### **ANNUAL REPORT**

Spago Nanomedical AB (publ)



2022



Nanomedicine for **diagnostics** and **treatment** of severe diseases





Spago Nanomedical AB (publ) is a Swedish clinical phase nanomedicine company, developing products for diagnostics and treatment of severe diseases. Spago Nanomedical´s share is listed on Nasdaq First North Growth Market (ticker: SPAGO).

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 in image diagnostics and treatment of severe diseases. With our development programs, we aim to improve the conditions for effective healthcare for large groups of patients while at the same time meeting the needs of commercial pharmaceutical companies for positioning, supplementing and renewing their product portfolio.

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.

**SpagoPix** aims to improve the precision of MRI scans of suspected cancers and other severe diseases by launching a groundbreaking selective contrast agent for more precise visualization of tumors and other lesions. Initial clinical results show that the product candidate SN132D provides high and relevant contrast in breast cancer tumors, in the liver and in the pancreas, while maintaining good safety. In a phase IIa clinical study, the possibility of increasing the precision in the diagnosis of endometriosis is currently being investigated.

**Tumorad®** aims to develop a novel drug for radionuclide therapy for aggressive cancer. Preclinical results show that the product candidate <sup>177</sup>Lu-SN201 accumulates in aggressive tumors, delays growth and prolongs survival at clinically useful doses. This opens up for wide use of <sup>177</sup>Lu-SN201 for the treatment of various forms of cancers. Work is currently underway to complete the clinical trial application and prepare for the start of a clinical phase I/IIa study in cancer patients.

#### PIPELINE

SpagoPix - Breast cancer  SpagoPix - Endometriosis	PROJECT & INDICATION	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III	MARKET
SpagoPix - Endometriosis	SpagoPix - Breast cancer						
	SpagoPix - Endometriosis						
Tumorad - Solid tumors	Tumorad - Solid tumors						
New Projects*	New Projects*						

<sup>\*</sup>Undisclosed indications

## Significant events during the year and after year-end

#### Phase I study with SpagoPix shows clear contrast enhancement



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.

#### Significantly reduced tumor growth with **Tumorad**



Results from a preclinical model of colorectal cancer show that 177Lu-SN201 delays tumor growth and prolongs survival by 37% compared to the control group.

#### **Rights issue**



Spago Nanomedical received approximately SEK 51.7 million after transaction costs in a rights issue with the aim of accelerating development and starting clinical studies in cancer patients with <sup>177</sup>Lu-SN201.

#### The company publishes scientific paper on positive preclinical data with Tumorad as treatment of solid tumors



The paper, titled "Characterization and Efficacy of a Nanomedical Radiopharmaceutical for Cancer Treatment", was published in the peer reviewed scientific journal ACS Omega. The results show that the candidate drug <sup>177</sup>Lu-SN201 accumulates in tumors to the same extent as a comparable market-approved benchmark and is well suited for systemic treatment of cancer. Furthermore, <sup>177</sup>Lu-SN201 delays tumor growth and prolongs survival in a preclinical model of colon cancer.





#### **Extended patent protection for SpagoPix**



Extended patent protection for SpagoPix in Japan and the US until at least 2038. The patent was previously granted in Europe, and further approvals in additional countries are expected.



#### The first patient was dosed in a phase IIa study in endometriosis

The first patient was dosed in a Phase IIa clinical trial with SpagoPix in patients with suspected endometriosis, a chronic, debilitating condition that affects up to 10% of women of reproductive age.

#### Phase I study with SpagoPix in breast cancer patients is concluded



The phase I study SPAGOPIX-01 in patients with confirmed breast cancer, which was conducted at two hospitals in Sweden, was concluded. A total of 14 patients were included and dosed. The initial results show that the primary and secondary objectives of the study were met as they show that SN132D is well tolerated and provides clear contrast in MRI images of solid tumors in the breast, as well as in the pancreas and liver. The results were presented at the 2022 San Antonio Breast Cancer Symposium® (SABCS) in December and the final report of the study is being prepared.



### CEO statement by Mats Hansen

For Spago Nanomedical, 2022 was a year of significant progress in both our leading development programs - within imaging, SpagoPix, and radionuclide therapy, Tumorad.

We have already established that the MRI contrast agent SN132D provides good contrast enhancement in tumors in patients with breast cancer, as well as in the pancreas and liver. Results from the SPAGOPIX-01 phase I clinical trial also provide strong support for our platform technology and for further development in both diagnostics and treatment.

The initial clinical results showing that SN132D is well tolerated and provides clear contrast in MRI images of solid tumors in the breast were presented at the San Antonio Breast Cancer Symposium 2022; we expect to present full results from the study later this year.

An important milestone during the year was the start of the company's first clinical phase II study with SN132D in patients with endometriosis, an underdiagnosed and undertreated disease that affects up to 10 percent of all women of reproductive age. Today, it often takes a very long time for women suffering from endometriosis to receive a correct diagnosis and relevant treatment. The need for better imaging diagnostics is therefore great and with this study we now have the opportunity to position SN132D in a significant indication where current contrast agents and other diagnostics do not fully meet the medical need.

With the Tumorad program, we have advanced our position and reduced the risk through promising preclinical results and the implementation of GMP manufacturing on a larger scale. Our main focus right now is the start of the first clinical study with the candidate drug <sup>177</sup>Lu-SN201 in cancer patients. Our target is to recruit the first patient at the beginning of the summer.

The need for more effective methods to treat metastatic and aggressive cancer remains very high and we see that interest in radionuclide therapies is steadily increasing among both pharmaceutical companies and investors. With modern radionuclide therapy, it is possible to combine the effectiveness of radiation treatment with high-precision targeting to treat tumors that were previously not possible to access with radiation. So far, there are only a few tumor types that can be targeted with biologically targeted drugs. In this context, Tumorad may have a place due to its mechanism based on physiological targeting, which means that significantly more types of tumors could be treated.

