ANNUAL REPORT

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Spago Nanomedical AB (publ)

2020



www.spagonanomedical.se

Spago Nanomedical develops nanomedicine for diagnostics and treatment of life-threatening diseases

TECHNOLOGY

First of its kind of clinically validated functional nanoparticles optimized for physiologic accumulation in tumours. Possibility of wide application for diagnostics and treatment of several forms of cancer.

EVIDENCE

Clinical data confirms the physiological accumulation of Spago Nanomedical's functional nanoparticles in solid tumors in human, a cornerstone of the platform technology.

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MARKET

Major clinical need for better-precision MRI diagnostics and possibility of effective treatment for patients with advanced cancer. Growing interest in radionuclides for systemic therapy, alone or in combination with established therapies.



TEAM

High level of education and many years of experience from the life sciences industry and pharmaceutical development.

PIPELINE

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SpagoPix - contrast agent in clinical development for tumor-selective MRI of breast cancer and the pancreas. Tumorad[®] - radionuclide therapy for treatment of advanced and metastatic cancer, about to enter clinical development.

BUSINESS MODEL

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Run nanomedical projects to the clinical phase, and subsequently out-license the technology for further development and market approval. This document is a translation of the original, published in Swedish. In cases of any discrepancies between the Swedish and English versions, or in any other context, the Swedish original shall have precedence.

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Spago Nanomedical in brief

Spago Nanomedical AB (publ) is a Swedish nanomedicine company in clinical development phase, developing products for diagnostics and treatment of life-threatening diseases.

The company's operations are based on a patented material for the design of functional nanoparticles that accumulate physilogically in tumors, thus enabling higher precision and improved cancer patient care. The current pipeline projects have the potential to facilitate diagnostics and improve the treatment of cancer indications with urgent medical needs.

SpagoPix aims to improve the precision of MRI scans for suspected cancers by launching a groundbreaking tumor-selective contrast agent that increases the precision of MRI visualization of tumors and metastases. Initial clinical data indicate that the product candidate SN132D provides imaging with good contrast of breast cancer and the pancreas, without compromising safety. With better cancer diagnostics, the chances of successful and cost-efficient treatment of cancer patients improve.

Tumorad[®] aims to develop a novel drug for radionuclide therapy for aggressive cancers based on nanoparticles loaded with a radioactive isotope. Preclinical findings indicate that the product candidate SN201 accumulates in aggressive tumors and delays tumor growth at clinically useful doses. This opens up a wide range of applications for SN201 in the treatment of various forms of cancer.

In both projects, the mechanism of action is based on the scientifically well-established EPR effect (Enhanced Permeability and Retention), which means that particles of a certain size can accumulate selectively in cancer tissue.

Spago Nanomedical's business model is based on the development of nanomedical projects up to the point of clinical proof-of-concept. The subsequent development to commercialization is carried out by means of licensing and partnership agreements with established companies in each project area, with global reach and sufficient capacity.

Spago Nanomedical AB (publ) Reg.no. 556574-5048

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Significant events in 2020

Spago Nanomedical AB (reg.no. 556574-5048) - Annual Report 2020

CEO statement by Mats Hansen

Despite a year of extraordinary pressure on society, the individual, and the healthcare system, we have resolutely taken our projects past crucial milestones. MRI images from patients with breast cancer showed that our unique nanomaterial accumulates in tumors in human. This is the fundamental principle on which both our projects are based. Encouraged by this, we continue to work for better diagnostic precision and successful treatment of cancer patients for whom the treatment options today are few.

The pandemic has undoubtedly had a major negative impact on the possibilities for conducting clinical studies in Sweden and abroad. During the spring, we succeeded in completing and summarizing the first dose group in the SPAGOPIX-01 study just before COVID-19 severely limited the opportunity to recruit patients. To increase the probability of progressing nevertheless, we opened another study center, and thereby succeeded in recruiting patients to the second dose group. After interim analysis during the fall, we were able to successfully note that SpagoPix gave a positive contrast effect in breast tumours. This not only provided an initial validation of SpagoPix but also provides support for our therapy project Tumorad®, as the latter is based on the same principle for physiological targeting of functional nanoparticles to tumours.

We continue to see an increasing need for higher precision in the diagnosis of breast cancer, both for the screening of risk groups and before surgery. With clearer MRI images, SpagoPix can contribute to more effective screening of women with dense breast tissue or hereditary predisposition to breast cancer, and better planning of surgery before an operation. In both cases, the objective is to safely detect and treat the cancer and consequently also save lives.

The positive interim results also provide us the opportunity to investigate the conditions for a broader use of SpagoPix, beyond breast cancer. It is reasonable to assume that other types of tumors can also be illuminated with the material and as such be given a better contrast effect. The results we have received so far in the study SPAGOPIX-01 further point to a positive contrast effect even in the pancreas, an area where there is currently a lack of good diagnostic imaging to detect and follow changes that can be or lead to cancer. Pancreatic cancer is one of the deadliest tumor diseases where the need for better diagnosis is significant. A well-substantiated material that shows the possibilities with SpagoPix in various indications should increase the value of the project.

During the year, we also selected candidate drug for Tumorad[®], a very important milestone which marks that we have achieved a material that possesses properties that allow it to be used for cancer treatment. The candidate drug SN201, is now being prepared for clinical development through regulatory preclinical studies, preparation of protocols for a clinical study in patients with advanced cancer of various origins, and production of materials. The study is intended to be designed so that patients are first screened with diagnostic imaging based on a low dose of SN201 to ensure that the principle works in the patient, and thereby also that there are opportunities for successful treatment. The target is to initiate a first clinical trial in 2022.

Despite great advances in diagnostics and treatment, many forms of cancer are still difficult to cure, which is one of the reasons why cancer is still the second most common cause of death globally. Aggressively growing cancer that has spread in the body and does not respond to existing treatment is the biggest challenge. New approaches and combinations of different drugs and treatments create opportunities to reduce the risk of premature death. Through its design and mechanism of action – physiological targeting of radioactive nanoparticles to tumors – Tumorad[®] can be an effective complement in the precision treatment of cancer that has spread.

With a promising pipeline that meets central medical needs, with reduced development risk in the projects, and with a strengthened cash flow after the share issue in early spring 2021, we are ready to take the company to the next level. Over the next year, we will focus on preparations for clinical development and on increased international visibility. In this way, we look forward with confidence to continuing to build value for both our owners and patients.

Mats Hansen

CEO Spago Nanomedical AB

"With a promising pipeline that meets central medical needs, with reduced development risk in the projects, and with a strengthened cash flow after the share issue in early spring 2021, we are ready to take the company to the next level."



VISION OBJECTIVES & STRATEGY



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Vision

Spago Nanomedical's vision is to engage in competitive and successful development of products that increase the survival and quality of life for cancer patients and thereby create long-term profitability for the company and its owners.



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Objectives

Spago Nanomedical's objective is to become a leading company within the development of diagnostics and therapy based on nanomedicine through the development of products that benefit patients and provide good health economics.

Strategy

Spago Nanomedical's overall strategy is to conduct development of medical projects based on the company's proprietary and patented nanomaterial. The business strategy builds on commercializing the company's development projects through collaborations and outlicensing to industrial partners that have the resources to bring the product to market and clinical use. This reduces the need of capital and the time before revenue is received, and increases the potential for successful market penetration.

Project - SpagoPix

SpagoPix is a tumor-selective contrast agent with extraordinary signal strength and potential to significantly improve cancer diagnostics based on magnetic resonance imaging (MRI). Through better and more precise visualization of soft tissue tumors and metastases, the chances of successful treatment of cancer patients and lower healthcare costs are improved.

IMAGE-BASED CANCER DIAGNOSTICS AND MEDICAL NEED

Cancer is today one of the most common causes of illness and death among adults, especially among elderly. Recent figures from the WHO estimate that 19.3 million people were diagnosed with cancer in 2020. At the current growth rate, this number is expected to grow to 28.4 million by 2040. To a great extent, the increase is believed to be attributable to an ageing population, but also on a growing population with a higher prevalence of risk factors associated with a higher socioeconomic standard.

In 2020, breast cancer passed lung cancer as the most common form of cancer in the world. According to the WHO, 2.1 million new cases of breast cancer were diagnosed during the year, corresponding to approximately 12 percent of all cancer cases. Breast cancer is one of the most common causes of cancerrelated death, with 685,000 registered cases worldwide in 2020 (Sung et al., CA CANCER J CLIN 2021;0:1–41). In Sweden, about 9,000 new breast cancer cases are diagnosed every year. This means that about 20 women per day develop the disease (according to Cancerfonden).

An early and accurate cancer diagnosis is, in many cases, crucial for a positive treatment outcome. The survival rate of, e.g., breast cancer, is highly dependent on an early diagnosis, since the possibilities of successful treatment are reduced if the cancer has had time to spread. The impact of the COVID-19 pandemic on the morbidity of breast cancer and other forms of cancer is still not known. It is clear, however, that the pandemic has led to major delays in diagnostics, including through screening programs being put on hold and reduced access to care. This is expected to lead to an increasing number of cancers diagnosed in later stages, which likely will result in increased mortality (Sung et al). Imaging-based technologies that are used to diagnose cancer include mammography, ultrasound, computed tomography (CT), positron emission tomography (PET) and magnetic resonance imaging (MRI).

MRI is primarily used within breast cancer diagnostics to provide in-depth knowledge of the localization and spread of the tumors before surgical treatment, and as a follow-up instrument to assess the outcome of treatment provided before and after surgery.

One of the advantages of MRI compared with, e.g., CT and PET, which are other highly sensitive alternatives for tumor detection, is that MRI does not involve the use of ionizing radiation which in itself is a risk factor for cancer. In patient groups with elevated risk of developing cancer, such as BRCA1/2 mutation carriers, screening is recommended annually or more often. Even if these women have an elevated risk of breast cancer, the majority of them will never develop the disease and the accumulated radiation from mammography screening would be the bigger risk. In this group, the radiation-free MRI method is preferrable over mammography. In addition, clinical studies have demonstrated that women with elevated risk of developing breast cancer improve their chances of early detection and treatment of the cancer with MRI screening compared with mammography examination only. In the United States, MRI screening is therefore recommended for women with elevated risk of developing breast cancer.

Benefits of SpagoPix over existing MRI contrast agents



- » Tumor selectivity improves the precision and makes it easier to distinguish between tumor and non-tumor tissue, thus reducing the frequency of misdiagnosis.
- » Exceptional enhancement of the MRI signal, a high signal strength (relaxivity) may make images more crisp and improve the chance of earlier discovery and accurate diagnosis of cancer.
- » Controlled build-up of the MRI signal, makes it possible to capture images for a longer timespan and enables high-resolution images.
- » **Free from gadolinium**, eliminated risk of negative side effects from the use of this substance foreign to the body that is present in existing MRI contrast agents.

