SPAGO NANOMEDICAL AB

Interim report

January- March 2022

Several important milestones in the first quarter

JANUARI – MARCH IN BRIEF

- Net sales for the quarter amounted to KSEK 211 (KSEK 100).
- The loss for the quarter amounted to KSEK –9,880 (KSEK -6,068).
- Operating expenses for the quarter amounted to KSEK -11,100 (KSEK -7,439).
- Earnings per share, before and after dilution, for the quarter amounted to SEK -0.24 (SEK -0.18).
- Cash and cash equivalents at the end of the quarter amounted to KSEK 40,992 (KSEK 85,225).

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

SIGNIFICANT EVENTS AFTER THE QUARTER

- Extended patent protection for SpagoPix in Japan until at least 2038.

CEO STATEMENT

The positive and intense spirit that characterized last year continued during the first quarter of this year with good news from both our projects, SpagoPix (SN132D) and Tumorad® (^{177}Lu-SN201). Of course, we are also following developments with regard to both Covid-19 and the tragic war in Ukraine; we do not currently see any immediate impact of these on our operations.

A priority area for us is to maximize the value of SPAGOPIX-01 - our Phase I clinical trial with the contrast agent SN132D. To this end, we have amended the study so that it can also include patients with pancreatic cancer. This is a cost-effective way to show the potential of SN132D in another cancer indication, thus enabling increased value. The recruitment of patients for the study with suspected or confirmed pancreatic cancer that has spread to the liver is ongoing.

At the same time, I would like to emphasize that there is no doubt that the study is positive. The interim results from the second dose group show that SN132D is well tolerated and provides clear contrast in MRI images of breast tumors, as well as in the pancreas and liver tissue. The study's internal safety committee has found that SN132D is safe at both dose levels.

The results also confirm that SN132D accumulates in solid tumors in humans, which, in addition to safety, has been our main goal of the study. We have thus confirmed that the principle on which we have built our platform - physiological enrichment of nanoparticles in tissue with EPR effect - works in the body and with the equipment available in hospitals. The very good correlation between preclinical and clinical results is of great importance and strengthens our confidence about the possibilities of using the platform also for therapy with Tumorad.

After showing that SN132D clearly accumulates in cancerous tumors and provides images with both high precision and positive contrast, additionally showing the tumor without background noise, we continue the dialogue with potential licensees. Our conclusion from these dialogues so far is that the study program should be expanded to more indications for a deal to be interesting. By including patients with cancer of the pancreas, we can demonstrate the greater potential of SN132D. We are also evaluating the possibilities in other indications where the EPR effect is well documented, both within and outside the cancer area. With the results we have achieved so far, we see good opportunities to position SN132D in important indications with a great clinical need for improved imaging diagnostics.

With the knowledge from the SpagoPix project, Tumorad has been able to develop at a very high pace. Now that we have confirmed that our materials accumulate in malignant tumor tissue in humans as well, our main focus is to enter into clinical trials as soon as possible with the drug candidate ^{177}Lu-SN201, our nanoparticle SN201 loaded with the clinically proven radioisotope Lutetium-177 (^{177}Lu). We plan to initiate the first study in humans during the year.

The work of optimizing the clinical development and the path to market approval for ^{177}Lu-SN201 is in an intensive phase. We intend to apply for orphan drug status for ^{177}Lu-SN201 for the treatment of ovarian cancer, provided that preclinical studies show strong results here as well. At the same time, we are also evaluating other ways to develop the ^{177}Lu-SN201 in both broad and more niche indications.

In parallel with developing a clinical program, we continue to build the preclinical package around the candidate drug. In January, we were able to show that ^{177}Lu-SN201 delays tumor growth and prolongs survival by 39% compared to the control group in a model for colorectal cancer, a statistically significant improvement. The results broaden our previous positive results with the drug candidate in a preclinical model for aggressive breast cancer. ^{177}Lu has been

clinically validated for long. With this, we show the strength and breadth of the technology and lay the foundation for clinical development.

Overall, we see a very large potential in the Tumorad project. Already at the current stage of development, we see a value for ^{177}Lu-SN201 which in the orphan drug indication ovarian cancer alone is significant and, with an optimized development strategy, rapidly increasing. To this can be added the value in other, larger indications.

