SPAGO NANOMEDICAL AB

Interim report

January- September, 2021

Tumorad® moves closer to clinical trials

JULY – SEPTEMBER IN BRIEF

- Net sales for the quarter amounted to KSEK 195 (KSEK 67).
- The loss for the quarter amounted to KSEK –10,103 (KSEK -4,485).
- Operating expenses for the quarter amounted to KSEK -11,756 (KSEK -6,011).
- Earnings per share, before and after dilution, for the quarter amounted to SEK -0.26 (SEK -0.14).
- Cash and cash equivalents at the end of the quarter amounted to KSEK 65,987 (KSEK 35,699).

JANUARY – SEPTEMBER IN BRIEF

- Net sales for the year amounted to KSEK 561 (KSEK 167).
- The loss for the year amounted to KSEK -27,778 (KSEK -14,304).
- Operating expenses for the year amounted to KSEK -32,645 (KSEK -19,050).
- Earnings per share, before and after dilution, for the year amounted to SEK -0.67 (SEK -0.56).

SIGNIFICANT EVENTS DURING THE QUARTER

- Paul Hargreaves was appointed Chief Development Officer (CDO). Paul will join the management team and have a key role in the clinical development of the company's project portfolio.

SIGNIFICANT EVENTS AFTER THE QUARTER

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

CEO STATEMENT

We continue to make important progress in the projects and during the third quarter we were, not least, able to move Tumorad® closer to clinical studies. The development is proceeding according to plan, and the target is to start the first clinical trial with the candidate drug SN201 in patients with advanced cancer in 2022.

Recruitment for the clinical study SPAGOPIX-01 remains in focus. The target is to complete the current dose group as soon as possible and decide on the next step. The interim results communicated from the study so far show that SpagoPix (SN132D) clearly accumulates in cancerous tumors to provide images of tumors with high precision and positive contrast without disturbing background.

Our platform technology thus provides the opportunity to clinically and precisely accumulate functional nanoparticles in solid tumors. In a preclinical model for aggressive breast cancer, SN201 has shown a positive effect by delaying tumor growth. We thus believe that Tumorad can be an important and effective addition to the treatment arsenal and that SN201 has a great potential against aggressive and spread cancer, and have a place in the growing market for radionuclide-based cancer treatment.

There is currently a lack of effective drugs for advanced stages of several major cancers where mortality is largely due to the tumors continuing to grow or spread. Targeted radionuclide therapy as a treatment for spread cancer has attracted increasing interest in recent years with the development success of big pharma with Novartis in the lead. Already market-approved drugs, and not least completed partnering deals in the field, show that there is a significant value in the radionuclide therapy market. As an example, Coherent Market Insight estimates that the PRRT (Peptide Receptor Radionuclide Therapy) market will grow annually by 27 percent and be worth approximately $ 1.6 billion in 2027.

Paul Hargreaves recently joined Spago Nanomedical as Chief Development Officer, and the appointment of Paul, who has almost 30 years of experience in clinical development from Pfizer, among others, puts further focus on our important work. I am convinced that Paul will be a very valuable asset for our projects, especially in the work of preparing and implementing the clinical development with Tumorad.

We are well set to vigorously progress the projects.

Mats Hansen, CEO Spago Nanomedical AB

“Already market-approved drugs, and not least completed partnering deals in the field, show that there is a significant value in the radionuclide therapy market.”

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 developed to be a gadolinium-free contrast agent for MRI, which enables earlier detection of tumors and metastases. Early detection 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.*

PROJECT - SPAGOPIX

BACKGROUND

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

SpagoPix 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, SpagoPix 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 in the patient. In addition to the good diagnostic properties, SpagoPix 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. SpagoPix is instead based on manganese, a naturally occurring element that is essential for many functions in the human body.

Together, these properties make SpagoPix 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 SpagoPix 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 SpagoPix, 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 SpagoPix (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.

The interim results generated so far from SPAGOPIX-01 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 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. This has prompted Spago Nanomedical to investigate the potential of SpagoPix as an MRI contrast agent in this area 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 this organ.

The study is ongoing, with the inclusion of additional patients in the second dose group to expand the patient base and information for future clinical studies. 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, 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 radionuclide therapy is very high and is shown not least by Novartis' 2018 acquisition of Advanced Accelerator Applications (with Lutathera) and Endocyte (with the phase III product Lu177-PSMA-617) for a total value of approximately US $ 6 billion. The market is expected to increase as these are used both as a complement to surgery, chemotherapy, and immunotherapies, as well as first treatment options. 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 a nanomaterial that circulates long enough in the body to provide the desired exposure to radioactivity in tumors, while minimizing the impact on other organs. Furthermore, preclinical efficacy studies have shown that Tumorad inhibits tumor growth and prolongs survival in a model for aggressive breast cancer. Preclinical dosimetry and toxicology studies, and GMP manufacturing are ongoing to prepare the product candidate, designated SN201, for clinical phase I/II. The goal is to initiate a clinical phase I/II trial in 2022.

FINANCIAL DEVELOPMENT

RESULTS

Operating expenses amounted to KSEK -11,756 (KSEK -6,011) for the quarter and KSEK -32,645 (KSEK -19,050) 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 1,619 (KSEK 1,526) for the quarter and KSEK 4,774 (KSEK 4,746) for the year, and primarily 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 -10,137 (KSEK -4,485) for the quarter and KSEK -27,871 (KSEK -14,304) for the year. Earnings per share before and after dilution amounted to SEK -0.26 (SEK -0.14) for the quarter and SEK -0.67 (SEK -0.56) for the year.

