ANNUAL REPORT

Spago Nanomedical AB (publ)



Nanomedicine for **diagnostics** and **treatment** of life-threatening diseases







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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.

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 physiologically in tumors, thus enabling higher precision and improved cancer patient care. The 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 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 together with Lutetium¹⁷⁷ (¹⁷⁷Lu) delays tumor growth at clinically useful doses. This opens up a wide range of applications for ¹⁷⁷Lu-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's share is listed on Nasdaq First North Growth Market (ticker: SPAGO).

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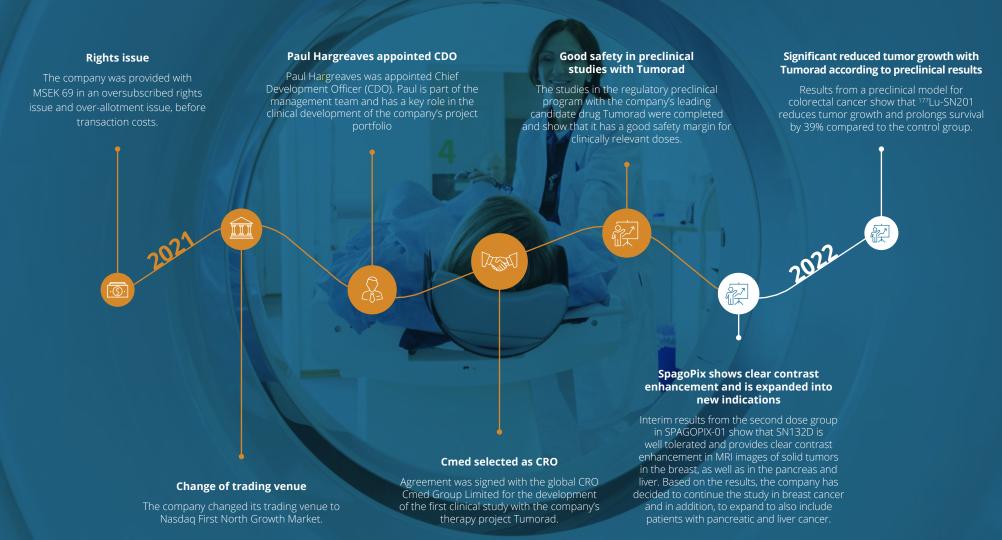
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Significant events during the year and after year-end



04



CEO statement by Mats Hansen

In 2021, we continued to make good progress with our projects, despite the still ongoing Covid-19 pandemic. We could in fact start the new year with some further exciting news around both projects. This makes me believe we have an exciting year ahead of us.

In early December, we completed the recruitment to the second dose group in our clinical phase I study SPAGOPIX-01 with the tumor-selective contrast agent SN132D in patients with confirmed breast cancer. Shortly after, in January 2022, we presented the interim results from the second dose group which show that SN132D is well tolerated and provides clear contrast enhancement in MRI images of solid tumors in the breast, as well as in the pancreas and liver. Based on the results, we decided to proceed the study in breast cancer and in addition, to expand to also include patients with pancreatic and liver cancer, where there also is a large clinical need.

It is very rewarding that we, also in the second dose cohort, can show that SN132D clearly accumulates in cancerous tumors and provide images that with both high precision and positive contrast show the tumor against a clean background. Strengthened by these positive results, together with previously presented data, we are continuing the project at full speed, both in breast cancer and in the new indications.

The interim results from SPAGOPIX-01 show that our platform technology makes it possible to clinically and precisely accumulate functional nanoparticles in solid tumors. This is also of great importance for our therapy project Tumorad, which aims to develop a precision treatment for several different cancers. Tumorad, with the candidate drug code ¹⁷⁷Lu-SN201, has previously demonstrated a positive effect by slowing tumor growth in a preclinical model for aggressive breast cancer.

In the last quarter, we completed the regulatory preclinical, IND-enabling studies for Tumorad. We see a good safety margin to clinically relevant doses, as the results show that the nanomaterial is safe to give in doses that widely exceed planned clinical doses and that radiation is distributed in a manner that allow dosing according to plan. This is a major risk reduction in the project.

Recently we could also communicate new preclinical results showing that ¹⁷⁷Lu-SN201 significantly reduces tumor growth and prolongs survival by 39% in a preclinical model for colorectal cancer. These new results provide additional support for the company's unique platform technology with nanoparticles for use in several different cancer indications.

