SPAGO NANOMEDICAL AB

Year-end report

January- December, 2021

Good progress in the projects

OCTOBER – DECEMBER IN BRIEF

- Net sales for the quarter amounted to KSEK 99 (KSEK 175).
- The loss for the quarter amounted to KSEK –11,293 (KSEK -4,624).
- Operating expenses for the quarter amounted to KSEK -13,078 (KSEK -7,161).
- Earnings per share, before and after dilution, for the quarter amounted to SEK -0.27 (SEK -0.15).
- Cash and cash equivalents at the end of the quarter amounted to KSEK 52,460 (KSEK 28,448).

JANUARY – DECEMBER IN BRIEF

- Net sales for the year amounted to KSEK 660 (KSEK 342).
- The loss for the year amounted to KSEK -39,071 (KSEK -18,928).
- Operating expenses for the year amounted to KSEK -45,723 (KSEK -26,207).
- Earnings per share, before and after dilution, for the year amounted to SEK -0.99 (SEK -0.70).

SIGNIFICANT EVENTS DURING THE QUARTER

- The regulatory preclinical program with Tumorad® (^{177}Lu-SN201) were completed and show a good safety margin for clinically relevant doses.
- All patients in the second dose group in the company's ongoing Phase I clinical trial SPAGOPIX-01 with the tumor-selective contrast agent SpagoPix (SN132D) were recruited.
- Agreement was signed with the global CRO Cmed Group Limited for the development of the first clinical study with the company's therapy project Tumorad.

SIGNIFICANT EVENTS AFTER THE QUARTER

- Interim results from the second dose group in SPAGOPIX-01 show that SN132D is well tolerated and provides clear contrast enhancement in MRI images of solid tumors in the breast, as well as in the pancreas and liver. Based on the results, the company has decided to continue the study in breast cancer and in addition, to expand to also include patients with pancreatic and liver cancer.
- Results from a preclinical model for colorectal cancer show that 177Lu-SN201 reduces tumor growth and prolongs survival by 39% compared to the control group.

OTHER

- The Board of Directors proposes that no dividend is paid for the financial year 2021.

CEO STATEMENT

In 2021, we continued to make good progress with our projects, despite the still ongoing Covid-19 pandemic, and the fourth quarter turned out to be a particularly busy period, where we passed a few important milestones with both SpagoPix and Tumorad. We could in fact start the new year with some further exciting news around both projects. This makes me believe we have an exciting year ahead of us.

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

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

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

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

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

Data from the preclinical studies, together with other documentation, will form the basis for the first clinical trial application for Tumorad. The plan is to submit the application and start the studies in humans in 2022. The aim of the first in human trial is to document safety at different doses of ^{177}Lu-SN201 in cancer patients as well as to evaluate signs of early proof-of-concept.

The preparations for Tumorad clinical development are ongoing at full speed, and a key person in this process is of course Paul Hargreaves, who joined as Chief Development Officer. With almost 30 years of experience in clinical development from Pfizer and Quantiles, among others, Paul significantly strengthens the team to allow further acceleration of our critical work going forward.

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

Strengthened by these important milestones, I believe we have an exciting year ahead of us. At the same time, we continue to carefully monitor the development of the Covid-19 pandemic, and we take every precaution to ensure that patients, healthcare staff and our organization are safe and well, and that our operations continue according to plan. I look forward to updating you as our projects continue to progress.

Mats Hansen, CEO Spago Nanomedical AB

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

SPAGO NANOMEDICAL IN BRIEF

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

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

***SpagoPix** is developing a gadolinium-free contrast agent for MRI with better precision in images of tumors and metastases. Imaging with improved precision increases the possibilities for successful treatment and survival.*

***Tumorad** is focused on the development of a completely form of radionuclide therapy for tumor-selective radiation treatment of cancer. The need for new radionuclide therapies for the treatment of difficult-to-threat, spread or aggressive tumors is great.*

*Spago Nanomedical's **vision** is to engage in competitive and successful development of products that increase the survival and quality of life for 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.*

Spago Nanomedical´s share is listed on Nasdaq First North Growth Market (ticker: SPAGO).