The initiation of the planned clinical study is based on the positive results achieved with <sup>177</sup>Lu-SN201 during the preclinical development phase. Recently, a summary of preclinical data was published in the scientific journal ACS Omega which, in brief, shows that <sup>177</sup>Lu-SN201 accumulates well in cancer tumors, slowing tumor growth, leading to longer survival in preclinical tumor models. These results, together with previous favorable data from regulatory toxicology studies, reinforce our view that <sup>177</sup>Lu-SN201 is a promising new radionuclide therapy for physiological targeting and tumor-selective treatment of cancer with the potential to target multiple solid tumor types.

Considering the uncertainty in the world and its impact on financial markets, we are carefully managing the company's resources while focusing on areas where we see the greatest opportunity to take projects forward and create long-term value. Spago Nanomedical has a unique platform technology and a strong team, and with positive momentum from an eventful 2022, I look forward to further important progress for the company in 2023.

Finally, I would like to extend my sincere thanks to all the employees of Spago Nanomedical for their dedicated work during 2022, the Board of Directors for governance and helpful advice, our shareholders for their continued support, and to all the patients and physicians involved in the development of our product candidates.

#### **Mats Hansen**

CEO Spago Nanomedical AB

"An important milestone during the year was the start of the company's first clinical phase II study with SN132D in patients with endometriosis, an underdiagnosed and undertreated disease that affects up to 10 percent of all women of reproductive age."







**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.



### Program - 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 other lesions, the chances of successful treatment of patients are increased.

### 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 18.1 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 is highly dependent on an early diagnosis, since the possibilities of successful treatment are reduced if the cancer has had time to spread. 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, 2.3 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 for women, 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 the gold standard for women with elevated risk of developing breast cancer.

Endometriosis is a chronic inflammatory disease that affects up to 10% of all women of reproductive age. The disease affects the female reproductive system where cells similar to those in the endometrium – the layer of tissue that normally lines the inside of the uterus – attaches and grows outside the uterus, causing pains and in many cases infertility. It is estimated that at least 176 million women in the world are affected, and endometriosis accounts for as high social healthcare costs as type 2 diabetes or rheumatoid arthritis. Current diagnostics are mainly based on ultrasound examination, in many cases supported by peephole surgery and in some cases MRI without contrast agent. The precision is relatively low and the average time to correct diagnosis is about 7 years. The clinical need for improved diagnostic methods, especially non-invasive ones, is great.

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 diagnosis of cancer and endometriosis is that today's contrast agents have relatively low

# **SpagoPix** potential unique benefits



Selectivity improves the precision and makes it easier to distinguish between lesions and other tissue, thus reducing the frequency of misdiagnosis.



Exceptional enhancement of 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.



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



Free from gadolinium, eliminates the risk of adverse effects and enviromental effects from the use of this substance that is present in existing MRI contrast agents. precision and are thus non-optimal for reliably distinguishing morbid lesions from 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 lesions and surrounding tissue. This has proved to result in difficulties in making an accurate assessment of the 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 nonmalignant, 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.

Today's MRI contrast agents are almost exclusively based on the metal gadolinium, which in some patients has been linked to side effects and accumulation in the body, e.g. in the brain. There is also increasing evidence that gadolinium can pose an environmental problem when it ends up in waste water. The authorities in all major markets have introduced bans and restrictions on the use of certain types of gadolinium contrast agent.

In summary 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 incorrect diagnoses, 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 and environmental effects.

#### **SPAGOPIX - PRECISION CONTRAST AGENT FOR MRI**

Spago Nanomedical's contrast agent SpagoPix (SN132D) has unique properties that make it possible to utilize the potential of MRI. SN132D can provide the ability to detect tumors and other lesions with higher precision than is possible with today's contrast agents, thereby opening up earlier diagnostics, more efficient surgery, screening of high-risk patients, monitoring and follow-up of patients before and after surgery, and facilitating automated image analysis for example with Al-based systems. Improved methods for accurate visualization and diagnosis of tumors would increase the probability of a successful treatment and thus the patients' chance of better survival and quality of life.

SN132D is designed to physiologically and selectively accumulate in tumors and other lesions. The mechanism of action is built on a well described principle called the Enhanced Permeability and Retention (EPR) effect that characterizes growing lesions such as e.g. tumors. Characteristic of these is a disorganized capillary network with porous vessel walls that allow particles through to the growing lesion. In combination with this increased permeability, tumor tissue often has limited lymphatic drainage which leads to particles that end up in tumors staying there longer than they would have done in healthy tissue.

The functional nanoparticles in the SpagoPix program are designed and optimized to exploit the EPR effect. After administration to the patient by injection, SN132D will circulate in the bloodstream until it reaches the tumor or lesion. 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 builds up over time, resulting in a clear contrast between tumor and healthy tissue when the patient is given the MRI scan. Images from breast cancer patients from the SPAGOPIX-01 study show 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



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missed tumors and false positives, is a major problem with current contrast agents, the findings indicate that SN132D could contribute to a significant improvement of cancer diagnostics.

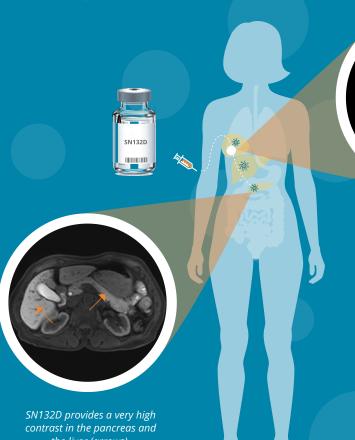
In addition to the selective accumulation of SN132D in cancer tumors and potentially in other lesions e.g. endometriosis, the contrast agent is also much better at enhancing the signal that is measured in an MRI examination (relaxivity) compared with the contrast agents currently in use. Relaxivity is 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.

The combination of the selectivity for lesions and the high signal strength, SN132D can provide a clearer and more precise image of the diseased tissue. This increase the opportunity for accurate diagnosis and precision of surgical treatment.

In addition, the SN132D is also 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 manganese (Mn) 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.