While MRI has significant potential to improve cancer diagnostics, the technology currently in use has its limitations. One reason why MRI is not used at full potential for cancer diagnostics is that the contrast agents which are necessary to enhance tumor contrast in the MRI imaging have relatively low accuracy. They are thus non-optimal to reliably distinguish between tumors and other tissue changes. The MRI contrast agents in use today are very similar to each other with regard to chemical structure, properties and clinical usability. These contrast agents are rapidly dispersed throughout the body upon injection (within minutes), resulting in a relatively low contrast between tumors and surrounding tissue. This has proved to result in difficulties in making an accurate assessment of the tumor distribution, which may lead to a need to repeat the breast cancer surgery or to tumors going undetected. There is a risk that a missed tumor diagnosis allows the tumor to grow to an advanced stage, where the prognosis is much worse. The unspecific accumulation of contrast agent may also lead to tumor findings that eventually turn out to be non-malignant, so-called false positive findings. False positive findings lead not only to anxiety and suffering for the individual patient, but also to significant costs for subsequent unnecessary examinations.

Moreover, the MRI contrast agents in use today are almost exclusively based on the metal gadolinium, which has been associated with a serious adverse effect, nephrogenic systemic fibrosis (NSF). NSF mostly affects patients with reduced kidney function, which has led to a special classification for all gadolinium-containing contrast agents and warnings issued by the US and European medical authorities. As a consequence, the contrast agents that have the highest risk of causing NSF have experienced a significant decline, losing major market shares to those associated with a somewhat lower risk. Over the last decade, several studies have also been published that demonstrate a correlation between the use of gadolinium-based contrast agents and accumulation of gadolinium, for example in the brain, even in patients with normal kidney function. It is not clear whether these gadolinium deposits are harmful, but the announcement has had a major impact on the use of these contrast agents, with authorities in the EU and the US (the EMA and the FDA, respectively) deciding to completely ban or severely restrict many gadolinium-based contrast agents.

All in all, MRI is a radiation-free and sensitive method that makes it possible to detect and characterize cancer at an early stage, more reliably and safer than with several other imaging diagnostic methods including mammography and CT. However, he lack of precision, which is a consequence of the non-specific MRI contrast agents currently in use and which results in missed tumors, unnecessary reoperation, and, in the case of false positives, unnecessary suffering and additional diagnostic procedures, serves as an obstacle to a more widespread use of MRI. In addition, the gadolinium in today's contrast agents is problematic considering the adverse effects.

SPAGOPIX – A TUMOR SELECTIVE CONTRAST AGENT

Spago Nanomedical's contrast agent SpagoPix (SN132D) has unique properties that make it possible to utilize the potential of MRI diagnostics for visualizing tumors more optimally. SpagoPix can provide the opportunity to detect tumors and metastases with higher precision than is possible with the contrast agents in use today, thereby opening up for more effective surgery, screening of high-risk patients without the use of ionizing radiation, monitoring of pre-operative treatment and follow-up of after surgery. Improved methods for accurate visualization and diagnosis of tumors would increase the probability of successful treatment, and thus also improve patient survival.

SpagoPix is designed to physiologically and selectively accumulate in tumors. The mechanism of action is built on a well described principle called the Enhanced Permeability and Retention (EPR) effect. For tumors and metastases to grow, they require a supply of blood to provide them with oxygen and nutrients. The blood vessels that surround tumors experience an uncontrolled and unnaturally fast growth, making them porous; they thus become more permeable for particles than healthy vessels are. In combination with this increased permeability, tumor tissue often has limited lymphatic drainage, which causes particles that end up in tumors to remain there for a longer time than they would have done in healthy tissue (retention).

Aggressive tumors tend to have a larger proportion of leaky vessels. This makes it possible to use the EPR effect to distinguish between benign and malignant tumors. The size of SpagoPix nanoparticles is tailored to take advantage of the EPR effect. After administration to the patient by injection, the SpagoPix contrast agent will circulate in the bloodstream until it reaches the tumor. The nanoparticles will then leave the blood vessels through the pores in the vessel walls and accumulate between the tumor cells. In this manner, the particle concentration in the tumor tissue is built up over a few hours, resulting in a clear contrast between tumor and healthy tissue when the patient is given an MRI scan. Imaging from breast cancer patients in the SPAGOPIX-01 study demonstrate that SpagoPix is distributed in tumor tissue but not in surrounding tissue, thus confirming the mechanism of action. Because uptake by surrounding tissue, which complicates the interpretation of the images and results in both missed tumors and false positives, is a major problem with current contrast agents, the findings indicate that SpagoPix could contribute to a significant improvement of cancer diagnostics.

In addition to the selective accumulation of SpagoPix in cancer tumors, the contrast agent is also much better at enhancing the signal that is measured in an MRI examination (relaxivity) compared with the contrast agents currently in use. Relaxivity is already a competition factor for the existing gadolinium-based MRI contrast agents, and SpagoPix has demonstrated several times higher relaxivity in measurements than the contrast agents on the market today. Data showing that the relaxivity of the SpagoPix candidate drug, SN132D, is among the highest measured for an MRI contrast agent, has been published in the European Journal of Inorganic Chemistry. (Gianolio et al. 2019)

Through its mode of action, the signal from SpagoPix is built up in the tumor over time. This provides flexibility to the image capturing, which is an advantage if several images have to be captured at the same time or when a whole body MRI scan is performed. In addition, the remaining signal allows highresolution images of the tumor to be captured; this is not possible with the gadolinium-based contrast agents in use today, since they leave the body in a couple of minutes.

Thanks to the combination of the tumor-selective mode of action and the high signal strength, SpagoPix can provide a clearer and more precise image of the tumor. This reduces the risk of the surgeon having to re-operate because of too small margins to healthy tissue. It further reduces the risk of missing the tumor entirely, which could have devastating consequences for the patient as the tumor in the meantime may grow to an advanced stage, where the prognosis is significantly worse. Moreover, SpagoPix may contribute to a reduced risk of false positive findings, which often result in additional biopsies and diagnostic procedures as well as considerable suffering and anxiety for the patient.

In addition to its excellent diagnostic properties, SpagoPix is free from gadolinium, which means that the risk of adverse effects from the use of this element, foreign to the body, is eliminated. Instead of gadolinium, SpagoPix uses the element manganese to enhance the signal that is detected in an MRI examination. Manganese is an essential element that occurs in many of our most common foods and is needed to maintain good health.

PROJECT STATUS

The ongoing clinical Phase 1 study SPAGOPIX-01 is conducted in two hospitals in Sweden and can include up to 20 patients with confirmed breast cancer. The primary purpose of the study is to study the safety of SpagoPix (SN132D) at different dose levels. A secondary objective is to document how this new contrast agent can enhance MRI imaging of breast cancer, the liver and the pancreas.

Analysis of obtained images from the first two dosage groups in the SPAGOPIX-01 study shows that SN132D works as predicted by the proposed mechanism of action and is tumor-selective, that is, distributes in tumors but not in surrounding tissue. These interim results is the most important milestone in the company's history to date. In addition to confirming that SN132D can improve diagnostics and monitoring of suspected and diagnosed breast cancer using MRI, the findings further confirm that the company's unique platform material accumulates in solid tumors in humans. This opens up for using the nanomaterial for therapeutic purposes as well (see Project Tumorad).

Aside from the positive contrast in breast cancer tumors, all MRI images in the study show that SN132D also offers good contrast

in the pancreas. This has prompted Spago Nanomedical to assess the potential of SpagoPix as an MRI contrast agent in this area also. In the initial discussions, radiologists and surgeons in Europe and the United States have pointed out that there is a distinct need to be able to identify and follow patients in various pre-stages of pancreatic cancer.

The SPAGOPIX-01 study continues with the inclusion of additional patients in the second dose group to expand the patient base and gather additional information for future clinical studies.

As the next step, SN132D will be tested in larger clinical studies before market approval. Spago Nanomedical's strategy is based on out-licensing of projects in clinical phase. On the basis of interim data that indicates good contrast enhancement in tumors and targeted organs and no disturbing background contrast, a process has been initiated to seek a licensing partner for the project. The costs and investments that the partner will be responsible for and the distribution of any future income will be subject to negotiation between the parties, and cannot be foreseen at this time.

PATENTS

Spago Nanomedical has extensive experience of patent work and is also working actively with a reputable Swedish patent agency to continuously strengthen the commercial protection of our products.

The company has a strategic patent protection in the largest MRI contrast agent markets, including the EU, the United States and Japan. The patents guarantee exclusivity for SpagoPix until at least 2032. Additional patent applications have been filed, and may both strengthen and extend the protection of SpagoPix.

MARKET OVERVIEW

Imaging diagnostics, including CT, mammography, ultrasound, PET, and MRI, is a cornerstone of modern cancer diagnostics. MRI and PET are normally used as more accurate methods to verify diagnoses made with cheaper and faster methods, such as mammography and ultrasound. MRI scanners are already present in most hospitals, and its use within cancer diagnostics is steadily increasing. The use of MRI will increase further as improved MRI contrast agents emerge, capable of providing better images and clearer information to be able to assess the patient's need for care. This will result in an expanding market for MRI contrast agents.

A growing and aging global population (and its increasing number of cancer patients) is driving growth in imaging diagnostics using MRI. Fortunately, cancer mortality rates are not increasing at the same pace as the number of cancer patients, which is because the healthcare sector has become better at treating cancer. As a result, the number of patients who need follow-up with imaging diagnostics is increasing, which further increases the market for, among other things, MRI contrast agents. The use of MRI may increase further as improved MRI contrast agents emerge, capable of providing better images and clearer information to be able to assess the patient's need for care.

Today, MRI constitutes the clinical practice with a number of different applications in cancer care, and the market for MRI contrast agents is significant. Use is expected to increase further in breast cancer and other major indications such as prostate cancer.

Tumor diagnostics with MRI are not fully exploited today because of the limitations of existing contrast agents. A new, specialized contrast agent that addresses the limitations that exist today has considerable potential to break new ground and increase the use of MRI in cancer. SN132D opens the way to significant improvements with regard to tumor visualization, which may lead to reduced suffering of patients as well as major savings on costs related to repeated surgery, cancers discovered to late, and unnecessary procedures due to misdiagnosis. The product is thus well placed to be a 'game changer' on the market.