In step with the positive development, several new patent applications have recently been submitted to extend patent protection and strengthen Tumorad's future position.

Tumorad is unique, and we see a clear interest for the project. In preparation for clinical trials, we have initiated dialogues with specialist investors. In this context, we can observe a great interest in radionuclide therapy among both investors and pharmaceutical companies, which has recently resulted in a number of investments and acquisitions in this area.

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

Mats Hansen, CEO
Spago Nanomedical AB

"Already at the current stage of development, we see a value for ^{177}Lu-SN201 which in the orphan drug indication alone is significant and, with an optimized development strategy, rapidly increasing."

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 to 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. SN132D can also provide the opportunity for better imaging of other disease states where the EPR effect is pronounced and thus open to earlier detection and more effective treatment of cancer and other diseases with a great medical need for improved imaging.

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 SN312D, there is an opportunity to broaden the use further both in the field of cancer, in breast cancer and other forms of solid tumors such as. pancreas, and in other diseases such as endometriosis. A tissue-selective product, free of gadolinium, is expected to be priced higher than today's products. This means that the possible market size is very attractive.

[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 24 patients with confirmed cancer in breast and pancreas, 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 cancer tumors in breast and pancreas with suspicious spread to the liver.

During the first quarter, positive results were reported based on analysis of the second dose group 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 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.

In addition to the positive contrast in breast cancer tumors, all MRI images in the study show that SN132D also generates good contrast in the pancreas and liver. Radiologists in Europe and the United States point out that there is a clear need to be able to identify and follow patients with various forms of precursors to cancer in pancreas and to determine if the cancer has spread to the liver. In total, 12 patients with confirmed breast cancer have been included in the study. To enable additional value in the project at an early clinical development stage, the study was broadened to also include patients with pancreatic cancer which is suspected to have been spread to the liver. The study continues with the inclusion of patients to expand the patient base and the information required for next stage.

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.

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 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. During the first quarter 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 the latter part of 2022.

FINANCIAL DEVELOPMENT

RESULTS

Operating expenses amounted to KSEK -11,100 (KSEK -7,439) for the quarter. The higher operating costs are primarily related to the production of material for the clinical phase I/II study in the Tumorad-project 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. The increased costs are also related to business development of SpagoPix.

Total revenue amounted to KSEK 1,198 (KSEK 1,352) for the quarter 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 -9,902 (KSEK -6,087) for the quarter. Earnings per share before and after dilution amounted to SEK -0.24 (SEK -0.18) for the quarter.

INVESTMENTS AND FINANCIAL POSITION

At the end of the quarter, cash and cash equivalents amounted to KSEK 40,992 (KSEK 85,225).

Cash flow from operating activities amounted to KSEK -10,929 (KSEK -6,504) for the quarter. 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 -540 (KSEK -982) for the quarter. The investments mainly consist of intangible assets, which are the development and patent expenses that were capitalized during the period. Cash flow from financing activities amounted to KSEK 0 (KSEK -64,263) for the quarter. The cash flow from last 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. 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 174,931 (KSEK 217,869) and the equity ratio to 96.8 percent (98,4 percent). Equity per share, before dilution, amounted to SEK 4.25 (SEK 5.29).

SHARES AND SHARE CAPITAL

The number of registered shares as of March 31, 2022 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 period were 2,723. 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 2021.

INCOME STATEMENT

Amounts in KSEK	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Income			
Net sales	211	100	660
Internal work capitalized	164	339	1 376
External work capitalized	376	559	2 879
Other operating income	447	354	1 617
Total income	**1 198**	**1 352**	**6 532**
Operating costs			
Project costs	-4 573	-1 394	-21 691
Other external costs	-2 036	-2 151	-7 542
Personnel costs	-4 208	-3 782	-15 990
Depreciation/amortization of fixed assets	-89	-104	-376
Other operating costs	-194	-8	-125
Total operating costs	**-11 100**	**-7 439**	**-45 723**
OPERATING RESULT	**-9 902**	**-6 087**	**-39 192**
Financial items			
Interest income and similar items	22	19	120
Total financial items	**22**	**19**	**120**
RESULT AFTER FINANCIAL ITEMS	**-9 880**	**-6 068**	**-39 071**
PROFIT/LOSS FOR THE PERIOD	**-9 880**	**-6 068**	**-39 071**

