SPAGO NANOMEDICAL AB

Interim report

January- September 2022

Intensive preparations to bring Tumorad into clinic

JULY –SEPTEMBER IN BRIEF

- Net sales for the quarter amounted to KSEK 397 (KSEK 195)
- The loss for the quarter amounted to KSEK –8,594 (KSEK -10,103)
- Operating expenses for the quarter amounted to KSEK -10,406 (KSEK -11,756)
- Earnings per share, before and after dilution, for the quarter amounted to SEK -0.11 (SEK -0.26)
- Cash and cash equivalents at the end of the quarter amounted to KSEK 71,234 (KSEK 65,987)

JANUARY – SEPTEMBER IN BRIEF

- Net sales for the year amounted to KSEK 912 (KSEK 561)
- The loss for the year amounted to KSEK -28,039 (KSEK -27,778)
- Operating expenses for the year amounted to KSEK -32,590 (KSEK -32,645)
- Earnings per share, before and after dilution, for the year amounted to SEK -0.51 (SEK -0.67)

SIGNIFICANT EVENTS DURING THE QUARTER

- Spago Nanomedical raised MSEK 51.7 after issue costs in the rights issue, in which the subscription period expired on June 28, 2022. The net proceeds are planned to be used to start the first part of a clinical phase I/IIa study in cancer patients with the company's radionuclide therapy project Tumorad.
- An abstract covering the initial results from the company's Phase I study SPAGOPIX-01 was accepted for poster presentation at the 2022 San Antonio Breast Cancer Symposium® (SABCS) on December 6-10, 2022

SIGNIFICANT EVENTS AFTER THE QUARTER

- No events to report

CEO STATEMENT

Thanks to a successful rights issue at the end of June, we were able to enter the third quarter with strengthened finances. It gives us room to take our radionuclide therapy project Tumorad® (^{177}Lu-SN201) further into clinical development, while within the framework of the previous budget, we can finish the ongoing phase I study with SpagoPix and prepare the project for the next step.

I am very happy and proud of the trust that existing and new shareholders have shown us. Through the capital raising, which added just over SEK 58 million to the company before issue costs, we now have the conditions to focus fully on continuing to build future value for both patients and shareholders.

Above all, we see great potential shareholder value in the development of the Tumorad project, with its unique treatment principle and significant market potential, as well as the increasing interest in radionuclide therapy among both pharmaceutical companies and investors. ^{177}Lu-SN201 belongs to a new generation of radionuclide treatments that provide the opportunity to treat cancer with precision, either as monotherapy or in combination with other drugs. Given that we can demonstrate a good clinical effect in our studies, ^{177}Lu-SN201 can thus become a welcome addition in cancer care.

Our primary focus is now to start clinical studies of ^{177}Lu-SN201 in cancer patients, and as previously announced, we aim to apply for approval for a phase I/IIa clinical study. At the same time as we focus on the preparatory work for the study, intensive preclinical activities are ongoing to demonstrate the breadth of Tumorad's potential treatment area within indications with major medical needs, both as monotherapy and in combination with other drugs. We consider these data to be of great importance for the positioning of the project as well as for laying the foundation for the continued clinical and regulatory strategy.

Another prioritized area for us is the completion of the phase I clinical trial SPAGOPIX-01 with the MRI contrast agent SN132D. We have already seen that SN132D clearly accumulates in cancer tumors and provides images that with both high precision and positive contrast show breast cancer tumors without background noise. A clear evidence of the scientific interest in SN132D is that the abstract covering the initial results from SPAGOPIX-01 has been accepted for poster presentation at the 2022 San Antonio Breast Cancer Symposium® (SABCS), a well respected symposium providing state-of-the-art information on the biology, diagnosis, and therapy of breast cancer to an international audience of 8,000 academics, researchers and physicians from more than 80 countries.

We see good opportunities to position SN132D in additional indications with great clinical need for improved imaging diagnostics. Here we mainly focus on areas with high market potential where the EPR effect (*Enhanced Permeability and Retention effect)* is well documented, both within and outside the cancer area. With strong clinical results and good prospects for SpagoPix, we continue the dialogue with potential development partners.

