SPAGO NANOMEDICAL AB

Interim report

January- June, 2021

Continued good pace in the business despite Covid-19

APRIL – JUNE IN BRIEF

- Net sales for the quarter amounted to KSEK 267 (KSEK 0).
- The loss for the quarter amounted to KSEK –11,607 (KSEK -4,764).
- Operating expenses for the quarter amounted to KSEK -13,450 (KSEK -6,269).
- Earnings per share, before and after dilution, for the quarter amounted to SEK -0.28 (SEK -0.19).
- Cash and cash equivalents at the end of the quarter amounted to KSEK 76 873 (KSEK 41,421).

JANUARY – JUNE IN BRIEF

- Net sales for the half-year period amounted to KSEK 367 (KSEK 100).
- The loss for the half-year period amounted to KSEK -17,675 (KSEK -9,819).
- Operating expenses for the half-year period amounted to KSEK -20,889 (KSEK -13,039).
- Earnings per share, before and after dilution, for the half-year period amounted to SEK -0.47 (SEK -0.43).

SIGNIFICANT EVENTS DURING THE QUARTER

- No events to report

SIGNIFICANT EVENTS AFTER THE QUARTER

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

CEO STATEMENT

In the second quarter, we continued to notice the effects of the Covid-19 pandemic, which, among many other things, have resulted in significant difficulties in conducting clinical trials effectively. Despite this, we were able to keep up the pace of business and make important progress in the Tumorad® project.

An important focus for us is the clinical development of SpagoPix, our contrast agent for increased precision in MRI of breast cancer and other cancers. The major advantage of SpagoPix is the ability to provide possibilities for high resolution imaging of tumors with high precision, which can provide vital information for correct diagnosis and treatment. As such, we can combine the primary advantages of MRI (high sensitivity) and PET (high specificity) into one product. SpagoPix has promising potential to become the first tumor-selective contrast agent for MRI and thus meet the continuing increased need for improved diagnostic precision.

The primary goal of the clinical study SPAGOPIX-01 is to build a foundation for future clinical studies and strengthen our position in dialogue with potential partners. The results from the study have so far shown that SN132D provides clinically valuable images and is safe at current dose levels. It is noteworthy that the study thus, despite the slow recruitment pace caused by the pandemic, has already provided a very important basis for discussion with potential licensing partners for the continued development of the project.

The clinical results also show that our nanoparticles safely accumulate in human solid tumors, a fundament of our platform technology. This opens in the next stage for treatment of cancer with Tumorad.

We have previously shown that the Tumorad candidate drug SN201 can delay tumor growth and extend survival in a preclinical model of aggressive breast cancer. It is very satisfying that we successfully completed the production of materials for regulatory preclinical studies which will form the basis for clinical development. These studies are progressing well and will be completed in the fall. In parallel, preparations for the first clinical study are ongoing, including GMP production and compilation of regulatory documentation. The goal is to start the first clinical trial with SN201 in patients with advanced cancer next year.

It is well-established that the principle for accumulation in tumors, the EPR effect, becomes more pronounced in fast growing tumors. There are currently few effective pharmaceutical treatments against large groups of advanced cancers where mortality is driven by resistant and metastatic tumors. We see Tumorad becoming an important addition to the future treatment arsenal. We believe that Tumorad has great potential as a general treatment for advanced and aggressive cancer, and we are moving the project forward with full speed.

We have an exciting time ahead of us and I look forward to updating you as our projects continue to progress.

Mats Hansen, CEO Spago Nanomedical AB

"The goal is to start the first clinical trial with SN201 in patients with advanced cancer next year."

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 almost 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 affects approximately 2.3 million people annually. 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 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, a process for applying for a license partner for the project has been initiated.

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 3 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 -13,450 (KSEK -6,269) for the quarter and KSEK -20,889 (KSEK -13,039) for the half-year period. 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 1,804 (KSEK 1,505) for the quarter and KSEK 3,155 (KSEK 3,220) for the half-year period, 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 -11,646 (KSEK -4,764) for the quarter and KSEK -17,734 (KSEK -9,819) for the half-year period. Earnings per share before and after dilution amounted to SEK -0.28 (SEK -0.19) for the quarter and SEK -0.47 (SEK -0.43) for the half-year period.

INVESTMENTS AND FINANCIAL POSITION

At the end of the quarter, cash and cash equivalents amounted to KSEK 76,873 (KSEK 41,421).

Cash flow from operating activities amounted to KSEK -7,171 (KSEK -5,894) for the quarter and KSEK -13,675 (KSEK -9,475) for the half-year period. The increased negative cash flow is driven by the ongoing clinic preparatory activities in the Tumorad project. Cash flow from investment activities amounted to KSEK -1,126 (KSEK -1,300) for the quarter and KSEK -2,109 (KSEK -2,721) for the half-year period. 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 -55 (KSEK 41,677) for the quarter and KSEK 64,208 (KSEK 41,468) for the half-year period. 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 206,208 (KSEK 168,803) and the equity ratio to 96.7 percent (98.3 percent). Equity per share, before dilution, amounted to SEK 5.01 (SEK 5.35).