The initial target indication for SN132D is breast cancer. The global incidence is 2.3 million new cases per year (WHO 2020). The scope of use of SN132D can also be broadened to other forms of solid tumors. For example, the SPAGOPIX-01 study has demonstrated that SN132D enhances not only breast tumors but also the liver and pancreas, which makes it possible to use

it in these tissues as well. In addition to breast cancer and the pancreas, the company also examines the conditions for using it in additional indications. A tumor-selective specialty product, free of gadolinium, is expected to be priced higher than today's products. This entails that the conceivable market size in breast cancer alone is very attractive. With use in further indications, the maximum market can be expected to be considerable.

COMPETITION

Among the leading companies in the market for MRI contrast agents are Bayer Healthcare, Bracco Imaging, GE Healthcare, and Guerbet. These can be seen as competitors, but also as potential future partners for Spago Nanomedical.

In addition to competition from existing and new MRI contrast agents that may be developed, research is also conducted in other areas to improve the ability to detect and visualize cancer. For example, the possibility of combining PET with MRI to increase sensitivity and specificity is under evaluation. However, this alternative is very expensive and has not yet proven to produce satisfactory results. Another technique that is under evaluation, in this case for breast cancer, is so-called breast tomosynthesis. This method provides higher sensitivity than mammography for some types of breast tissue, but currently comes at the cost of an elevated radiation dose. Another example is the development of automated ultrasound examination to give visibility to breast cancer.

SpagoPix



Project - Tumorad®

Radiation therapy has been used effectively in the fight against cancer for more than 100 years. Along with surgery and chemotherapy, radioherapy is a cornerstone in the treatment of several cancers. In the Tumorad[®] project, nanoparticles are loaded with radioactive isotopes, thus enabling internal radiation therapy, so-called radionuclide therapy, against cancer. Like the contrast agent SpagoPix, the Tumorad[®] particles are designed to physiologically accumulate in tumors, which enables internal radiation therapy with high precision against aggressive and metastatic cancer.

CANCER TREATMENT - MEDICAL NEED

Surgery, chemotherapy and radiotherapy have been used for a long time and form the basis for the treatment of most cancers. However, despite important advances and new therapies, longterm survival in many cases remains unsatisfactory, especially in the treatment of metastatic cancer. Treatment resistance is a significant challenge in cancer care, and there is therefore a clear clinical need for new treatment alternatives.

Radiation is an effective treatment for cancer. Usually, an external radiation source is used to target a certain tumor, but it is also possible to utilize molecules or particles that accumulate in multiple tumors after distribution in the blood stream, so-called radionuclide therapy. The latter has been used successfully in certain specific cancers for a long time, and may be a valuable alternative or complement to other types of treatment, especially in metastatic or aggressive cancers. A representative example is the treatment of thyroid cancer with radioactive iodine, where a cure can be achieved despite extensive spread.

TUMORAD[®] - NANOPARTICLES FOR RADIONUCLIDE THERAPY

Spago Nanomedical's Tumorad® particles are loaded with radioactive isotopes and thus enable internal radiotherapy, so-called radionuclide therapy. The advantage of radionuclide therapy compared to external beam radiation is its ability to selectively deliver radioactivity to tumors and thereby irradiate multiple soft tissue tumors or metastases simultaneously. The technology also enables irradiation of tumors that would be untreatable with external beam radiation, such as deeper tumors or tumors adjacent to vital organs.

As with SpagoPix, Tumorad[®] can be passively accumulated in tumors via the EPR effect. The local accumulation opens for delivery of an adapted radiation dose sufficient to treat the tumors while minimizing undesirable effects on surrounding tissue. This mechanism for physiological accumulation also allows the use of Tumorad[®] for the treatment of several types of tumors. This is where Tumorad[®] differs from other targeted radionuclide therapies based on, for example, antibodies, which are developed to reach only a particular type of tumor.

Tumorad[®]´s potential unique advantages



- » Tumor selectivity, passive targeting of tumors, offers potential for use in the treatment of several different types of cancer
- » Nanoparticles with radioisotopes makes it possible to apply radiation treatment to metastasized, aggressive and difficult-to-access cancers.
- » Complementary treatment enables combination with other kinds of therapy.
- » Simple preparation at hospitals facilitates logistics and may reduce costs.

PROJECT STATUS

As the core of the Tumorad[®] particles is based on the same platform as the nanoparticles used for SpagoPix, there are significant synergies between the projects regarding structure and production of the material.

An extensive development and optimization effort has previously resulted in a nanomaterial that circulates long enough in the body to deposit the desired exposure of radioactivity in tumors while minimizing the impact on other organs. The positive results from pre-clinical efficacy studies, which demonstrated that Tumorad® inhibits tumor growth and increases survival in a model of aggressive breast cancer, led to the decision to select a candidate drug in August 2020. The candidate drug, designated SN201, will now be advanced to pre-clinical studies. Scaled-up production of SN201 for regulatory pre-clinical studies has been carried out internally, and the work to transfer the production process to a contract manufacturing organization (CMO) for GMP manufacturing in view of clinical trials is ongoing. The aim is to initiate a clinical Phase1/2 trial during 2022.

After the initial clinical study, SN201 is expected to undergo additional studies before market authorization can be obtained. As in the SpagoPix project, Spago Nanomedical intends to seek a development and commercialization partner for Tumorad[®] at a stage when clinical data indicates proof-of-concept and we assess the timing to be right from a valuation perspective. In this way, the Company intends to optimize the time-to-revenue and maximize the possibility of a successful market launch.

PATENTS

The company has product protection for Tumorad[®] in the strategically most important markets for radionuclide therapy, including the EU, the United States and Japan, until at least 2035. An application for product protection has been filed in additional countries and is expected to further strengthen market rights in the future. The design of the particle selected as candidate drug also provides opportunities to further extend the patent protection. Tumorad[®] is a registered trademark.

Tumorad[®]

DESIGN	PROPERTIES	BENEFIT
Functional nanoparticles	Carrier of therapeutic isotope Optimized for accumulation in tumors	Tumor-selective alternative to chemotherapy and targeting treatment
Radioisotope with therapeutic properties	 Lutetium-177 clinically validated with therapeutic effect Radiation optimized for treatment of solid tumors 	 Effective internal radiotherapy, which may reduce the risk of recurrence Easily prepared in hospitals Enables screening with imaging diagnostics
Physiological accumulation in tumors	 Selective accumulation in tumors and less in healthy tissue Increased accumulation in aggressive tumors 	 Effective treatment of aggressive and metastatic cancer Broad use against various types of cancer
Unique composition	 Nanomedical radionuclide therapy, novel treatment option Complementary to other therapies 	 Treatment of resistant tumors Possibility of combination treatments for higher efficiency

MARKET OVERVIEW

Radionuclide therapy is in clinical use today against a limited number of tumor types, while the pace of development within the field is picking up with several novel products under development. Based on public sales figures from global players with market-approved products, the market for such products is currently estimated to be worth at least USD 700 million. Examples of systemic radionuclide pharmaceuticals include Xofigo, which was approved in 2013 for the treatment of prostate cancer metastases in bone tissue. In early 2018, the drug Lutathera was approved for the treatment of so-called neuroendocrine tumors.

These new radiopharmaceuticals may be used both as a single treatment alternative and in combination with surgery, chemotherapy, and immunotherapies. Interest in the field is shown not least by Novarti's acquisition of both Advanced Accelerator Applications (with Lutathera) and Endocyte (with the Phase 3 product Lu177-PSMA-617) for a total value of approximately USD 6 billion in 2018, according to the companies' press releases. The market for radionuclide therapies can thus be expected to continue to increase. Compared to the targeted therapies on the market today, Tumorad® has the advantage of providing the opportunity for treatment of various types of

solid tumors, and thus a potentially greater market value. Based on mortality data (Brey et al. 2018) from a number of major cancer indications (colorectal, gastric, breast, pancreatic and ovarian cancer) that from clinical science could be expected to be candidates for Tumorad[®] treatment (indications with documented EPR effect; Natfji et al., 2017), and prices of comparable existing drugs, the global addressable market is estimated at more than EUR 100 billion a year.

COMPETITION AND DEVELOPMENT IN RADIONUCLIDE THERAPY

Investments to develop new radioactive drugs have increased and new products may be launched in the coming years. Bayer Healthcare, Novartis, Spectrum Pharmaceuticals, Jazz Pharmaceuticals, GE Pharmaceuticals, Immunomedics, Antisoma and Progenics Pharmaceuticals are examples of companies that market or develop radioactive drugs. Additional large pharmaceutical companies are involved in collaborations with smaller companies that develop radionuclide therapies. Compared to targeted therapies on the market today, Tumorad[®] has the advantage of providing the opportunity for treatment of various types of solid tumors, and thus a potentially greater market value.

"Compared to targeted therapies on the market today, Tumorad® has the advantage of providing the opportunity for treatment of various types of solid tumors, and thus a potentially greater market value."



Tumor selectivity based on the EPR effect enables **higher accuracy** in MRI diagnostics and radionuclide therapy



Unlike the MRI contrast agents in clinical use today, which are distributed in the different tissues of the body after injection(A), the contrast between tumor and non-tumor is enhanced after injecting the MRI contrast agent SpagoPix (B). The same principle is employed in Tumorad[®] (C), where the radionuclidecontaining nanoparticles accumulate in tumors after injection, exposing them to selective irradiation.







Organization

Tove Sivik Sonne

Mats Hansen

Oskar Axelsson

Hanna Olsson

Spago Nanomedical has an organization with extensive experience in the development of contrast agents and medicines. At present, the company has 18 employees – including 13 with a doctorate – who conduct research and development. The company strives to conduct operations in a cost-effective manner and therefore outsources parts of the development process – such as production and clinical studies – to external parties. Established collaborations with consultants and medical advisors contribute to optimizing the work on, for example, regulatory strategies and clinical studies.

MATS HANSEN

Chief Executive Officer (CEO)

Born: 1971

Employee since: 2015

Holdings (related parties included): 49,122 shares, 60,000 Series TO11 warrants

Education and experience: Mats Hansen holds a Ph.D. in plant biochemistry and a Master in biology. He has extensive experience in project management, clinical development and business development within oncology pharmaceuticals. His prior roles include director of Project Management and Head of Knowledge Management at Active Biotech AB, where he previously also held several key positions within information management, IP and business development.

Other appointments: Member of the board of Ekoscandica Naturguide AB

TOVE SIVIK SONNE

Head of Development

Born: 1980

Employee since: 2013

Holdings (related parties included): 20,000 Series TO11 warrants and 5,000 Series TO8 warrants

Education and experience: Tove Sivik Sonne holds a Master in biomedicine, and a Ph.D. in oncology from Linköping University. Tove has over six years of industrial experience from both preclinical and clinical development work. Tove is the head of the company's development department.