Data from the preclinical studies, together with other documentation, will form the basis for the first clinical trial application for Tumorad. The plan is to submit the application and start the studies in humans in 2022. The aim of the first in human trial is to document safety at different doses of ¹⁷⁷Lu-SN201 in cancer patients as well as to evaluate signs of early proof-of-concept. The preparations for Tumorad clinical development are ongoing at full speed, and a key person in this process is of course Paul Hargreaves, who joined as Chief Development Officer. With almost 30 years of experience in clinical development from Pfizer and Quantiles, among others, Paul significantly strengthens the team to allow further acceleration of our critical work going forward.

Earlier in the year, our share started trading on Nasdaq First North Growth Market, which provides an opportunity for increased exposure and sends an important signal of our long- term ambitions to become a leading company in the development of nanomedicine. During the year, we were busy presenting the company and our exciting project portfolio at conferences and industry events. We will continue to do so in 2022.

Strengthened by these important milestones, I believe we have an exciting year ahead of us. I look forward to updating you as our projects continue to progress.

Mats Hansen CEO Spago Nanomedical AB

"The interim results from SPAGOPIX-01 show that our platform technology makes it possible to clinically and precisely accumulate functional nanoparticles in solid tumors. This is also of great importance for our therapy project Tumorad..."



Vision Objectives.& Strategy



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.



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.



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.

Vision Mål & Strate

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. Data 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.

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).

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 cancer related death, with 685,000 registered

cases worldwide in 2020 (Sung et al., 2021). 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 higher 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.

Pancreatic cancer is one of the deadliest cancers and leads to more than 400,000 deaths worldwide each year. Today, there is a lack of effective imaging diagnostics, both to detect local tumors in the pancreas and to determine if the disease has spread to the liver. The medical need for contrast agents with high precision for tumors is thus large.

SpagoPix potential unique benefits

Tumor selectivity improves the precision and makes it easier to distinguish between tumor and non-tumor tissue, thus reducing the frequency of misdiagnosis.



the MRI signal and several times higher signal strength (relaxivity) than other contrast agents on the market. A high level of relaxation can make the images clearer and improve the possibilities for earlier detection and accurate diagnosis of cancer.

Controlled build-up of the MRI signal, makes it possible to capture images for a longer timespan and enables highresolution images.

Free from gadolinium, eliminates the risk of adverse 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 for tumors going undetected. There is a risk that a missed tumor diagnosis allows the tumor to develop 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, the 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.

SN132D 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 time, 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 SN132D 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 SN132D 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 SN132D has demonstrated several times higher relaxivity in measurements than the contrast agents on the market today. Data showing that the relaxivity of 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 SN132D 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, SN132D 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, SN132D 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, SN132D 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, SN132D 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. In addition to confirming that SN132D can improve the diagnosis and monitoring of suspected and diagnosed breast cancer with MRI, the results also confirm the ability of the company's unique platform material to accumulate in solid tumors in humans. This allows for the use of the nanomaterial also for therapeutic purposes.

> Clinically relevant contrast enhancement in breast tumor (arrow) with SN132D.

SN132D provides a very high contrast in the pancreas and the liver (arrows).

SN132D

PROJECT STATUS

The ongoing phase I clinical study SPAGOPIX-01 is being conducted at two hospitals in Sweden and can include up to 20 patients with confirmed breast cancer. The primary purpose of the study is to study safety at different doses of SN132D. A secondary objective is to document how this new contrast agent can enhance MRI images of breast cancer tumors, as well as those in the liver and pancreas.

Recently, positive results were reported based on analysis of the first two dose groups with a total of 12 patients showing that SN132D gives a positive contrast in MRI images of breast cancer tumors in humans while maintaining a good safety profile. In addition to confirming that SN132D can improve the diagnosis

and monitoring of suspected and diagnosed breast cancer with MRI, the results also confirm the ability of the company's unique platform material to accumulate in solid tumors in humans. This verifies the possibilities of using the nanomaterial also for therapeutic purposes.

In addition to the positive contrast in breast cancer tumors, all MRI images in the study show that SN132D also generates good contrast in the pancreas and liver. Radiologists in Europe and the United States point out that there is a clear need to be able to identify and follow patients with various forms of precursors to cancer in pancreas and to determine if the cancer has spread to the liver. The study continues with the inclusion of additional breast cancer patients and is broadened to also include patients with pancreatic cancer which is suspected to have been spread to the liver. This provides an opportunity for an expanded patient base, a faster path to completion, and strengthening of the project. In the next stage, SN132D will be tested in larger clinical studies and/or in different indications prior to market approval. Spago Nanomedical's strategy is based on the licensing of projects in the clinical phase. On the basis of interim data, which shows good contrast enhancement in tumors and target organs without disturbing background contrast, the company is currently evaluating the commercial possibilities.

