

SPAGO NANOMEDICAL AB (publ)

Interim report

January-March 2021

Successful rights issue strengthens project development

JANUARY – MARCH IN BRIEF

- Net sales for the quarter amounted to KSEK 100 (KSEK 100).
- The loss for the quarter amounted to KSEK -6,068 (KSEK -5,054).
- Operating expenses for the quarter amounted to KSEK -7,439 (KSEK -6,769).
- Earnings per share, before and after dilution, for the quarter amounted to SEK -0.18 (SEK -0.24).
- Cash and cash equivalents at the end of the quarter amounted to KSEK 85,225 (KSEK 6 938).

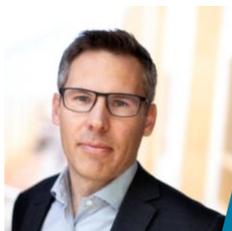
SIGNIFICANT EVENTS DURING THE QUARTER

- Spago Nanomedical was provided with MSEK 69 in an oversubscribed rights issue and over-allotment issue, which meant that the company's share capital increased by SEK 9,219,463, divided into 9,219,463 shares. In addition, a further 418,307 shares were issued in a directed share issue to the guarantors in the rights issue who chose to receive remuneration in the form of newly issued shares in the company. In total, the company raised approximately MSEK 64, after transaction costs.
- In order to strengthen the company's long-term financing opportunities, the company changed its trading venue from Spotlight Stock Market to Nasdaq First North Growth Market. The first day of trading on the Nasdaq First North Growth Market was March 26, 2021.

SIGNIFICANT EVENTS AFTER THE QUARTER

- No events to report

CEO STATEMENT



"The change of trading venue provides an opportunity for increased exposure, and sends an important signal of our long-term ambitions to become a leading company in the development of nanomedicine."

The first quarter provided a good start to the new year for Spago Nanomedical. We, like everyone else, are of course aware of the effects of the Covid-19 pandemic, which, among other things, means that clinical studies are more difficult to conduct and carry out on time, but we continue to keep pace with our activities and are making progress in our projects.

Progressing clinical development of our contrast agent, SpagoPix, for increased precision in magnetic resonance imaging (MRI) of breast cancer and of the pancreas, is certainly important. The clinical study SPAGOPIX-01 is underway to build a foundation for commercial partnering and future clinical studies. Enrollment continues, but at a slower pace than originally planned due to the pandemic.

SpagoPix has promising potential to become the first tumor-selective contrast agent for MRI and as such meets the present and increasing need for improved diagnostic precision of breast cancer, both in connection with screening of risk groups and prior to surgery. Previous clinical interim results show the enrichment of our nanoparticles in solid tumors in humans, a foundation for our platform technology. This opens in the next stage for the treatment of cancer with our second important project, Tumorad®.

In the Tumorad® project, we have shown, in a preclinical model for aggressive breast cancer, that our material has a positive effect, with both delayed tumor growth and prolonged survival. It is indeed satisfactory that we have now successfully completed the production of materials for regulatory preclinical studies that will form the basis for clinical development. As a general treatment for widespread and aggressive cancer, we believe that Tumorad® has great potential, and we will drive the project forward with full force.

To make this possible - and strengthen the company ahead of upcoming partnership discussions with SpagoPix - we conducted a successful, fully secured rights issue in February. The interest to participate in the rights issue was high, and, including the utilization of an over-allotment issue of approximately MSEK 10, we raised a total of approximately MSEK 69, before issue costs. I am truly happy about the confidence that existing and new owners showed in the company and our projects. Now we can vigorously pursue the Tumorad® project to the clinical phase, and at the same time complete the clinical trial with SpagoPix.

On March 26, we entered the Nasdaq First North Growth Market. We believe that the company is ready to meet a broader interest from international and institutional investors. The change of trading venue provides an opportunity for increased exposure and sends an important signal of our long-term ambitions to become a leading company in the development of nanomedicine.

We have an exciting year ahead of us, and I look forward to updating you as the activities continue.

Mats Hansen, CEO
Spago Nanomedical AB

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-treat, 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 cancer 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 brain², 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

¹ Eriksson et al., 2014

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

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.

STATUS

The ongoing phase 1 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. The product candidate, designated SN201, is now moving on to clinic-preparatory preclinical dosimetry and toxicology studies. Production of SN201 on a greater scale to meet the need for materials in regulatory preclinical studies has been carried out internally, and the work of transferring the production process to a contract manufacturer for GMP manufacturing prior to clinical studies is ongoing. The goal is to initiate a clinical phase 1/2 trial in 2022.

FINANCIAL DEVELOPMENT

RESULTS

Operating expenses amounted to KSEK -7,439 (KSEK -6,769) for the quarter. The higher costs during the year are primarily related to the change of marketplace for the company's share to Nasdaq First North Growth Market.

Total revenue amounted to KSEK 1,352 (KSEK 1,715) for the quarter, and primarily relates to development expenses and patent expenses for the SpagoPix project that were capitalized in the balance sheet during the period. The lower capitalization is thereby an effect of lower expenses in the project compared with the corresponding period last year, and is explained by an increased allocation of internal resources to the Tumorad[®] project, which is not capitalized in the balance sheet, and lower external expenses in the project.

The operating result amounted to KSEK -6,087 (KSEK -5,054) for the quarter. Earnings per share before and after dilution amounted to SEK -0.18 (SEK -0.24) for the quarter.

INVESTMENTS AND FINANCIAL POSITION

At the end of the quarter, cash and cash equivalents amounted to KSEK 85,225 (KSEK 6,938).