Other appointments:

OSKAR AXELSSON VP and Chief Scientific Officer (CSO)

Born: 1962

Employee since: 2007

Holdings (related parties included): 69,922 shares, 129,031 Series TO8 warrants

Education and experience: Oskar Axelsson holds a Ph.D. in organic chemistry and has extensive experience primarily from contrast agent research at Nycomed Innovation, Amersham, GE Healthcare and other companies. Oskar is leading the research department of Spago Nanomedical and is responsible for the Company's patent issues. He has participated in over 50 patent applications and a number of scientific publications.

Other appointments: -

HANNA OLSSON

Chief Financial Officer (CFO)

Born: 1980

Employee since: 2019

Holdings (related parties included): 12,500 shares, 25,000 Series TO11 warrants

Education and experience: Hanna Olsson holds a Master in Business Administration and has long experience from different roles in auditing, analysis, financial control and business planning, in both small and large national and international groups such as Deloitte, Schneider Electric, and, most recently, from the role as CFO at System Verification.

Other appointments: -

Organization

BOARD OF DIRECTORS



EUGEN STEINER (Chairman of the Board)

Born: 1954

Member of the board since: 2019

Holdings (related parties included): 112,500 shares, 60,000 Series TO10 warrants

Education and experience: Eugen Steiner is a medical doctor and a specialist in clinical pharmacology, holding a Ph.D. from Karolinska Institutet. He has long experience of leading life science companies in various development phases, and has worked as CEO and on the boards of Swedish, Norwegian, English and American companies. He has been a venture partner in HealthCap since 1997.

Other appointments: Chairman of the Board of Empros Pharma AB. Board member of BioArctic AB, Apotek Produktion & Laboratorier AB, Inbox Capital AB, Inbox Intressenter 1 AB, Inbox Intressenter 2 AB, Inbox Intressenter 3 AB, Karolinska Institutet Holding AB, Karolinska Institutet Innovations AB and Stockholm School of Entrepreneurship.

Independent in relation to the company's major shareholders, the company and the executive management.

PETER LEANDER

Born: 1957

Member of the board since: 2012

Holdings (related parties included): -

Education and experience: Peter Leander is associate professor and specialist in medical radiology. He is the Head of Radiology at the Peritus Clinic, has conducted research on contrast agents for MRI and CT, and holds a Ph.D. in the field. Peter has extensive experience in radiology, with many years' experience as a radiologist in Malmö and as Regional Chief Physician in the Skåne Region. He is a member of the Swedish Society of Radiology (SMFR), where he also chairs the Swedish contrast agent group.

Other appointments: Member of the board of Lument AB.

Independent in relation to the company's major shareholders, the company and the executive management.

STEN NILSSON

Born: 1948

Member of the board since: 2013

Holdings (related parties included): 18,324 shares.

Education and experience: Sten Nilsson is a specialist and professor emeritus in oncology, as well as a specialist in nuclear medicine. Sten has been responsible for study design and was the Principal Investigator of the early clinical development of Xofigo™ (previously Alpharadin™). Sten was previously the chairman of the Swedish Oncology Association (SOF) and the Swedish Association for Nuclear Medicine (SFNM) and member of EANM's Radionuclide Therapy Task Force. He has published over 200 scientific articles.

Other appointments: Board member of Dextech Medical AB and Egetis Therapeutics AB (publ), owner and member of the board of DETRUSOR AB. Co-founder of Micropos Medical AB (publ) and board member and chairman of Rehnman & Partners Asset Management AB's scientific advisory board.

Independent in relation to the company's major shareholders, the company and its management.



BOARD OF DIRECTORS



KARI GRØNÅ

Born: 1965

Member of the board since: 2018

Holdings (related parties included): 20,000 Series TO10 warrants

Education and experience: Kari Grønås is a pharmacist and has long experience of industrial development of contrast agents and pharmaceuticals from Bayer AS, Algeta ASA, PhotoCure ASA, Amersham Health and other companies. She was the project manager of Xofigo, a role which included applications for marketing authorization to the EMA and the FDA and responsibility for CMC in the contacts between Algeta and Bayer. Kari has also been the project manager of the development of the contrast agent Hexvix until it obtained market authorization in the EU/EEA.

Other appointments: Kari is a consultant for start-up companies in the pharmaceutical and biotech industries. She is the owner and CEO of K og K AS, owner and board member of Ultimovacs ASA, board member of Arxx Therapeutics AS and owner of Oncopeptides AB.

Independent in relation to major shareholders, the company and the executive management.

NICKLAS WESTERHOLM

Born: 1976

Member of the board since: 2019

Holdings (related parties included): 3,675 shares, 4,000 Series TO10 warrants

Education and experience: Nicklas Westerholm is the external CEO of Egetis Therapeutics AB (publ) since 2017. Before that, he had since 1995 worked within the AstraZeneca Group in a number of global roles in various business areas, most recently as Vice President of Project & Portfolio Management, Cardiovascular and Metabolic Diseases, Global Medicines Development Unit. Prior to that, Nicklas held positions such as Executive Officer & Vice President Japan Operations and Director Investor Relations, Head of Global API Supply and Head of Development Manufacture. Nicklas has studied analytical and organic chemistry at Stockholm University and chemical engineering at the Royal Institute of Technology. He has also studied at the University of Warwick and Harvard Business School.

Other appointments: Chairman of the Board, CEO and board member of Rare Thyroid Therapeutics International AB.

Independent in relation to major shareholders, the company and the executive management.

MEDICAL ADVISORS

SOFIA ZACKRISSON

Sofia Zackrisson is a professor of diagnostic radiology at Lund University and senior physician at Skåne University Hospital. Sophia's work aims to develop new methods for better breast cancer screening and advanced technology for detection of tumors and more accurate diagnostics. Dr. Zackrisson was recently named Cancer Researcher of the Year 2020 by the Swedish Cancer Society.

PER HALL

Per Hall is Professor at the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet and Senior physician at the Department of Oncology at Södersjukhuset, Stockholm. Dr. Hall has a long experience in clinical cancer research and randomized controlled trials. He has coordinated six research projects funded by the EU and three research projects funded by NIH.

TIMOTHY ROBERTS

Timothy Roberts, Professor of Radiology, is the Vice-chair of Research at the Department of Radiology at the Perelman School of Medicine, University of Pennsylvania, where he also holds the Oberkircher Family Endowed Chair in Pediatric Radiology. Prof. Roberts' research is focused on translational development of medical imaging technologies. "The SpagoPix findings validate that our nanoparticles accumulate in solid tumors in human, a cornerstone of our platform technology, and opens the way to cancer treatment with Tumorad® in the next step."

Share information for Spago Nanomedical AB

Since March 26, 2021, Spago Nanomedical's share is traded on Nasdaq First North Growth Market under the ticker SPAGO. On that date, the company changed trading venue from Spotlight Stock Market where the share had been traded since the end of 2012. "With one project in clinical phase and one more on a clear path towards clinical development, we believe that the company is ready to meet the wider interest of international and institutional investors. The change of trading venue offers a possibility to increase exposure and sends a strong message on our long-term ambitions to become a leading company in nanomedicine development," says CEO Mats Hansen.

TRADING OF SHARES AND SHARE PERFORMANCE

During 2020, a total of 32 million shares were traded, worth MSEK 240.

Spago Nanomedical's share price decreased during the year, from SEK 14.3 at the beginning of the year to SEK 8.52 at the end of the year. The company's market capitalization at year-end was MSEK 269 (MSEK 299).

SHARE STRUCTURE

At the end of 2020, the share capital in Spago Nanomedical amounted to SEK 31,544,517 and was distributed across 31,544,517 shares. The quota value per share is SEK 1. Each share entitles its owner to one vote, and each voting member may vote at the Annual General Meeting (AGM) for the full number of shares owned and represented. Each share has equal right to shares in the Company's assets and profit.

A share issue was completed in 2020 and brought the company MSEK 47.3 before transaction costs. The share issue was registered at the Swedish Companies Registration Office 2020-06-01 and increased the number of shares by 10,514,839 and the share capital by SEK 10,514,839.

During the first quarter of 2021, a rights issue was carried out, which raised MSEK 59 in net proceeds and a further MSEK 10 before transaction costs from an overallotment issue. The share issues increased the company's share capital by a further SEK 9,219,463, distributed across 9,219,463 shares. In addition, 418,307 shares were subscribed in a directed share issue to those guarantors of the rights issue that chose to receive compensation in the form of newly issued shares in the company. The directed issue to guarantors provided the company approximately MSEK 3 in proceeds.

WARRANTS

The company has a total of three outstanding incentive programs. Program TO8, which was adopted at the AGM on May 17, 2017, comprises a total of 333,062 warrants and is held by employees of the company plus two major owners. The program

has a term of five years (2017-2022) and gives a right at the end of the program to acquire one share per warrant in the company at a subscription price of SEK 24.82.

At an Extraordinary General Meeting (EGM) on November 13, 2019, a warrant program was approved for the Board (TO10) and a warrant program for employees (TO11), both with a term of three years (2019-2022). As a result of the programs, 229,490 warrants were issued and sold to the Board of Directors and employees according to market valuation. Each warrant entitles the holder to acquire one share in the company at the end of the respective program at a subscription price of SEK 17.76.

The participants in the incentive programs have entered into customary agreements on repurchases and home bids, which means the participants do not freely exercise their warrants during the respective term of the program.

OWNERSHIP STRUCTURE

The number of shareholders at year-end amounted to 3,003 (1,996), which represents an increase of about 50 percent during the year. Of these, one shareholder, Peter Lindell, has direct and indirect holdings representing more than ten percent of the votes. The ten largest shareholders controlled 58.52 percent of the company's shares as at the end of the year.

DIVIDEND POLICY

For the financial year 2020, the Board of Directors of Spago Nanomedical proposes no dividend to be paid. Spago Nanomedical intends to retain any profits as long as the investment need remains extensive. Any future dividend payments will be decided by the shareholders at general meetings, and will be determined on the basis of, among other things, the company's profitability, performance, acquisition opportunities and financial position.

ANALYSES

During the year, analyses of the company were performed by Redeye (Klas Palin/Ludvig Svensson), and by Erik Penser Bank (Johan Löchen/Klas Palin).