#### **CLINICAL PROGRAM**

The clinical phase I study SPAGOPIX-01, conducted at two hospitals in Sweden, was concluded in the last quarter in 2022. In total, 14 patients with confirmed cancer in breast were included and dosed. The primary objective with the study was to study safety at different doses of SN132D. A secondary objective was to document how this new contrast agent can enhance MRI images of cancer tumors in breast and pancreas with suspicious spread to the liver.

Based on analysis of the second dose group, the interim results show that SN132D gives a positive contrast in MRI images of breast cancer tumors in humans while maintaining a good safety profile. 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. Beyond 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 selectively and without background noise in solid tumors in humans. This can be seen as a clinical validation of the platform technology and allows for the use of the company's nanomaterial also for therapeutic purposes. The interim results from the study were be presented at the 2022 San Antonio Breast Cancer Symposium and the final report of the study is in preparation.

In the end of the year, the company dosed the first patient in a phase Ila clinical study, SPAGOPIX02, in patients with suspected endometriosis. The study will include up to 18 patients and will

be conducted at Skåne University Hospital in Malmö. The study evaluates the safety and MRI enhancing properties of SN132D in participants with suspected endometriosis. Comparisons will be made with transvaginal ultrasound and non-contrast enhanced MRI to consider the diagnostic potential of SN132D in endometriosis.

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. The process of evaluating potential licensees is ongoing and has so far resulted in valuable feedback. On the basis of this and interim data, which shows good contrast enhancement in tumors and target organs without background noise, the company is currently evaluating the commercial possibilities in cancer and other diseases.

### Pipeline - SpagoPix

PROJECT & INDICATION	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III	MARKET
SpagoPix - Breast cancer						
SpagoPix - Endometriosis						
Tumorad - Solid tumors						
<b>New projects</b> - Undisclose						



#### **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 its 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 2038. Additional patent applications are pending approval, which may both strengthen and extend protection for 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 in cancer and other diseases is steadily increasing, among other things as a result of increased use of various diagnostic blood tests. 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. As a result of the fact that healthcare has generally become better at treating cancer and prolonging the survival of cancer patients, the number of patients who may need to be followed up with diagnostic imaging is also increasing. This can have a positive impact on the MRI contrast agent market.

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, delayed diagnosis, and unnecessary procedures due to misdiagnosis. The product is thus well placed to be a 'game changer' on the market.

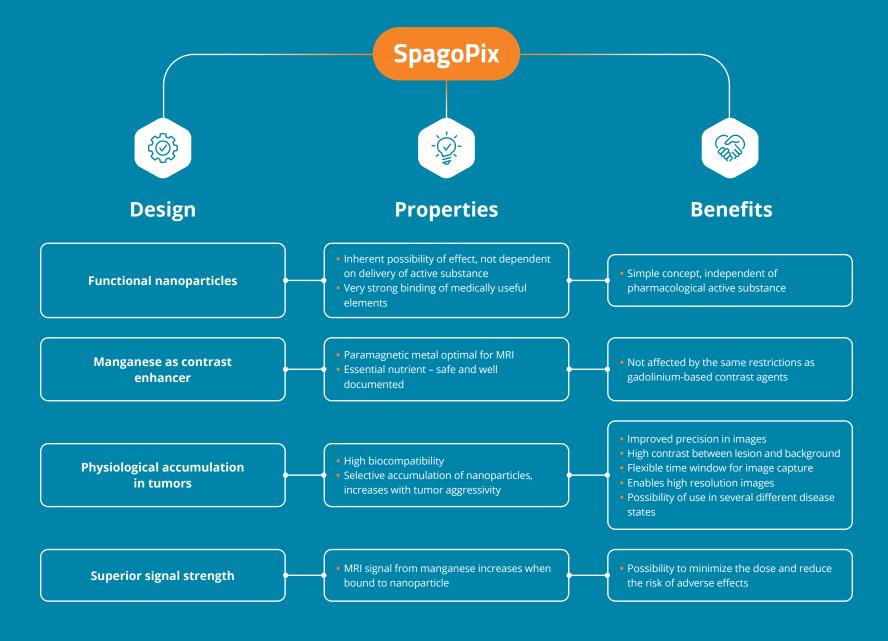
The initial target indication for SN132D is breast cancer. The global incidence is 2.3 million new cases per year (WHO 2020). The scope of use of SN132D can also be broadened to other forms of solid tumors. For example, the SPAGOPIX-01 study has demonstrated that SN132D enhances not only breast tumors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

Endometriosis is a neglected disease that affects many women and represents a very interesting opportunity to position SN132D in an indication where selective contrast agents for MRI are currently lacking. The need for non-invasive methods to shorten the time to correct diagnosis and increase the possibilities for effective treatment is great. If SN132D shows positive results in the ongoing phase Ila study, it could provide the opportunity for a significant increase in market potential.

#### 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 endometriosis, the need for improved diagnostic methods is great, to reduce the time to diagnosis and increase the possibilities for effective surgical treatment.







### Program - Tumorad

Radiation therapy has long been used effectively in the fight against cancer. Along with surgery and chemotherapy, radiotherapy is a cornerstone in the treatment of several cancers. In Tumorad, nanoparticles are loaded with radioactive isotopes, thus enabling internal radiation therapy, so-called radionuclide therapy, against cancer. Like in 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, which has been used successfully since 1942 and where a cure can be achieved despite extensive spread.

### TUMORAD - NANOPARTICLES FOR RADIONUCLIDE THERAPY

Spago Nanomedical's leading candidate drug for Tumorad (SN201) is loaded with radioactive isotopes, lutetium<sup>177</sup> (<sup>177</sup>Lu) 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, <sup>177</sup>Lu-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 <sup>177</sup>Lu-SN201 for the treatment of several types of tumors. This is where <sup>177</sup>Lu-SN201 differs from other targeted radionuclide therapies based on, for example, antibodies, which are developed to reach only a particular type of tumor.

#### PROGRAM 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 regards to the material's structure and production.

Extensive development and optimization work has previously resulted in the candidate drug, SN201, which coupled with <sup>177</sup>Lu provides the desired exposure to radioactivity in tumors, while minimizing the impact on other organs.