PROJECT & INDICATION	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III	MARKET
SpagoPix - Breast cancer						
SpagoPix - Pancreas canc	er					
Tumorad - Solid tumors						
New Projects – Undisclosed						

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 SN132D until at least 2037. Additional patent applications have been filed, and may both strengthen and extend the protection of SN132D.

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.

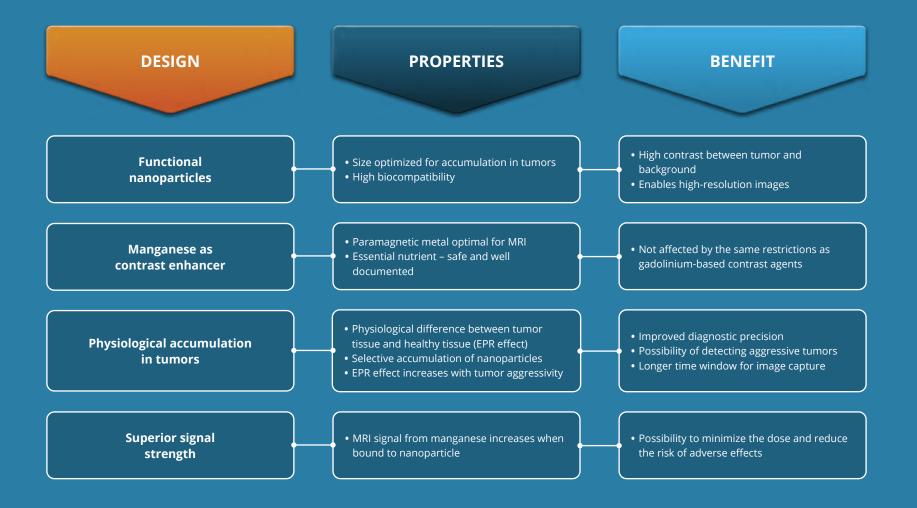
COMPETITION

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. With regard to pancreatic cancer, the need for improved diagnostic methods is great, especially as there is currently no effective imaging to guide the treatment when the disease has spread to the liver.



SpagoPix



Project - Tumorad

Radiation therapy has been used effectively in the fight against cancer for more than 100 years. Along with surgery and chemotherapy, radiotherapy 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 leading candidate drug within the Tumorad project (SN201) is loaded with radioactive isotopes, lutetium¹⁷⁷ (¹⁷⁷Lu) and thus enable internal radiotherapy, socalled 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 SN132D, ¹⁷⁷Lu-SN201 can be physiologically 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 ¹⁷⁷Lu-SN201 for the treatment of several types of tumors. This is where ¹⁷⁷Lu-SN201 differs from other targeted radionuclide therapies based on, for example, antibodies, which are developed to reach only a particular type of tumor.

Tumorads potential unique benefits

Tumor selectivity, physiological targeting of tumors, offers potential for use in the treatment of several different types of cancer types.

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.

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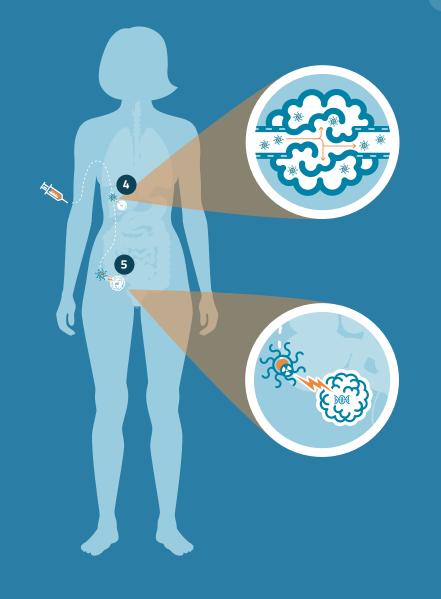
Physiological targeting of tumors gives potential to treat several different cancers

The isotope lutetium¹⁷⁷ (¹⁷⁷Lu) is clinically effective and allows tumor imaging.

The nanoparticle is optimized for physiological and selective accumulation in tumors

- Simple preparation in hospital facilitates logistics and can reduce costs.
- Physiological accumulation of functional nanoparticles in aggressive tumors and metastases.

Delivery of an adapted radiation dose with sufficient force to treat the tumors while minimizing the impact on surrounding tissue.



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 with regard the material's structure and production.

Extensive development and optimization work has previously resulted in the candidate drug, SN201, which coupled with the isotope lutetium¹⁷⁷ (¹⁷⁷Lu) provides the desired exposure to radioactivity in tumors, while minimizing the impact on other organs. Furthermore, preclinical efficacy studies have shown that ¹⁷⁷Lu-SN201 inhibits tumor growth and prolongs survival in a model for aggressive breast cancer. Recently the company could also communicate new results showing that ¹⁷⁷Lu-SN201 reduces tumor growth and prolongs survival by 39% in a preclinical model for colorectal cancer compared to the control group. The material has shown a good safety profile in regulatory preclinical toxicology studies, as well as favorable distribution in the body (biodistribution) in preclinical dosimetry studies. Production of SN102 on a larger scale for clinical studies is ongoing. The goal is to initiate a clinical phase I/II trial in 2022.

