2029 in Europe and China and until 2031 in the USA. After that period, the pulse technology could be used by other companies. The FlexiPulse however, which is an important part of NeoNavia, is protected until at least 2034/2035, which is a long time for a patent. The patent on the handheld unit could also increase the patent protection of the system.



## Medical background and regulatory development

NeoDynamics is active in the diagnostics segment of breast cancer treatment. In this section, the medical background to NeoNavia is described, as well as how NeoNavia fits in the current treatment and screening paradigm. We also describe the clinical trials with NeoNavia.

### Diagnosis of breast cancer

There are around 20 million new cancer cases each year around the world and around 10 million deaths from cancer. The most common cancer type is breast cancer, accounting for 2.3 million new cases each year.

Breast cancer is normally detected from lumps in the breast. In order to distinguish between a harmless benign cyst and cancer, a biopsy has to be performed. This results in a cell or tissue sample that is looked at by an expert under a microscope. Often, a DNA, protein or RNA test is also done on the sample. The tissue sample is called a biopsy specimen. There are three main types of biopsy in breast cancer:

- Fine needle aspiration (FNA)
- Core needle biopsy (CNB) or vacuum assisted biopsy (VAB)
- Surgical biopsy

Surgical biopsies have largely been superseded by needle biopsies in Western countries. Needle biopsies are performed under MRI, ultrasound or stereotactic X-ray guidance, except when the lump from which a tissue sample is taken is located near the surface. It is generally not possible to locate the lump inside the breast without imaging guidance. Ultrasound is the most common type of guidance (the device is similar to the ones used for fetal ultrasound).

If the lesion is not easily identified with ultrasound, different methods are used. Stereotactic imaging is the second most common imaging technique. It is practically always used with VAB. This method is not intended for NeoNavia, which is a handheld device. In VAB, the vacuum needle is not handheld, rather it is mounted in a fixture which is part of a larger stereotactic imaging device. MRI (magnetic resonance imaging) is less common as an imaging technique. It utilizes large and expensive MRI scanners and VAB. This imaging method is generally also not compatible with NeoNavia.

Core needle biopsies are much more useful than FNA, but have somewhat larger side-effects, since a larger amount of tissue is removed. FNA provides cytology samples, that is a small mass of more or less free-floating cells. The core needle provides a histology sample, that is a piece of flesh or continuous tissue. A cancer diagnosis can normally be given from a cytology (or cell) sample. However, a histology sample is needed to identify the exact type of cancer and give a differential diagnosis. Therefore, practically all needle biopsies are CNB or VAB.

Needle biopsies are non-invasive medical procedures and typically have few side effects. A local analgesic is administered to the area where the biopsy is to be taken to reduce pain. If a core needle biopsy is performed, a small incision is made where the needle enters the body. A dressing is applied after the procedure is finished, so stitching is not necessary. When a core needle biopsy is done, a tissue marker or clip is normally inserted into the area where tissue was removed. Thereby the area of the biopsy specimen can be detected in later imaging.

Often a lymph node biopsy also has to be performed when breast cancer is suspected, as the lymph nodes close to the armpit are the first area the cancer spreads to. Today, this is generally made surgically. Only a few clinics use CNB for this. VAB cannot be used, as the needles are too thick.

Thanks to the introduction of needle biopsies, which have replaced surgical biopsies in most western countries, the screening of lesions has become much more cost effective and safe. As around 80 percent of all lesions found are benign, the number of surgeries performed has fallen drastically. This is due to the fact that surgery it is only required when cancer is detected. Even when a cancer tumour is found, the number of surgeries per patient decreases compared to when surgical biopsies are the preferred method, from 2.01 to 1.25 (Mahoney et al., 2013).

Examples of modern spring-loaded core needle instruments include:  
 Sertera from Hologic  
 PreciseCore from Inrad  
 BioPince Ultra from Argon Medical

## Types of breast cancer

Cancers with solid tumours (such as breast cancer) are defined based on how much they have grown and have four stages (I-IV) depending on size and how far they have spread. Stage IV means that the cancer has metastasized.

Pre-cancerous formations in the breast are often treated. Atypical hyperplasia is an accumulation of abnormal cells in the milk ducts and lobules. This often develops into cancer over time. Treatment consists of surgical removal of the abnormal cells. Calcifications are a different type of abnormality that nowadays typically is removed through vacuum assisted biopsy, which means that no surgery is necessary.

Most breast cancers are classified into in situ or non-invasive or invasive types. In situ means that the cancer is stage 0 or stage I. Invasive means that it has spread into surrounding tissue. Cancer is also categorized based on the type of cell in which it originates. The two most common cells in which cancer originates are lobular cells (milk producing cells) and ductal cells (cells that form the channel through which milk pass). There are several other less common types that start in the blood vessels, skin or connective tissue of the breast. The most common cancer types are:

- ductal carcinoma in situ (DCIS) – up to 15-20%
- invasive ductal carcinoma (IDC) – up to 70-80%
- invasive lobular carcinoma (ILC) – up to 10%

Furthermore, each type of cancer can have different genetic features. The most common ones are:

- HER2 positive - 20-25%
- Estrogen receptor-positive
- Progesterone receptor-positive
- Triple negative - around 15%

Triple negative means that the cancer lacks all of the aforementioned genetic features: estrogen and progesterone receptors and additional HER2 proteins on the surface.

Core needle biopsy can distinguish between in situ and invasive cancer, which fine-needle aspiration cannot. A core needle biopsy specimen is also necessary to detect the genetic features of the cancer. To correctly diagnose breast cancer, it is necessary to identify its type, stage and genetic features. A correct diagnosis is necessary to give the patient the correct treatment. Therefore, core-needle biopsy is essential for the treatment of breast cancer.

If cancer is detected, the most common treatment is breast conserving surgery and removal of the closest lymph node. Additional drug treatment or removal of more lymph nodes may be necessary depending on the stage of the cancer.

### Efficacy

Core-needle and vacuum assisted biopsies are highly accurate. They are very similar in sensitivity and specificity. Sensitivity rate is the true positive rate while specificity is the true negative rate.

### Sensitivity and specificity in common biopsy methods

| Biopsy method                           | Sensitivity | Specificity |
|---|-------------|-------------|
| Freehand                                | 0.91        | 0.98        |
| Ultrasound, automated                   | 0.99        | 0.97        |
| Ultrasound, vacuum-assisted             | 0.97        | 0.98        |
| Stereotactially guided, automated       | 0.97        | 0.97        |
| Stereotactially guided, vacuum-assisted | 0.99        | 0.92        |

Source: Clinician Summary, 2016.

### Sentinel lymph node dissection and biopsy

Around 20-25 percent of patients from a screening program that show signs of breast cancer also have cancer positive axillary nodes. Imaging of the axilla lymph nodes, mainly

through ultrasound, is therefore standard of care when breast cancer is detected. If no abnormality is detected, the sentinel node is removed at the same time as the breast tumour is removed. The first lymph node that drains the area of a cancer is called a sentinel node. Before the operation, a tracer material is injected around the tumour which drains to the closest lymph node. The tracer, which can be a simple ink, enables its identification.

If an abnormality in an axillary lymph node is detected through ultrasound, a core-needle biopsy (CNB) can be performed in certain specialized clinics in certain countries. If cancer is detected, all lymph nodes in the axilla have to be removed (axillary node clearance, ANC) and not just the sentinel node.

FNA can be used, but the sensitivity is much lower compared to CNB. CNB has higher risk and leads to more complications. Vacuum assisted biopsy cannot be used, as the needle is too thick and removes too much tissue, which risks damaging surrounding nerves and blood vessels. Surgical biopsy is usually performed as a removal of the sentinel node during the removal of breast tumour. If cancer is detected in the lymph biopsy specimen, a second operation has to be performed, ANC.

FNA or CNB are less reliable in diagnosing sentinel node cancer than breast cancer. In one meta study (Balasubramanian et al.1998), the sensitivity of ultrasound-guided CNB was found to be 88 percent and US-FNA 74 percent, so there should be room for improvement.

One might ask why a fine needle or core needle biopsy is performed when a surgical biopsy is always performed in any case if cancer is detected. The answer is that it saves time and resources. A fine needle or core needle biopsy is a minimally invasive procedure, while an open biopsy is a surgical intervention that may in some cases involve general anesthesia (which puts the patient to sleep). If no cancer is found in the sentinel node, the patient only has to remove the breast tumour and sentinel node in one procedure. If cancer is found, she also only has to go through it once and not twice, since the removal of the breast tumour can be done at the same time as the axillary dissection (complete removal of the axillary lymph nodes). The alternative is to remove the breast tumour and sentinel tumour, analyze the latter and proceed with a second surgical intervention (axillary dissection) if cancer is detected.

There is a place for new biopsy instruments in this setting. The ideal instrument would have the side effects of FNA and at least the same sensitivity and specificity as CNB. NeoNavia is being tested in two clinical trials, one in Germany and one in the UK, in this indication. They will provide clinical evidence for the use of NeoNavia in axillary biopsy. See the section below on clinical trials.

25 to 43 percent of breast cancer patients have radiologically detected abnormalities in axillary lymph nodes when they are first diagnosed. This is the main group that NeoNavia targets in the initial stage of commercialization.

## Complications

70-80 percent of biopsies will show negative results for cancer and cover a spectrum of diagnoses, from benign to preinvasive disease. Therefore, it is important that the side effects are limited. Fine needle aspiration has negligible side effects. The main side effect of core needle biopsy is bleeding, which can be handled by applying pressure. Hematomas are about as common as bleeding. Vacuum assisted biopsies lead to more bleeding than core needle biopsies. Infection is another potential, though less common, side effect. Pain is a common though less serious side effect.

Open surgical biopsies have much larger complication rates compared to core needle biopsies. The rate of hematomas is 2-10 percent, and the rate of infections is 4-6 percent, as compared to 1.4 or 1.2 percent respectively for core-needle biopsy. Open surgical biopsies are performed in more difficult cases where needles cannot be used. For these cases, there is a need for new more advanced biopsy instruments such as NeoNavia. However, surgical breast biopsies are much less common compared to CNB or VAB. In our judgement, the biopsy methods used for detecting breast cancer are generally efficacious and have no serious side effects.

The situation is different for axillary biopsies. CNB had significantly higher complication rates compared to FNA in axillary lymph nodes, 7.1 versus 1.3 percent according to a meta study (Balasubramanian et al.1998). Surgical biopsies are frequent in this indication. In our

opinion, there is an unmet need for a biopsy instrument with less complications in this setting.

## Pre-Clinical trials

The samples from NeoNavia and its three proprietary needles have been evaluated with regards to size and quality. Sample sizes are consistently larger. The samples obtained with FlexiPulse are in the order of four times larger (300%) than those from CNB devices. CorePulse and VacuPulse also provide larger samples. Quality is at least equal to the gold standard of care. Larger samples means that fewer ones have to be taken. Normally 5-6 samples are taken with for example CNB.

### Summary preclinical trials, sample weight compared to gold standard

|            | 2018     | 2021 |
|------------|----------|------|
| FlexiPulse | 250-360% | 300% |
| CorePulse  |          | 37%  |
| VacuPulse  |          | 12%  |

Source: Schässburger et al. 2018, Paepke et al. 2021

### Schässburger et al. 2018

The first scientific publication is from 2018 (Schässburger et al.). Sample sizes and quality from FlexiPulse needles were evaluated. Turkey breast, swine pancreas and calf thymus were used as proxy tissue. The control group consisted of samples taken with the Magnum CNB-device, which is the oldest and most used version of its type. In Turkey breast, NeoNavia provided samples with a mean weight of 49.6 mg versus 14.3 from Magnum. In swine pancreas, NeoNavia provided samples with a mean weight of 45.8 mg versus 10.1 from Magnum. In calf thymus, NeoNavia provided samples with a mean weight of 66.5 mg versus 14.3 from Magnum. In other words, NeoNavia provided sample sizes about 3.5-4.6 times larger than those from a spring-loaded core needle. Furthermore, a pathologist analyzed 38 samples from breast cancer tissue donated from patients. He concluded that they were equivalent in quality to tissue obtained with standard CNB and VAB devices.