SHAREHOLDERS As of 2020-12-31	Total number of shares	Share of capital (%)
Peter Lindell with company & related parties	5,338,994	16.93%
Avanza Pension	2,741,666	8.69%
Mikael Lönn	1,980,000	6.28%
Ranny Davidoff	1,785,440	5.66%
Eva Redhe	1,750,774	5.55%
Thord Wilkne with related parties	1,534,500	4.86%
Tiel Ridderstad	1,121,406	3.55%
Andreas Bunge with company & related parties	1,052,756	3.34%
Claes Dahlbäck with company	762,912	2.42%
Nordnet Pensionsförsäkring	391,425	1.24%
Total of the above	18,459,873	58.52%
Other shareholders	13,084,644	41.48%

TOTAL:	31,544,517	100%
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DEVELOPMENT OF THE SHARE

CAPITAL

YEAR	Transaction	Change, number of shares	Increase of share capital (SEK)	Total share capital (SEK)	Number of shares	Quota value
1993	Initial establishment	100,000	100,000	100,000	100,000	1
2008	Share issue	25,000	25,000	125,000	125,000	1
2009	Share issue	23,500	23,500	148,500	148,500	1
2010	Share issue	35,273	35,273	183,773	183,773	1
2012	Bonus issue	1,653,957	1,653,957	1,837,730	1,837,730	1
2012	Share issue	1,479,543	1,479,543	3,317,273	3,317,273	1
2014	Share issue	2,211,514	2,211,514	5,528,787	5,528,787	1
2015	Share issue	2,073,295	2,073,295	7,602,082	7,602,082	1
2016	Share issue	1,000,000	1,000,000	8,602,082	8,602,082	1
2017	Share issue	5,734,721	5,734,721	14,336,803	14,336,803	1
2018	Share issue	2,379,680	2,379,680	16,716,483	16,716,483	1
2019	Share issue	4,313,195	4,313,195	21,029,678	21,029,678	1
2020	Share issue	10,514,839	10,514,839	31,544,517	31,544,517	1

Administration report

The Board of Directors and the Chief Executive Officer of Spago Nanomedical AB (publ), reg.no. 556574-5048, hereby present their annual report for the financial year 2020-01-01 to 2020-12-31.

OPERATIONS

Spago Nanomedical is a Swedish nanomedical company in clinical development phase. The company's development projects are built on a patented platform of polymeric materials with unique properties that can enable more accurate diagnosis and treatment of solid tumors.

The company's overall strategy is to conduct development of medical projects based on the company's proprietary and patented nanomaterial. The business strategy builds on commercializing the company's development projects through collaborations and outlicensing to industrial partners that have the resources to bring the product to market and clinical use.

Development, preclinical and clinical verification of projects is carried out in cooperation with academic institutions, consultants and partners. In the development process, special focus is given to the market's commercial demand and to critical success factors in the verification process.

The primary focus is on diagnostics and treatment of cancer through the development of SpagoPix, for use as a cancerselective MRI contrast agent, and on the Tumorad[®] drug for cancer-selective radionuclide therapy. Thus, operating costs and company resources are attributable to the above.

PERSONNEL

The average number of employees during the period amounted to 15 (17).

RESEARCH AND DEVELOPMENT

Advanced research and development within the company is a prerequisite for advancing the project to the commercialization phase. The company believes that the existing projects and staff as recruited well meet the opportunities for continued progress.

PATENTS

The company has a strategic patent protection in the largest MRI contrast agent markets, including the EU, the United States and Japan. The patent guarantees exclusivity for SpagoPix until at least 2032. Additional patent applications for product and process protection have been filed, and may both strengthen and extend the protection of SpagoPix.

The company has product protection for Tumorad[®] in the strategically most important markets for radionuclide therapy, including the EU, the United States and Japan. The patent entitled "Nanostructures and applications thereof" (patent number 3122383) is valid until at least 2035. An application for product protection has been filed in additional countries and is expected to further strengthen market rights in the future. The design of the particle selected as candidate drug also provides opportunities to further extend the patent protection. Tumorad[®] is a registered trademark.

SHARE INFORMATION AND OWNERSHIP

Since March 26, 2021, Spago Nanomedical's share is traded on Nasdaq First North Growth Market (previously on Spotlight Stock Market) under the ticker SPAGO. At the end of the year, the company's share capital amounted to SEK 31,544,517 and the number of shares to 31,544,517, each carrying one vote. The largest shareholders in the company were, at the end of the year, Peter Lindell & company, Avanza Pension, Mikael Lönn, Ranny Davidoff and Eva Redhe. As of 2020-12-31, these represented approximately 43 percent of the votes. For supplementary information, please refer to the section 'Share information for Spago Nanomedical' in this annual report.

The company currently has three outstanding warrant programs. For more information, please refer to the section 'Share-related incentive programs' under Note 4 in this annual report.

RESULT AND FINANCIAL POSITION

The operating costs for the year amounted to kSEK -26,207 (-39,226). The higher costs during 2019 were mainly attributable to the production of material for the Phase 1 study with SpagoPix, which was completed prior to commencement of the study in September 2019. The higher cost was also due to a slightly larger number of employees in 2019.

Total income amounted to kSEK 7,245 (19,015) and is mostly attributable to development expenses and patent expenses for the SpagoPix project that were capitalized on the balance sheet during the period. The lower capitalization is thus a consequence of a reduction in expenditure compared with the corresponding period in 2019, and is attributable to an increased allocation of internal resources to the Tumorad[®] project, which is not capitalized on the balance sheet, and to lower external spending in the project.

Operating result amounted to kSEK -18,962 (-20,211). The slight improvement of the result derives from the somewhat lower costs for the Tumorad[®] project, which is not capitalized on the balance sheet. Earnings per share, before and after dilution, amounted to SEK -0.70 (-1.01) for the year.

At year-end, cash and cash equivalents amounted to kSEK 28,448 (12,149). During the first quarter of 2021, a rights issue was carried out, which raised MSEK 59 in net proceeds and a further MSEK 10 before transaction costs from an overallotment issue.

Cash flow from operating activities amounted to kSEK -18,766 (-21,288) and cash flow from investing activities amounted to kSEK -6,383 (-18,214). Investments mainly consist of intangible assets, i.e., the development expenses and patent expenses that have been capitalized during the period. Cash flow from financing activities amounted to kSEK 41,448 (35,180). The positive cash flow during the year refers to the net proceeds from the rights issue that was carried out during the second quarter of 2020 and from the issue of warrants to the Board and employees that was carried out during the last quarter of 2019 but not received until the first quarter of 2020. A total of 10,514,839 new shares were issued in the rights issue, providing the company MSEK 47.3 before transaction costs.

At the end of the year, the company's equity amounted to kSEK 159,675 (137,631) and equity ratio to 98.1 percent (97.9 percent). Equity per share before dilution amounted to SEK 5.06 (6.54).

The company's carryforward of unused tax losses amounts to kSEK 112,646 (87,390).

RISK FACTORS Development of new medical and diagnostic products

Research and development of new nanomedical products is time and resource demanding, and requires considerable expertise. Regulatory authorities require both pre-clinical and clinical trials to be carried out, including the development of a manufacturing process, for a product to be commercialized for human use. The outcome of such studies may be unpredictable and undesired, and as a consequence, the company's estimated costs and timeframes relating to these studies involve considerable uncertainty.

Recruitment of subjects

An essential element of Spago Nanomedical's clinical trials is the recruitment of subjects, as the outcome of the recruitment has a substantial impact on the timetable for the clinical trial. As a result of reprioritizations in healthcare due to COVID-19, the recruitment of subjects has been slower than anticipated, and this has delayed the clinical trial with SpagoPix in patients with breast cancer. Regardless of delays following the spread of the coronavirus, recruitment of patients may be very timeconsuming for other reasons. There is a risk that the recruitment of subjects takes longer or becomes more expensive than planned, which then would result in increased costs and delayed study results.



Significant events during the year and after the end of the period

- Tumorad[®] patent granted in Japan.
- A rights issue provided Spago Nanomedical net proceeds of approximately MSEK 47.
- The company selected SN201 as candidate drug after successful results that demonstrated that Tumorad[®] reduces tumor growth and extends survival in an established pre-clinical model of aggressive breast cancer.
- Interim data showed that SpagoPix provides sharp contrast in MRI imaging of breast cancer tumors in human, confirming pre-clinical studies that showed that the unique nanomaterial accumulates in solid tumors with maintained safety profile. In addition, a positive contrast was documented in MRI images of the pancreas.
- SpaxoPix patent granted by the European Patent Office (EPO).
- The Board resolved on a fully-guaranteed rights issue of MSEK 59.1 before transaction costs, and, in the event of oversubscription, a directed issue of maximum MSEK 10.
- The Board resolved to initiate a process to change trading venue to Nasdaq First North Growth Market.

2021

2020

A rights issue provided the company proceeds of approximately MSEK 59 and an overallotment issue provided a further MSEK 10, before transaction costs. Spago Nanomedical changed trading venu

to Nasdaq First North Growth Market.

Collaborations for the development and commercialization of projects

At present, none of Spago Nanomedical's projects have been commercialized, and further studies and authorization from authorities are deemed necessary before a commercialization of any of the company's candidate drugs can become relevant. There is a risk that relevant authorities fail to approve the products developed by the company or its partners, preventing the launch of said products. This would cause the company's ability to generate revenue to decrease significantly. Moreover, Spago Nanomedical currently lacks the organizational prerequisites necessary to be able to develop and commercialize a product on its own, and depends, therefore, on being able to enter into agreements with partners. In the absence of a collaboration agreement, Spago Nanomedical may not be able to realize the full value of a product, or, as a result, to benefit from the progress made.

Suppliers for production and product development

Products for evaluation in regulatory pre-clinical and clinical studies must be manufactured in sufficient amounts and in such a manner that they meet high standards of quality. To that end, the company has collaborated with a manufacturer to prepare the product SpagoPix for the clinical trial. Should the manufactured product material prove insufficient, or should additional manufacture be required for coming trials or market launch, there is a risk that the same supplier will not be able to meet the company's need at a reasonable cost, or at all. A change of supplier is not only a complex, but also a highly time-consuming and costly procedure.

Competition

Spago Nanomedical has projects in areas where there is already an established market, which means that the competition in the respective market of each project may be significant. Spago Nanomedical's competitors include major international diagnostic and pharmaceutical companies, and many competitors have significantly greater resources than Spago Nanomedical in, for example, research and development, application procedures with relevant authorities, and marketing, and a better financial position overall. This may confer a market advantage on products developed by the company's competitors. Should Spago Nanomedical or its partner(s) fail to compete effectively in the market, the company's ability to generate revenue may decrease significantly.

Intellectual property rights

Spago Nanomedical's conditions for success largely depend on the company's ability to obtain and maintain patent protection for the company's projects and keep its research confidential, to prevent others from using the company's inventions and proprietary information. Patents must be filed and protected in different jurisidictions, and granted patents may be contested, annulled or circumvented. Nor can it be ruled out that new patents in the field or new discoveries may affect the company's potential for future commercialization of its projects. Such a negative impact on future commercialization may have a negative impact on the company's financial position and future performance.

