NEODYNAMICS AB

www.neodynamics.com

Sector: Healthcare
List: Spotlight
Market cap: 122m SEK
Share price: SEK 2,03 (9

Initial research report: April 27 2021 (fair value per share: 5,55 SEK)

An important part of precision medicine

The number of people affected by breast cancer is expected to grow rapidly in the foreseeable future. At the same time, precision medicine is becoming a significant part of the treatment regimen. As the use of liquid biopsies becomes more widespread, the need for tissue biopsies is expected to increase significantly to ensure and identify the cancer cell tissue precisely to provide the best possible treatment. NeoDynamics has clear competitive advantages over the standard of care in tissue biopsy. From our point of view, NeoDynamics is well-positioned to become an essential part of the future of biopsy- and treatment of cancer.

How to detect breast cancer

There are around 20 million new cancer cases each year around the world and around 10 million deaths. The most common cancer type is breast cancer, accounting for 2.3 million new cases each year, with nearly 6 million completed biopsies.

Breast cancer is usually 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 an expert looks at under a microscope. Often, a DNA, protein, or RNA test is also done on the sample. The tissue sample is called a biopsy specimen.

Differences between tissue and liquid biopsies

There are some fundamental differences between tissue biopsies and liquid biopsies.

Liquid biopsies

Liquid biopsies work by measuring cell-free DNA (cfDNA) in a sample of fluid from the body. It is theorized that when cell death occurs, the cell releases DNA into the fluids they are associated with. In oncology, some of the most important cfDNA is circulating tumor DNA (ctDNA), which comes from a cancerous cell. Also significant for analysis are circulating tumor cells (CTC), which shed from a primary tumor

Liquid biopsies utilize genetic sequencing for many purposes in oncology. They can be uniquely used as a screening tool for early detection, either by testing the entire sample for mutations or looking for specific mutations in the sample. Furthermore, liquid biopsies are vital in precision treatment and tracking relapse in patients with remission. In all these cases, WGS (Whole genome sequencing) methods are used to detect genetic alterations.

Another area where liquid biopsies excel is when a tumor has metastasized, meaning it has spread to multiple sites in the body (Parnell). It is not practical or often possible to collect tissue from each tumor for analysis. Thus, liquid biopsies are more advantageous to prove an overview of the mutations present in each of the tumor sites or when tumors are in an unreachable area where tissue cannot be collected via needle or surgical methods, and cfDNA must be used.

Tissue biopsies

Tissue biopsies require solid matter from the body. This specimen is removed either directly from a tumor or bone marrow. Specimen extraction from the body may require surgical methods.

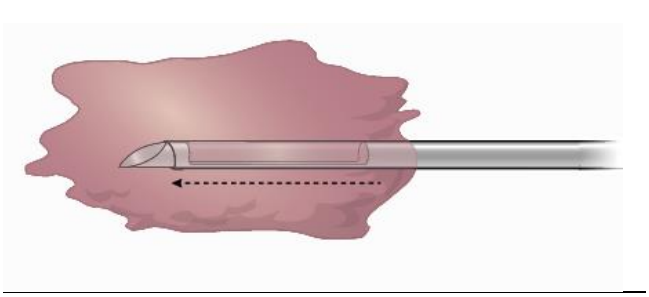
Tissue biopsies are irreplaceable in identifying the nature of tumors: type of cancer, gene expression of the cancer cell, and presence of treatment-resistant mutations. However, that is affected by several components of origin, such as tumor location, tissue amount available, and accessibility for surgical removal. The unstable nature of tumors makes

them heterogeneous, meaning tissue from certain tumors may have radically different mutations and genetic expressions than other areas. This could provide inaccurate information.

Standard of care in breast cancer

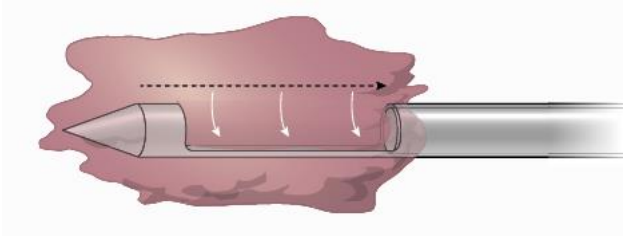
Standard of care within breast cancer biopsies employs either a spring-loaded core needle biopsy (CNB) or vacuum-assisted breast biopsy (VAB). See pictures below. Both were developed during the 90s.

Spring-loaded core needle (CNB)



Source: Company information.

Vacuum needle (VAB)



Source: Company information.

The third generation of tissue biopsy

CNB is dependent on a spring to position the needle in and then cut through a lesion. Some VAB also uses mechanisms (typically also a spring) to place the hand inside the lesion. In both cases, the high force employed can fracture and displace tissue inside the lesion. The significant 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.

