neodynamics

Information regarding share subscription NeoDynamics AB (publ)

(in this folder "NeoDynamics" or "The Company").

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INTRODUCTION

NeoDynamics AB (publ) is a Swedish medical technology company dedicated to advancing diagnosis and care of breast cancer. The company has developed an innovative biopsy system, NeoNavia®. The precision biopsy system is built on a patented micro-pulse technology, based on research at the Karolinska Institutet in Sweden. The system is designed to offer clinicians and patients accurate lesion targeting and high tissue yield for correct diagnosis and individualized treatment. With three biopsy needle types, NeoNavia to has the potential to replace ultrasound guided biopsy systems currently used in breast cancer diagnosis. NeoDynamics (NEOD) is listed on Spotlight Stock Market.

Breast cancer is one of the most common types of cancer. Early, quick and safe diagnosis raise chances of survival. With customized cancer treatments, also called "Precision Medicine", introduced in recent years follows a growing need of efficient and accurate tissue sampling. NeoDynamics innovation goes hand in hand with this development.

NeoNavia is the brand name for the entire biopsy system intended to be used under ultrasound guidance. NeoNavia consists of a base unit, a handheld driver, and three different types of biopsy needles. Each needle type is driven by the micro-pulses enabling high precision and control when inserting and positioning the biopsy needle in a suspicious lesion. The system is designed to offer accurate lesion targeting and high tissue yield for correct diagnosis and individualized treatment. Thanks to the controlled needle insertion and the self-developed needle with open tip design (FlexiPulse), technically challenging lesions such as in axillary lymph nodes, close to implants, chest wall or lung or in dense breast tissue can be safely and precisely sampled.

NeoNavia is being evaluated at leading clinics in the UK, Germany, and Sweden. A commercial launch is expected during the second quarter of 2020 based from these reference hospitals. NeoDynamics' aim is to establish the system as the new industry standard and replace current ultrasound guided biopsy methods.

The system is well documented, has a high degree of innovation, strong IP protection and good opportunities for continuous development. Regulatory approval in Europe for the study version of the biopsy system was originally granted in July 2016 and has since been in use in clinical studies in Europe. The approval was extended in October 2019 with the commercial product versions. An application for registration in the US will be submitted by mid 2020. Volume production has been secured through international partners. The start of sales is being prepared together with specialist salesmen in key markets. An early entry to China is part of NeoDynamics strategy and The Company's Chinese owners are operating within female health, which may facilitate establishment on this very large market.

Needles for all types of ultrasound guided biopsies

Thanks to the NeoNavia system, offering both the two needle types being used today for ultrasound guided biopsies, as well as inhouse-developed, patented, third needle type intended to be used for technically challenging cases, the system can replace all ultrasound guided biopsy methods currently used. The self-developed FlexiPulse-needle can also be used for tissue sampling of the axilla (i.e. armpit), a procedure that today entails patients coming back to, and under anesthesia, being taken care of by a surgical team. With NeoNavia, this tissue sample can be taken in connection with the breast sampling using only local anesthetics. Essentially, a streamlining with health economic benefits and shorter processing times for doctors and patients. All three needle types advance forward, millimeters by millimeters, with high precision, using The Company's micro-pulse technology that has been patented on the world's largest markets. The biopsy needles are disposables whilst the handheld unit and base unit are equipment with a long lifetime.

Patent portfolio

The Company's patent portfolio stems from the research at Karolinska Institutet. The Company already has patents in many countries around the world on NeoNavia's micro-pulse technology, the unique technology that differentiates NeoNavia from other biopsy instruments. The micro-pulse technology has received patent protection in the larger European countries as well as in China and the US. Design-specific patents for the needle designed by NeoDynamics have already been approved. A patent application has been turned in for the NeoNavia system as well.