INVESTMENTS AND FINANCIAL POSITION

At the end of the quarter, cash and cash equivalents amounted to KSEK 65,987 (KSEK 35,699).

Cash flow from operating activities amounted to KSEK -9,767 (KSEK -4,196) for the quarter and KSEK -23,442 (KSEK -13,671) 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 -1,119 (KSEK -1,509) for the quarter and KSEK -3,228 (KSEK -4,230) 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 -17) for the quarter and KSEK 64,208 (KSEK 41,450) 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 196,105 (KSEK 164,300) and the equity ratio to 96.5 percent (98.2 percent). Equity per share, before dilution, amounted to SEK 4.76 (SEK 5.21).

SHARES AND SHARE CAPITAL

The number of registered shares as of September 30, 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 2,835. 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.

RESULTATRÄKNING

Amounts in KSEK	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Income					
Net sales	195	67	561	167	342
Internal work capitalized	359	587	1 107	2 242	2 580
External work capitalized	656	507	1 933	1 574	3 192
Other operating income	409	365	1 173	764	1 132
Total income	**1 619**	**1 526**	**4 774**	**4 746**	**7 245**
Operating costs					
Project costs	-6 590	-1 444	-14 651	-4 759	-6 530
Other external costs	-1 628	-1 233	-5 717	-3 890	-5 212
Personnel costs	-3 398	-3 228	-11 898	-10 130	-14 095
Depreciation/amortization of fixed assets	-85	-105	-290	-261	-362
Other operating costs	-55	-1	-88	-10	-7
Total operating costs	**-11 756**	**-6 011**	**-32 645**	**-19 050**	**-26 207**
OPERATING RESULT	**-10 137**	**-4 485**	**-27 871**	**-14 304**	**-18 962**
Financial items					
Interest income and similar items	34	0	92	0	34
Total financial items	**34**	**0**	**92**	**0**	**34**
RESULT AFTER FINANCIAL ITEMS	**-10 103**	**-4 485**	**-27 778**	**-14 304**	**-18 928**
PROFIT/LOSS FOR THE PERIOD	**-10 103**	**-4 485**	**-27 778**	**-14 304**	**-18 928**

BALANCE SHEET

ASSETS

Amounts in KSEK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
Non-current assets			
Intangible			
Capitalized expenditure for development work	127 685	123 941	125 364
Patents	7 263	6 011	6 544
Materiella anläggningstillgångar			
Equipment, tools, fixtures and fittings	976	981	1 078
Total non-current assets	**135 923**	**130 933**	**132 986**
Current assets			
Accounts receivables	0	0	31
Other current assets	318	364	676
Prepaid expenses and accrued income	923	361	679
Cash and cash equivalents	65 987	35 699	28 448
Total current assets	**67 229**	**36 424**	**29 834**
TOTAL ASSETS	**203 152**	**167 357**	**162 820**

EQUITY AND LIABILITIES

Amounts in KSEK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
Eqiuty			
Equity	196 105	164 300	159 675
Total Equity	**196 105**	**164 300**	**159 675**
Current liabilities			
Accounts payables	3 901	1 223	927
Tax liabilities	44	93	134
Other current liabilities	390	382	393
Accrued expenses and deferred income	2 713	1 358	1 692
Total current liabilities	**7 047**	**3 057**	**3 146**
TOTAL EQUITY AND LIABIITES	**203 152**	**167 357**	**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			-6 344			**-6 344**
Capitalization of development expenses		3 816		-3 816		**0**
Profit/loss					-14 304	**-14 304**
Closing balance Sep 30, 2020	**31 545**	**78 208**	**200 797**	**-131 945**	**-14 304**	**164 300**
Opening balance Oct 1, 2020	**31 545**	**78 208**	**200 797**	**-131 945**	**-14 304**	**164 300**
Issuance costs			-2			**-2**
Capitalization of development expenses		1 956		-1 956		**0**
Profit/loss					-4 624	**-4 624**
Closing balance Dec 31, 2020	**31 545**	**80 164**	**200 795**	**-133 902**	**-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		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**

CASHFLOW STATEMENT IN SUMMARY

Amounts in KSEK	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Cash flow from operating activities and before changes in working capital	**-10 172**	**-4 474**	**-28 010**	**-14 362**	**-18 979**
Changes in working capital	405	279	4 568	691	213
Cash flow from operating activities	**-9 767**	**-4 196**	**-23 442**	**-13 671**	**-18 766**
Cash flow from investing activities	-1 119	-1 509	-3 228	-4 230	-6 383
Cash flow from financing activities	0	-17	64 208	41 450	41 448
Cash flow for the period	**-10 886**	**-5 721**	**37 539**	**23 550**	**16 299**
Cash and cash equivalents at the beginning of the period	76 873	41 421	28 448	12 149	12 149
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	**65 987**	**35 699**	**65 987**	**35 699**	**28 448**

DATA PER SHARE

	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Earnings per share, before and after dilution, SEK	-0.26	-0.14	-0.67	-0.56	-0.70
Equity per share, before dilution, SEK	4.76	5.21	4.76	5.21	5.06
Average number of shares before dilution	41 182 287	31 544 517	38 813 909	25 711 468	27 177 699
Average number of shares after dilution	41 744 839	32 107 069	39 376 461	26 274 020	27 740 251
Number of shares at the end of the period	41 182 287	31 544 517	41 182 287	31 544 517	31 544 517

OTHER KEY FIGURES

	Jul-Sep 2021	Jul-Sep 2020	Jan-Sep 2021	Jan-Sep 2020	Jan-Dec 2020
Average number of employees	17	15	17	15	15
Equity ratio, %	96.5	98.2	96.5	98.2	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 November 10, 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