# **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 therapies.



Simple preparation at hospitals facilitates logistics and may reduce costs compared to other radionuclide therapies.

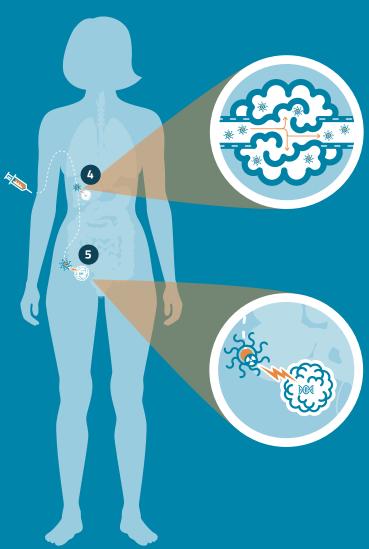
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# Physiological targeting of tumors gives potential to treat several different cancers



- 1 The isotope lutetium-<sup>177</sup> (<sup>177</sup>Lu) is clinically effective and allows tumor imaging.
- The nanoparticle is optimized for physiological and selective accumulation in tumors
- 3 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.





Furthermore, preclinical efficacy studies have shown that <sup>177</sup>Lu-SN201 inhibits tumor growth and prolongs survival in a model for aggressive breast cancer. The company has also showed that <sup>177</sup>Lu-SN201 reduces tumor growth and prolongs survival by 37% 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 SN201 on a larger scale for clinical studies is completed. Work is underway to complete the clinical trial application and prepare for the start of a clinical phase I/IIa trial in cancer patients.

#### **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.

#### **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 1 billion. 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 and in 2022, the drug Pluvicto was approved for the treatment of advanced prostate cancer.

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 Novartis' acquisition of both Advanced Accelerator Applications (with Lutathera) and Endocyte (with the

### Pipeline - Tumorad

PROJECT & INDICATION	DISCOVERY	PRECLINICAL	PHASE I	PHASE II	PHASE III	MARKET
SpagoPix - Breast cancer						
SpagoPix - Endometriosis						
Tumorad - Solid tumors						
New projects - Undisclosed in	ndications					

Phase 3 product Lu<sup>177</sup>-PSMA-617) for a total value of approximately USD 6 billion in 2018, according to the company's press release. In 2014, Bayer completed the acquisition of Norway's Algeta for USD 2.4 billion to obtain the rights to Xofigo, an anti-prostate cancer drug. In 2021, Bayer continued to complement its portfolio in radionuclide treatments against prostate cancer with the acquisitions of Noria and PSMA Therapeutics. The market for radionuclide therapies can thus be expected to continue to increase. Compared to the targeted therapies on the market today, <sup>177</sup>Lu-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.

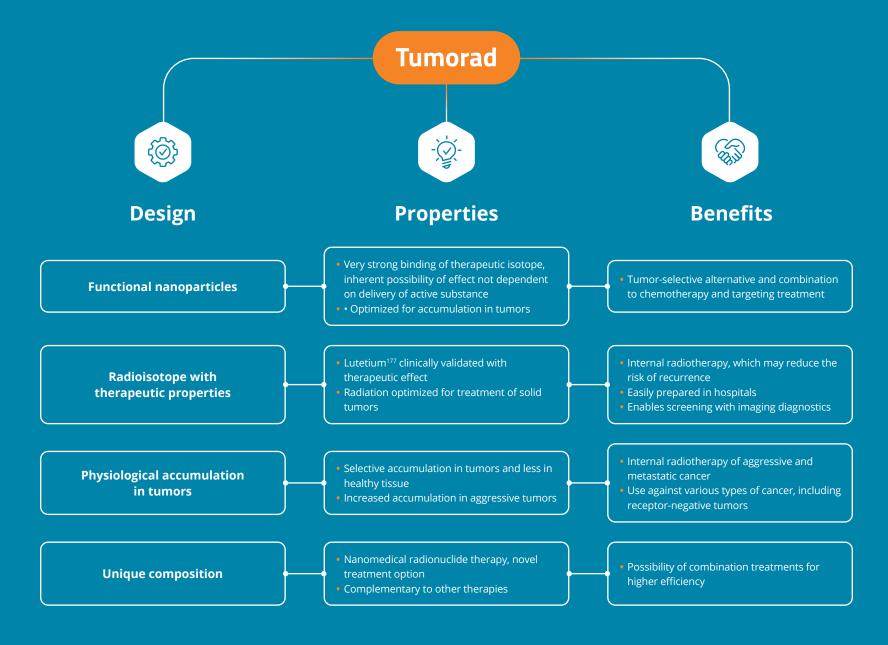
### COMPETITION AND DEVELOPMENT IN RADIONUCLIDE THERAPY

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.







### Organization

Spago Nanomedical has an organization with extensive experience in the development of contrast agents and medicines. At present, the company has 14 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): 160 522

shares

**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

**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): 25 000 shares

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

**CFO since:** 2019

Holdings (related parties included): 28 125 shares

**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 as CFO at System Verification.

Other appointments: -



#### **BOARD OF DIRECTORS**

**Eugen Steiner** 

Chairman of the Board



Peter Leander

Board member



**Sten Nilsson** 

Board member



**Born:** 1954

Member of the board since: 2019

Holdings (related parties included): 253 125 shares

**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, A3P Biomedical AB (publ), Epiendo Pharmaceuticals ehf, Stockholm School of Entrepreneurship, Board member and CEO of Setraco AB.

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

**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.

**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:** 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.



#### Kari Grønås

**Board** member



Nicklas Westerholm

Board member



Born: 1964

Member of the board since: 2018

Holdings (related parties included): 83 333 shares

**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 and board member of Arxx Therapeutics AS.

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

**Born:** 1976

Member of the board since: 2019

Holdings (related parties included): 8 265 shares

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.

### 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.

**MEDICAL ADVISORS** 

#### **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.







### Share information for Spago Nanomedical AB

Since 2021, Spago Nanomedical's share is traded on Nasdaq First North Growth Market under the ticker SPAGO. The company then 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 2022, a total of 26 million shares were traded, worth MSEK 30.