PROJECT - SPAGOPIX

BACKGROUND

The SpagoPix project has the potential to significantly improve the imaging of tumors and metastases compared to conventional contrast agents for magnetic resonance imaging (MRI). Improved methods for accurate visualization and diagnosis of tumors increase the likelihood of successful treatment, and thereby the patients' chances of survival.

The product candidate within SpagoPix, SN132D, is designed for physiological and selective accumulation in tumors via the scientifically well-established mechanism "Enhanced Permeability and Retention (EPR) effect"[1]. Furthermore, the contrast agent has a significantly better ability to amplify the signal measured in MRI examinations (relaxivity) compared with current contrast agents.

The combination of the tumor-selective mechanism of action and the high signal strength gives MRI images better contrast between cancer tissue and the surrounding tissue, which creates better opportunities to detect small and aggressive tumors with high specificity, and provides a more accurate and clearer image of the tumor. This reduces the risk that the surgeon will have to perform another operation if it turns out that the margins for healthy tissue have been too small. It also reduces the risk of the tumor being missed completely, which can have devastating consequences for the patient as the tumor can grow in the meantime and reach the advanced stage, and as such significantly worsen the prognosis for successful treatment. In addition, SN132D can help reduce the risk of false positive findings that often lead to additional biopsies and diagnostic procedures, and a great deal of suffering and anxiety for the patient.

In addition to the good diagnostic properties, SN132D is also free of gadolinium, an element that is found in all clinically used MRI contrast agents at present. Gadolinium has been shown to, among other things, accumulate in the brain[2], which has led to several authorities introducing restrictions on the use of gadolinium-based MRI contrast agents. SN132D is instead based on manganese, a naturally occurring element that is essential for many functions in the human body.

Together, these properties make SN132D a unique contrast agent with the potential to significantly improve the imaging of tumors and metastases compared to conventional MRI contrast agents, and thereby allows more efficient surgery, screening of high-risk patients without ionizing radiation, monitoring of preoperative treatment, and even follow-up of patients after surgery.

MARKET

The development of the SpagoPix project initially focuses on MRI examination of breast cancer, a disease that annually affects approximately 2.3 million people globally. Already today, MRI is a clinical practice with several different areas of application in cancer, and a gadolinium-free contrast agent with higher precision can both take market shares from existing preparations and increase its use further. Based on the mechanism of action of SN132D, there is an opportunity to broaden its use further, both in breast cancer and in other forms of solid tumors, as well as the pancreas. A tumor-selective special product, free of gadolinium, is expected to be priced higher than current products. This means that the possible market size in the area of breast cancer alone is very attractive. With use in additional indications, the maximum market can be expected to be significant.

[1] Eriksson et al., 2014
[2] Kanda et al., 2014, Radiol. 270: 834-841; McDonald et al., 2015, Radiol. 275: 772-782

STATUS

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

Recently, positive results were reported based on analysis of the first two dose groups with a total of 12 patients showing that SN132D gives a positive contrast in MRI images of breast cancer tumors in humans while maintaining a good safety profile. In addition to confirming that SN132D can improve the diagnosis and monitoring of suspected and diagnosed breast cancer with MRI, the results also confirm the ability of the company's unique platform material to accumulate in solid tumors in humans. This allows for the use of the nanomaterial also for therapeutic purposes.

In addition to the positive contrast in breast cancer tumors, all MRI images in the study show that SN132D also generates good contrast in the pancreas and liver. This has prompted Spago Nanomedical to investigate the potential of SpagoPix as an MRI contrast agent in these areas as well. In initial discussions, radiologists in Europe and the United States point out that there is a clear need to be able to identify and follow patients with various forms of precursors to cancer in these organs.

The study continues with the inclusion of additional breast cancer patients and is broadened to also include patients with pancreatic cancer which is suspected to have been spread to the liver. This provides an opportunity for an expanded patient base, a faster path to completion, and strengthening of the project. In the next stage, SN132D will be tested in larger clinical studies and/or in different indications prior to market approval. Spago Nanomedical's strategy is based on the licensing of projects in the clinical phase. On the basis of interim data, which shows good contrast enhancement in tumors and target organs without disturbing background contrast, the company is currently evaluating the commercial possibilities.