Strengthened by both the outcome of the rights issue and the continued positive development in our projects, I look forward to updating you on upcoming milestones.

Mats Hansen, CEO Spago Nanomedical AB

"At the same time as we focus on the preparatory work for the study, intensive preclinical activities are ongoing to demonstrate the breadth of Tumorad's potential treatment area within indications with major medical needs, both as monotherapy and in combination with other drugs."

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 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

In order to effectively demonstrate clinical proof of concept for the project and the company's platform technology, 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, 14 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. The company has also showed 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 in parallel with the preparations to apply for approval for a clinical phase I/IIa trial.

FINANCIAL DEVELOPMENT

RESULTS

Operating expenses amounted to KSEK -10,406 (KSEK -11,756) for the quarter and KSEK -32,590 (KSEK -32,645) for the year. The operating costs during the year are primarily related to the production of material for the planned clinical phase I/IIa 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.

Total revenue amounted to KSEK 1,751 (KSEK 1,619) for the quarter and KSEK 4,452 (KSEK 4,774) 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 -8,655 (KSEK -10,137) for the quarter and KSEK -28,138 (KSEK -27,871) for the year. Earnings per share before and after dilution amounted to SEK -0.11 (SEK -0.26) for the quarter and KSEK -0.51 (KSEK -0.67) for the year.

INVESTMENTS AND FINANCIAL POSITION

At the end of the quarter, cash and cash equivalents amounted to KSEK 71,234 (KSEK 65,987).

Cash flow from operating activities amounted to KSEK -9,941 (KSEK -9,767) for the quarter and KSEK -30,663 (KSEK -23,442) for the year. The 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 -885 (KSEK –1-119) for the quarter and KSEK -2,370 (KSEK -3,228) for the year. 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 52,647 (KSEK 0) for the quarter and KSEK 51,807 (KSEK 64,208) for the year. The cash flow in year relates to the net proceeds received in the rights issue, in which the subscription period expired on June 28, 2022.

At the end of the quarter, the company's equity amounted to KSEK 208,314 (KSEK 196,105) and the equity ratio to 98,0 percent (96.5 percent). Equity per share, before dilution, amounted to SEK 2,29 (SEK 4,76).

SHARES AND SHARE CAPITAL

The number of registered shares as of September 30, 2022 amounted to 90,943,723. 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 2,795. The largest owners at the end of the period were Peter Lindell, with companies and related parties, Avanza Pension, Mikael Lönn, Eva Redhe and Nolsterby Invest.

SUBSCRIPTION WARRANTS

The company has a total of two 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	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Jan-Dec 2021
Income					
Net sales	397	195	912	561	660
Internal work capitalized	134	359	389	1 107	1 376
External work capitalized	751	656	1 848	1 933	2 879
Other operating income	469	409	1 303	1 173	1 617
Total income	**1 751**	**1 619**	**4 452**	**4 774**	**6 532**
Operating costs					
Project costs	-4 423	-6 590	-13 331	-14 651	-21 691
Other external costs	-1 730	-1 628	-6 125	-5 717	-7 542
Personnel costs	-4 051	-3 398	-12 523	-11 898	-15 990
Depreciation/amortization of fixed assets	-92	-85	-274	-290	-376
Other operating costs	-111	-55	-337	-88	-125
Total operating costs	**-10 406**	**-11 756**	**-32 590**	**-32 645**	**-45 723**
OPERATING RESULT	**-8 655**	**-10 137**	**-28 138**	**-27 871**	**-39 192**
Financial items					
Interest income and similar items	61	34	99	92	120
Total financial items	**61**	**34**	**99**	**92**	**120**
RESULT AFTER FINANCIAL ITEMS	**-8 594**	**-10 103**	**-28 039**	**-27 778**	**-39 071**
PROFIT/LOSS FOR THE PERIOD	**-8 594**	**-10 103**	**-28 039**	**-27 778**	**-39 071**