Spago Nanomedical's share price decreased during the year, from SEK 4.80 at the beginning of the year to SEK 0.63 at the end of the year. The company's market capitalization at year-end was MSEK 57 (MSEK 198).

#### **SHARE STRUCTURE**

At the end of 2022, the share capital in Spago Nanomedical amounted to SEK 90,943,723 and was distributed across 90,943,723 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 second and third quarter 2022, a rights issue was carried out, which raised MSEK 58.4 before transaction costs. The share issue increased the company's share capital by SEK 48,682,275 distributed across 48,682,275 shares. In addition, 1,079,161 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.

#### **OWNERSHIP STRUCTURE**

The number of shareholders at year-end amounted to 2,765 (2,791). Of these, one shareholder, Peter Lindell, has direct and indirect holdings representing more than ten percent of the votes. The ten largest shareholders controlled 52 percent of the company's shares as at the end of the year.

#### **DIVIDEND POLICY**

For the financial year 2022, the Board of Directors of Spago Nanomedical proposes no dividend to be paid. Spago Nanomedical intends to retain any profits as long as the investment need remains extensive. Any future dividend payments will be decided by the shareholders at general meetings, and will be determined on the basis of, among other things, the company's profitability, performance, acquisition opportunities and financial position.

#### **ANALYSES**

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



#### SHAREHOLDERS

As of 2022-12-31	Total number of shares	Share of capital (%)
Peter Lindell with company & related parties	17,910,981	19.69
Avanza Pension	6,558,541	7.21
Mikael Lönn	6,223,951	6.84
Eva Redhe	4,402,717	4.84
Tiel Ridderstad	3,399,180	3.74
Nordnet Pensionsförsäkring	2,661,089	2.93
Nolsterby Invest	2,505,346	2.75
Hans Lycketorp	1,360,000	1.50
Filippa Lindström	1,290,206	1.42
Dan Peters	1,000,000	1.10
Total of the above	47,312,011	52.02
Other shareholders	43,631,712	47.98
TOTAL:	90,943,723	100.00

#### **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	Initial establishment	100,000	100,000	100,000	100,000	1
2008	Share issue	25,000	25,000	125,000	125,000	1
2009	Share issue	23,500	23,500	148,500	148,500	1
2010	Share issue	35,273	35,273	183,773	183,773	1
2012	Bonus issue	1,653,957	1,653,957	1,837,730	1,837,730	1
2012	Share issue	1,479,543	1,479,543	3,317,273	3,317,273	1
2014	Share issue	2,211,514	2,211,514	5,528,787	5,528,787	1
2015	Share issue	2,073,295	2,073,295	7,602,082	7,602,082	1
2016	Share issue	1,000,000	1,000,000	8,602,082	8,602,082	1
2017	Share issue	5,734,721	5,734,721	14,336,803	14,336,803	1
2018	Share issue	2,379,680	2,379,680	16,716,483	16,716,483	1
2019	Share issue	4,313,195	4,313,195	21,029,678	21,029,678	1
2020	Share issue	10,514,839	10,514,839	31,544,517	31,544,517	1
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
2022	Share issue	48,682,275	48,682,275	89,864,562	89,864,562	1
2022	Share issue	1,079,161	1,079,161	90,943,723	90,943,723	1



### Administration report

The Board of Directors and the Chief Executive Officer of Spago Nanomedical AB (publ), reg. no. 556574-5048, hereby present their annual report for the financial year 2022-01-01 – 2022-12-31.

#### **OPERATIONS**

Spago Nanomedical is a Swedish nanomedical company in clinical development phase, developing products fpr diagnostics and treatment of severe diseases. The registered office is in Lund, where also the company's operations are. The operations are based on a patented material for the design of functional nanoparticles that accumulate physiologically in tumors, thus enabling an opportunity for higher precision and improved healthcare for patients. Current pipeline projects have the potential to facilitate diagnostics and improve patient care for diseases with urgent medical needs.

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 development of SpagoPix, a MRI contrast agent with improved precision in images of cancers and other severe diseases, and on Tumorad for cancer-selective radionuclide therapy. Thus, operating costs and company resources are attributable to the above.

#### **PERSONNEL**

The average number of employees during the period amounted to 15 (16).

#### **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.

#### **PATENT**

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 the year 2038. Additional patent applications for product and process protection are pending approval and may both strengthen and extend protection for SpagoPix.

The company has product protection for Tumorad in the strategically most important markets for radionuclide therapy, including EU, the United States and Japan. The patent entitled "Nanostructures and applications thereof" (patent number 3122383) is valid until at least 2035. Applications for product protection have been filed in additional countries and are expected to further strengthen the market rights in the future. The design of the particle selected as candidate drug also provides opportunities to further extend patent protection. Tumorad is a protected 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 90,943,723 and the number of shares to 90,943,723, each carrying one vote. The largest shareholders in the company were, at the end of the year, Peter Lindell & company, Avanza Pension, Mikael Lönn, Eva

Redhe and Tiel Ridderstad. As of 2022 -12-31, these represented approximately 42 percent of the votes. For supplementary information, please refer to the section 'Share information for Spago Nanomedical' in this annual report.

#### **RESULT AND FINANCIAL POSITION**

The operating costs for the year amounted to kSEK -45,925 (-45,723). The operating costs during the year are primarily related to the production of material for the planned clinical phase I/Ila study in the Tumorad program as well as other clinic preparatory activities such as the design of the clinical study protocol and compilation of material for the clinical trial application, consultation and advice with relevant regulatory agencies, and identification of suitable clinical sites for the study.

Total income amounted to kSEK 6,460 (6,532) and is mostly attributable to development expenses and patent expenses for the SpagoPix program that were capitalized on the balance sheet during the period.

Operating result amounted to kSEK -39,465 (-39,192). Earnings per share, before and after dilution, amounted to SEK -0.61 (-0.99) for the year.