SHARES AND SHARE CAPITAL

The number of registered shares as of June 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 period was 2,929. 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	Apr-Jun 2021	Apr-Jun 2021	Jan-Jun 2021	Jan-Jun 2020	Jan-Dec 2020
Income					
Net sales	267	0	367	100	342
Internal work capitalized	409	768	748	1 654	2 580
External work capitalized	718	531	1 277	1 067	3 192
Other operating income	411	206	764	399	1 132
Total income	**1 804**	**1 505**	**3 155**	**3 220**	**7 245**
Operating costs					
Project costs	-6 667	-1 733	-8 061	-3 315	-6 530
Other external costs	-1 939	-1 257	-4 090	-2 657	-5 212
Personnel costs	-4 719	-3 195	-8 500	-6 902	-14 095
Depreciation/amortization of fixed assets	-101	-78	-205	-156	-362
Other operating costs	-25	-6	-33	-9	-7
Total operating costs	**-13 450**	**-6 269**	**-20 889**	**-13 039**	**-26 207**
OPERATING RESULT	**-11 646**	**-4 764**	**-17 734**	**-9 819**	**-18 962**
Financial items					
Interest income and similar items	39	0	58	0	34
Total financial items	**39**	**0**	**58**	**0**	**34**
RESULT AFTER FINANCIAL ITEMS	**-11 607**	**-4 764**	**-17 675**	**-9 819**	**-18 928**
PROFIT/LOSS FOR THE PERIOD	**-11 607**	**-4 764**	**-17 675**	**-9 819**	**-18 928**

BALANCE SHEET

ASSETS

Amounts in KSEK	Jun 30, 2021	Jun 30, 2020	Dec 31, 2020
Non-current assets			
Intangible			
Capitalized expenditure for development work	126 936	122 847	125 364
Patents	6 997	6 010	6 544
Materiella anläggningstillgångar			
Equipment, tools, fixtures and fittings	957	672	1 078
Total non-current assets	**134 890**	**129 529**	**132 986**
Current assets			
Accounts receivables	0	0	31
Other current assets	443	361	676
Prepaid expenses and accrued income	1 076	421	679
Cash and cash equivalents	76 873	41 421	28 448
Total current assets	**78 393**	**42 203**	**29 834**
TOTAL ASSETS	**213 282**	**171 732**	**162 820**

EQUITY AND LIABILITIES

Amounts in KSEK	Jun 30, 2021	Jun 30, 2020	Dec 31, 2020
Eqiuty			
Equity	206 208	168 803	159 675
Total Equity	**206 208**	**168 803**	**159 675**
Current liabilities			
Accounts payables	4 349	896	927
Tax liabilities	49	88	134
Other current liabilities	409	397	393
Accrued expenses and deferred income	2 268	1 547	1 692
Total current liabilities	**7 075**	**2 929**	**3 146**
TOTAL EQUITY AND LIABIITES	**213 282**	**171 732**	**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			-6 327			**-6 327**
Capitalization of development expenses		2 721		-2 721		**0**
Profit/loss					-9 819	**-9 819**
Closing balance Jun 30, 2020	**31 545**	**77 114**	**200 815**	**-130 851**	**-9 819**	**168 803**
Opening balance Jul 1, 2020	**31 545**	**77 114**	**200 815**	**-130 851**	**-9 819**	**168 803**
Issuance costs			-19			**-19**
Capitalization of development expenses		3 050		-3 050		**0**
Profit/loss					-9 109	**-9 109**
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		2 025		-2 025		**0**
Profit/loss					-17 675	**-17 675**
Closing balance Jun 30, 2021	**41 182**	**82 189**	**255 366**	**-154 854**	**-17 675**	**206 208**

CASHFLOW STATEMENT IN SUMMARY

Amounts in KSEK	Apr-Jun 2021	Apr-Jun 2020	Jan-Jun 2021	Jan-Jun 2020	Jan-Dec 2020
Cash flow from operating activities and before changes in working capital	**-11 665**	**-4 780**	**-17 838**	**-9 887**	**-18 979**
Changes in working capital	4 495	-1 114	4 163	412	213
Cash flow from operating activities	**-7 171**	**-5 894**	**-13 675**	**-9 475**	**-18 766**
Cash flow from investing activities	-1 126	-1 300	-2 109	-2 721	-6 383
Cash flow from financing activities	-55	41 677	64 208	41 468	41 448
Cash flow for the period	**-8 352**	**34 483**	**48 425**	**29 272**	**16 299**
Cash and cash equivalents at the beginning of the period	85 225	6 938	28 448	12 149	12 149
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	**76 873**	**41 421**	**76 873**	**41 421**	**28 448**

DATA PER SHARE

	Apr-Jun 2021	Apr-Jun 2020	Jan-Jun 2021	Jan-Jun 2020	Jan-Dec 2020
Earnings per share, before and after dilution, SEK	-0.28	-0.19	-0.47	-0.43	-0.70
Equity per share, before dilution, SEK	5.01	5.35	5.01	5.35	5.06
Average number of shares before dilution	41 182 287	24 496 108	37 610 093	22 762 893	27 177 699
Average number of shares after dilution	41 744 839	25 058 660	38 172 645	23 325 445	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

	Apr-Jun 2021	Apr-Jun 2020	Jan-Jun 2021	Jan-Jun 2020	Jan-Dec 2020
Average number of employees	17	16	16	16	15
Equity ratio, %	96.7	98.3	96.7	98.3	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.

CALENDAR

Interim report Jan-Sep November 10

The reports above will be available on the company's website
www.spagonanomedical.se

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 August 24, 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