### Paepke et al. 2021

A study coordinated by dr. Stefan Paepke from the University Hospital r.d. Isar at the Technical University of Munich compared NeoNavia and the three proprietary needles of NeoDynamics with today's respective gold standard. CorePulse obtained samples that were 37 percent heavier compared to CNB while those from VacuPulse were 12 percent heavier than VAB samples. The best results were obtained with FlexiPulse. They were 299 percent heavier than today's gold standard, which we interpret as CNB. This is to be expected since the geometry of FlexiPulse is that of a cylinder with an open tip, while CNB uses needles with the geometry of a closed cylinder with a groove cut into it. Assuming the same radius, the volume of FlexiPulse must obviously be larger than standard core needles. This is not necessarily the case with FlexiPulse and VacuPulse, so the results with these needles are promising. The data will be published in the scientific journal the Breast at a later date.

## Clinical trials

Clinical trials are particularly important for NeoDynamics since spring-loaded core needles and vacuum assisted core needles are well-liked and have a very good performance. NeoNavia thus faces strong competition from existing products. By showing superiority over CNB in axillas, it should be a comparatively straight-forward to place NeoNavia units in clinics that perform axilla biopsy, as CNB is not a satisfactory tool for this procedure. From there, sales can expand to ordinary breast biopsies. Clinical trials are therefore very important for NeoDynamics sales strategy.

At present, two clinical trials are under way, COMPULSE in the United Kingdom with around 400 participants, which is still recruiting, and a smaller one named PULSE in Germany with 140 participants where all patients have been recruited. Both trials are evaluating FlexiPulse for biopsies in the axilla.

PULSE is a registry study (case study) without a control group. COMPULSE has a control group in order to be able to demonstrate efficacy. The purpose of PULSE is to evaluate how well biopsies can be performed in the axilla, including difficult cases where core needles are considered a risk, from a qualitative perspective. Since there is no control group, it

One of the goals with the clinical trials is to gain a foothold in the respective markets. We have consulted ClinicalTrials.gov to see which clinics are included. In Germany, seven clinics took part in the trial, Klinikum Esslingen, Universitätsfrauenklinik Tübingen, Agaplesion Markus Krankenhaus, Universitäts-Frauenklinik, HJK Erkelenz, Kliniken Essen-Mitte, Uniklinik Köln.

Eight clinics plan to take part in the British clinical trial: Addenbrooke's Hospital, University Hospital of Wales, Western General Hospital, St James's University Hospital, King Edward VII's Hospital, King's College, Wythenshawe Hospital, The Royal Marsden.

cannot not demonstrate efficacy (superiority over standard methods). The purpose of COMPULSE is to demonstrate efficacy in various parameters where NeoNavia FlexiPulse can be directly compared to CNB; it excludes difficult cases where CNB cannot be used (but were FlexiPulse might conceivably be used).

### **PULSE - Evaluation of NeoNavia Biopsy System in Axillary Lymph Nodes**

Number of participants: 140 (according to ClinicalTrials.gov)

Estimated study period: February 14, 2019 – June 30, 2021

All patients in the study have been enrolled and the interim analysis is under way. Topline results should be available by the middle of 2021.

The inclusion criteria are: “patients with histologically confirmed breast cancer or highly suspicious breast lesions presenting with suspicious axillary lymph nodes”. In other words, it includes all types of patients who need a biopsy specimen from the axilla.

The primary endpoint is the rate of successful biopsies after histopathological analysis of tissue samples, that is, whether there is enough tissue for the histologist to make a diagnosis. Secondary endpoints include sensitivity and specificity, rate of patients presenting with risk parameters, rate of cases in which it was possible to target a lymph node and rate of cases in which pulses facilitated needle control.

### **COMPULSE - Comparison Trial of Open-tip Pulsed Needle Biopsy and Conventional Core Biopsy in Axillary Lymph Nodes**

Number of participants: up to 400 with randomized parallel assignment

Estimated study period: July 13, 2020 – December 31, 2021

The aim of the study is to compare NeoDynamics’ FlexiPulse with traditional CNB. One arm is to be treated with conventional core needle biopsy, the other with NeoNavia’s FlexiPulse.

The primary endpoint is adequacy rate of tissue sampling after histopathological analysis of tissue samples, that is, whether there is enough tissue for the histologist to make a diagnosis. A large number of secondary endpoints will also be measured. Among others, pain, rate of complications, sensitivity and number and quality of samples will be measured.

### **PMCF trial**

The post market clinical follow-up will look at around 1000 patients from 50 sites in Europe to confirm safety and performance for the commercial product. It is part of regulatory compliance for medical devices in the EU. It will take up to two years and provide substantial additional evidence.

### **US multicenter clinical trial**

A clinical trial sponsored by NeoDynamics is foreseen for the American market upon FDA acceptance. It should start in parallel with the first sales efforts. 50-100 patients will be included in at least five centers. The clinical trial should commence in 2022 given a positive outcome of the 510(k) review. Key Opinion leaders should also be recruited for the trial.

## Market and comparable companies

The market in which NeoDynamics is active consists of the five to six million breast biopsies performed worldwide each year. We estimate that about 3 million biopsies are performed each year in Europe and the USA and a larger number of additional ones in China. While there are several producers of moderately priced CNB instruments, the market for advanced biopsy instruments is comparatively consolidated. Finally, we list some transactions in the sector.

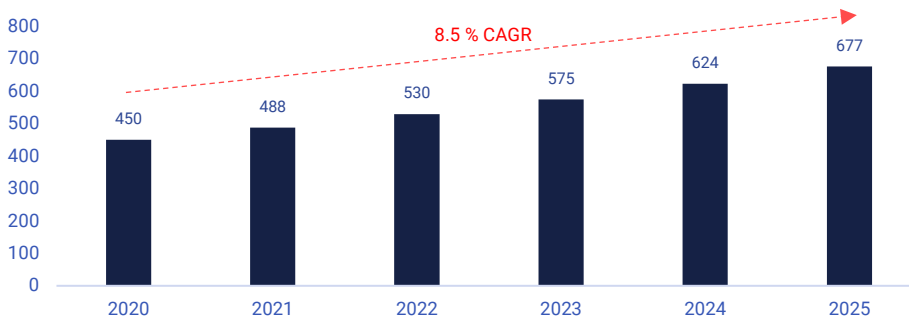
### Overview

The overall market for breast biopsies can be divided in two parts: imaging devices and biopsy instruments and accessories. There are some surveys available for the breast biopsy market. Markets and Markets projects that it will grow from USD 725 million in 2020 to USD 1,094 million by 2025 at a CAGR of 8.6%. Technological advancements in the field of a breast biopsy and the rising incidence of breast cancer are the major factors driving the growth of this market. (Markets and Markets, 2019b). According to a different report from ASDReports, the global breast biopsy market is expected to grow from USD 703m in 2019 to USD 1 174m by the end of 2025 (ASDReports 2020). Both of these market surveys include guidance systems (typically used for VAB), so they overstate the potential with regards to NeoNavia.

There are also market surveys available specifically for biopsy needles for all types of organs. Markets and Markets estimates the aspiration and biopsy needle market to grow at a CAGR of 7.3 percent from USD 894m in 2019 to USD 1 272m by 2024 (Markets and Markets, 2019a). This includes aspiration and biopsy needles for various types of cancers, of which breast cancer is the largest segment, constituting around a third of all cases.

Neodynamics has stated that the market for breast biopsy instruments is worth USD 400-500m (Prospectus 2020, p. 20). In our opinion, this is a reasonable estimate when vacuum assisted biopsy devices are included. One should also consider that the market should grow at 8-9 percent per year. If we assume a market growth of 8,5 percent per year, a market estimated at USD 450m in 2020 will grow to USD 680 in 2025.

### Market size breast biopsy instruments, mUSD



Source: Carlsquare Estimates.

One should also consider that NeoNavia is a premium instrument that adds additional functionality compared to existing instruments. Therefore, it will not only compete with cheaper instruments in the market, but should also expand the total size of the market when it is introduced.

The US is the largest market followed by Europe, which is about half the size of the US market. APAC is even smaller, in particular since the incidence of breast cancer is smaller, but it is the fastest growing region.

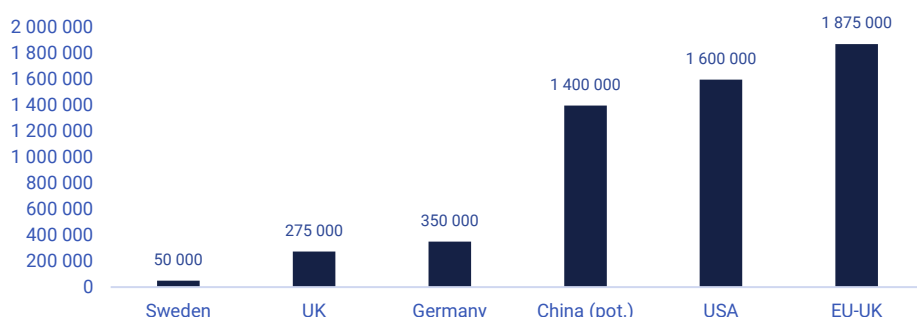
### Breast biopsies

There are around 2.3 million new cases of breast cancer worldwide each year. Neodynamics estimates that over 6 million biopsies in the world are performed each year. There are other estimates of 5 million biopsies and that breast biopsy devices account for 1/3 the entire biopsy device market. Thus, there are 2.6 – 2.2 breast biopsies per cancer case in the world. Countries with developed screening programs will perform more biopsies compared to countries with no or less developed programs.



The overall market for biopsies should grow as the overall world economy grows, as the standard of care in emerging market improve and as the world population ages and adopts a less healthy lifestyle (with higher calory food, more sweet beverages and less physical activity). Thus, we should expect more breast cancer cases in the future as well as more biopsies per cancer diagnosis as more countries can afford screening programs. The by far largest increase should come from an increased number of biopsies per cancer case. The market potential in terms of biopsies in the first three countries where Neonavia is introduced together with the three main markets is showed below. However, the USA is a much larger market than the EU-UK in terms of monetary value. More modern and expensive biopsy instruments are used there.

### Annual number of breast biopsies performed (potential numbers for China)



Source: Carlsquare Estimates.

#### EU-UK

The UK has 68 million inhabitants. There are around 55 000 breast cancer cases per year. Assuming five biopsies per cancer case, we calculate that around 275 000 biopsies should be performed each year. There are around 1250 hospitals in the country. This equates to 220 biopsies per hospital per year. The UK is important since most clinics are part of the NHS. In other countries, such as Germany, healthcare is constituted by several different organizations, which makes sales more complicated as there are several counterparties.

Germany has 84 million inhabitants and around 70 000 breast cancer cases per year, which translates to around 350 000 biopsies assuming five biopsies per cancer case. There are around 1900 hospitals in Germany. This equates to slightly more than 180 biopsies per hospital per year.

Sweden has a population of 10 million. There are around 10 000 cases of breast cancer each year. We assume five biopsies per cancer case, which translates to around 50 000 biopsies performed each year. There are around 100 hospitals in Sweden, which equates to around 500 biopsies per hospital per year.

In the EU-27, with a population of 450 million, (which does not include the UK) there are around 355 000 breast cancer cases per year. If we assume four to five breast biopsies per year this means that 1.4-1.8 million breast biopsies are performed each year. Adding the UK, we calculate that around 1.9 million biopsies are performed in the EU-UK region per year.

#### US

There are around 280 000 new breast cancer cases each year in the USA, which has a population of 330 million. Around 1.6 million biopsies are performed each year. This equates to 5.7 biopsies performed per breast cancer case, which is higher compared to most countries in the world.

#### China

There is no good data available for China. The China National Cancer Center reported 248 620 new breast cancer cases in 2011. The incidence is believed to be much lower compared to western countries, but it is increasing. There should be at least 300 000 new cases per year by now. East Asian countries in general have a much lower incidence compared to western countries, which is believed to in part be due to different diets and in part genetics. The standard of care in breast cancer screening in Kina is different compared to Europe and the US. Needle biopsies are less common. We have no good data for the



number of biopsies performed, but we can assume that there is a potential for 1.2-1.6 million breast biopsies each year when more modern technologies accepted.

### **Other regions**

APAC including Japan, Australia, South Korea and New Zealand are potential markets for NeoDynamics. Canada, Mexico, South America and the Middle East are other potential markets. However, they are small in terms of monetary value compared to the EU-UK, US or China and difficult to reach. There is also not the same level of patent protection in these countries and regions. They will not be targeted by NeoDynamics in the near future.