At year-end, cash and cash equivalents amounted to kSEK 62,101 (52,460). Cash flow from operating activities amounted to kSEK -38,187 (-35,569). The increased negative cash flow is driven by the ongoing clinic preparatory activities in the Tumorad program. Cash flow from investing activities amounted to kSEK -3,829 (-4,627). 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 51,657 (64,208). The cash flow for the year relates to the net proceeds received in the rights issue, in which the subscription period expired on June 28, 2022. A total of 49,761,436 new shares were issued, bringing in mSEK 58.4, before transaction costs.



At the end of the year, the company's equity amounted to kSEK 197,156 (184,812) and equity ratio to 95.7 percent (96.5 percent). Equity per share before dilution amounted to SEK 2.17 (4.49).

The company's carryforward of unused tax losses amounts to kSEK 207,108 (159,762).

#### SINGNIFICANT EVENT DURING THE YEAR

- Results from a preclinical model of colorectal cancer show that <sup>177</sup>Lu-SN201 delays tumor growth and prolongs survival by 37% compared to the control group.
- Extended patent protection for SpagoPix in Japan and the US until at least 2038. The patent was previously granted in Europe, and further approvals in additional countries are expected.
- Spago Nanomedical received approximately SEK 51.7 million after transaction costs in a rights issue with the aim of accelerating development and starting clinical studies in cancer patients with <sup>177</sup>Lu-SN201.
- The first patient was dosed in a Phase IIa clinical trial with SpagoPix in patients with suspected endometriosis, a chronic, debilitating condition that affects up to 10% of women of reproductive age.
- The phase I study SPAGOPIX-01 in patients with confirmed breast cancer, which was conducted at two hospitals in Sweden, was concluded. A total of 14 patients were included and dosed. The initial results show that the primary and secondary objectives of the study were met as they show that SN132D is well tolerated and provides clear contrast in MRI images of solid tumors in the breast, as well as in the pancreas and liver. The results were presented at the 2022 San Antonio Breast Cancer Symposium® (SABCS) in December and the final report of the study is being prepared.

#### SINGNIFICANT EVENT AFTER THE REPORTING PERIOD

For significant events after the reporting period, please refer to Note 18.

#### **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. There is a risk that the recruitment of subjects, for different reasons, takes longer or becomes more expensive than planned, which then would result in increased costs and delayed study results. Such delays can lead to additional costs and that expected revenues are postponed to the future, which has a negative impact on the company's operations and future prospects.

### 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 don't approve the products developed by the company or its partners, preventing the launch of such 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 collaborates with a manufacturer to prepare the product Tumorad 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), Nasdaq First North Growth Market's regulations 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 2023, and at the Annual General Meeting on May 18, 2022, 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 14 recorded meetings over the course of the year. Issues addressed are strategy and long-term focus, financing issues, reporting, and information and communication issues. In addition to the recorded meetings, the Chairman of the Board and other members of the Board have had continuous contact with the company's CEO.

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

### PROPOSED APPROPRIATION OF THE COMPANY'S PROFIT OR LOSS

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

Total	18,099,363
Net profit or loss for the year	-39,196,936
Retained earnings	-199,849,696
Share premium reserve	257,145,996

### The Board of Directors proposes the following distribution of funds:

Total	18,099,363
To be carried forward	18,099,363



### Financial information in summary

#### **EXTRACTS FROM THE INCOME STATEMENT**

(Amounts in kSEK)	2022	2021	2020	2019	2018
Sales	6,460	6,532	7,245	19,015	29,724
Operating costs	-45,925	-45,723	-26,207	-39,226	-40,816
OPERATING RESULT	-39,465	-39,192	-18,962	-20,211	-11,092
NET PROFIT OR LOSS FOR THE YEAR	-39,197	-39,071	-18,928	-20,211	-11,092

#### **EXTRACTS FROM THE BALANCE SHEET**

(Amounts in kSEK)	2022-12-31	2021-12-31	2020-12-31	2019-12-31	2018-12-31
Non-current Assets	140,710	137,237	132,986	126,964	109,108
Current assets	65,243	54,387	29,834	13,576	17,212
- of which cash and cash equivalents	62,101	52,460	28,448	12,149	16,471
TOTAL ASSETS	205,953	191,624	162,820	140,540	126,320
Equity	197,156	184,812	159,675	137,631	122,223
Current liabilities	8,797	6,812	3,146	2,909	4,097
TOTAL EQUITY AND LIABILITIES	205,953	191,624	162,820	140,540	126,320

#### **EXTRACTS FROM THE CASH FLOW STATEMENT**

(Amounts in kSEK)	2022	2021	2020	2019	2018
Cash flow from operating activities	-38,187	-35,569	-18,766	-21,288	-10,510
Cash flow from investing activities	-3,829	-4,627	-6,383	-18,214	-28,868
- of which intangible non-current assets	-3,695	-4,254	-5,772	-18,167	-28,471
Cash flow from financing activities	51,657	64,208	41,448	35,180	25,535
CASH FLOW FOR THE YEAR	9,641	24,012	16,299	-4,322	-13,843

DATA PER SHARE	2022	2021	2020	2019	2018
Earnings per share before and after dilution, SEK	-0.61	-0.99	-0.70	-1.01	-0.71
Equity per share before dilution, SEK	2.17	4.49	5.06	6.54	7.31
Average number of shares before dilution	63,810,559	39,410,870	27,177,699	20,084,320	15,530,622
Average number of shares after dilution	64,173,887	39,973,422	27,740,251	21,438,641	20,613,603
Number of shares at the end of the period	90,943,723	41,182,287	31,544,517	21,029,678	16,716,483

OTHER KEY INDICATORS	2022	2021	2020	2019	2018
Average number of employees	15	16	15	17	16
Equity ratio %	95.7	96.5	98.1	97.9	96.8