After the initial clinical study, ¹⁷⁷Lu-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-ofconcept 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 SN201 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.

PROJECT & INDICATION	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III	MARKET
SpagoPix - Breast cancer						
SpagoPix - Pancreas cancer						
Tumorad - Solid tumors						
New Projects – Undisclosed i						

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MARKET OVERVIEW

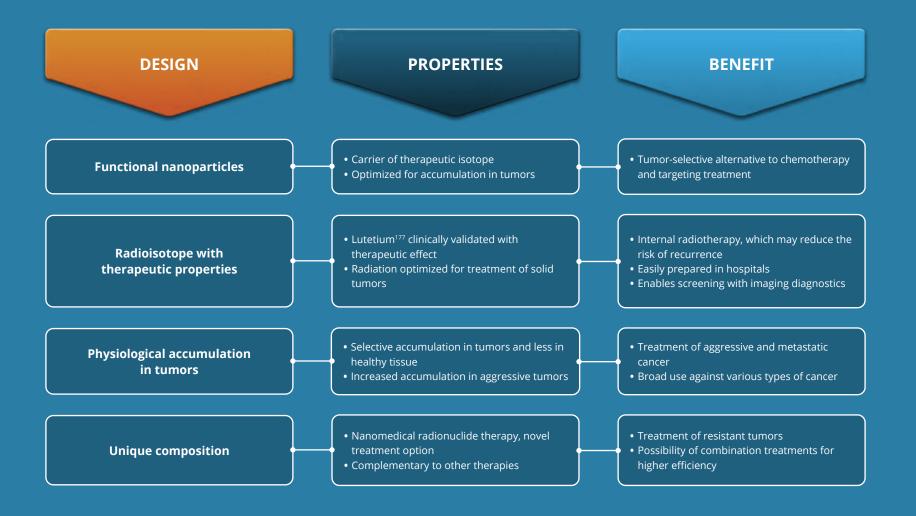
Radionuclide therapy is in clinical use today against a limited number of tumor types, while the pace of development within the field is picking up with several novel products under development. Based on public sales figures from global players with market-approved products, the market for such products 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 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 company's press release. The market for radionuclide therapies can thus be expected to continue to increase. Compared to the targeted therapies on the market today, ¹⁷⁷Lu-SN201 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 ¹⁷⁷Lu-SN201 treatment (indications with documented EPR effect), and prices of comparable existing drugs, the global addressable market is estimated to amount to billions.

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."

Tumorad





Organization

Spago Nanomedical has an organization with extensive experience in the development of contrast agents and medicines. At present, the company has 18 employees 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

CEO 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



Oskar Axelsson

VP and Chief Scientific Officer (CSO)

Born: 1962

In management team 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: -



Paul Hargreaves

Chief Development Officer (CDO)

Born: 1969

CDO since: 2021

Holdings (related parties included): -

Education and experience: Paul Hargreaves holds both an MSc. in clinical pharmacology and an MBA. He has extensive experience in international drug development across multiple therapeutic areas. His prior roles include Development Team Lead at Pfizer, Vice President Phase I for Quintiles and Global Head of Clinical Operations at LEO Pharma. Most recently he has been working as an independent consultant and CDO.

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: -

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, Inbox Capital AB, Inbox Intressenter 1 AB, Inbox Intressenter 2 AB, Inbox Intressenter 3 AB, Inbox Intressenter 4 AB Karolinska Institutet Holding AB, Karolinska Institutet Innovation and A3P Biomedical AB (publ). Board member and CEO of Setraco AB.

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

Peter Leander

Board member



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

Board member



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, 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.

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.



Nicklas Westerholm

Board member



Born: 1965

Kari Grønås

Board member

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.

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: CEO of Egetis Therapeutics AB, chairman of the Board and CEO of Rare Thyroid Therapeutics International AB.

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

"With SN201, we have a good safety margin to clinically relevant doses, as the results show that the nanomaterial is safe to give in doses that widely exceed planned clinical doses and that radiation is distributed in a manner that allow dosing according to plan. This is a major risk reduction in the project."

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.

TRADING OF SHARES AND SHARE PERFORMANCE

During 2021, a total of 10 million shares were traded, worth MSEK 67.