BALANCE SHEET

ASSETS

Amounts in KSEK	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
Non-current assets			
Intangible			
Capitalized expenditure for development work	129 327	126 116	128 848
Patents	7 375	6 690	7 314
Materiella anläggningstillgångar			
Equipment, tools, fixtures and fittings	986	1 058	1 075
Total non-current assets	**137 688**	**133 864**	**137 237**
Current assets			
Accounts receivables	87	0	38
Other current assets	696	1 419	856
Prepaid expenses and accrued income	1 184	814	1 033
Cash and cash equivalents	40 992	85 225	52 460
Total current assets	**42 960**	**87 457**	**54 387**
TOTAL ASSETS	**180 647**	**221 322**	**191 624**

EQUITY AND LIABILITIES

Amounts in KSEK	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
Equity			
Equity	174 931	217 869	184 812
Total eqiuty	**174 931**	**217 869**	**184 812**
Current liabilities			
Accounts payables	1 545	1 174	3 860
Other current liabilities	414	429	407
Accrued expenses and deferred income	3 757	1 850	2 545
Total current liabilities	**5 716**	**3 453**	**6 812**
TOTAL EQUITY AND LIABILITIES	**180 647**	**221 322**	**191 624**

CHANGES IN EQUITY

Amounts in KSEK	Share capital	Dev. fund	Share prem. reserve	Retained earnings	Profit/ loss	Total equity
Opening balance Jan 1, 2021	**31 545**	**80 164**	**200 795**	**-133 902**	**-18 928**	**159 674**
Share issue	9 638		62 646			**72 284**
Issuance costs			-8 020			**-8 020**
Capitalization of development expenses		898		-898		**0**
Profit/loss					-6 068	**-6 068**
Closing balance Mar 31, 2021	**41 182**	**81 062**	**255 420**	**-134 800**	**-24 996**	**217 869**
Opening balance Apr 1, 2021	**41 182**	**81 062**	**255 420**	**-134 800**	**-24 996**	**217 869**
Appropriations of net results according to the AGM's resolution				-18 928	18 928	**0**
Issuance costs			-55			**-55**
Capitalization of development expenses		3 356		-3 356		**0**
Profit/loss					-33 003	**-33 003**
Closing balance Dec 31, 2021	**41 182**	**84 418**	**255 366**	**-157 083**	**-39 071**	**184 812**
Opening balance, Jan 1, 2022	**41 182**	**84 418**	**255 366**	**-157 083**	**-39 071**	**184 812**
Capitaliazation of development expenses		540		-540		**0**
Profit/loss					-9 880	**-9 880**
Closing balance Mar 31, 2022	**41 182**	**84 958**	**255 366**	**-157 623**	**-48 951**	**174 931**

CASHFLOW STATEMENT IN SUMMARY

Amounts in KSEK	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Cash flow from operating activities			
and before changes in working capital	**-9 813**	**-6 173**	**-38 695**
Changes in working capital	-1 116	-331	3 126
Cash flow from operating activities	**-10 929**	**-6 504**	**-35 569**
Cash flow from investing activities	-540	-982	-4 627
Cash flow from financing activities	0	64 263	64 208
Cash flow for the period	**-11 469**	**56 776**	**24 012**
Cash and cash equivalents at the beginning of the period	52 460	28 448	28 448
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	**40 992**	**85 225**	**52 460**

DATA PER SHARE

	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Earnings per share, before and after dilution, SEK	-0.24	-0.18	-0.99
Equity per share, before dilution, SEK	4.25	5.29	4.49
Average number of shares before dilution	41 182 287	33 998 207	39 410 870
Average number of shares after dilution	41 744 839	34 560 759	39 973 422
Number of shares at the end of the period	41 182 287	41 182 287	41 182 287

OTHER KEY FIGURES

	Jan-Mar 2022	Jan-Mar 2021	Jan-Dec 2021
Average number of employees	15	16	16
Equity ratio, %	96.8	98.4	96.5

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 25-26 in the annual report for 2021.

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 2021.

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 April 27, 2022

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