### **Summary**

The main markets for NeoDynamics are expected to be the EU-UK, USA and China. They have around 940 000 new breast cancer cases each year. Around 3 million biopsies are performed each year in the EU-UK and US. A large number of additional biopsies are performed in China.

### **Axillary biopsies**

Most axillary biopsies over the world are surgical. Thus, the market for medical devices in this segment is almost inexistent today. We estimate that around a quarter of all cancer positive breast patients could benefit from a core needle biopsy of the axilla. This equates to around 235 000 biopsies per year in NeoDynamics' three core markets. The FlexiPulse needle is intended for this indication (among other indications). Assuming a price of SEK 2000 and 940 000 breast cancer patients from NeoDynamics' core markets and a price of SEK 200 000 for a base unit that lasts for 5000 biopsies, the potential annual revenue for NeoNavia in this indication is SEK 480m.

If we make the same assumptions for the first three markets, the UK, Germany and Sweden, almost 34 000 axillary biopsies could be performed per year. This market would be worth up to SEK 70m.

### **Future potential markets**

The accuracy of core needles in other types of soft tissue cancer is generally less impressive than in breast cancer. If NeoNavia could show superiority over core needles in other cancer types, the potential market size could improve. Common cancer types in which core needle biopsies are used include prostate cancer, liver cancer and kidney cancer. In particular, prostate cancer is a large indication that uses core-needles similar to those in breast cancer. Side effects, such as sepsis and infections, is a much bigger issue compared to breast biopsies. Almost all biopsies are transrectal, but percutaneous biopsy is also a possibility (through the perineum). The pulse system could enable a better placement of the needle with less risk of hitting non-intended areas and the pulse system could conceivably make percutaneous biopsies easier. NeoDynamics is part of an international research group that evaluates NeoNavia in osteoarthritis.

In particular, prostate biopsies are almost as common as breast biopsies in the US with around 1 million procedures per year. The same type of core needles are used but with a smaller diameter (18 G). If NeoDynamics could enter this market, it would correspond to an increase in market size of 60 percent in terms of number of biopsies.

Thus, the market potential could almost double by expanding to new areas. The only biopsies for which NeoNavia is not adapted are endoscopic ones, such as gastric biopsy or colon biopsy.

## **Breast biopsy companies**

### **Large public direct competitors with VAB instruments**

Three large multinational companies produce vacuum assisted biopsy systems and together dominate the breast biopsy market in terms of revenue (as these devices are much more expensive than spring-loaded core needle instruments): DB, Danaher and Hologic. Danaher and Hologic had a combined turnover of USD 430m in the breast intervention segment, judging from the last available figures. We do not possess the figure for DB, but we believe it is in the same order of magnitude. The turnover of these three companies in the breast intervention segment should therefore be in the range of 600-700 mUSD. The main market of these companies is the US. These figures are not directly comparable with the ones presented above in the market overview, as not exclusively breast biopsy instruments are included in the numbers from Danaher's and Hologic's segment reports.

### **BD - Becton, Dickinson and Company**

BD has a vacuum assisted biopsy system. Bard was acquired by BD in 2017. With them came a range of spring-loaded core needle devices (Magnum). BD also offers a range of fine and core needles for biopsies from various organs including breasts through Carefusion, which was acquired in 2014.

### **Danaher**

Leica Biosystems is part of Danaher. In 2014 Leica Biosystems acquired Devicor Medical Products whose product line Mammotome includes the first vacuum assisted biopsy device. Revenue was around USD 170m at the time. According to Dun & Broadstreet, revenue was USD 228m in 2018.

### **Hologic**

Hologic biopsy products mainly consists of vacuum assisted systems: ATEC and the Eviva systems for stereotactic biopsy. According to Hologic, Eviva is used globally in nearly 3,000 facilities and has been used in over 2.4 million biopsies.

Hologic is the only company that states revenues from breast health in its annual reports. Breast Health is one of the business segments. In turn, Breast Health is subdivided into Breast Imaging, which is the largest sub-segment, and Interventional Breast Solutions, which includes biopsy systems. Revenue for this segment is shown below. It was just below USD 200m in 2020. We have included the figures from 2017 to 2020 below.

#### **Selected business segment results (mUSD)**

|  | 2017         | 2018         | 2019         | 2020         |
|--|--------------|--------------|--------------|--------------|
| <b>Interventional breast solutions</b> |              |              |              |              |
| US                                     | 152,6        | 169,4        | 184,8        | 166,6        |
| Intl.                                  | 23,5         | 32,3         | 34,8         | 31,7         |
| <b>Total</b>                           | <b>176,1</b> | <b>201,7</b> | <b>219,6</b> | <b>198,3</b> |
| Growth                                 |              | 13%          | 8%           | -11%         |
| <b>Breast Health</b>                   |              |              |              |              |
| Revenue                                | 1138,3       | 1218,2       | 1314,2       | 1151,9       |
| Income                                 | 399,3        | 399,7        | 373,4        | 192,8        |
| Income margin                          | 35%          | 33%          | 28%          | 17%          |
| Dep.                                   | 19,7         | 22,7         | 36,8         | 48,8         |
| Capital exp.                           | 50,9         | 57,7         | 59,2         | 22,4         |
| Assets                                 | 824          | 972,4        | 1127,8       | 1200,9       |

Source: Danaher annual reports.

Breast Health includes Breast Imaging and is showed above. Income is only accounted for by segment (and not by sub-segment). The income margin for Breast Health segment has gradually decreased from 35 percent in 2017 to 17 percent in 2020.

### **Other direct competitors without VAB instruments**

There are several producers of traditional spring-loaded core needles and fine needles, which are high volume products with more moderate margins. Some examples include Italian Sterylab with their product range Multicore, INRAD Inc with three unique needles, Quick-Core Auto from IZI Medical products, BioPince from Argon Medical and Achieve from Merit Medical.

### **BIBBInstruments**

BIBBInstruments is a Swedish start-up that develops biopsy instruments, mainly endoscopic ones. They are currently focusing on their Model X, which is a power-driven endoscopic biopsy instrument somewhat similar to NeoDynamics FlexiPulse needle, though with a flexible cutting part. The product received CE approval during the second half of 2020. The company also has a second endoscopic biopsy instrument that is CE marked and sold on a small scale, EndoDrill.

BIBBInstruments has also developed EndoDrill Core Needle which is a direct competitor to NeoNavia. It received CE approval in 2019 and sales activities commenced the same year. However, at the beginning of 2020 sales activities ceased and capitalized development

work related to EndoDrill Core Needle was later depreciated in its entirety. According to the press release of February 4 2020, resources might be devoted to the development of core needle products with the Model X-technology in the future if there is interest from practitioners. We therefore assume that the EndoDrill Core Needle has been discontinued.

Since BIBBINstruments and Neonavia are both Swedish start-up companies developing biopsy products, it is interesting to compare their relative valuations and development stages. Around SEK 80m has been invested into BIBBINstruments, as compared to about SEK 320 for NeoDynamics. At the moment BIBBINstruments also has two clinical trials ongoing, one involving Model X in Sweden that will recruit 20 patients, and one involving Endodrill that will include 20 patients. 17 patients have been enrolled in previous studies on Endodrill. These are much smaller trials compared to NeoNavia's ongoing Pulse and Compulse with 140 and up to 400 patients respectively. A market introduction in Sweden is planned for 2022 for Model X, while NeoNavia was introduced in 2020.

At a share price of around SEK 8, the market cap is SEK 156m, which is similar to Neodynamics' market cap. Considering how much further Neodynamics is in product development, marketing and its clinical programme, it has to be said that the current market cap of NeoDynamics is very low compared to BIBBINstruments. Furthermore, more money has been invested in NeoDynamics. On the other hand, we have not evaluated the sales potential of Model X, which might exceed that of NeoNavia and in part account for the comparatively higher valuation of BIBBINstruments.

## Large MedTech companies – valuations and margins

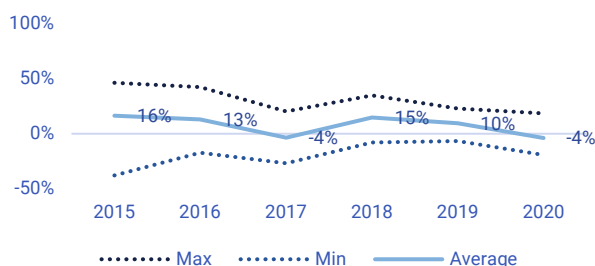
In order to analyze the international MedTech sector, we have selected some of the world's largest MedTech companies as a sector proxy. The total market cap of these companies is around EUR 900 billion. We have analyzed valuations with respect to sales and EBITDA. In general, valuations are comparatively high. Based on the expected figures for 2021, the EV/sales multiple is 5.3 in median. The EV/EBITDA multiple is 18.1 in median. The average values are similar. There is not that much spread in the group. It should be noted that sales decreased during the Covid-19 crisis which might distort the valuations slightly upwards (since market prices are forward looking and discount future growth into the share prices).

### Large MedTech companies

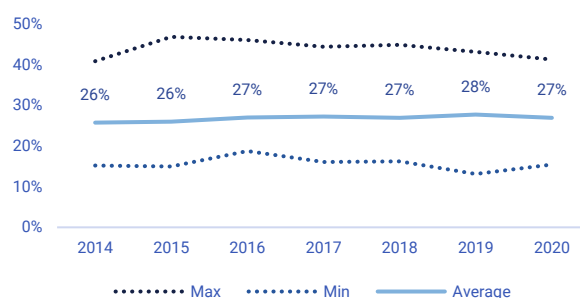
| Company name               | Country of Exchange | Market cap. (EURm) | EV/Sales, 2021E | EV/EBITDA, 2021E |
|----------------------------|---------------------|--------------------|-----------------|------------------|
| Becton Dickinson and Co    | US                  | 59 241             | 4,2x            | 14,5x            |
| Danaher Corp               | US                  | 137 645            | 6,4x            | 20,4x            |
| Hologic Inc                | US                  | 15 916             | 3,9x            | 5,9x             |
| Medtronic PLC              | US                  | 136 539            | 5,5x            | 22,2x            |
| Abbott Laboratories        | US                  | 178 135            | 5,2x            | 18,1x            |
| Siemens Healthineers AG    | DE                  | 52 762             | 3,3x            | 16,2x            |
| Stryker Corp               | US                  | 78 939             | 5,5x            | 21,6x            |
| Baxter International Inc   | US                  | 35 666             | 3,4x            | 15,1x            |
| Boston Scientific Corp     | US                  | 46 174             | 4,9x            | 18,9x            |
| Zimmer Biomet Holdings Inc | US                  | 28 775             | 4,7x            | 14,9x            |
| Intuitive Surgical Inc     | US                  | 76 555             | 13,9x           | 38,8x            |
| Varian Medical Systems Inc | US                  | 13 663             | NaN             | NaN              |
| Getinge AB                 | SE                  | 6 219              | 2,7x            | 13,1x            |
| Hill-Rom Holdings Inc      | US                  | 6 205              | 2,8x            | 14,0x            |
| Steris plc                 | US                  | 14 199             | 4,4x            | 20,0x            |
| Teleflex Inc               | US                  | 16 468             | 6,3x            | 24,4x            |
| Merit Medical Systems Inc  | US                  | 2 831              | NaN             | NaN              |
| <b>Median</b>              |                     | <b>35 666</b>      | <b>5,3x</b>     | <b>18,1x</b>     |
| <b>Average</b>             |                     | <b>53 290</b>      | <b>6,2x</b>     | <b>18,6x</b>     |
| <b>Max</b>                 |                     | <b>178 135</b>     | <b>19,7x</b>    | <b>38,8x</b>     |
| <b>Min</b>                 |                     | <b>2 831</b>       | <b>2,3x</b>     | <b>5,9x</b>      |

Source: Refinitiv Eikon, 2021-04-26.

We have also analyzed the sector with respect to growth and margins. Average growth rates since 2014 are eight percent. EBITDA-margins are high in the sector, on average 26-28 percent between 2014 and 2020. The most profitable companies have EBITDA-margins around 40 percent. NeoDynamics has a premium product with comparatively high margins. In the long-term, we therefore assume above sector average industry margins for the company.

**Growth, avg., max and min**


Source: Refinitiv Eikon.

**EBITDA-margin, avg. and median**


Source: Refinitiv Eikon.