Spago Nanomedical's share price decreased during the year, from SEK 8.54 at the beginning of the year to SEK 4.80 at the end of the year. The company's market capitalization at year-end was MSEK 198 (MSEK 269).

SHARE STRUCTURE

At the end of 2020, the share capital in Spago Nanomedical amounted to SEK 41,182,287 and was distributed across 41,182,287 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.

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 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 2,791 (3,003). Of these, one shareholder, Peter Lindell, has direct and indirect holdings representing more than ten percent of the votes. The ten largest shareholders controlled 57 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.

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ANALYSES

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

INNEHÅLL



SHAREHOLDERS

As of 2021-12-31	Total number of shares	Share of capital (%)
Peter Lindell with company & related parties	6,673,742	16.21%
Avanza Pension	5,521,459	13.41%
Mikael Lönn	2,475,000	6.01%
Ranny Davidoff	2,297,006	5.58%
Eva Redhe	1,750,774	4.25%
Tiel Ridderstad	1,371,111	3.33%
Andreas Bunge with company & related parties	1,075,825	2.61%
Thord Wilkne	851,756	2.07%
Claes Dahlbäck with company	762,912	1.85%
Jonas Pålsson	700,000	1.7%
Total of the above	23,479,585	57.01%
Other shareholders	17,702,702	42.99%
TOTALT:	41,182,287	100%

DEVELOPMENT OF THE SHARE CAPITAL

YEAR	Transaction	Increase, number of shares	Increase of share capital (SEK)	Total share capital (SEK)	Total number of shares	Quota value
1993	lnitial 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
2021	Share issue	7,886,129	7,886,129	39,430,646	39,430,646	1
2021	Share issue	1,333,334	1,333,334	40,763,980	40,763,980	1
2021	Share issue	418,307	418,307	41,182,287	41,182,287	1

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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 2021-01-01 to 2021-12-31.

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 16 (15).

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's 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 41,182,287 and the number of shares to 41,182,287, 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 2021 -12-31, these represented approximately 45 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 -45,723 (-26,207). The higher costs are primarily related to the regulatory preclinical studies and start of the GMP manufacturing required to initiate clinical phase I/II studies of the Tumorad project. The increased costs are also related to business development of SpagoPix and change of marketplace for the company's share to Nasdaq First North Growth Market.

Total income amounted to kSEK 6,532 (7,245) and is mostly attributable to development expenses and patent expenses for the SpagoPix project that were capitalized on the balance sheet during the period.

Operating result amounted to kSEK -39,192 (-18,962). 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 -0.99 (-0.70) for the year. At year-end, cash and cash equivalents amounted to kSEK 52,460 (28,448). Cash flow from operating activities amounted to kSEK -35,569 (-18,766). The increased negative cash flow is driven by the ongoing clinic preparatory activities in the Tumorad project. Cash flow from investing activities amounted to kSEK -4,627 (-6,383). 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 64,208 (41,448). The cash flow for the year relates to the net proceeds received in the rights issue, including the over-allotment issue, as well as the directed share issue that was carried out to guarantors during the first quarter. A total of 9,637,770 new shares were issued, bringing in mSEK 72.3, before transaction costs.

At the end of the year, the company's equity amounted to kSEK 184,812 (159,675) and equity ratio to 96.5 percent (98,1 percent). Equity per share before dilution amounted to SEK 4.49 (5.06).

The company's carryforward of unused tax losses amounts to kSEK 159,762 (112,646).

SINGNIFICANT EVENT DURING THE YEAR

During the first quarter, the company was provided with MSEK 69 in an oversubscribed rights issue and over-allotment issue, before transaction costs.

To strengthen the company's long-term financing opportunities, the company changed its trading venue from Spotlight Stock Market to Nasdaq First North Growth Market. During the third quarter, Paul Hargreaves was appointed Chief Development Officer (CDO). Paul is part of the management team and has a key role in the clinical development of the company's project portfolio

Agreement was signed with the global CRO Cmed Group Limited for the development of the first clinical study with the company's therapy project Tumorad.

The studies in the regulatory preclinical program with the company's leading candidate drug Tumorad were completed and show that it has a good safety margin for clinically relevant doses.

SINGNIFICANT EVENT AFTER THE REPORTING PERIOD

For significant events after the reporting period, please refer to Note 14.

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 preclinical 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 time consuming 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.

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 preclinical 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 timeconsuming 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 2022, and at the Annual General Meeting on May 5, 2021, 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 12 recorded meetings over the course of the year. All Board members have been present at all of the Board meetings during 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.