Clinical data provides clear competitive advantage

NeoNavia's three needle types provide significantly larger tissue samples than today's standard of care. According to results from a preclincial trial, NeoNavia's needles provide 299 percent larger samples sizes with the FlexiPulse, 37 per cent higher with CorePulse, and 12 percent higher with VacuPulse. On November 8, the Company announced that it would present data from the PULSE study at the British Society of Breast Radiology (BSBR) scientific meeting from 7-9 November. Early data from 115 subjects indicate that NeoNavia's pulse technology stabilizes the target lymph node, improves needle control during insertion, and allows for more samples with single needle insertion. Which, from our view, is a clear competitive advantage.

Significant need for tissue biopsies in precision medicines

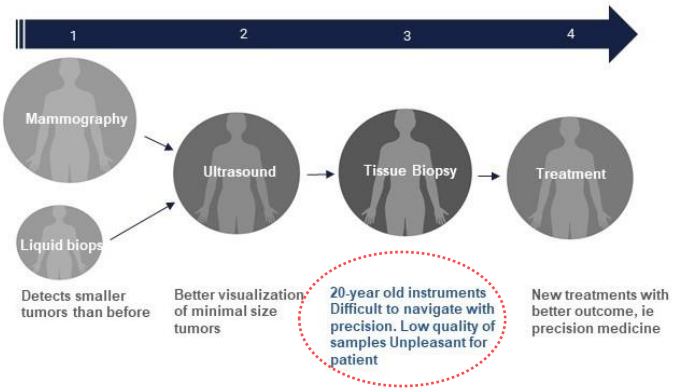
We feel that the stock market sometimes makes a miscalculation when looking at Neodynamics and NeoNavia market possibilities. Some think that the demand for tissue biopsies will decline due to the strong growth from liquid biopsies, particularly in precision medicine. In our opinion, it is rather that radiologists see a bigger need for tissue biopsy in correlation with the growth of liquid biopsies in breast cancer to ensure the most accurate treatment possible.

NeoNavia can play an essential role for the radiologist

The image below is the dynamics of identifying the right treatment for breast cancer. As the picture indicates, liquid biopsy is rather used early and allows more significant evidence for the radiologist. We believe that this will increase the need for tissue biopsies as more patients can be detected earlier as a result of liquid biopsies; however, these samples will need to be secured by tissue biopsies.

NeoNavia's innovative technique based on pulse system can be seen as the third generation of tissue biopsy with clear advantages over the golden standard. This makes us believe that NeoDynamics is an essential part of precision medicine today and in the future.

Market dynamics from the radiologist's perspective



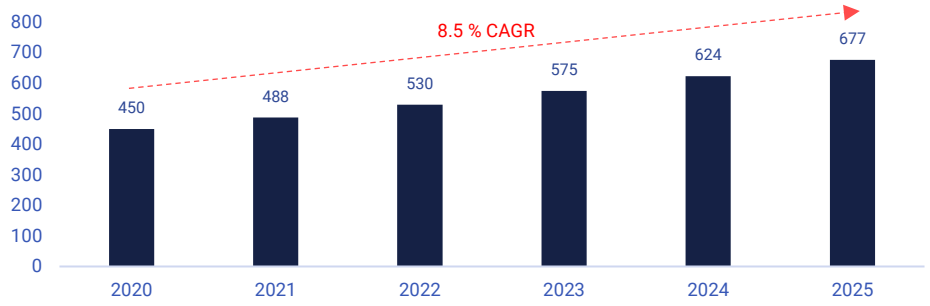
Source: Company information

Strong market growth in breast biopsies

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 per cent. Technological advancements in breast biopsy and the rising incidence of breast cancer are the major factors driving the growth of this market.

Markets and Markets estimate the aspiration and biopsy needle market to grow at a CAGR of 7.3 per cent from USD 894m in 2019 to USD 1 272m by 2024, of which breast cancer accounts for about a third of the market. Our market assumptions are presented in the tables below.

Market size breast biopsy instruments, mUSD



Source: Carlsquare Estimates.

NeoDynamics benefits from changing market dynamics

As mentioned earlier, the market dynamics in breast cancer and cancer therapies are expected to evolve. Technological developments and broader use of liquid biopsy are expected to increase the number of patients needing tissue biopsy to secure and confirm the tissue of the cancer cell, which will enable correct treatment. As precision medicine becomes an increasingly important part of cancer treatment, the need to ensure the tissue of the cancer cell will become an essential part, something that benefits NeoDynamics.

We will provide an updated analysis after the company presents its third quarterly report.

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