**Transactions**

Transactions within the space of breast health are comparatively frequent. We list some of the most recent ones that are relevant to NeoDynamics below. If the market introduction of NeoNavia is successful, particularly if it is successful on the American market, the company will likely become an acquisition target.

**2020 Hologic**

In Januari 2020, Hologic acquired the German biopsy needle and marker producer Somatex. The main reason for the transaction was Hologic's wish to acquire the Tumark Vision range of breast marker clips. It also benefited Hologic's sales in Europe, since they acquired new sales channels there, particularly in Germany. Somatex was expected to have a revenue of USD 13m in 2020 and was sold for USD 64m. The EV/sales multiple is thus calculated to be 4.9x (assuming no cash followed with the company).

This transaction is interesting from NeoDynamics' point of view. In April 2017, Somatex signed a distribution agreement with Hologic for the US market. It covered the exclusive rights to sell certain Tumark marker clips. Less than three years later, Hologic buys the company. NeoDynamics might very well follow a similar course of events.

**2019 Hologic**

Hologic made an interesting acquisition in 2019 when it acquired SuperSonic Imagine, a French producer of cart-based ultrasound units. The enterprise deal value was valued at a maximum of USD 85m. Supersonic generated a revenue of around USD 29m in 2018. This puts the EV/Sales ratio at 2.9. The company was founded in 2005.

**2019 IZI Medical**

IZI Medical acquired soft tissue biopsy and breast localization needle assets from Cook Medical in January 2019. The portfolio of products consists of the Quick-Core Biopsy Needle, MReye Breast Localization Coil, and the Kopans and X-Reidy Lesion Localization Needles. Both companies are private. No transaction price was disclosed.

**2018 Merit Medical**

In 2018 Merit Medical acquired Cianna Medical for up to USD 200m (upfront 135m). Cianna produces a breast cancer localization and guidance device called Scout, which improves radiology workflow in breast cancer. Revenue in 2018 was expected to USD 29m representing a five percent market share. Sales increased drastically to USD 49.5m in 2019. EV/Sales is thus estimated 6.9x on a trailing basis and 4x on a forward basis. It is an interesting case compared to NeoDynamics, since it was medical device company active in breast biopsies with only two products, though Scout was the most important one (they also produce the SAVI Brachy that delivers radiation internally after a lumpectomy). It is also an interesting illustration in sales expansion after a purchase.

**2018 Merit Medical**

Merit Medical has an oncology division that produces various fine needle aspiration and spring-loaded core needle devices. In 2018 it acquired BD's soft tissue core needle biopsy line after BD had acquired Bard in 2017, consisting of Achieve and Temno biopsy systems and Tru-Cut biopsy needles, as well as Bard's drainage catheter lines. The price was 100m. The annualized revenue from the acquired product ranges was USD 42-48m, which puts the EV/Sales multiple at around 2.2x.

## Carlsquare estimates and financial history

We combine a bottom-up with a top-down approach, leading to peak sales of SEK 466m in 2030. We forecast the highest sales growth in the US, assuming that a partner with an existing sales organization can be found. We forecast a positive cash flow and positive EBITDA from 2024. We forecast a long-term EBITDA margin of 36 percent.

### Sales and COGS forecast

Important input parameters in our model are prices for the needles and sales mix. We assume a price of SEK 600 for CorePulse, SEK 3000 for VacuPulse and SEK 2000 for FlexiPulse. We assume a price of SEK 200 000 for the base unit, which lasts for 5000 procedures. This equates to a price per procedure of SEK 40. In other words, the cost of the base unit will have a low impact on total sales in the long run. We assume a sales mix of 75 percent CorePulse, 15 percent VacuPulse and 10 percent FlexiPulse. We also assume a total market share of 15 percent of axilla biopsies, for which FlexiPulse is used, which is in addition to the above numbers. We assume an average cost of goods sold (COGS) of 30 percent on the above-mentioned prices. We assume an annual inflation of two percent.

For China and the US we assume that the prices will be lower, as we assume that they will be sold by distributors who will have to bear the sales costs. We assume a price discount of 45 percent for China and 15 percent for the US. We assume the same production costs per item as in Europe. This means that COGS are 55 percent in China and 35 percent in the US. Our assumptions are summarized below to the left.

#### Pricing assumptions (SEK)

|                      | CorePulse | VacuPulse | FlexiPulse |
|----------------------|-----------|-----------|------------|
| Needle price         | 600       | 3000      | 2000       |
| Salex mix            | 75%       | 15%       | 10%        |
| Price discount USA   |           |           | 15%        |
| Price discount China |           |           | 45%        |

Source: Carlsquare Estimates.

#### Market assumptions (mSEK), breast biopsies

| Region            | Biopsies 2030 | Market share | Peak sales |
|-------------------|---------------|--------------|------------|
| Axillary biopsies | 264 649       | 15%          | 78         |
| EU-UK             | 1 929 705     | 5%           | 144        |
| US                | 1 749 896     | 7%           | 110        |
| China             | 1 613 375     | 9%           | 133        |
| <b>Sum</b>        |               |              | <b>466</b> |

Source: Carlsquare Estimates.

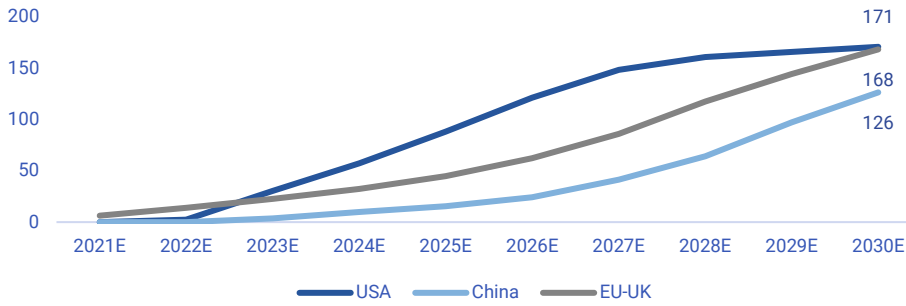
We will combine a bottom-up with a top-down approach for our sales forecast. We assume that sales will start in 2021 in the clinics taking part in the two clinical trials in Germany and the UK, consisting of seven hospitals in Germany and eight in the UK. We also assume sales to six hospitals in Sweden that have been involved in testing the pre-production version of NeoNavia. We assume a forty percent share within all the mentioned hospitals by 2023. From 2024 onwards we apply a sales curve that connects our bottom-up estimates with a top-down calculation of total market share.

We use the same approach for the US market, with sales initiation in 2022 in selected hospitals, and the Chinese market, with sales initiation in 2023 in selected hospitals.

For the top-down approach, we calculate the estimated number of biopsies on each market by 2030. We then assume a certain market share on each market for NeoNavia. Today, around 60 percent of biopsies in western countries are ultrasound guided, which is the type of imaging technique that NeoNavia is intended for. This somewhat limits the potential market share of NeoNavia. We have made a separate estimate of the number of axillary biopsies performed and assumed a market share of 15 percent. The market assumptions are summarized in the graph above to the right. The market share is defined as the percentage of total breast biopsies where NeoNavia is used. (The figures have to be divided by 0.6 to get the market share in the ultrasound guided sub-market). We assume a higher market share in China since the major players are not active there, and consequently there should be less competition.

The result of our combined bottom-up and top-down approach is summarized in our graph below, where our sales estimates for each region until 2030 are shown. We have assumed that a partner with an existing distribution network can be found for the US market during 2022. This makes sales take off during 2023. We assume a high growth rate in the following years. We assume slower organic growth rates for EU-UK and China, as a sales organization has to be created and expanded in these regions, though with slightly higher growth rates for China.

**Sales estimates per region, 2021-2030, mSEK**



Source: Carlsquare Estimates.

The total sales and growth rates for 2021-2030 are summarized in the graph below. There is a spike in the growth rate for 2023, which is the year we estimate that a partner could be found for the US market. The growth rate gradually wears off until 2030. In our estimates, most of the revenue growth until about 2025 will come from the US market, where a full market share can be reached quicker compared to the other markets.

**Sales estimates and growth rates, 2021-2030, mSEK**

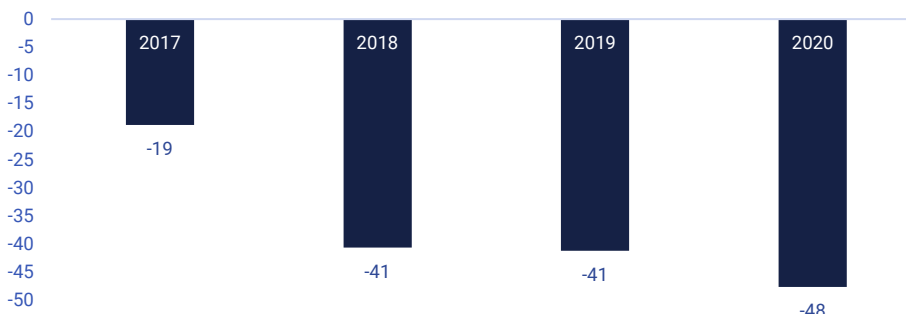


Source: Carlsquare Estimates.

**Operating Costs**

The company has had operating costs of about SEK 40m in 2018 and 2019. The costs have increased somewhat during 2020 to almost SEK 50m. We expect further increases in 2021 and 2022.

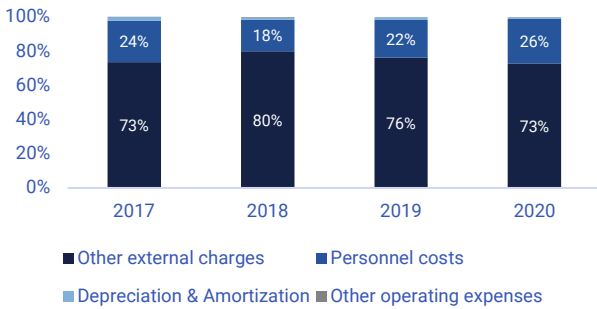
**Historical operating costs, 2017-2020**



Source: Carlsquare estimates.

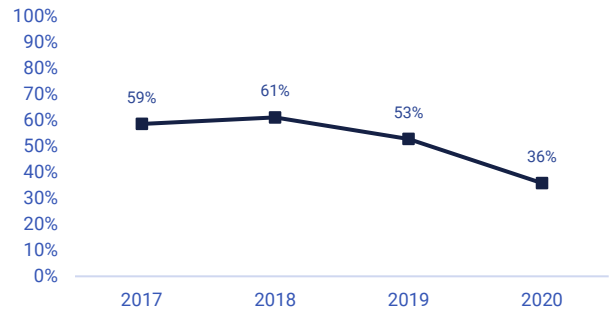
We have calculated the cost distribution in our graph below to the left. About 70-80 percent of costs have been other external charges, and about a quarter personnel costs. Below to the right we have plotted capitalized development work divided by historical operating costs. This is charges for product development related to NeoNavia, most of which is part of other external charges. As a part of total costs, it has decreased from about 60 percent in 2017-2018 to 36 percent in 2020.

**Distribution of historical costs**



Source: Carlsquare Estimates.

**Capitalized development work as percentage of total**



Source: Carlsquare Estimates.

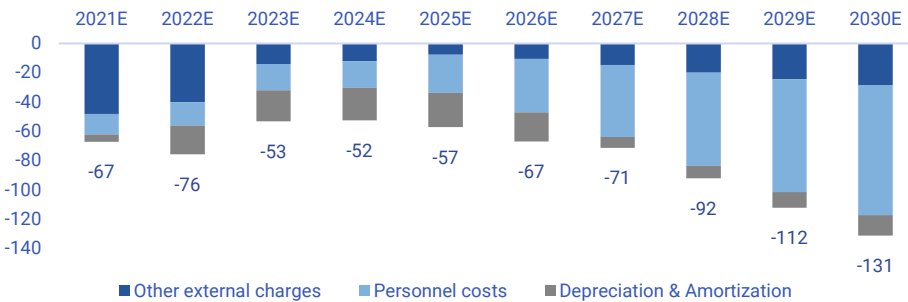
In our forecast, we have assumed that capitalized development work should decrease even further during 2021 and ahead, as the production version of NeoNavia is fully developed.

Our forecast for operating costs until 2030 is shown below. Other external charges should increase during 2021 and 2022, but decrease substantially thereafter as all clinical trials should be finished by 2023 and as NeoNavia should have completed its market launch in EU-UK and the US by 2023.