BALANCE SHEET

ASSETS

Amounts in KSEK	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
NON-CURRENT ASSETS			
Intangible			
Capitalized expenditure for development work	130 466	127 685	128 848
Patents	7 933	7 263	7 314
Materiella anläggningstillgångar			
Equipment, tools, fixtures and fittings	934	976	1 075
Total non-current assets	**139 333**	**135 923**	**137 237**
CURRENT ASSETS			
Accounts receivables	0	0	38
Other current assets	520	318	856
Prepaid expenses and accrued income	1 511	923	1 033
Cash and cash equivalents	71 234	65 987	52 460
Total current assets	**73 264**	**67 229**	**54 387**
TOTAL ASSETS	**212 597**	**203 152**	**191 624**

EQUITY AND LIABILITIES

Amounts in KSEK	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
Equity			
Equity	208 314	196 105	184 812
Total eqiuty	**208 314**	**196 105**	**184 812**
Current liabilities			
Accounts payables	1 242	3 901	3 860
Other current liabilities	454	434	407
Accrued expenses and deferred income	2 587	2 713	2 545
Total current liabilities	**4 283**	**7 047**	**6 812**
TOTAL EQUITY AND LIABILITIES	**212 597**	**203 152**	**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**	**159 675**
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**
Capitalization of development expenses		3 040		-3 040		**0**
Profit/loss					-27 778	**-27 778**
Closing balance Sep 30, 2021	**41 182**	**83 204**	**255 366**	**-155 869**	**-27 778**	**196 105**
Opening balance Oct 1, 2021	**41 182**	**83 204**	**255 366**	**-155 869**	**-27 778**	**196 105**
Capitalization of development expenses		1 214		-1 214		**0**
Profit/loss					-11 293	**-11 293**
Closing balance Dec 31, 2021	**41 182**	**84 418**	**255 366**	**-157 084**	**-39 071**	**184 812**
Opening balance, Jan 1, 2022	**41 182**	**84 419**	**255 366**	**-157 084**	**-39 071**	**184 812**
Appropriations of net results according to the AGM's resolution				-39 071	39 071	**0**
Share issue	49 761		9 952			**59 714**
Issuance costs			-8 172			**-8 172**
Capitaliazation of development expenses		2 236		-2 236		**0**
Profit/loss					-28 039	**-28 039**
Closing balance Sep 30, 2022	**90 944**	**86 655**	**257 146**	**-198 391**	**-28 039**	**208 314**

CASHFLOW STATEMENT IN SUMMARY

Amounts in KSEK	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Jan-Dec 2021
Cash flow from operating activities and before changes in working capital	**-8 563**	**-10 172**	**-27 864**	**-28 010**	**-38 695**
Changes in working capital	-1 378	405	-2 799	4 568	3 126
Cash flow from operating activities	**-9 941**	**-9 767**	**-30 663**	**-23 442**	**-35 569**
Cash flow from investing activities	-885	-1 119	-2 370	-3 228	-4 627
Cash flow from financing activities	52 647	0	51 807	64 208	64 208
Cash flow for the period	**41 820**	**-10 886**	**18 773**	**37 539**	**24 012**
Cash and cash equivalents at the beginning of the period	29 414	76 873	52 460	28 448	28 448
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	**71 234**	**65 987**	**71 234**	**65 987**	**52 460**

DATA PER SHARE

	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Jan-Dec 2021
Earnings per share, before and after dilution, SEK	-0.11	-0.26	-0.51	-0.67	-0.99
Equity per share, before dilution, SEK	2.29	4.76	2.29	4.76	4.49
Average number of shares before dilution	81 196 060	41 182 287	54 666 782	38 813 909	39 410 870
Average number of shares after dilution	81 425 550	41 744 839	55 137 328	39 376 461	39 973 422
Number of shares at the end of the period	90 943 723	41 182 287	90 943 723	41 182 287	41 182 287

OTHER KEY FIGURES

	Jul-Sep 2022	Jul-Sep 2021	Jan-Sep 2022	Jan-Sep 2021	Jan-Dec 2021
Average number of employees	15	17	15	17	16
Equity ratio, %	98.0	96.5	98.0	96.5	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 November 8, 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