Cash flow for the quarter from operating activities amounted to KSEK -6,504 (KSEK -3,581), and cash flow from investment activities amounted to KSEK -982 (KSEK -1,421). 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 64,263 (KSEK -209) for the quarter. The cash flow 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, and MSEK 64.3 after transaction costs.

At the end of the quarter, the company's equity amounted to KSEK 217,869 (KSEK 131,891) and the equity ratio to 98.4 percent (97 percent). Equity per share, before dilution, amounted to SEK 5.29 (SEK 6.27).

SHARES AND SHARE CAPITAL

The number of registered shares as of March 31, 2021 amounted to 41,182,287. Since March 26, 2021 the share has been traded on the Nasdaq First North Growth Market, with the ticker SPAGO. The company then changed trading venue from Spotlight Stock Market, where it has been listed since the end of 2012. The share's quota value amounts to SEK 1, whereby the share capital is equal to the number of shares. The number of shareholders at the end of the period was 3,058. 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

Income	Jan-Mar 2021	Jan-Mar 2020	Jan-Dec 2020
Net sales	100	100	342
Internal work capitalized	339	886	2 580
External work capitalized	559	535	3 192
Other operating income	354	194	1 132
Total income	1 352	1 715	7 245
Operating costs			
Project costs	-1 394	-1 583	-6 530
Other external costs	-2 151	-1 399	-5 212
Personnel costs	-3 782	-3 706	-14 095
Depreciation/amortization of fixed assets	-104	-78	-362
Other operating costs	-8	-3	-7
Total operating costs	-7 439	-6 769	-26 207
OPERATING RESULT	-6 087	-5 054	-18 962
Financial items			
Interest income and similar items	19	0	34
Total financial items	19	0	34
RESULT AFTER FINANCIAL ITEMS	-6 068	-5 054	-18 928
PROFIT/LOSS FOR THE PERIOD	-6 068	-5 054	-18 928

BALANCE SHEET

ASSETS

<i>Amounts in KSEK</i>	Mar 31, 2021	Mar 31, 2020	Dec 31, 2020
Non-current assets			
Intangible			
Capitalized expenditure for development work	126 116	121 551	125 364
Patents	6 690	6 006	6 544
Materiella anläggningstillgångar			
Equipment, tools, fixtures and fittings	1 058	750	1 078
Total non-current assets	133 864	128 307	132 986
Current assets			
Accounts receivables	0	31	31
Other current assets	1 419	578	676
Prepaid expenses and accrued income	814	157	679
Cash and cash equivalents	85 225	6 938	28 448
Total current assets	87 457	7 704	29 834
TOTAL ASSETS	221 322	136 011	162 820

EQUITY AND LIABILITIES

<i>Amounts in KSEK</i>	Mar 31, 2021	Mar 31, 2020	Dec 31, 2020
Equity			
Equity	217 869	131 891	159 675
Total Equity	217 869	131 891	159 675
Current liabilities			
Accounts payables	1 174	1 963	927
Tax liabilities	58	118	134
Other current liabilities	371	440	393
Accrued expenses and deferred income	1 850	1 599	1 692
Total current liabilities	3 452	4 120	3 146
TOTAL EQUITY AND LIABILITIES	221 322	136 011	162 820

CHANGES IN EQUITY

<i>Amounts in KSEK</i>	Share capital	Development fund	Share premium reserve	Retained earnings	Profit/loss	Total equity
Opening balance Jan 1, 2020	21 030	74 392	170 339	-107 919	-20 211	137 631
Issuance costs			-687			-687
Capitalization of development expenses		1 421		-1 421		0
Profit/loss					-5 054	-5 054
Closing balance Mar 31, 2020	21 030	75 814	169 653	-109 340	-25 265	131 891
Opening balance Apr 1, 2020	21 030	75 814	169 653	-109 340	-25 265	131 891
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			-5 659			-5 659
Capitalization of development expenses		4 350		-4 350		0
Profit/loss					-13 873	-13 873
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
Share issue	9 638		62 646			72 283
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

CASHFLOW STATEMENT IN SUMMARY

<i>Amounts in KSEK</i>	Jan-Mar 2021	Jan-Mar 2020	Jan-Dec 2020
Cash flow from operating activities and before changes in working capital	-6 173	-5 107	-18 979
Changes in working capital	-331	1 526	213
Cash flow from operating activities	-6 504	-3 581	-18 766
Cash flow from investing activities	-982	-1 421	-6 383
Cash flow from financing activities	64 263	-209	41 448
Cash flow for the period	56 776	-5 211	16 299
Cash and cash equivalents at the beginning of the period	28 448	12 149	12 149
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	85 225	6 938	28 448

DATA PER SHARE

	Jan-Mar 2021	Jan-Mar 2020	Jan-Dec 2020
Earnings per share, before and after dilution, SEK	-0.18	-0.24	-0.70
Equity per share, before dilution, SEK	5.29	6.27	5.06
Average number of shares before dilution	33 998 207	21 029 678	27 177 699
Average number of shares after dilution	34 560 759	21 592 230	27 740 251
Number of shares at the end of the period	41 182 287	21 029 678	31 544 517

OTHER KEY FIGURES

	Jan-Mar 2021	Jan-Mar 2020	Jan-Dec 2020
Average number of employees	16	16	15
Equity ratio, %	98.4	97.0	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
Average number of shares before dilution	Result for the period in relation to the average number of shares
Average number of shares 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

Annual General Meeting	May 5
Interim report Jan-Jun	August 24
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

Remuneration to the Board of Directors and senior executives is paid in accordance with market agreements or in accordance with resolutions at the Annual General Meeting.

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 28, 2021

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

Eugen Steiner
Chairman of the board

Mats Hansen
CEO

Sten Nilsson
Board member

Peter Leander
Board member

Nicklas Westerholm
Board member

Kari Grønås
Board member