Immaterial assets are depreciated linearly over a five-year period starting from when the product is entirely developed and ready to be sold. Depreciation should start in 2021 as sales begins. Thus, we expect depreciation to be a major part of costs in the future. It is just an accounting cost, however, and will not impact the real expenditure of the company.

In the long term, personnel costs will make up the main part of operating costs as the company develops into a freestanding specialized commercial MedTech company.

**Operating costs forecast, 2021-2030**

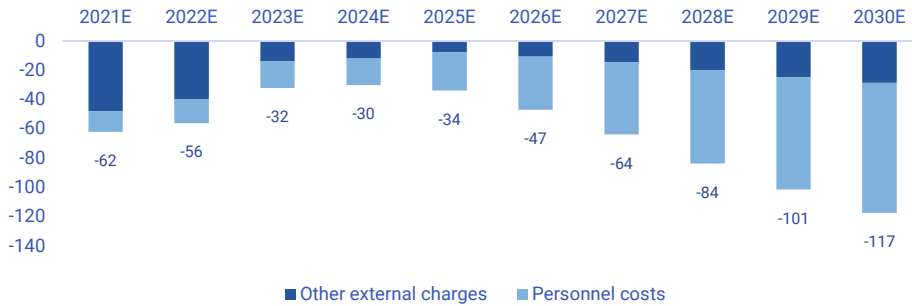


Source: Carlsquare Estimates.

In order to get a better overview of the real costs, we have subtracted depreciation and amortization from the operating costs forecast in the graph below. According to our estimates, operating costs minus depreciation should be around SEK 60m in 2021 and 2022, before falling in 2023, as international distributors should have been acquired by then, and initial marketing activities and clinical trials have been concluded. The main cost for handling distributors is administration.



**Operating costs forecast minus D&A**



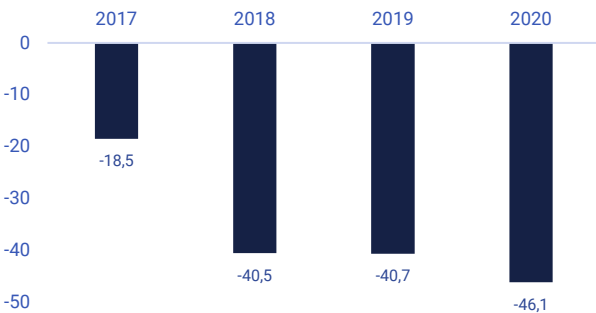
Source: Carlsquare estimates.

An American clinical trial with about 100 participants starting in 2022 and the COMPULSE clinical trial in the UK with up to 400 participants will account for some of other external charges in 2021 and 2022. Marketing and sales costs related to the market introduction will account for most of the remaining costs.

**EBITDA**

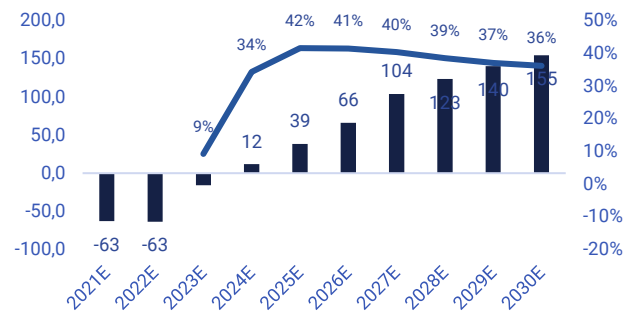
In our model, the company will start showing positive EBITDA figures from 2024. Long-term, our model forecasts an adjusted EBITDA margin of 36 percent. It decreases as market shares China and Europe grow, where prices are lower compared to the USA.

**Historical EBITDA**



Source: Carlsquare Estimates.

**Forecast of adj. EBITDA and adj. EBITDA-margin**



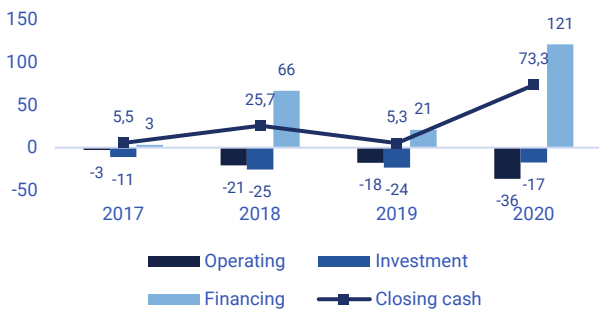
Source: Carlsquare Estimates.

### Cash flow

The company's operating cash flow has been around minus SEK 20m during 2018-2019 and minus SEK 36m in 2020, while the investment cash flow has been around minus SEK 25 during 2018-2019 and minus SEK 17m in 2020. The investment cash flow consists of investments into product development. Cash flow mirrors costs, in that cash flows related to product development are decreasing and are expected to decrease further while costs related to marketing and clinical trials should increase. The financing cash flows represents the net cash flow from loans, repayments of loans and share issues.

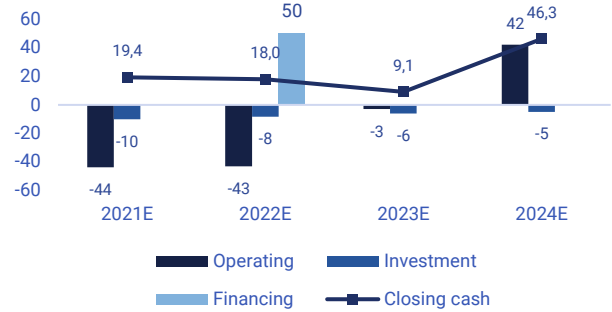
Our estimates until 2024 are shown below to the right. We estimate that a further share issue will be necessary during 2022 at SEK 50m. We have assumed a share issue price of SEK 4. The company should be cash flow neutral by 2023 assuming that a partner in the US has been found.

#### Historical cash flow, 2017-2020



Source: Carlsquare estimates.

#### Estimated future cash flow, 2021-2024



Source: Carlsquare estimates.

## Valuation and valuation methods

In the section, we use the forecasts to complete a discounted cash flow valuation of NeoDynamics. Using a discount rate of 14.7 percent and a DCF valuation method, we value the company at SEK 5.55 in the base scenario. We also compare the company to Swedish MedTech companies listed on Spotlight and First North. NeoDynamics is among the lowest valued companies in its group.

### Multiples based valuation

In order to perform a valuation based on comparable companies, we have selected all medical device companies we could find from Spotlight Stock Market and First North. We defined companies as commercial when sales (defined as revenue minus capitalized development work) were at least around SEK 10m in 2020 or 2019. We defined the other companies as developing. We found nine companies in the first group and 18 in the second (including NeoDynamics).

The commercial companies are listed below. Almost all the companies are in an early stage of commercialization. The median sales for 2020 was SEK 18m and the median last full year (LFY) EV/sales multiple was 12x. The median enterprise value was SEK 503m while the median market cap was SEK 481m (the market cap of a company should be higher than the enterprise value, but in this case we are comparing groups). The valuations have increased substantially for this group over one year, by a median of 54 percent.

#### Commercial small Swedish medical device companies

| Company name                  | Mcap         | EV           | Equity/Mcap  | Total 1yr Return | Sales 2020 | EV/Sales 2020 |
|-------------------------------|--------------|--------------|--------------|------------------|------------|---------------|
| Surgical Science Sweden AB    | 5 048        | 4 994        | 11,8x        | 119%             | 105        | 47,7          |
| Paxman AB                     | 998          | 1 049        | 91,7x        | 98%              | 78         | 13,4          |
| Dignitana AB                  | 481          | 415          | 6,2x         | 10%              | 47         | 8,9           |
| Redsense Medical AB           | 656          | 591          | 9,0x         | 251%             | 18         | 32,6          |
| Zenicor Medical Systems AB    | 66           | NaN          | NaN          | 8%               | 18         | NaN           |
| ScandiDos AB                  | 178          | 172          | 3,9x         | 101%             | 16         | 10,9          |
| Inhalation Sciences Sweden AB | 84           | 78           | 8,0x         | 18%              | 10         | 7,7           |
| Senzime AB                    | 1 429        | 1 279        | 6,2x         | 34%              | 9,3        | 137,0         |
| iZafe Group AB                | 102          | 101          | 3,5x         | 54%              | 8,9        | 11,4          |
| <b>Median</b>                 | <b>481</b>   | <b>503</b>   | <b>7,1x</b>  | <b>54%</b>       | <b>18</b>  | <b>12</b>     |
| <b>Average</b>                | <b>1 005</b> | <b>1 085</b> | <b>17,5x</b> | <b>77%</b>       | <b>34</b>  | <b>34</b>     |
| <b>Max</b>                    | <b>5 048</b> | <b>4 994</b> | <b>91,7x</b> | <b>251%</b>      | <b>105</b> | <b>137</b>    |
| <b>Min</b>                    | <b>66</b>    | <b>78</b>    | <b>3,5x</b>  | <b>8%</b>        | <b>9</b>   | <b>8</b>      |

Source: Refinitiv Eikon & Carlsquare, 2021-04-26.

This group provides an idea of how the valuation of NeoDynamics could grow as sales commences. The EV for NeoDynamics today is SEK 110m while the market cap is about SEK 180m. In our forecast, NeoDynamics has sales of SEK 16.2m during 2023. If the EV/sales number of 12 below is applied, the EV should grow to around SEK 200m at the end of 2023 (based on the LTM sales multiple). If NeoDynamics is growing faster than the group below, which is our assumption, the valuation should be even higher on a comparative basis. If we use the average of the group is used instead of the mean, the EV becomes SEK 550m at the end of 2023 based on our forecast.

The developing companies are listed below. The group has had a lower median share price increase in one year compared to the commercial companies at 14 percent. Since they are not commercial, it is inappropriate to use multiples related to sales or earnings. Instead, one can compare enterprise values and price book multiples, though caution has to be applied. The median enterprise value for the group is SEK 269m. This is more than twice the value of NeoDynamics' SEK 110m. The median market cap of the group is SEK 238m, while NeoDynamics' market cap is SEK 180m. We judge that NeoDynamics should have at least the same market potential as the average company in the group. Furthermore, NeoDynamics is above average in development phase, as the product development phase is concluded and the commercial phase just been initiated. Our conclusion is that the valuation of NeoDynamics is low compared to the other companies' enterprise values and market caps.

## Developing small Swedish medical device companies

| Company name                 | Mcap         | EV           | Mcap/Equity   | Total 1yr Return | Sales 2020 |
|------------------------------|--------------|--------------|---------------|------------------|------------|
| Irras AB                     | 415          | 286          | 2,3x          | -5%              | 7,4        |
| BrainCool AB                 | 679          | 671          | 11,2x         | 106%             | 7,0        |
| Acusort AB                   | 283          | 275          | 29,5x         | 175%             | 6,8        |
| Micropos Medical AB          | 310          | 310          | 352,7x        | 127%             | 3,9        |
| Senzime AB                   | 1 429        | 1 279        | 6,2x          | 34%              | 3,5        |
| SciBase Holding AB           | 395          | 360          | 8,4x          | 509%             | 3,1        |
| Acarix AB                    | 194          | 132          | 2,4x          | -20%             | 2,2        |
| Invent Medic Sweden AB       | 103          | 94           | 8,5x          | -22%             | 1,5        |
| NeoDynamics AB               | 182          | 110          | 1,1x          | -3%              | 1,5        |
| VibroSense Dynamics AB       | 102          | 90           | 6,1x          | 18%              | 1,2        |
| Medfield Diagnostics AB      | 159          | 153          | 3,1x          | 2%               | 1,2        |
| ObsteCare AB                 | 56           | 50           | 1,5x          | -52%             | 0,9        |
| Pharmacolog I Uppsala AB     | 37           | NaN          | NaN           | -29%             | 0,7        |
| BibbInstruments AB           | 120          | 102          | 8,3x          | 115%             | 0,6        |
| Phase Holographic Imaging AB | 159          | 138          | 5,0x          | 70%              | 0,2        |
| Calmark Sweden AB            | 386          | 389          | 13,1x         | 9%               | 0          |
| Ortoma AB                    | 303          | 269          | 3,8x          | 93%              | 0          |
| PEXA AB                      | 512          | 504          | 4,9x          | -32%             | 0          |
| <b>Median</b>                | <b>238</b>   | <b>269</b>   | <b>6,1x</b>   | <b>14%</b>       | <b>1,4</b> |
| <b>Average</b>               | <b>324</b>   | <b>307</b>   | <b>27,5x</b>  | <b>61%</b>       | <b>2,3</b> |
| <b>Max</b>                   | <b>1 429</b> | <b>1 279</b> | <b>352,7x</b> | <b>509%</b>      | <b>7,4</b> |
| <b>Min</b>                   | <b>37</b>    | <b>50</b>    | <b>1,1x</b>   | <b>-52%</b>      | <b>0,0</b> |

Source: Refinitiv Eikon & Carlsquare, 2021-04-26

When we examine the companies' book values (defined as market cap / equity), we observe that the median value is 6.1. The lowest valued company in the group according to this parameter is NeoDynamics, with a figure of 1.1. In other words, NeoDynamics has an extremely low valuation on this metric. However, for most of these companies, equity is largely derived from cash and intangible assets, derived from capitalized development work. Companies that do not capitalize their development work will have lower equity, which increases the price/book value, so one has to be careful before drawing any firm conclusions. Our tentative conclusion is that NeoDynamics has a low valuation compared to the group in relation to the money that has been invested in the company.