PROPOSED APPROPRIATION OF THE COMPANY'S PROFIT OR LOSS

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

Net profit or loss for the year	-39,071,363
Retained earnings	-157,083,414
Share premium reserve	255,365,788

The Board of Directors proposes the following distribution of funds:

To be carried forward	59,211,012
Total	59,211,012



Financial information in summary

EXTRACTS FROM THE INCOME STATEMENT

(Amounts in kSEK)	2021	2020	2019	2018	2017
Sales	6,532	7,245	19,015	29,724	18,294
Operating costs	-45,723	-26,207	-39,226	-40,816	-27,380
OPERATING RESULT	-39,192	-18,962	-20,211	-11,092	-9,086
NET PROFIT OR LOSS FOR THE YEAR	-39,071	-18,928	-20,211	-11,092	-9,457

EXTRACTS FROM THE CASH FLOW STATEMENT

(Amounts in kSEK)	2021	2020	2019	2018	2017
Cash flow from operating activities	-35,569	-18,766	-21,288	-10,510	-7,730
Cash flow from investing activities	-4,627	-6,383	-18,214	-28,868	-18,082
- of which intangible fixed assets	-4,254	-5,772	-18,167	-28,471	-17,611
Cash flow from financing activities	64,208	41,448	35,180	25,535	39,356
CASH FLOW FOR THE YEAR	24,012	16,299	-4,322	-13,843	13,545

EXTRACTS FROM THE BALANCE SHEET

(Amounts in kSEK)	2021-12-31	2020-12-31	2019-12-31	2018-12-31	2017-12-31
Fixed Assets	137,237	132,986	126,964	109,108	80,616
Current assets	54,387	29,834	13,576	17,212	30,975
- of which cash and cash equivalents	52,460	28,448	12,149	16,471	30,314
TOTAL ASSETS	191,624	162,820	140,540	126,320	111,591
Equity	184,812	159,675	137,631	122,223	107,780
Short-term liabilities	6,812	3,146	2,909	4,097	3,811
TOTAL EQUITY AND LIABILITIES	191,624	162,820	140,540	126,320	111,591



DATA PER SHARE	2021	2020	2019	2018	2017
Earnings per share before and after dilution, SEK	-0.99	-0.70	-1.01	-0.71	-1.00
Equity per share before dilution, SEK	4.49	5.06	6.54	7.31	7.52
Average number of shares before dilution	39,410,870	27,177,699	20,084,320	15,530,622	9,458,619
Average number of shares after dilution	39,973,422	27,740,251	21,438,641	20,613,603	10,613 470
Number of shares at the end of the period	41,182,287	31,544,517	21,029,678	16,716,483	14,336,803

OTHER KEY INDICATORS	2021	2020	2019	2018	2017
Average number of employees	16	15	17	16	17
Equity ratio %	96.5	98.1	97.9	96.8	96.6



Income statement

(Amounts in kSEK)	Note	2021	2020
Operating income			
Net sales		660	342
External work capitalized		2,879	3,192
Internal work capitalized		1,376	2,580
Other operating Income	2	1,617	1,132
Total income		6,532	7,245
Operating costs			
Project costs		-21,691	-6,530
Other external costs	3	-7,542	-5,212
Personnel costs	2.4	-15,990	-14,095
Depreciation/amortization of fixed assets	8	-376	-362
Other operating costs	5	-125	-7
Total operating costs		-45,723	-26,207
OPERATING RESULT		-39,192	-18,962
Financial items			
Other operating income and similar items		120	34
Total financial items		120	34
PROFIT OR LOSS AFTER FINANCIAL ITEMS		-39,071	-18,928
PROFIT OR LOSS FOR THE YEAR		20.074	10 000
PROFIL OR LOSS FOR THE YEAK		-39,071	-18,928

Balance sheet

ASSETS (Amounts in kSEK)	Note	2021-12-31	2020-12-31
FIXED ASSETS			
Intangible fixed assets			
Capitalized expenditure for development Patents	6	128,848	125,364
Patent	7	7,314	6,544
Total intangible fixed assets		136,162	131,908
Tangible fixed assets			
Equipment, tools, fixtures and fittings	8	1,075	1,078
Total tangible fixed assets		1,075	1,078
TOTAL FIXED ASSETS		137,237	132,986
CURRENT ASSETS			
Accounts receivable		38	31
Other current receivables		856	676
Prepayments and accrued income		1,033	679
Total current receivables		1,927	1,386
Cash and cash equivalents		52,460	28,448
TOTAL CURRENT ASSETS		54,387	29,834
TOTAL ASSETS		191,624	162,820