Regulatory review, legislation and regulations

Spago Nanomedical and future partners will not be able to market any of Spago Nanomedical's products without first obtaining approval from relevant authorities. Nor can it be ruled out that the authorities' approval processes can lead to requirements to conduct extended studies and present further documentation of the product. The marketing authorization process for a new project may take many years and usually requires extensive financial and other resources. If the necessary permits or approvals are not obtained, the Company's operations and results, and, in turn, the financial position of Spago Nanomedical may be adversely affected.

Capital needs

Project and product development in the area of Life Science is usually especially capital intensive, and Spago Nanomedical may in the future need to seek external financing to continue its operations. There is a risk that new capital cannot be raised when the need arises or that it cannot be obtained on satisfactory terms for the company.

CORPORATE GOVERNANCE AND COMMITTEES

Corporate governance within Spago Nanomedical is based on applicable laws, rules and recommendations, such as the Swedish Companies Act (2005:551), the Annual Accounts Act (1995:1554), Spotlight Stock Market's regulations (up to and including March 25, 2021), Nasdaq First North Growth Market's regulations (as of March 26, 2021) and Spago Nanomedical's articles of association and internal rules and guidelines. As Spago Nanomedical's shares are not admitted to trading on a regulated market, the company is not obliged to apply the Swedish Code of Corporate Governance (the Code) but has adapted to the Code in parts where the Code is deemed to be relevant to Spago Nanomedical and its shareholders. In view of the company's current size and scope of operations, the Board has made the assessment that no special committees, such as audit and remuneration committees, are required.

Nomination Committee

The principal owners of Spago Nanomedical have established a Nomination Committee for the Annual General Meeting 2021, and at the Annual General Meeting on May 8, 2019, an instruction for the Nomination Committee's work was adopted. The Nomination Committee consists of Peter Lindell (Chairman), Eva Redhe and Mikael Lönn. The members of the Nomination Committee are not in receipt of any compensation from the company. The Nomination Committee's task is to submit proposals to the Annual General Meeting for the Chairman and other members of the Board, as well as proposals for fees and other remuneration to each of the Board members. The Nomination Committee shall also submit proposals for election and remuneration of auditors.

Board of Directors

According to the company's articles of association, the Board shall consist of between three and seven members and at least zero and at most seven alternates. The Board is elected annually at the Annual General Meeting, up until the end of the next Annual General Meeting. The Board currently consists of five ordinary members, the Chairman included.

The Board held 11 recorded meetings over the course of the year. Issues addressed are strategy and long-term focus, financing issues, reporting, and information and communication issues. In addition to the recorded meetings, the Chairman of the Board and other members of the Board have had continuous contact with the company's CEO.

The Board receives continuous reports on the company's earnings and financial position in accordance with established reporting instructions. The Board is responsible for the company's organization and management, and continuously assesses the company's financial situation. The Board of Directors has adopted a written framework of procedure, containing rules and guidelines for the division of work between the Board and the CEO.

Presence at board meetings in 2020

Eugen Steiner	11 out of 11
Peter Leander	11 out of 11
Sten Nilsson	11 out of 11
Peter Wulff ¹	3 out of 6
Kari Grønås	10 out of 11
Nicklas Westerholm	9 out of 11

1. Resigned at the Annual General Meeting 2020.

PROPOSED APPROPRIATION OF THE COMPANY'S PROFIT OR LOSS

The following funds (SEK) are available to the Annual General Meeting:

Total	47,966,081
Net profit or loss for the year	-18,927,608
Retained earnings	-133,901,538
Share premium reserve	200,795,227

The Board of Directors proposes the following distribution of funds:

To be carried forward	47,966,081
Total	47,966,081

Financial information in summary

EXTRACTS FROM THE INCOME STATEMENT

(Amounts in kSEK)	2020	2019	2018	2017	2016
Sales	7,245	19,015	29,724	18,294	10,768
Operating costs	-26,207	-39,226	-40,816	-27,380	-18,075
OPERATING RESULT	-18,962	-20,211	-11,092	-9,086	-7,307
NET PROFIT OR LOSS FOR THE YEAR	-18,928	-20,211	-11,092	-9,457	-7,540

EXTRACTS FROM THE BALANCE SHEET

(Amounts in kSEK)	2020-12-31	2019-12-31	2018-12-31	2017-12-31	2016-12-31
Fixed Assets	132,986	126,964	109,108	80,616	62,921
Current assets	29,834	13,576	17,212	30,975	17,143
- of which cash and cash equivalents	28,448	12,149	16,471	30,314	16,769
TOTAL ASSETS	162,820	140,540	126,320	111,591	80,064
Equity	159,675	137,631	122,223	107,780	71,844
Long-term Liabilities	-	-	-	-	6,037
Short-term liabilities	3,146	2,909	4,097	3,811	2,183
TOTAL EQUITY AND LIABILITIES	162,820	140,540	126,320	111,591	80,064

EXTRACTS FROM THE CASH FLOW STATEMENT

(Amounts in kSEK)	2020	2019	2018	2017	2016
Cash flow from operating activities	-18,766	-21,288	-10,510	-7,730	-7,863
Cash flow from investing activities	-6,383	-18,214	-28,868	-18,082	-10,710
- of which intangible fixed assets	-5,772	-18,167	-28,471	-17,611	-10,144
Cash flow from financing activities	41,448	35,180	25,535	39,356	14,026
CASH FLOW FOR THE YEAR	16,299	-4,322	-13,843	13,545	-4,547

DATA PER SHARE	2020	2019	2018	2017	2016
Earnings per share before and after dilution, SEK	-0.70	-1.01	-0.71	-1.00	-0.91
Equity per share before dilution, SEK	5.06	6.54	7.31	7.52	8.35
Equity per share after dilution, SEK	5.36	6.95	7.83	8.35	8.61
Average number of shares before dilution	27,177,699	20,084,320	15,530,622	9,458,619	8,257,820
Average number of shares after dilution	27,740,251	21,438,641	20,613,603	10,613,470	8,536,252
Number of shares at the end of the period	31,544,517	21,029,678	16,716,483	14,336,803	8,602,082

OTHER KEY INDICATORS	2020	2019	2018	2017	2016
Average number of employees	15	17	16	17	13
Equity ratio %	98.1	97.9	96.8	96.6	89.7

Income statement

(Amounts in kSEK) Note	2020	2019
Operating income		
Net sales	342	30
External work capitalized	3,192	13,155
Internal work capitalized	2,580	5,012
Other operating Income 2	1,132	818
Total income	7,245	19,015
Operating costs		
Project costs	-6,530	-15,544
Other external costs 3	-5,212	-6,242
Personnel costs 2.4	-14,095	-16,957
Depreciation/amortization of fixed assets 8	-362	-357
Other operating costs 5	-7	-126
Total operating costs	-26,207	-39,226
OPERATING RESULT	-18,962	-20,211
Financial items		
Other operating income and similar items	34	-
Total financial items	34	-
PROFIT OR LOSS AFTER FINANCIAL ITEMS	-18,928	-20,211
PROFIT OR LOSS FOR THE YEAR	-18,928	-20,211

Balance sheet – Assets

(Amounts in kSEK)	Note	2020-12-31	2019-12-31
FIXED ASSETS			
Intangible fixed assets			
Capitalized expenditure for development	6	125,364	120,234
Patents	7	6,544	5,902
Total intangible fixed assets		131,908	126,964
Tangible fixed assets			
Equipment, tools, fixtures and fittings	8	1,078	828
Total tangible fixed assets		1,078	828
TOTAL FIXED ASSETS		132,986	126,964
CURRENT ASSETS			
Accounts receivable		31	-
Other current receivables		676	843
Prepayments and accrued income		679	584
Total current receivables		1,386	1,427
Cash and cash equivalents	14	28,448	12,149
TOTAL CURRENT ASSETS		29,834	13,576
TOTAL ASSETS		162,820	140,540

Balance sheet (cont'd) – Equity and liabilities

(Amounts in kSEK) Note	2020-12-31	2019-12-31
EQUITY 14		
Restricted equity		
Share capital 9	31,545	21,030
Fund for development expenses	80,164	74,392
Total restricted equity	111,710	95,422
Non-restricted equity		
Share premium reserve	200,795	170,339
Retained earnings	-133,902	-107,919
Net profit or loss for the year	-18,928	-20,211
Total non-restricted equity	47,965	42,209
TOTAL EQUITY	159,675	137,631
LIABILITIES		
Short-term liabilities		
Accounts payable	927	525
Tax liabilities	134	147
Other short-term liabilities	393	433
Accruals and deferred income 10	1,692	1,804
Total short-term liabilities	3,146	2,909
TOTAL LIABILITIES	3,146	2,909
TOTAL EQUITY AND LIABILITIES	162,820	140,540

Cash flow statement

(Amounts in kSEK)	Note	2020	2019
OPERATING ACTIVITIES			
Operating result		-18,962	-20,211
Adjustments for items not included in cash flow	11	362	357
Interest received		35	-
Income tax paid		-413	-461
Cash flow from operating activities before change in working capital		-18,979	-20,315
Increase/Decrease in operating receivables		-437	-247
Increase/Decrease in operating liabilities		650	-726
Cash flow from operating activities		-18,766	-21,288
INVESTING ACTIVITIES			
Investments in intangible fixed assets	6, 7	-5,772	-18,167
Investments in tangible fixed assets	8	-612	-47
Cash flow from investing activities		-6,383	-18,214
FINANCING ACTIVITIES			
Share issue	12	41,448	35,180
Cash flow from financing activities		41,448	35,180
Cash flow for the year		16,299	-4,322
Cash and cash equivalents at the beginning of the year		12,149	16,471
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR		28,448	12,149

Changes in equity

(Amounts in kSEK)	Share capital	Development fund	Share premium reserve	Retained earnings	Profit or loss for the year	Total equity
Opening balance, 2019-01-01	16,716	56,226	139,033	-78,660	-11,092	122,223
Appropriations of profit/loss according to the AGM's resolution				-11,092	11,092	-
Share issue	4,313		32,895			37,208
Transaction costs			-1,589			-1,589
Capitalization of development expenses		18,167		-18,167		-
Profit or loss for the year					-20,211	-20,211
Closing balance, 2019-12-31	21,030	74,392	170,339	-107,919	-20,211	137,631
Opening balance, 2020-01-01	21,030	74,392	170,339	-107,919	-20,211	137,631
Appropriations of profit/loss according to the AGM's resolution				-20,211	20,211	-
Share issue	10,515		36,802			47,317
Transaction costs			-6,346			-6,346
Capitalization of development expenses		5,772		-5,772		-
Profit or loss for the year					-18,928	-18,928
Closing balance, 2020-12-31	31,545	80,164	200,795	-133,902	-18,928	159,675

Notes

NOTE 1 - ACCOUNTING PRINCIPLES

This annual report is prepared in accordance with the Swedish Annual Accounts Act and the general recommendations of the Swedish Accounting Standards board BFNAR 2012:1 Annual accounts and consolidated financial statements (K3).