## DCF Valuation inputs

### Discount rate

The required rate of return on equity is calculated using the CAPM model. In the model, we have assumed a risk-free interest rate of zero percent and a beta value of 1.2. The market risk premium is assumed to be 7.7 percent in line with PwC's "Risk premium in the Swedish equity market" from June 2020. We have added a small company premium of 4.5 percent the market risk premium, in line with the same source. This leads to a required rate of return of 14.7 percent.

### Shares outstanding

The company has two warrant programs, 2018/21 with 550 000 warrants at a strike price of SEK 10.50 and 2020/23 with 1 021 900 at a strike price of 4.71. Since the warrants are not in the money, we will omit them from the valuation.

We assume that a capital raise of SEK 50m at a share price of SEK 4 (the latest share issue price was SEK 3.71) during 2022 leads to the issuing of 12.5 million new shares. We thus calculate with a fully diluted share count of 72.8 million shares.

### Cash

As per 31 December 2020, the company had a cash position of SEK 73m.

### Terminal value

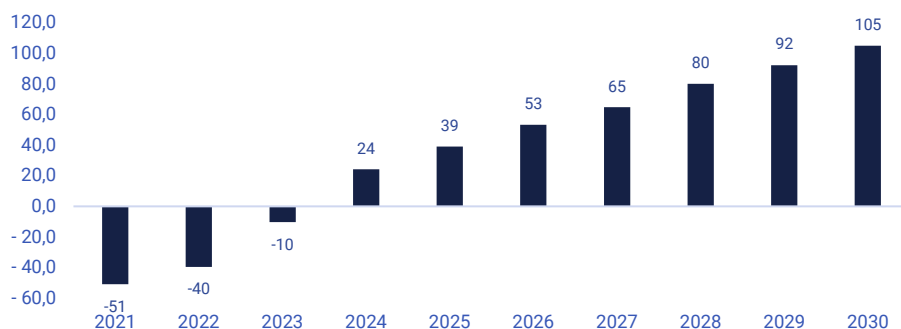
In a DCF valuation of a company that is a going concern, the terminal value will make up the largest part of the valuation. This is determined by the end cash flow and the perpetual growth factor. We set the perpetual growth to three percent. This is motivated by the fact

that the breast biopsy market should grow with at least one percent per year (due to world population growth and an aging population) and inflation should be at least two percent.

### DCF valuation

The estimated free cash flows of NeoDynamics are visualized below. By discount all the cash flow to their present value (with the discount rate mentioned above) and adding the terminal value also discounted to the present value, adding the cash, and dividing the resulting value with the fully diluted number of shares, **we calculate a fair value per share of SEK 5.55.**

#### Free cash flows



Source: Carlsquare estimates

### Fair value within an interval

The valuation with a discounted cash flow (DCF) model is summarized below. The valuation of all companies will have a margin of error. In order to estimate this margin of error, we have made a bull and a bear sales estimate and calculated the discounted cash flows based on these new estimates (see below). **This leads to an interval of SEK 2.90 – SEK 7.76.**

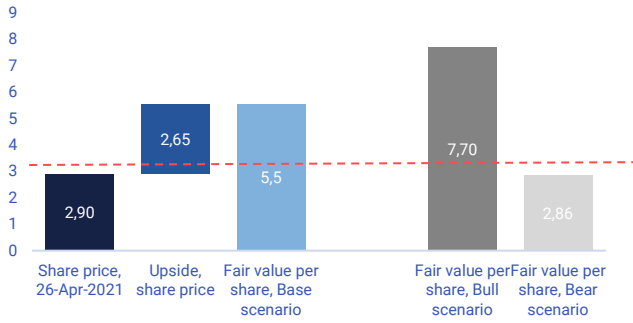
#### Valuation (SEK, mSEK)

| DCF valuation                              |             | Disc. rate                       | forecast period | Assumptions                         |       |
|--|-------------|----------------------------------|-----------------|-------------------------------------|-------|
| Present value cash flow (UFCF)             | 83          | Risk free rate                   | 0.0%            | CAGR. 2021-2030                     | 55.8% |
| Present value. terminal value (TV)         | 246         | Market premium                   | 7.7%            | Adj. EBITDA-margin 2030             | 36.2% |
| <b>Enterprise value (EV)</b>               | <b>330</b>  | Size premium                     | 4.5%            | Adj. EBIT-margin. 2030              | 33.2% |
|  |             | Beta                             | 1.2x            |                                     |       |
| Cash at hand                               | 73.3        | <b>Required return on equity</b> | <b>14.7%</b>    | Tax rate                            | 20.6% |
| Debt                                       | 0.0         |                                  |                 | Company spec. add.                  | 0.0   |
| <b>Equity value</b>                        | <b>404</b>  | Tax adj. int. on debt            | 0.0%            | Disc. rate TV                       | 14.7% |
|  |             | Debt ratio                       | 0.0%            |                                     |       |
| Existing number of shares                  | 60.3        |                                  |                 | <u>Implicit multiples valuation</u> |       |
| New shares after rights issues             | 12.5        | WACC                             | 14.7%           | EV/sales. 2021E                     | 51.9x |
| Diluted number of shares                   | 72.8        | Company specific add.            | 0.0%            | EV/EBITDA. 2021E                    | n.m.  |
|  |             |                                  |                 | P/S. 2021E                          | 63.5x |
| <b>Value per share, base case scenario</b> | <b>5.55</b> | <b>Disc. rate</b>                | <b>14.7%</b>    | P/E. 2021P                          | n.m.  |

Source: Carlsquare estimates

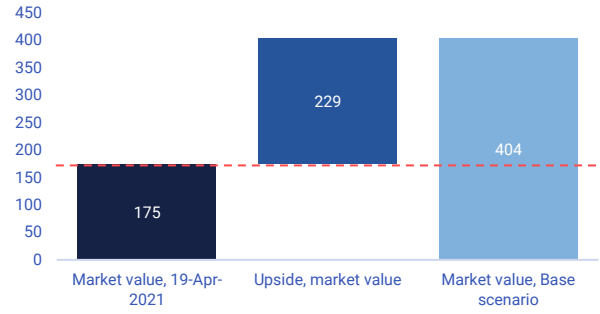
The fair fully diluted value per share in relation to the actual share price is shown below to the left. The fair market value is visualized below to the right. No future dilution is taken into account in this case.

**Visualization fair value per share, Base scenario (SEK)**



Source: Carlsquare estimates

**Visualization market value, Base scenario (mSEK)**

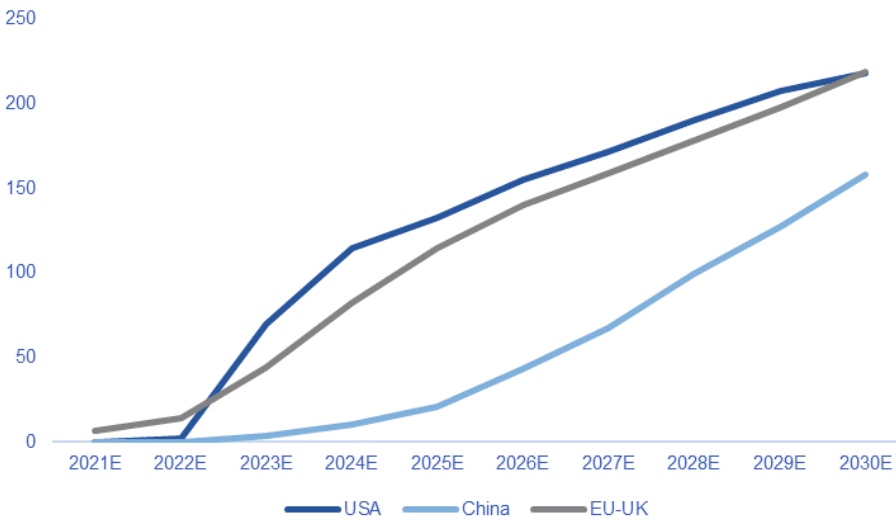


Source: Carlsquare Estimates

**Bull Scenario**

In the bull scenario, we assume 30 percent higher sales figures for the final year, 2030. We also assume much higher sales growth rates in Europe and China. **This leads to a fully diluted fair value per share of SEK 7.76.**

**Bull scenario sales estimates**

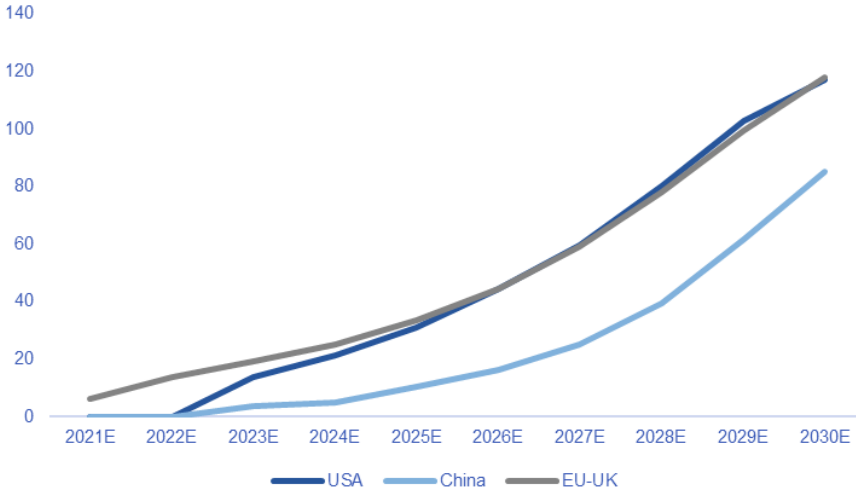


Source: Carlsquare Estimates.

**Bear Scenario**

In the bear scenario, we assume 30 percent lower sales figures for the final year, 2030. We also assume slower growth rates across all markets. Due to the slower sales growth, the company will need to raise more money, SEK 60m instead of SEK 50m in the base case scenario. We also assume that the share price for the capital raise is lower, SEK 3. **This leads to a fully diluted fair share value of SEK 2.90.**

**Bear scenario sales estimates**

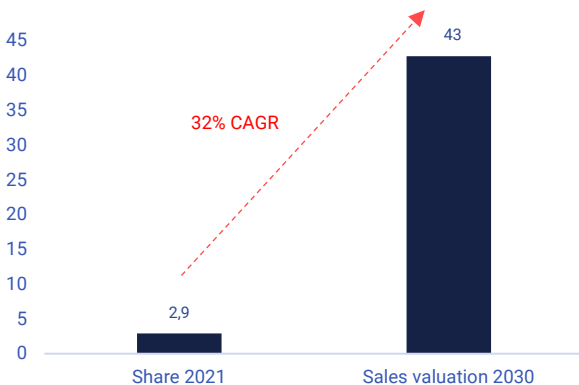


Source: Carlsquare Estimates.