Other products in development

NeoDynamics also has a complementing biopsy product, a biopsy marker, in early development. Biopsy markers can improve the efficiency of diagnosing breast cancer. During the next decade, the use of biopsy markers is expected to increase as the imaging technology becomes more advanced and the visibility of these products during imaging continues to improve. It is already common in the US and more doctors are expected to use these products when they perform biopsies. An increase in sales of biopsy markers will increase the revenue for operators selling biopsy needles today.

Strategy

NeoDynamics' strategy is to establish NeoNavia as a leading biopsy system in Europe, the US, and China. This will happen through collaborations with leading researchers and specialists, within the breast biopsy field, in their respective country and by anchoring the company's offer to specialist societies and their working groups.

Through regulatory approval and clinical studies on the main markets, attention, acceptance, and knowledge about the products and procedures are gained - mainly among key specialists who often are Key Opinion Leaders (KOL's), that have influence within the area and that in their turn will influence their colleagues. The studies weren't required for a regulatory approval in the EU but was rather a part of the initial marketing effort to reach larger university clinics.

By having strong and recognized clinics behind the company and the products, momentum in the market is created, which shortens the time until the products have gained a strong foothold. During NeoNavia's first 12 months on the market, the company's experienced salesforce will show the strength of the product and produce reference clinics for the biopsy system. Afterwards, the aim is to initiate negotiations with potential distributors and/or partners. Focus during 2020 will initially be Germany, the UK, and Sweden.

An application for regulatory approval will be submitted to the American FDA in mid-2020, and to the Chinese regulatory authorities in 2021.

- Launch in Germany, the UK, and Sweden in the first half-year of 2020
- Submission of FDA 510K in mid-2020 and US launch 2021
- At least 50& market share at the selected university hospitals within two years from launch, i.e. every single hospital that admits NeoNavia will use these needles on at least half of patients having ultrasound led biopsy.

Motivation for the rights issue

The Board of Directors assesses The Company's current working capital insufficient for financing The Company's working capital needs and below stated assumptions during the coming 12-month period calculated from the date of the Offer. NeoDynamics is now implementing a rights issue of approximately SEK 46 million, before deductions for issue costs, mainly with the purpose of financing the continued effort towards reaching the key markets in the EU as well as receiving the FDA 510K approval in the US.

Use of proceeds

In the case of a full subscription, NeoDynamics will receive approximately SEK 46 million, before deductions for issue costs of approximately SEK 5,8 million (of which costs for guarantee commitments amount to approximately SEK 2 million). In addition to repayment of loan facility of approximately SEK 10 million, the proceeds are intended to be percentage divided according to below and, in the case of all actions not being carried out, according to the priority below:

- Staff (30 % of proceeds)
    - Sales people and staff

- Administration (11 % of proceeds)

- Product development, patent and quality/regulatory (16% of proceeds)
    - Finish verification and validation activities
    - Documentation and management of the regulatory process in the US

- Clinical market trials and sales (30% of proceeds)
    - Launch products on the market
    - Market research to ensure the right message and price
    - Build reference center with opinion leaders that recommend NeoNavia
    - Clinical market trials with approved products in the UK, Germany, and the US
    - Participation in national and local congresses

- Investments in fixed assets (CAPEX) and storage (13 % of proceeds)

A biopsy system

NeoNavia is an innovative biopsy system in late-stage development. The system is built on a patented micro-pulse technology based on research at the Karolinska Institutet in Sweden. NeoNavia is designed to offer accurate lesion targeting and high tissue yield for correct diagnosis and individualized treatment. A commercial launch is expected in 2020.

NeoNavia is intended to be used under ultrasound guidance and consists of:

1. A Base Unit
2. A Handheld driver
3. Three types of biopsy needles

Each needle type is driven by the micro-pulses enabling high precision and control when inserting and positioning the biopsy needle in a suspicious lesion.

The base unit generates pressurized air needed for the micro-pulses as well as generates negative pressure for the vacuum suction function.

The handheld driver is the user interface with activation buttons for all functions.

The three needle types contain micro-pulse versions of a core needle (CNB), a vacuum assisted biopsy needle (VAB) and an innovative open tip micro-pulse needle of same size as core needles.

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