PROJECT - TUMORAD

BACKGROUND AND MARKET

Tumorad focuses on tumor-selective radiation therapy of cancer with a clinically relevant radioactive isotope bound to Spago Nanomedical's unique nanoparticles. As with the contrast agent SpagoPix, the Tumorad particles have been designed for physiological accumulation in tumors. The local accumulation allows for the delivery of a customized radiation dose with sufficient strength to treat the tumors while minimizing unwanted effects on surrounding tissue.

Despite important advances in the treatment of disseminated cancer, long-term survival is in many cases still unsatisfactory. Surgery, external radiation therapy, and chemotherapy are seldom curative and often have side effects that limit treatment options. Internal radiation therapy, so-called radionuclide therapy (RNT), is a valuable alternative or complement to existing treatment, especially in cases of disseminated or aggressive cancer. A few drugs are used clinically at present, but unlike those that target specific cancers, Tumorad has the advantage of providing the opportunity to treat different types of solid tumors, and as such has a potentially higher market value.

Interest in RNT is very high and is shown not least by a number of deals in recent years where large pharmaceutical companies have acquired or invested billions in RNT projects. Today there are just over a handful of approved RNT products and the market is expected to grow rapidly in steps with further market approvals, increased subsides, and a remaining large medical need. Tumorad is expected to be used both as a complement to surgery, chemotherapy, and immunotherapies, as well as first treatment options. This opens up opportunities for optimized development and for broad use in the market. Based on the number of people who die annually from disseminated and inoperable cancer in indications with a documented EPR effect, and a price on a par with current preparations, the annual market potential for Tumorad is estimated to amount to billions.

STATUS

As the core of the Tumorad particles is based on the same platform as the nanoparticles used for SpagoPix, there are significant synergies between the projects with regard the material's structure and production.

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

FINANCIAL DEVELOPMENT

RESULTS

Operating expenses amounted to KSEK -13,078 (KSEK -7,161) for the quarter and KSEK -45,723 (KSEK -26,207) for the year. The higher costs are primarily related to the regulatory preclinical studies and start of the GMP manufacturing required to initiate clinical phase I/II studies of the Tumorad project. The increased costs are also related to business development of SpagoPix and change of marketplace for the company's share to Nasdaq First North Growth Market.

Total revenue amounted to KSEK 1,757 (KSEK 2,499) for the quarter and KSEK 6,532 (KSEK 7,245) for the year, and relates to development expenses and patent expenses for the SpagoPix project that were capitalized in the balance sheet during the period.

The operating result amounted to KSEK -11,321 (KSEK -4,661) for the quarter and KSEK -39,192 (KSEK -18,928) for the year. Earnings per share before and after dilution amounted to SEK -0.27 (SEK -0.15) for the quarter and SEK -0.99 (SEK -0.70) for the year.

INVESTMENTS AND FINANCIAL POSITION

At the end of the quarter, cash and cash equivalents amounted to KSEK 52,460 (KSEK 28,448).

Cash flow from operating activities amounted to KSEK -12,127 (KSEK -5,095) for the quarter and KSEK -35,569 (KSEK -18,766) for the year. The increased negative cash flow in the quarter is driven by the ongoing clinic preparatory activities in the Tumorad project. Cash flow from investment activities amounted to KSEK -1,399 (KSEK -2,154) for the quarter and KSEK -4,627 (KSEK -6,383) for the year. The investments mainly consist of intangible assets, which are the development expenses and patent expenses that were capitalized during the period. Cash flow from financing activities amounted to KSEK 0 (KSEK -2) for the quarter and KSEK 64,208 (KSEK 41,448) for the year. The cash flow for the year relates to the net proceeds received in the rights issue, including the over-allotment issue, as well as the directed share issue that was carried out to guarantors during the first quarter. A total of 9,637,770 new shares were issued, bringing in MSEK 72.3, before transaction costs.

At the end of the quarter, the company's equity amounted to KSEK 184,812 (KSEK 159,675) and the equity ratio to 96,5 percent (98.1 percent). Equity per share, before dilution, amounted to SEK 4,49 (SEK 5.06).