FOREIGN CURRENCY

Receivables and liabilities in foreign currency are valued at the exchange rate at the balance sheet date.

FIXED ASSETS

Tangible and intangible fixed assets are recognized at the acquisition value less accumulated depreciation according to plan. Depreciation according to plan takes place systematically across estimated economic life. Tangible fixed assets are depreciated from the time they are put into operation and intangible fixed assets are depreciated from the time when commercial production commences. The following depreciation periods are applied:

- Patents, 5 years
- Capitalized expenditure for development work, 5 years
- Equipment, tools, fixtures and fittings, 5 years

FINANCIAL INSTRUMENTS

A financial asset or financial liability is recognized in the balance sheet in accordance with the contractual terms of the instrument. A financial asset is derecognized from the balance sheet when the contractual right to cash flow from the asset ceases, is regulated, or when the company loses control of it. A financial liability, or part thereof, is removed from the balance sheet when the contractual obligation is fulfilled or otherwise terminated. The company's financial assets and liabilities comprise cash and cash equivalents and accounts payable as per year-end.

When valuing after the first accounting date, current assets are valued according to the principle of lowest value, that is, the lower of the acquisition value and net sales on the balance sheet date. Accounts receivable are valued at cost, less deductions for expected losses. Accounts payable and other non-interestbearing liabilities are valued at nominal amounts. Long-term liabilities are valued at the accrued acquisition value after the first accounting date.

IMPAIRMENT

At the time of each report, an assessment is made as to whether there is any indication of a decrease in the value of the company's assets. If so, the recoverable amount of the asset is calculated. The recoverable amount is the highest of net realizable value and value in use. The value in use is calculated and is based on an estimate of the future payments that the asset is expected to give rise to in its current operations. A discount of future payments with a 12% interest rate has been made, which is intended to take into account the market's assessment of risk-free interest rates and risk associated with the asset. This calculation of value in use aligns estimated future cash flow to present value. Projects are also assessed based on their likelihood of reaching the market and the estimates and percentages used are industry average figures. Estimates regarding royalties and milestones are the company's own assessments based on contacts with potential partners and comparisons with similar business events in the industry.

However, impairment testing is more frequent if there are indications that impairment has occurred. Regardless of whether an indication of impairment of the company's assets exists, impairment testing is carried out at least once per annum. Impairment losses are recognized through the income statement. Impairment losses are reversed if changes have occurred in the assumptions that led to the original impairment, and this means that the impairment is no longer justified. Such reversals are recognized in the income statement.

REVENUE RECOGNITION

The company's net sales emanate primarily from sale of services. Revenue recognition of service assignments is made when the financial outcome for service work performed can be reliably calculated and the financial benefits accrue to the company.

PUBLIC CONTRIBUTIONS

Public grants not linked to future performance requirements are recognized as revenue when the conditions for receiving the grant are met. Public grants associated with requirements for future performance are recognized as revenue when that performance takes place. If the grant has been received before the conditions for reporting revenue have been met, the received grant is recognized as a liability. Public grants that support covering costs are reported as other income. Grants received and intended to cover development costs for ongoing projects reduce the balanced intangible costs.

RESEARCH AND DEVELOPMENT WORK

Research is expensed immediately. Expenses related to development projects related to the design and testing of new or improved products are capitalized as intangible assets to the extent that these are technically deemed to be capable of leading to products, and that these expenses are expected to generate future economic benefits. Other development is expensed as arised. Development that was previously expensed is not capitalized as assets in later periods. Development expenses that are capitalized are amortized linearly over the period for which the expected benefits are expected to accrue to the company, and from the time when commercial production commences. Any impairment losses are assessed based on estimates of future payment flows,

PATENTS

Expenses for prospective patents and acquired patents are capitalized as intangible assets to the extent that they are deemed capable of leading to completed patents.

Amortization begins when the patent is approved and commercialization has begun of the finished product to which the patent belongs. The amortization period is judged on assessment of economic lifespan and is reported at cost less accumulated amortization and any impairment. Any impairment losses are assessed based on estimates of future payment flows.

EMPLOYEE COMPENSATION

Compensation in the form of salary, paid vacation, paid sick leave, etc. and pensions are recognized as they are earned. Pensions are a defined contribution and the company pays fixed fees to a separate independent legal entity, having no obligation to pay additional fees.

LEASES

Leasing agreements where all risks and benefits associated with ownership do not fall on the company are classified as operating leasing agreements. Leasing fees relating to these are recognized as an expense in the income statement and are distributed linearly over the term of the agreement.

CASH FLOW STATEMENT

The cash flow statement is drawn up using an indirect method. Reported cash flow only covers transactions that involve incoming or outgoing payments. Cash and bank balances are classified as cash and cash equivalents.

FINANCIAL RISKS

The company's financial risks include liquidity risk, i.e., a risk that the company will have difficulty obtaining liquid funds to meet commitments associated with the business. Liquidity is monitored and forecasted in the company on an ongoing basis. If, in the longer term, the company fails to generate revenue or raise new capital, a liquidity shortage may occur. There is no exposure to interest rate risk as no holdings of any such instruments exist. Spago Nanomedical's cash and cash equivalents are today placed in a bank account. See further in the Director's Report under the section 'risk factors'.

IMPORTANT ESTIMATES AND ASSUMPTIONS FOR ACCOUNTING PURPOSES

Important estimates and assumptions have been made regarding impairment testing of intangible assets for Spago Nanomedical's projects.

These assessments include assumptions about market sizes, which are based on reports and information from independent marketing and analysis companies. Other assumptions made concern the project's probability of reaching the market, as well as royalty levels, which are based on industry standards. Assumptions have also been made regarding yield requirements and the time frame for future cash flows.

TAX

Income tax refers to all taxes that are based on the company's earnings. The taxable result is the surplus or deficit for a period that forms the basis for calculating current tax for the period, according to current legislation. The tax expense or tax revenue for the period consists of current and deferred tax. Deferred tax liability or deferred tax assets are taxes that relate to taxable or deductible temporary differences, resulting in or reducing tax in the future. A deferred tax asset is recognized only to the extent of the probability that tax deficits can be offset by any future tax surplus.

In accounting, no deferred tax assets have been reported due to difficulty in assessing the probability in size and timing of future revenue streams.

It should be added that the possibility of utilizing loss deductions could be affected by, among other things, changes in ownership structure, so it cannot be ruled out that some loss deductions may lapse.

INVESTMENTS

Spago Nanomedical's investments comprise investments in patents, intangible assets and tangible assets.

THE BOARD OF DIRECTORS

The company's Board of Directors currently comprises six members.

FORECASTS

The Company does not present any forecasts.

NOTE 2 - OTHER OPERATING INCOME

885	763
164	-
83	55
1,132	818
	83

NOTE 3 - AUDITOR'S FEE

(Amounts in kSEK)	2020	2019
BDO Mälardalen AB		
Audit assignment	200	200
Other audit engagements separate from audit assignment	52	52
Total	252	252

Audit assignments refer to the examination of the Company's Annual Report and accounts and the administration of the Company's affairs by the Board of Directors, other tasks which are for the Company's auditor to perform, and consultation and other assistance in response to observations made during the aforementioned examination and other tasks.

NOTE 4 - STAFF AND SENIOR MANAGEMENT

AVERAGE NUMBER OF EMPLOYEES	2020	2019
Women	7	6
Men	8	11
Total	15	17

GENDER DISTRIBUTION OF SENIOR MANAGEMENT	2020	2019
Board of Directors		
Women	1	1
Men	4	5
Total	5	6
CEO and other senior executives		
Women	2	1
Men	2	2
Total	4	3

SALARIES AND OTHER REMUNERATIONS	2020	2019
Board of Directors and CEO	1,857	2,081
Other senior management	2,301	1,909
Other employees	5,312	6,929
Total	9,470	10,919
Social security contributions	2,505	3,380
Pension costs	1,533	1,796
Total social security contributions and pension costs	4,038	5,176
Total salaries, remunerations, social security contributions and pension costs	13,508	16,095

Capitalized salary expenses

In Spago Nanomedical, salary expenses in the amount of kSEK 2,580 (5,012) have been capitalized as Capitalized expenditure for development.

REMUNERATION TO THE BOARD OF DIRECTORS AND SENIOR MANAGEMENT

	_	Variable			
2020 (Amounts in kSEK)	Base pay	remuneration	Other benefits	Pension	Total
Members of the board					
Peter Wulff ¹	40	-	-	-	40
Sten Nilsson	95	-	-	-	95
Peter Leander	95	-	-	-	95
Kari Grönås	95	-	-	-	95
Eugen Steiner	200	-	-	-	200
Nicklas Westerholm	95	-	-	-	95
CEO Mats Hansen	1,235	-	6	377	1,618
Other senior management (3)	2,210	91	9	573	2,883
Total	4,065	91	15	950	5,121

1. Resigned at the Annual General Meeting 2020.

2010 (Amounts in KSEK)	Paco nav	Variable remuneration	Other benefits	Pension	Total
2019 (Amounts in kSEK)	Base pay	remuneration	Other benefits	Pension	TOLAI
Members of the board					
Peter Wulff	93	-	-	-	93
Sten Nilsson	93	-	-	-	93
Peter Leander	93	-	-	-	93
Andreas Bunge ¹	53	-	-	-	53
Mikael Lönn ¹	30	-	-	-	30
Kari Grönås	93	-	-	-	93
Eugen Steiner ²	133	-	-	-	133
Nicklas Westerholm ²	63	-	-	-	63
CEO Mats Hansen	1,183	248	5	444	1,880
Other senior management (2)	1,562	347	8	526	2,443
Total	3,396	595	13	970	4,974

1. Resigned at the Annual General Meeting 2019. 2. Elected at the Annual General Meeting 2019. 3. Pertains to health care insurance

Terms for the Board of Directors

The fees to board members, including the Chairman of the Board, are resolved upon by the Annual General Meeting. The Annual General Meeting on May 28, 2020, resolved that directors' fees up until the end of the next Annual General Meeting shall, as proposed by the Nomination Committee, be paid in the amount of kSEK 200 (200) to the Chairman of the Board and kSEK 95 (95) to each of the other board members. No additional remuneration has been paid to the members or the Chairman of the Board during 2019 or 2020, and the company has no provisioned or accrued amounts for provisioning for pensions, benefits or the like after the termination of service or assignment for any of the Board members or the Chairman of the Board.