EQUITY AND LIABILITIES (Amounts in kSEK)	lote	2021-12-31	2020-12-31
EQUITY			
Restricted equity			
Share capital	9	41,182	31,545
Fund for development expenses	5	84,418	80,164
Total restricted equity		125,600	111,710
Non-restricted equity			
Share premium reserve		255,366	200,795
Retained earnings		-157,083	-133,902
Net profit or loss for the year		-39,071	-18,928
Total non-restricted equity		59,212	47,965
TOTAL EQUITY		184,812	159,675
LIABILITIES			
Short-term liabilities			
Accounts payable		3,860	927
Other short-term liabilities		407	527
Accruals and deferred income	10	2,545	1,692
Total short-term liabilities		6,812	3,146
TOTAL LIABILITIES		6,812	3,146
TOTAL EQUITY AND LIABILITIES		191,624	162,820



Cash flow statement

(Amounts in kSEK)	Note	2021	2020
OPERATING ACTIVITIES			
Operating result		-39,192	-18,962
Adjustments for items not included in cash flow	11	376	362
Interest received		120	35
Cash flow from operating activities before change in working capital		-38,695	-18,566
Increase/Decrease in operating receivables		-540	-437
Increase/Decrease in operating liabilities		3,666	237
Cash flow from operating activities		-35,569	-18,766
INVESTING ACTIVITIES			
Investments in intangible fixed assets	6, 7	-4,254	-5,772
Investments in tangible fixed assets	8	-373	-612
Cash flow from investing activities		-4,627	-6,383
FINANCING ACTIVITIES			
Share issue	12	64,208	41,448
Cash flow from financing activities		64,208	41,448
Cash flow for the year		24,012	16,299
Cash and cash equivalents at the beginning of the year		28,448	12,149
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR		52,460	28,448



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, 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

(Amounts in kSEK)	Share capital	Development fund	Share premium reserve	Retained earnings	Profit or loss for the year	Total equity
Opening balance, 2021-01-01	31,545	80,164	200,795	-133,902	-18,928	159,675
Appropriations of profit/loss according to the AGM's resolution				-18,928	18,928	-
Share issue	9,638		62,646			72,283
Transaction costs			-8,075			-8,075
Capitalization of development expenses		4,254		-4,254		-
Profit or loss for the year					-39,071	-39,071
Closing balance, 2021-12-31	41,182	84,418	255,366	-157,083	-39,071	184,812

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-interest- bearing 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.

FORECASTS

The Company does not present any forecasts.

NOTE 2 - OTHER OPERATING INCOME

(Amounts in kSEK)	2021	2020
Other operating Income		
R&D contributions	1,375	885
Other government grants Other operating Income	193	164
Other operating income	49	83
Total	1,617	1,132

NOTE 4 - STAFF AND SENIOR MANAGEMENT

AVERAGE NUMBER OF EMPLOYEES	2021	2020
Women	7	7
Men	9	8
Total	16	15

GENDER DISTRIBUTION OF SENIOR MANAGEMENT	2021	2020
Board of Directors		
Women	1	1
Men	4	4
Total	5	5
CEO and other senior executives		
Women	2	2
Men	2	2
Total	4	4

NOTE 3 - AUDITOR'S FEE

(Amounts in kSEK)	2021	2020
BDO Mälardalen AB		
Audit assignment	200	200
Other audit engagements separate from audit assignment	60	52
Total	260	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.

SALARIES AND OTHER REMUNERATIONS	2021	2020
Board of Directors and CEO	1,979	1,857
Other senior management	2,399	2,301
Other employees	5,791	5,312
Total	10,169	9,470
Social security contributions	3,084	2,505
Pension costs	1,719	1,533
Total social security contributions and pension costs	4,803	4,038
Total salaries, remunerations, social security contributions	14,972	13,508
and pension costs		-

Capitalized salary expenses

In Spago Nanomedical, salary expenses in the amount of kSEK 1,376 (2,580) have been capitalized as Capitalized expenditure for development.

2021		Variable	Other		
(Amounts in kSEK)	Base pay	remuneration	benefits	Pension	Tota
Members of the board					
Sten Nilsson	95	-	-	-	95
Peter Leander	95	-	-	-	95
Kari Grönås	95	-	-	-	95
Eugen Steiner	200	-	-	-	200
Nicklas Westerholm	95	-	-	-	95
CEO Mats Hansen	1,399	-	9	436	1,844
Other senior management (3)	2,339	60	10	603	3,012
Total	4,223	60	19	1,039	5,341
2020		Variable	Other		
(Amounts in kSEK)	Base pay	remuneration	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
-	200 95	-	-	-	
Nicklas Westerholm		-	- - 6	- - 377	95
Eugen Steiner Nicklas Westerholm CEO Mats Hansen Other senior management (3)	95	- - - 91	- - 6 9		200 95 1,618 2,883

1. Resigned at the Annual General Meeting 2020.

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 5, 2021, 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 2021 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 months 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)	2021	2020
Foreign exchange losses	-125	-7
Total	-125	-7