**Potential growth in share value**

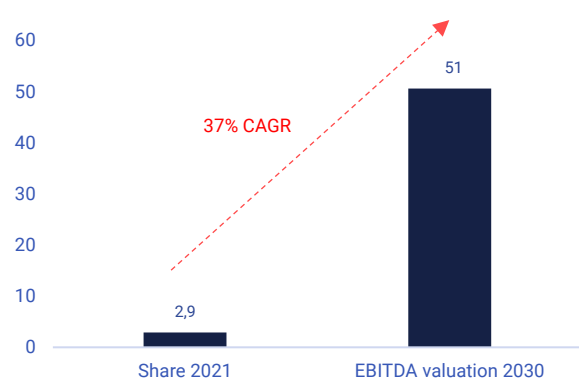
As a final exercise, we have estimated the potential appreciation in share value in the long term by applying the MedTech sector mean multiples from the Market and comparable companies section to our forecast values for NeoDynamics in 2030. The EV/sales multiple is 5.3x in median and the EV/EBTDA multiple is 18.1x for this sector. We have added the cash position in 2030 from the cash flow valuation (assuming no dividends until then). Based on our estimated share count in 2030, the potential future valuation together with the share value growth rates are shown below. This is not the basis for our valuation of the company, rather, it is an illustration of potential value increase if the company succeeds commercially. This exercise does not take any risks into account.

**Potential share value 2030 based on sales multiple, SEK**



Source: Carlsquare estimates

**Potential share value 2030 based on EBIDA multiple, SEK**



Source: Carlsquare estimates

One caveat is that the MedTech companies we compare NeoDynamics with are much larger than it could be by 2030. In other words, they should have somewhat lower WACCs and consequently larger valuation multiples, though NeoDynamics has a higher EBITDA margin in our forecast, which means that the EV/sales valuation is understated.

Regarding the CAGR (Compound Annual Growth Rate), most of the share value accretion would occur after a sales breakthrough, as further sales would be discounted into the share price.



## Risks

NeoDynamics' main risks are commercial in nature. The company will need to reach the target audience and get them to try NeoNavia and then order it. The product needs to be introduced to the US and Chinese markets. The company is subjected to certain regulatory risks in that the FDA 510 (k) application might theoretically be a failure and that the two ongoing clinical trials might not show good enough results, though these risks are smaller than the commercial ones in our opinion.

## Risks and challenges

### Commercial risk

NeoDynamics has only received one order on a NeoNavia unit, but so far not demonstrated any net sales. Companies that transition from a development stage to a commercial stage typically have an increased risk profile, as new types of competencies are demanded in the company.

There is a market risk in that the market for breast biopsies is highly developed with a good availability of effective instruments at acceptable prices (at least for CNB). There is no large unmet need to satisfy. Even if NeoNavia is superior to older generations of products, the users have to be convinced to try it. If the user is already satisfied with the solution he uses, it might be difficult to convince him or her to even test a new product. The management of NeoDynamics is clearly aware of this risk. That is why they initiated clinical trials in axillary biopsies, where there is a large unmet need, and where there is a potential for a quick uptake of a new medical device that can perform core needle biopsies. There is still the risk that the use of NeoNavia might not spread from axillary biopsies to breast biopsies.

Assuming that NeoDynamics manages to introduce the product and reach the initial sales targets for Germany, Sweden and the UK, there is the further challenge of increasing sales to more clinics and more countries. A sales organization would have to be built up in pace with the increase in sales. This process could be slower than anticipated. NeoDynamics could also go the route of selling through distributors in Europe. This should lead to a higher sales growth at a lower risk, but with lower margins and no control of the product or the sales network and no direct contact with the end customer.

### Dependency on international distributors

In order to reach its full sales potential, NeoNavia has to be introduced on international markets. It is vital that it is sold in the USA, which has a higher price level and uses more advanced equipment. The most logical way to expand into the US market would be through an exclusive distribution agreement with a large company that sells breast imaging products. A license deal would also be conceivable if the volumes are large enough. NeoDynamics intends to introduce the product to the US market on its own, and then find a partner for the sales expansion. If the company does not succeed in finding a partner, or cannot find a good partner or a good deal, sales in the US might not materialize at all or be lower than our estimates.

The situation in China is very different. The difficulty there is to find market acceptance for a new type of medical device, as surgical biopsies are still common. NKY Medical, NeoDynamics' largest shareholder, will have to build a new sales network, rather than introducing a better version of an existing product, as is the case in Europe and the US. There is a risk that this might take more time and effort than expected, resulting in a slower sales growth and lower market penetration compared to our estimates.

### Dependency on clinical trials

The clinical trials in the UK and Germany are used as a way to introduce NeoNavia in these markets. The trials involve using NeoNavia in axillary biopsies. If satisfactory results are not obtained, it will be more difficult to market NeoNavia to new hospitals. Larger sample sizes should clearly be obtained from FlexiPulse compared to standard CNB, but its usefulness in the axilla is still to be determined. If NeoNavia with FlexiPulse cannot be used in a substantially larger number of cases compared to CNB, it might be questioned by practitioners and not adopted widely.

# Accounts and key figures

## Income statement (SEK million)

|                                      | 2018         | 2019         | 2020         | 2021E        | 2022E        | 2023E       | 2024E       | 2025E        |
|--------------------------------------|--------------|--------------|--------------|--------------|--------------|-------------|-------------|--------------|
| Net sales                            | 0,0          | 0,0          | 0,0          | 6,3          | 16,2         | 56,8        | 99,6        | 148,8        |
| Other operating income               | 0,1          | 0,5          | 1,5          | 0,0          | 0,0          | 0,0         | 0,0         | 0,0          |
| <b>Total sales</b>                   | <b>0,1</b>   | <b>0,5</b>   | <b>1,5</b>   | <b>6,3</b>   | <b>16,2</b>  | <b>56,8</b> | <b>99,6</b> | <b>148,8</b> |
| Capitalized development work         | 24,9         | 21,8         | 17,1         | 10,0         | 8,2          | 6,0         | 5,0         | 7,4          |
| Other external charges               | -32,4        | -31,3        | -34,6        | -48,0        | -40,0        | -14,0       | -12,0       | -7,6         |
| Personnel costs                      | -7,5         | -9,2         | -12,4        | -14,0        | -16,0        | -18,0       | -18,1       | -26,1        |
| Depreciation & Amortization          | -0,6         | -0,6         | -0,5         | -5,2         | -19,5        | -21,2       | -22,4       | -23,4        |
| Other operating expenses             | -0,2         | -0,1         | -0,1         | 0,0          | 0,0          | 0,0         | 0,0         | 0,0          |
| <b>EBIT</b>                          | <b>-15,6</b> | <b>-18,9</b> | <b>-29,0</b> | <b>-52,8</b> | <b>-55,3</b> | <b>-9,9</b> | <b>16,8</b> | <b>46,0</b>  |
| Adj. EBIT                            | -40,5        | -40,7        | -46,1        | -62,8        | -63,5        | -15,9       | 11,8        | 38,6         |
| <b>EBITDA</b>                        | <b>-15,1</b> | <b>-18,3</b> | <b>-28,6</b> | <b>-47,6</b> | <b>-35,8</b> | <b>11,2</b> | <b>39,1</b> | <b>69,4</b>  |
| Adj. EBITDA                          | -39,9        | -40,1        | -45,7        | -57,6        | -44,0        | 5,2         | 34,2        | 61,9         |
| Result from financial items          | -2,6         | -0,5         | -2,0         | 0,0          | -3,5         | 0,0         | 0,0         | 0,0          |
| <b>EBT</b>                           | <b>-18,2</b> | <b>-19,4</b> | <b>-31,0</b> | <b>-52,8</b> | <b>-58,8</b> | <b>-9,9</b> | <b>16,8</b> | <b>46,0</b>  |
| Adj. EBT                             | -43,1        | -41,2        | -48,1        | -62,8        | -67,0        | -15,9       | 11,8        | 38,6         |
| Taxes                                | 0,0          | 0,0          | 0,0          | 0,0          | 0,0          | 0,0         | 0,0         | 0,0          |
| <b>Profit or loss for the period</b> | <b>-18,2</b> | <b>-19,4</b> | <b>-31,0</b> | <b>-52,8</b> | <b>-58,8</b> | <b>-9,9</b> | <b>16,8</b> | <b>46,0</b>  |
| Adj. profit or loss for the period   | -43,1        | -41,2        | -48,1        | -62,8        | -67,0        | -15,9       | 11,8        | 38,6         |

|                                    | 2018 | 2019 | 2020 | 2021E | 2022E | 2023E | 2024E | 2025E |
|------------------------------------|------|------|------|-------|-------|-------|-------|-------|
| Growth                             |      |      |      |       |       |       |       |       |
| Net sales                          |      | n/a  | n/a  | n/a   | 157%  | 251%  | 75%   | 49%   |
| Total sales                        |      | 390% | 197% | 333%  | 157%  | 251%  | 75%   | 49%   |
| EBITDA                             |      | 21%  | 56%  | 67%   | -25%  | -131% | 248%  | 77%   |
| Adj. EBITDA                        |      | 0%   | 14%  | 26%   | -24%  | -112% | 552%  | 81%   |
| EBIT                               |      | 21%  | 54%  | 82%   | 5%    | -82%  | -269% | 174%  |
| Adj. EBIT                          |      | 0%   | 13%  | 36%   | 1%    | -75%  | -174% | 227%  |
| EBT                                |      | 7%   | 60%  | 70%   | 11%   | -83%  | -269% | 174%  |
| Adj. EBT                           |      | -4%  | 17%  | 30%   | 7%    | -76%  | -174% | 227%  |
| Profit or loss for the period      |      | 7%   | 60%  | 70%   | 11%   | -83%  | -269% | 174%  |
| Adj. profit or loss for the period |      | -4%  | 17%  | 30%   | 7%    | -76%  | -174% | 227%  |

|                    | 2018 | 2019 | 2020 | 2021E | 2022E | 2023E | 2024E | 2025E |
|--------------------|------|------|------|-------|-------|-------|-------|-------|
| Margins            |      |      |      |       |       |       |       |       |
| EBITDA-margin      | n/a  | n/a  | n/a  | -757% | -221% | 20%   | 39%   | 47%   |
| Adj. EBITDA-margin | n/a  | n/a  | n/a  | -916% | -272% | 9%    | 34%   | 42%   |
| EBIT-margin        | n/a  | n/a  | n/a  | -839% | -342% | -17%  | 17%   | 31%   |
| Adj. EBIT-margin   | n/a  | n/a  | n/a  | -998% | -392% | -28%  | 12%   | 26%   |
| EBT-margin         | n/a  | n/a  | n/a  | -839% | -363% | -17%  | 17%   | 31%   |
| Adj. EBT-margin    | n/a  | n/a  | n/a  | -998% | -414% | -28%  | 12%   | 26%   |
| Profit margin      | n/a  | n/a  | n/a  | -839% | -363% | -17%  | 17%   | 31%   |
| Adj. profit margin | n/a  | n/a  | n/a  | -998% | -414% | -28%  | 12%   | 26%   |

Source: Company information and Carlsquare estimates.