Terms for the CEO

The CEO's employment has a nine month period of notice when terminated by either party. No contractual severance payment is awarded. The CEO has the right to reallocate his salary within the salary space in favor of other remuneration instead. The company must provide health insurance in accordance with the company's policy at all times.

Equity-related incentive programs

The company has a total of three outstanding incentive programs. Program TO8, which was adopted at the AGM on May 17, 2017, comprises a total of 333,062 warrants and is held by employees of the company plus two major owners. The program has a term of five years (2017-2022) and gives a right at the end of the program to acquire one share per warrant in the company at a subscription price of SEK 24.82.

At an Extraordinary General Meeting (EGM) on November 13, 2019, a warrant program was approved for the Board (TO10) and a warrant program for employees (TO11), both with a term of three years (2019-2022). As a result of the programs, 229,490 warrants were issued and sold to the Board of Directors and employees according to market valuation. Each warrant entitles the holder to acquire one share in the company at the end of the respective program at a subscription price of SEK 17.76.

The participants in the incentive programs have entered into customary agreements on repurchases and home bids, which means the participants do not freely exercise their warrants during the respective term of the program.

NOTE 5 - OTHER OPERATING INCOME

(Amounts in kSEK)	2020	2019
Foreign exchange losses	-7	-124
Other	-	-2
Total	-7	-126

NOTE 6 - CAPITALIZED EXPENDITURE FOR DEVELOPMENT

(Amounts in kSEK)	2020	2019
Acquisition value, opening balance	120,234	102,466
Capitalized during the year	5,130	17,768
Accumulated acquisition value, closing balance	125,364	120,234
Closing balance at the end of the year	125,364	120,234

NOTE 7 - PATENTS

(Amounts in kSEK)	2020	2019
Acquisition value, opening balance	5,902	5,504
Acquisitions during the year	642	398
Accumulated acquisition value, closing balance	6,544	5,902
Closing balance at the end of the year	6,544	5,902

NOTE 8 - EQUIPMENT, TOOLS, FIXTURES AND FITTINGS

2020	2019
3,379	3,332
612	47
-51	-
3,940	3,379
0.554	2.40.4
-2,551	-2,194
-362	-357
52	-
-2,861	-2,551
1,078	828
	3,379 612 -51 3,940 -2,551 -362 52 -2,861

NOTE 9 - NUMBER OF SHARES AND SHARE CAPITAL

	2020	2019
B shares		
Opening number of shares	21,029,678	16,716,483
Share issue registered on 2019-04-10	-	4,313,195
Share issue registered on 2020-06-01	10,514,839	-
Closing number of shares	31,544,517	21,029,678

According to the registered articles of association of Spago Nanomedical, the share capital shall be between SEK 20,000,000 and SEK 80,000,000, divided on no less than 20,000,000 and no more than 80,000,000 shares. The shares are priced in SEK and each share has a quota value of SEK 1.

NOTE 10 - ACCRUALS AND DEFERRED INCOME

1,051	1,023
330	321
62	71
249	389
1,692	1,804
	330 62 249

NOTE 11 - ITEMS NOT INCLUDED IN CASH FLOW

(Amounts in kSEK)	2020	2019
Depreciation	362	357
Total	362	357

NOTE 12 - CASH FLOW FROM NEW ISSUES OF SHARES AND WARRANTS

(Amounts in kSEK)	2020	2019
Swedish Companies Registration Office 2019-04-10	-	36,662
Swedish Companies Registration Office 2019-12-201	477	-
Swedish Companies Registration Office 2020-06-01	47,317	-
Transaction costs	-6,346	-1,482
Total	41,448	35,180

1. The net proceeds from the issue of warrants to the board and staff was not received until January 2020.

NOTE 13 - RELATED PARTY TRANSACTIONS

Disclosures about remuneration to the Board of Directors and senior executives is presented in Note 4.

Remuneration is paid in accordance with market-based agreements or in accordance with the AGM's decision. During the period when Mikael Lönn was a board member of both Spago Nanomedical and Redeye, Redeye invoiced the company for financial advice, assignment analysis and investment events. Invoicing has been done according to agreements based on market conditions.

NOTE 14 - SIGNIFICANT EVENTS AFTER THE BALANCE SHEET DATE

During the first quarter 2021, the company carried out a rights issue including an overallotment issue, which increased the company's share capital by SEK 9,219,463 distributed on 9,219,463 shares. In addition, 418,307 shares were issued in a directed share issue to those guarantors of the rights issue that chose to receive compensation in the form of newly issued shares in the company. In total, the company was provided net proceeds approximately MSEK 64.

With a view to strengthening the company's long-term financing possibilities, the company changed trading venue from Spotlight Stock Market to Nasdaq First North Growth Market. The first day of trading on Nasdaq First North Growth Market was March 26, 2021.

Signatures

Lund, April 13, 2021

Eugen Steiner Chairman of the Board Mats Hansen Chief Executive Officer

Nicklas Westerholm

Kari Grønås

Sten Nilsson

Our auditor's report was submitted on April 13, 2021

BDO Mälardalen AB

Jörgen Lövgren Authorized Public Accountant **Peter Leander**

Auditor's report

To the general meeting of the shareholders of Spago Nanomedical AB (publ). Corporate identity number 556574-5048

REPORT ON THE ANNUAL ACCOUNTS Opinions

We have audited the annual accounts of Spago Nanomedical AB (publ) for the year 2020. The annual accounts of the company are included on pages 21-40 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Spago Nanomedical AB (publ) as of December 31, 2020, and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Spago Nanomedical AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Other information than the annual accounts

The Board of Directors and the Managing Director are responsible for the other information. The other information comprises page 1-20 in this document (but does not include the annual accounts and our auditor's report thereon).

Our opinion on the annual accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information. In connection with our audit of the annual accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Director's and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or have no realistic alternative but to do so.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual

accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company to cease to continue as a going concern.

• Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS Opinions

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Director's and the Managing Director of Spago Nanomedical AB (publ) for the year 2020 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Director's and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Spago Nanomedical AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Director's and the **Managing Director**

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes, among other things, continuous assessment of the company's financial situation and ensuring that the company's organization is designed so that the accounting, management

of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and, among other matters, take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional skepticism throughout the audit. The review of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts.

Additional audit procedures performed are based on the auditor's professional judgment guided by risk and materiality. This means that the auditor focuses the review on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. The auditor reviews and tests decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to the opinion concerning discharge from liability. As a basis for the opinion on the Board of Directors' proposed appropriations of the company's profit or loss, the auditor reviewed whether the proposal is in accordance with the Companies Act.

Sollentuna, April 13, 2021

BDO Mälardalen AB

Jörgen Lövgren

Authorized Public Accountant

Glossary and financial definitions

GLOSSARY

BREAST TOMOSYNTHESIS

A type of tomography that can provide great benefits for breasts that are rich in glands. Tomosynthesis means that a number of X-ray images are taken from different angles, and then slices ("cuts") of the chest are mathematically reconstructed. In normal mammography images, there is a risk that tumors are hidden by glandular tissue.

СТ

Computed Tomography, or CT-scan, is a special kind of x-ray device that transmits multiple small x-rays from different angles through the body (as opposed to ordinary x-rays where only a single x-ray is sent through the body). This creates multiple cross-sectional images of the part of the body being scanned, giving an image in three dimensions.

CLINICAL STUDY

Studies conducted in humans during the development of drugs and contrast agents to study safety and efficacy. Clinical studies are required to obtain regulatory approval for drugs and contrast agents.

Phase I studies are small studies, often with healthy volunteers, aimed at demonstrating that the drug or contrast agent is safe for human use.

Phase II studies are done with patients who have a relevant disease to determine the correct dose of the drug or contrast agent and to demonstrate that the intended effect can be achieved.

Phase III studies include a larger number of patients and aim to demonstrate that the drug or contrast agent provides a statistically reliable effect or improved diagnosis (for contrast agents).

Phase IV studies are carried out after the product has been approved by the authorities to document long-term effects, any unusual side effects and to support the marketing of the product.

MAMMOGRAPHY

An X-ray examination of breasts using X-rays (ionizing radiation).

MRI

Magnetic resonance tomography, a medical imaging technique using a magnetic resonance tomograph (magnetic camera, MRI camera). The technology is used to detect, determine the location of and classify certain diseases and injuries that are hidden or difficult to see in X-ray or computed tomography examination. MRI is also recommended as an alternative to X-ray, where possible, since the technology does not use X-rays (ionizing radiation).

PET

Positron emission tomography is a method of examining various functions in the body using radioactively labeled biochemical substances. The radioactive substances emit signals that are recorded and converted into a layered X-ray image.

PRECLINICAL STUDY

Studies performed on cells, subcellular components, organs or laboratory animals. These studies aim to demonstrate the efficacy and safety of a drug or contrast agent. Documented preclinical studies to study the safety of the drug or contrast agent are required by the authorities to start clinical studies.

RADIONUCLIDE

A radioactive nuclide of a certain element. The word nuclide comes from the Latin "nucleus", meaning core. A nuclide is an atomic nucleus with a certain number of protons and neutrons. Nuclide is often used synonymously with isotope, which, however, is not completely chemically correct

SCREENING

Programs that examine risk groups on a larger scale to try to identify people with a particular disease, e.g. mammography screening aimed at finding women with breast cancer.

ULTRASOUND

The ultrasound method is based on technology where highfrequency sound waves are emitted across the area to be examined. The body sends back an echo that is recorded and converted into images. The examination is performed by a radiologist who interprets the images while the examination is ongoing.

FINANCIAL DEFINITIONS

EQUITY RATIO

Equity in relation to the balance sheet total

EARNINGS PER SHARE BEFORE DILUTION

Profit for the year in relation to the average number of shares

EARNINGS PER SHARE AFTER DILUTION

Profit for the year in relation to the average number of shares increased by the number added at full dilution. In accordance with IAS 33, no dilution effect arises where a conversion results in a lower loss per share.

EQUITY PER SHARE BEFORE DILUTION

Equity in relation to the number of shares at year-end

EQUITY PER SHARE AFTER DILUTION

Equity after dilution in relation to the number of shares at yearend, as though full dilution had occurred

ANNUAL GENERAL MEETING

The Annual General Meeting will be held on May 5, 2021.

Notice has been given by press release, announced in the Swedish Gazette ("Post- och Inrikes Tidningar") and published on the website of Spago Nanomedical, www.spagonanomedical.se

CALENDAR:

Interim report Q1 2021	April 28, 2021
Annual General Meeting	May 5, 2021
Interim report Q2 2021	August 24, 2021
Interim report O3 2021	November 10, 2021



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