### Income statement

(Amounts in kSEK)	Not	2022	2021
Operating income			
Net sales		1,054	660
External work capitalized		3,254	2,879
Internal work capitalized		441	1,376
Other operating Income	2	1,711	1,617
Total income		6,460	6,532
Operating costs			
Project costs		-20,353	-21,691
Other external costs	3, 4	-8,071	-7,542
Personnel costs	2, 5	-16,765	-15,990
Depreciation/amortization of fixed assets	9	-356	-376
Other operating costs	6	-380	-125
Total operating costs		-45,925	-45,723
OPERATING RESULT		-39,465	-39,192
Financial items			
Other operating income and similar items		268	120
Total financial items		268	120
PROFIT OR LOSS AFTER FINANCIAL ITEMS		-39,197	-39,071
PROFIT OR LOSS FOR THE YEAR		-39,197	-39,071



### Balance sheet

ASSETS (Amounts in kSEK)	Not	2022-12-31	2021-12-31
NON-CURRENT ASSETS			
Intangible assets			
Capitalized expenditure for development Patents	7	131,744	128,848
Patent	8	8,113	7,314
Total intangible assets		139,857	136,162
Tangible assets			
Equipment, tools, fixtures and fittings	9	853	1,075
Total tangible assets		853	1 075
Financial assets			
Shares in group companies	10	1	-
Total financial assets		1	-
TOTAL NON-CURRENT ASSETS		140,710	137,237
CURRENT ASSETS			
Accounts receivable		49	38
Other current receivables		662	856
Prepaid expenses and accrued income		2,431	1,033
Total current receivables		3,141	1,927
Cash and cash equivalents		62,101	52,460
TOTAL CURRENT ASSETS		65,243	54,387
TOTAL ASSETS		205,953	191,624

EQUITY AND LIABILITIES (Amounts in kSEK)	2022-12-31	2021-12-31
EQUITY		
Restricted equity		
Share capital 11	90,944	41,182
Fund for development expenses	88,113	84,418
Total restricted equity	179,057	125,600
Non-restricted equity		
Share premium reserve	257,146	255,366
Retained earnings	-199,850	-157,083
Net profit or loss for the year	-39,197	-39,071
Total non-restricted equity	18,099	59,212
TOTAL EQUITY	197,156	184,812
LIABILITIES		
Current liabilities		
Accounts payable	4,725	3,860
Other current liabilities	494	407
Accruals and deferred income 12	3,578	2,545
Total current liabilities	8,797	6,812
TOTAL LIABILITIES	8,797	6,812
TOTAL EQUITY AND LIABILITIES	205,953	191,624



### Cash flow statement

(Amounts in kSEK) Not	2022	2021
OPERATING ACTIVITIES		
Operating result	-39,465	-39,192
Adjustments for non-cash items 13	356	376
Interest received	268	120
Cash flow from operating activities before change in working capital	-38,841	-38,695
Increase/Decrease in operating receivables	-1,215	-540
Increase/Decrease in operating liabilities	1,869	3,666
Cash flow from operating activities	-38,187	-35,569
INVESTING ACTIVITIES		
Investments in intangible assets 7, 8	-3,695	-4,254
Investments in tangible assets 9	-134	-373
Cash flow from investing activities	-3,829	-4,627
FINANCING ACTIVITIES		
	E4 657	64.200
Share issue 14	51,657	64,208
Cash flow from financing activities	51,657	64,208
Cash flow for the year	9,641	24,012
Cash and cash equivalents at the beginning of the year	52,460	28,448
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR	62,101	52,460



### 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, 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, 2020-12-31	41,182	84,418	255,366	-157,083	-39,071	184,812

(Amounts in kSEK)	Share capital	Development fund	Share premium reserve	Retained earnings	Profit or loss for the year	Total equity
Opening balance, 2022-01-01	41,182	84,418	255,366	-157,083	-39,071	184,812
Appropriations of profit/loss according to the AGM's resolution				-39,071	-39,071	-
Share issue	49,761		9,952			59,714
Transaction costs			-8,172			-8,172
Capitalization of development expenses		3,695		-3,695		-
Profit or loss for the year					-39,197	-39,197
Closing balance, 2022-12-31	90 944	88,133	257,146	-199,850	-39,197	197,156



### 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).

#### CONSOLIDATED ACCOUNTS

No operations have been conducted in the subsidiary during 2022 and the company prepares, with reference to the Swedish Annual Accounts Act 7:3 a, no consolidated accounts for the financial year 2022.

#### **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)	2022	2021
Other operating Income		
Research deduction from employer contributions	1,439	1,375
Other government grants Other operating Income	16	193
Other operating income	256	49
Total	1,711	1,617



#### **NOTE 3 - AUDITOR'S FEE**

(Amounts in kSEK)	2022	2021
BDO Mälardalen AB		
Audit assignment	-240	-200
Other audit engagements separate from audit assignment	-24	-60
Total	-264	-260

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.

#### **NOT 4 - OPPERATION LEASING**

Opperating leasing agreement refersto premises rent.

(Amounts in kSEK)	2022	2021
Current year's leasing fees	-2,354	-1,616
Future minimum fees for non-cancelable leases are due as follows:		
within 1 year	-2,620	-2,350
Between 2 to 5 years	-8,430	-8,610
Later than 5 years	-	-1,970
Total	-11,050	-12,930

#### **NOTE 5 - STAFF AND SENIOR MANAGEMENT**

AVERAGE NUMBER OF EMPLOYEES	2022	2021
Women	7	7
Men	8	9
Total	15	16

GENDER DISTRIBUTION OF SENIOR MANAGEMENT	2022	2021
Board of Directors		
Women	1	1
Men	4	4
Total	5	5
CEO and other senior executives		
Women	1	2
Men	3	2
Total	4	4



SALARIES AND OTHER REMUNERATIONS	2022	2021
Board of Directors and CEO	2,218	1,979
Other senior management	2,770	2,399
Other employees	5,503	5,791
Total	10,491	10,169
Social security contributions	3,210	3,084
Pension costs	2,031	1,719
Total social security contributions and pension costs	5,241	4,803
Total salaries, remunerations, social security	15,732	14,972
contributions and pension costs		

#### **Capitalized salary expenses**

In Spago Nanomedical, salary expenses in the amount of kSEK -441 (kSEK -1,376) have been capitalized as Capitalized expenditure for development.