NOTE 6 - CAPITALIZED EXPENDITURE FOR DEVELOPMENT

(Amounts in kSEK)	2021	2020
Acquisition value, opening balance	125,364	120,234
Capitalized during the year	3,484	5,130
Accumulated acquisition value, closing balance	128,848	125,364
Closing balance at the end of the year	128,848	125,364

NOTE 7 - PATENTS

(Amounts in kSEK)	2021	2020
Acquisition value, opening balance	6,544	5,902
Acquisitions during the year	770	642
Accumulated acquisition value, closing balance	7,314	6,544
Closing balance at the end of the year	7,314	6,544

NOTE 9 - NUMBER OF SHARES AND SHARE CAPITAL

	2021	2020
B shares		
Opening number of shares	31,544,517	21,029,678
Share issue registered on 2020-06-01	-	10,514,839
Share issue registered on 2021-03-09	7,886,129	-
Share issue registered on 2021-03-09	1,333,334	-
Share issue registered on 2021-03-11	418,307	-
Closing number of shares	41,182,287	31,544,517

NOTE 8 - EQUIPMENT, TOOLS, FIXTURES AND FITTINGS

(Amounts in kSEK)	2021	2020
Acquisition value, opening balance	3,940	3,379
Acquisitions during the year	373	612
Retirements during the year	-	-51
Accumulated acquisition value, closing balance	4,312	3,940
Depreciation, opening balance	-2,861	-2,551
Depreciation according to plan for the year	-376	-362
Retirements during the year	-	52
Accumulated depreciation, closing balance	-3,237	-2,861
Closing balance at the end of the year	1,075	1,078

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

(Amounts in kSEK)	2021	2020
Accrued salaries and holiday pay	1,424	1,381
Accrued board fees incl. social security contributions	62	62
Other items	1,059	249
Total	2,545	1,692

NOTE 11 - ITEMS NOT INCLUDED IN CASH FLOW

(Amounts in kSEK)	2021	2020
Depreciation	376	362
Total	376	362

NOTE 13 - RELATED PARTY TRANSACTIONS

No transactions with related parties to report.

NOTE 14 - SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

Interim results from the second dose group in SPAGOPIX-01 show that SN132D is well tolerated and provides clear contrast enhancement in MRI images of solid tumors in the breast, as well as in the pancreas and liver. Based on the results, the company has decided to continue the study in breast cancer and in addition, to expand to also include patients with pancreatic and liver cancer.

Results from a preclinical model for colorectal cancer show that ¹⁷⁷Lu-SN201 reduces tumor growth and prolongs survival by 39% compared to the control group.

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

(Amounts in kSEK)	2021	2020
Swedish Companies Registration Office 2019-12-201	-	477
Swedish Companies Registration Office 2020-06-01	-	47,317
Swedish Companies Registration Office 2021-03-09	69,146	-
Transaction costs ²	-4,938	-6,346
Total	64,208	41,448

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

2. Two of the guarantors in the rights issue that were registered on 2021-03-09 chose to receive compensation in the form of new shares. These transactions thus did not generate a cash flow impact.



Signatures

Lund, February 23, 2022

Eugen Steiner Chairman of the Board

Mats Hansen Chief Executive Officer

Sten Nilsson

Nicklas Westerholm

Kari Grønås

Peter Leander

Our auditor's report was submitted on February 23, 2022

BDO Mälardalen AB

Jörgen Lövgren

Authorized Public Accountant

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 2021. The annual accounts of the company are included on pages 24-41 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 31 December 2021 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

This document also contains other information than the annual

accounts and is found on pages 1-23. The Board of Directors and the Managing Director are responsible for this other information.

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 Directors 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 intends to liquidate the company, to cease operations, or has 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 Directors and the Managing Director of Spago Nanomedical AB (publ) for the year 2021 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 Directors 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 Directors 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 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 scepticism throughout the audit. The examination 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 our professional judgment with starting point in risk and materiality. This means that we focus the examination 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. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Sollentuna 2022-02-23

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

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

EARNINGS PER SHARE AFTER DILUTION

Result 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 lower loss per share.

EQUITY PER SHARE BEFORE DILUTION

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

ANNUAL GENERAL MEETING

The Annual General Meeting will be held on May 18, 2022.

Notice will be press released, announced in the Swedish Gazette ("Post- och Inrikes Tidningar") and published on the website of Spago Nanomedical, www.spagonanomedical.se

CALENDAR

Interim report Q1 2022	April 27, 2022
Annual General Meeting	May 18, 2022
Interim report Q2 2022	August 24, 2022
Interim report Q3 2022	November 8, 2022

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