**Balance sheet (SEK million)**

|                                       | 2 018       | 2019        | 2020        | 2021E       | 2022E       | 2023E       | 2024E       | 2025E       |
|---------------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| <b>Fixed assets</b>                   |             |             |             |             |             |             |             |             |
| Intangible assets                     | 48,8        | 71,0        | 87,6        | 92,4        | 81,1        | 65,9        | 48,6        | 32,6        |
| Tangible fixed assets                 | 1,2         | 1,3         | 1,3         | 1,3         | 1,3         | 1,3         | 1,3         | 1,3         |
| Financial assets                      | 0,0         | 0,1         | 0,1         | 0,1         | 0,1         | 0,1         | 0,1         | 0,1         |
| <b>Total Fixed Assets</b>             | <b>50,1</b> | <b>72,4</b> | <b>89,0</b> | <b>93,8</b> | <b>82,5</b> | <b>67,3</b> | <b>50,0</b> | <b>34,1</b> |
| <b>Current Assets</b>                 |             |             |             |             |             |             |             |             |
| Inventory                             | 0,0         | 0,0         | 1,8         | 1,9         | 3,1         | 9,8         | 8,8         | 13,3        |
| Accounts receivable                   | 0,0         | 0,3         | 7,2         | 0,6         | 1,6         | 5,7         | 10,0        | 14,9        |
| Prepayments and accrued income        | 0,2         | 0,4         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         |
| Deferred Tax Asset                    | 0,3         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         |
| Other short-term receivables          | 6,2         | 13,0        | 0,0         | 7,0         | 7,0         | 7,0         | 7,0         | 7,0         |
| <b>Total current assets</b>           | <b>6,7</b>  | <b>13,7</b> | <b>9,0</b>  | <b>9,5</b>  | <b>11,7</b> | <b>22,5</b> | <b>25,8</b> | <b>35,2</b> |
| Cash and cash equivalents             | 25,7        | 6,3         | 73,3        | 19,4        | 21,5        | 14,0        | 45,6        | 100,0       |
| <b>Total Assets</b>                   | <b>82</b>   | <b>92</b>   | <b>171</b>  | <b>123</b>  | <b>116</b>  | <b>104</b>  | <b>121</b>  | <b>169</b>  |
| <b>EQUITY</b>                         |             |             |             |             |             |             |             |             |
| Total equity                          | 74,6        | 55,6        | 165,6       | 112,8       | 104,0       | 94,1        | 110,9       | 156,9       |
| <b>Long-term liabilities</b>          |             |             |             |             |             |             |             |             |
| Other liabilities                     | 0,5         | 0,0         | 0,3         | 0,3         | 0,3         | 0,3         | 0,3         | 0,3         |
| <b>Total long-term liabilities</b>    | <b>0,5</b>  | <b>0,0</b>  | <b>0,3</b>  | <b>0,3</b>  | <b>0,3</b>  | <b>0,3</b>  | <b>0,3</b>  | <b>0,3</b>  |
| <b>Short-term liabilities</b>         |             |             |             |             |             |             |             |             |
| Accounts payable                      | 3,8         | 2,2         | 1,3         | 6,4         | 7,0         | 4,9         | 4,8         | 5,4         |
| Current tax liabilities               | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         |
| Other short-term liabilities          | 1,2         | 31,7        | 1,1         | 0,0         | 1,0         | 2,0         | 3,0         | 4,0         |
| Accruals and deferred income          | 2,4         | 2,9         | 3,1         | 3,2         | 3,5         | 2,5         | 2,4         | 2,7         |
| <b>Total short-term liabilities</b>   | <b>7,4</b>  | <b>36,8</b> | <b>5,4</b>  | <b>9,6</b>  | <b>11,5</b> | <b>9,4</b>  | <b>10,2</b> | <b>12,1</b> |
| <b>Total liabilities</b>              | <b>7,9</b>  | <b>36,8</b> | <b>5,7</b>  | <b>10,0</b> | <b>11,8</b> | <b>9,7</b>  | <b>10,5</b> | <b>12,4</b> |
| <b>TOTAL LIABILITIES &amp; EQUITY</b> | <b>82</b>   | <b>92</b>   | <b>171</b>  | <b>123</b>  | <b>116</b>  | <b>104</b>  | <b>121</b>  | <b>169</b>  |
| <b>Activity</b>                       |             |             |             |             |             |             |             |             |
| Working capital (without cash)        | -0,7        | -23,1       | 3,6         | -0,1        | 0,3         | 13,1        | 15,6        | 23,1        |
| Working capital, business             | 25,0        | -16,9       | 76,9        | 19,3        | 21,8        | 27,0        | 61,2        | 123,1       |
| Working capital / net sales           | n/a         | n/a         | n/a         | 3,1x        | 1,6x        | 1,2x        | 1,9x        | 2,7x        |
| <b>Liquidity</b>                      |             |             |             |             |             |             |             |             |
| Current ratio                         | 4,4         | 0,5         | 15,2        | 3,0         | 2,9         | 3,9         | 7,0         | 11,2        |
| Quick ratio                           | 3,5         | 0,2         | 14,9        | 2,1         | 2,0         | 2,1         | 5,5         | 9,5         |
| Cash ratio                            | 3,5         | 0,2         | 13,5        | 2,0         | 1,9         | 1,5         | 4,5         | 8,3         |
| <b>Solvency</b>                       |             |             |             |             |             |             |             |             |
| Net debt (-)/Cash(+)                  | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         | 0,0         |
| Net debt /EBITDA                      | 0,0x        | 0,0x        | 0,0x        | 0,0x        | 0,0x        | 0,0x        | 0,0x        | 0,0x        |
| Net debt / adj. EBITDA                | 0,0x        | 0,0x        | 0,0x        | 0,0x        | 0,0x        | 0,0x        | 0,0x        | 0,0x        |
| Net debt/equity                       | -34%        | -11%        | -44%        | -17%        | -21%        | -15%        | -41%        | -64%        |
| Gross debt/equity                     | 0%          | 0%          | 0%          | 0%          | 0%          | 0%          | 0%          | 0%          |
| Solvency ratio                        | 90%         | 60%         | 97%         | 92%         | 90%         | 91%         | 91%         | 93%         |
| <b>Measures of profitability</b>      |             |             |             |             |             |             |             |             |
| ROA                                   | -22%        | -21%        | -18%        | -43%        | -51%        | -10%        | 14%         | 27%         |
| ROE                                   | -24%        | -35%        | -19%        | -47%        | -57%        | -11%        | 15%         | 29%         |
| ROIC                                  | -37%        | -39%        | -33%        | -56%        | -71%        | -12%        | 26%         | 80%         |

Source: Company information and Carlsquare estimates.

**Cash Flow (SEK million)**

|  | 2018         | 2019         | 2020         | 2021E        | 2022E        | 2023E       | 2024P       | 2025P       |
|--|--------------|--------------|--------------|--------------|--------------|-------------|-------------|-------------|
| <b>Cash flows from operating activities</b>  |              |              |              |              |              |             |             |             |
| Operating result                             | -17,9        | -18,8        | -30,6        | -52,8        | -55,3        | -9,9        | 16,8        | 46,0        |
| <b>Adjustments:</b>                          |              |              |              |              |              |             |             |             |
| Amortisation & non-cash flow items           |              |              |              | 5,2          | 19,5         | 21,2        | 22,4        | 23,4        |
| Interest received                            |              |              |              | 0,0          | 0,0          | 0,0         | 0,0         | 0,0         |
| Interest paid                                |              |              |              | 0,0          | -3,5         | 0,0         | 0,0         | 0,0         |
| Income tax expense                           |              |              |              | 0,0          | 0,0          | 0,0         | 0,0         | 0,0         |
| <b>Change in working capital</b>             |              |              |              |              |              |             |             |             |
| Change in inventories and work in progress   | 0,5          | 0,0          | -1,8         | -0,1         | -1,2         | -6,6        | 0,9         | -4,4        |
| Change in receivables                        | 0,0          | 0,0          | -3,6         | 6,6          | -1,0         | -4,1        | -4,3        | -4,9        |
| Change in deferred income & prepayments      | 0,0          | 3,1          | -0,5         | -7,0         | 0,0          | 0,0         | 0,0         | 0,0         |
| Change in payables                           | -1,6         | 0,0          | 0,0          | 5,2          | 0,5          | -2,0        | -0,1        | 0,6         |
| Change in current liabilities                | -1,8         | 3,1          | -3,6         | -0,9         | 1,3          | 0,0         | 0,9         | 1,3         |
| <b>Net cash from operating activities</b>    | <b>-20,8</b> | <b>-17,7</b> | <b>-36,5</b> | <b>-43,8</b> | <b>-39,7</b> | <b>-1,5</b> | <b>36,6</b> | <b>61,9</b> |
| <b>Cash flows from investment activities</b> |              |              |              |              |              |             |             |             |
| Investments in intangible fixed assets       | -25,8        | -22,9        | -17,1        | -10,0        | -8,2         | -6,0        | -5,0        | -7,4        |
| Investments in tangible fixed assets         | 0,4          | -0,6         | -0,4         | 0,0          | 0,0          | 0,0         | 0,0         | 0,0         |
| Investment in financial fixed assets         | 0,0          | -0,1         | 0,0          | 0,0          | 0,0          | 0,0         | 0,0         | 0,0         |
| <b>Net cash from investment activities</b>   | <b>-25,5</b> | <b>-23,5</b> | <b>-17,5</b> | <b>-10,0</b> | <b>-8,2</b>  | <b>-6,0</b> | <b>-5,0</b> | <b>-7,4</b> |
| <b>Cash flows from financing activities</b>  |              |              |              |              |              |             |             |             |
| New share issue                              | 66,1         | 0,0          | 141,4        | 0,0          | 50,0         | 0,0         | 0,0         | 0,0         |
| New borrowing                                | 0,4          | 20,8         | -20,5        | 0,0          | 0,0          | 0,0         | 0,0         | 0,0         |
| Dividends                                    | 0,0          | 0,0          | 0,0          | 0,0          | 0,0          | 0,0         | 0,0         | 0,0         |
| <b>Net cash from financing activities</b>    | <b>66,4</b>  | <b>20,8</b>  | <b>120,9</b> | <b>0,0</b>   | <b>50,0</b>  | <b>0,0</b>  | <b>0,0</b>  | <b>0,0</b>  |
| <b>Net cash flow</b>                         | <b>20,1</b>  | <b>-20,4</b> | <b>67,0</b>  | <b>-53,8</b> | <b>2,1</b>   | <b>-7,5</b> | <b>31,6</b> | <b>54,4</b> |
| Opening cash and cash equivalents            | 5,5          | 25,7         | 6,3          | 73,3         | 19,4         | 21,5        | 14,0        | 45,6        |
| Closing cash and cash equivalents            | 25,7         | 5,3          | 73,3         | 19,4         | 21,5         | 14,0        | 45,6        | 100,0       |
| <b>Key Ratios</b>                            |              |              |              |              |              |             |             |             |
| Cash flow, op. activities/net sales          | -208,3x      | -36,1x       | -25,1x       | -7,0x        | -2,5x        | 0,0x        | 0,4x        | 0,4x        |
| Cash flow, op. activities/assets             | -0,3x        | -0,2x        | -0,2x        | -0,4x        | -0,3x        | 0,0x        | 0,3x        | 0,4x        |
| Dividend per share                           | 0,0          | 0,0          | 0,0          | 0,0          | 0,0          | 0,0         | 0,0         | 0,0         |

Source: Company information and Carlsquare estimates.

## Bibliography

ASDReports, 2020 - Breast Biopsy Market - Global Forecast to 2025 - Cumulative Impact of COVID-19, <https://www.asdreports.com/market-research-report-566316/breast-biopsy-market-global-forecast-cumulative-impact-covid>, accessed 2021-04-26.

Balasubramanian et al., 1998 – I Balasubramanian, C A Fleming, M A Corrigan, H P Redmond, M J Kerin, A J Lowery *British Journal of Surgery*, 105:10, 2018, 'Meta-analysis of the diagnostic accuracy of ultrasound-guided fine-needle aspiration and core needle biopsy in diagnosing axillary lymph node metastasis', 1244–1253.

Clinician Summary, 2016 - AHRQ Pub. No. 14(16)-EHC040-3-EF, May 2016, 'Core-Needle Biopsy for Breast Abnormalities'.

Mahoney et al., 2013 – Mary C. Mahoney, Mary S. Newell, *Radiology*, 268:1, 2013, 'HOW I DO IT: Breast Intervention', 12-24.

Markets and Markets, 2019a – *Aspiration & Biopsy Needles Market by Product (Fine-needle Aspiration, Biopsy (Core & Vacuum Assisted)), Site, Procedure (Image-guided (Ultrasound, MRI, Stereotactic), Nonimage-guided), Enduser (Hospital, Academia) - Global Forecast to 2024*, <https://www.marketsandmarkets.com/Market-Reports/aspiration-biopsy-needles-market-71036825.html>, accessed 2021-04-26.

Markets and Markets, 2019b - *Breast Biopsy Market by Product (Needles, Tables, Assay Kit), by Type (Needle Biopsy (CNB, FNAB, VAB), Liquid Biopsy (CTC, ctDNA)), Guidance (Image-Guided (Mammography, Ultrasound, MRI), Liquid Biopsy (NGS, PCR, Microarray-based)) - Global Forecasts to 2025*, <https://www.marketsandmarkets.com/Market-Reports/biopsy-devices-breast-biopsy-market-189011805.html>, accessed 2021-04-26.

Schässburger et al., 2018 – Kai-Uwe Schässburger, Stefan Paepke, Ariel Saracco, Edward Azavedo, Christina Ekström, Hans Wiksell, *Physia Medica* 46 (2018), 'High velocity pulse biopsy device enables controllable and precise needle insertion and high yield tissue acquisition', 25-31.

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