SHARES AND SHARE CAPITAL

The number of registered shares as of December 31, 2021 amounted to 41,182,287. Since March 26, 2021 the share has been traded on the Nasdaq First North Growth Market, with the ticker SPAGO. The company then changed trading venue from Spotlight Stock Market, where it has been listed since the end of 2012. The share's quota value amounts to SEK 1, whereby the share capital is equal to the number of shares. The number of shareholders at the end of the were 2,791. The largest owners at the end of the period were Peter Lindell, with companies and related parties, Avanza Pension, Mikael Lönn, Ranny Davidoff and Eva Redhe.

SUBSCRIPTION WARRANTS

The company has a total of three outstanding share-related incentive programs. For further information, see the description in Note 4 of the company's annual report for 2020.

INCOME STATEMENT

Amounts in KSEK	Oct-Dec 2021	Oct-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Income				
Net sales	99	175	660	342
Internal work capitalized	269	338	1 376	2 580
External work capitalized	946	1 618	2 879	3 192
Other operating income	444	368	1 617	1 132
Total income	**1 757**	**2 499**	**6 532**	**7 245**
Operating costs				
Project costs	-7 040	-1 771	-21 691	-6 530
Other external costs	-1 824	-1 323	-7 542	-5 212
Personnel costs	-4 091	-3 966	-15 990	-14 095
Depreciation/amortization of fixed assets	-86	-101	-376	-362
Other operating costs	-37	0	-125	-7
Total operating costs	**-13 078**	**-7 161**	**-45 723**	**-26 207**
OPERATING RESULT	**-11 321**	**-4 661**	**-39 192**	**-18 962**
Financial items				
Interest income and similar items	28	37	120	34
Total financial items	**28**	**37**	**120**	**34**
RESULT AFTER FINANCIAL ITEMS	**-11 293**	**-4 624**	**-39 071**	**-18 928**
PROFIT/LOSS FOR THE PERIOD	**-11 293**	**-4 624**	**-39 071**	**-18 928**

BALANCE SHEET

ASSETS

Amounts in KSEK	**Dec 31, 2021**	**Dec 31, 2020**
Non-current assets		
Intangible		
Capitalized expenditure for development work	128 848	125 364
Patents	7 314	6 544
Materiella anläggningstillgångar		
Equipment, tools, fixtures and fittings	1 075	1 078
Total non-current assets	**137 237**	**132 986**
Current assets		
Accounts receivables	38	31
Other current assets	856	676
Prepaid expenses and accrued income	1 033	679
Cash and cash equivalents	52 460	28 448
Total current assets	**54 387**	**29 834**
TOTAL ASSETS	**191 624**	**162 820**

EQUITY AND LIABILITIES

Amounts in KSEK	**Dec 31, 2021**	**Dec 31, 2020**
Equity		
Equity	184 812	159 675
Total eqiuty	**184 812**	**159 675**
Current liabilities		
Accounts payables	3 860	927
Other current liabilities	407	527
Accrued expenses and deferred income	2 545	1 692
Total current liabilities	**6 812**	**3 146**
TOTAL EQUITY AND LIABILITIES	**191 624**	**162 820**

CHANGES IN EQUITY

Amounts in KSEK	Share capital	Dev. fund	Share prem. reserve	Retained earnings	Profit/ loss	Total equity
Opening balance Jan 1, 2020	**21 030**	**74 392**	**170 339**	**-107 919**	**-20 211**	**137 631**
Appropriations of net results according to the AGM's resolution				-20 211	20 211	**0**
Share issue	10 515		36 802			**47 317**
Issuance costs			-6 346			**-6 346**
Capitalization of development expenses		5 772		-5 772		**0**
Profit/loss					-18 928	**-18 928**
Closing balance Dec 31, 2020	**31 545**	**80 164**	**200 795**	**-133 901**	**-18 928**	**159 675**
Opening balance, Jan 1, 2021	**31 545**	**80 164**	**200 795**	**-133 902**	**-18 928**	**159 675**
Appropriations of net results according to the AGM's resolution				-18 928	18 928	**0**
Share issue	9 638		62 646			**72 283**
Issuance costs			-8 075			**-8 075**
Capitaliazation of development expenses		4 254		-4 254		**0**
Profit/loss					-39 071	**-39 071**
Closing balance Dec 31, 2021	**41 182**	**84 418**	**255 366**	**-157 083**	**-39 071**	**184 812**