#### REMUNERATION TO THE BOARD OF DIRECTORS AND SENIOR MANAGEMENT

2022		Variable remunera-	Other		
(Amounts in kSEK)	Base pay	tion	benefits	Pension	Total
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	1,638	-	7	436	2,081
Other senior management (3)	2,770	-	-	887	3,657
Total	4,988	-	7	1,323	6,318

2021	_	Variable remunera-	Other		
(Amounts in kSEK)	Base pay	tion	benefits	Pension	Total
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	4.318	60	19	1.039	5.436



#### 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 18, 2022, 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 2022 or 2021, 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.

#### **NOTE 6 - OTHER OPERATING INCOME**

(Amounts in kSEK)	2022	2021
Foreign exchange losses	-380	-125
Total	-380	-125

#### **NOTE 7 - CAPITALIZED EXPENDITURE FOR DEVELOPMENT**

(Amounts in kSEK)	2022	2021
Acquisition value, opening balance	128,848	125,364
Capitalized	2,896	3,484
Accumulated acquisition value, closing balance	131,744	128,848
Closing balance at the end of the year	131,744	128,848

#### **NOTE 8 - PATENTS**

(Amounts in kSEK)	2022	2021
Acquisition value, opening balance	7,314	6,544
Acquisitions	799	770
Accumulated acquisition value, closing balance	8,113	7,314
Closing balance at the end of the year	8,113	7,314

#### **NOTE 9 - EQUIPMENT, TOOLS, FIXTURES AND FITTINGS**

(Amounts in kSEK)	2022	2021
Acquisition value, opening balance	4,312	3,940
Acquisitions	134	373
Utgående ackumulerade anskaffningsvärden	4,446	4,312
Depreciation, opening balance	-3,237	-2,861
Depreciations	-356	-376
Accumulated depreciation, closing balance	-3,593	-3,237
Closing balance at the end of the year	853	1,075



#### **NOT 10 - SHARES IN GROUP COMPANIES**

In December 2022, Spago Nanomedical AB incorporated a fully owned Australian subsidiary in order to take advantage of the innovation support and research and development opportunities available in the region.

Name	CIN	Registered office	Share of equity	Number of shares	Net booked value (Amounts in kSEK)
Spago Nanomedical AU Pty Ltd	45 664 495 283	Adelaide, Australia	100%	100	1

#### **NOTE 11 - NUMBER OF SHARES AND SHARE CAPITAL**

	2022	2021
B shares		
Opening number of shares	41,182,287	31,544 517
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
Share issue registered on 2022-07-19	48,682,275	-
Share issue registered on 2022-07-20	1,079,161	-
Closing number of shares	90,943,723	41,182,287

According to the registered articles of association of Spago Nanomedical, the share capital shall be between SEK 40,000,000 and SEK 160,000,000, divided on no less than 40,000,000 and no more than 160,000,000 shares. The shares are priced in SEK and each share has a quota value of SEK 1.

#### **NOTE 12 - ACCRUALS AND DEFERRED INCOME**

(Amounts in kSEK)	2022	2021
Accrued salaries and holiday pay	1,502	1,424
Accrued board fees incl. social security contributions	58	62
Other items	2,017	1,059
Total	3,578	2,545



#### **NOTE 13 - ITEMS NOT INCLUDED IN CASH FLOW**

(Amounts in kSEK)	2022	2021
Depreciation	356	376
Total	356	376

#### **NOTE 14 - CASH FLOW FROM NEW ISSUES OF SHARES AND WARRANTS**

(Amounts in kSEK)	2022	2021
Swedish Companies Registration Office 2022-07-19	58,419	-
Swedish Companies Registration Office 2021-03-09	-	69,146
Transaction costs <sup>1</sup>	-6,762	-4,938
Total	51,657	64,208

<sup>1.</sup> Some guarantors in the rights issue chose to receive compensation in the form of new shares. These transactions thus did not generate a cash flow impact.

#### **NOT 15 - RECONCILIATION OF EFFECTIVE TAX**

(Amounts in kSEK)	2022	2021
Profit or loss before tax	-39,197	-39,097
Tax under applicable tax rate 20,6% (20,6%)	8,075	8,049
Non-deductible expenses	-5	-6
Tax adjustments	1,683	1,663
Tax effect on loss carry-forward non capitalized	-9,753	-9,706
Total	-	-

#### **NOTE 16 - RELATED PARTY TRANSACTIONS**

No transactions with related parties to report.

#### NOT 17 - PROPOSED APPROPRIATION OF THE COMPANY'S PROFIT OR LOSS

(Amounts in kSEK)	2022
The following funds (SEK) are available to the Annual General Meeting:	
Share premium reserve	257,145,996
Retained earnings	-199,849,696
Net profit or loss for the year	-39,196,936
Total	18,099,363
The Board of Directors proposes the following distribution of funds:	
To be carried forward	18,099,363
Total	18,099,363

#### **NOTE 18 - SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD**

 The paper, titled "Characterization and Efficacy of a Nanomedical Radiopharmaceutical for Cancer Treatment", was published in the peer reviewed scientific journal ACS Omega. The results shows that the candidate drug <sup>177</sup>Lu-SN201 accumulates in tumors to the same extent as a comparable market approved benchmark and is well suited for systemic treatment of cancer. Furthermore, <sup>177</sup>Lu\_SN201 delays tumor growth and prolongs survival in a preclinical model of colon cancer.



### Signatures

Lund, March 29, 2023

<b>Eugen Steiner</b> Chairman of the Board	<b>Mats Hansen</b> Chief Executive Officer	Sten Nilsson	
licklas Westerholm	 Kari Grønås	Peter Leander	

Our auditor's report was submitted on March, 29, 2023

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 2022. The annual accounts of the company are included on pages 24-39 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 2022 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 2022 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 2023-03-29

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.

#### CT

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 high-frequency 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



The Annual General Meeting will be held on May 10, 2023.

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 2023	May 9, 2023
Annual General Meeting	May 10, 2023
Interim report Q2 2023	August 23, 2023
Interim report Q3 2023	November 8, 2023



Spago Nanomedical AB (publ) org.nr. 556574-5048

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