CASHFLOW STATEMENT IN SUMMARY

Amounts in KSEK	Oct-Dec 2021	Oct-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Cash flow from operating activities and before changes in working capital	**-11 115**	**-4 523**	**-38 695**	**-18 566**
Changes in working capital	-1 012	-572	3 126	-200
Cash flow from operating activities	**-12 127**	**-5 095**	**-35 569**	**-18 766**
Cash flow from investing activities	-1 399	-2 154	-4 627	-6 383
Cash flow from financing activities	0	-2	64 208	41 448
Cash flow for the period	**-13 526**	**-7 251**	**24 012**	**16 299**
Cash and cash equivalents at the beginning of the period	65 987	35 699	28 448	12 149
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	**52 460**	**28 448**	**52 460**	**28 448**

DATA PER SHARE

	Oct-Dec 2021	Oct-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Earnings per share, before and after dilution, SEK	-0.27	-0.15	-0.99	-0.70
Equity per share, before dilution, SEK	4.49	5.06	4.49	5.06
Average number of shares before dilution	41 182 287	31 544 517	39 410 870	27 177 699
Average number of shares after dilution	41 744 839	32 107 069	39 973 422	27 740 251
Number of shares at the end of the period	41 182 287	31 544 517	41 182 287	31 544 517

OTHER KEY FIGURES

	Oct-Dec 2021	Oct-Dec 2020	Jan-Dec 2021	Jan-Dec 2020
Average number of employees	16	15	16	15
Equity ratio, %	96.5	98.1	96.5	98.1

FINANCIAL DEFINITIONS

EQUITY RATIO
Equity in relation to total balance sheet

EQUITY PER SHARE, BEFORE DILUTION
Equity in relation to the number of shares at the end of the period

EARNINGS PER SHARE, BEFORE DILUTION
Result for the period in relation to the average number of shares

EARNINGS PER SHARE, AFTER DILUTION
Result for the period 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 in cases where a conversion entails a lower loss per share.

SIGNIFICANT RISKS AND UNCERTAINTIES

Spago Nanomedical's operations are exposed to a number of risk factors and elements of uncertainty, both operational and financial. Risk and uncertainty factors mainly consist of risks related to research and development, clinical trials, patents and other rights, collaborations and commercialization of projects, and financing. A detailed account of the company's significant financial risks is described on pages 22–24 in the annual report for 2020.

ACCOUNTING PRINCIPLES

Spago Nanomedical AB (publ) reports in accordance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's general advice BFNAR2012:1. The company's accounting principles are described in Note 1 in the company's annual report for 2020.

Amounts are expressed in KSEK, which in this report refers to thousands of Swedish kronor. Amounts in parentheses refer to comparative figures from the previous year.

TRANSACTIONS WITH RELATED PARTIES

No transactions with related parties to report.

INVESTOR RELATIONS

This report can be downloaded from the website www.spagonanomedical.se
or ordered from the company by e-mail or mail: Spago Nano Medical AB, Scheelevägen 22, 223 63 Lund, Sweden.

For further information, please contact CEO Mats Hansen on 046 811 88 or e-mail mats.hansen@spagonanomedical.se or CFO Hanna Olsson on 0763 14 80 63 or e-mail hanna.olsson@spagonanomedical.se

OTHER

This report has not been reviewed by the company's auditors. This is a translation of the Swedish interim report.

CERTIFICATION

The board and the CEO ensure that the interim report provides a fair overview of the company's operation, financial position and results and describes significant risks and uncertainties to which the company is exposed.

Lund February 2, 2021

Spago Nanomedical AB (publ)
Org.no: 556574-5048

Eugen Steiner
Chairman of the board

Mats Hansen
CEO

Sten Nilsson

Peter Leander

Nicklas Westerholm

Kari Grønås