

Interim report

January- June 2022

Strengthened finances support the development program

APRIL – JUNE IN BRIEF

- Net sales for the quarter amounted to KSEK 304 (KSEK 267).
- The loss for the quarter amounted to KSEK -9,565 (KSEK -11,607).
- Operating expenses for the quarter amounted to KSEK -11,084 (KSEK -13,450).
- Earnings per share, before and after dilution, for the quarter amounted to SEK -0.23 (SEK -0.28).
- Cash and cash equivalents at the end of the quarter amounted to KSEK 29,414 (KSEK 76,873). The net proceeds of MSEK 51.7 from the rights issue ("Rights Issue"), in which the subscription period expired on June 28, 2022, were received after the end of the quarter.

JANUARY – JUNE IN BRIEF

- Net sales for the half-year period amounted to KSEK 515 (KSEK 367).
- The loss for the half-year period amounted to KSEK -19,445 (KSEK -17,675).
- Operating expenses for the half-year period amounted to KSEK -22,184 (KSEK -20,889).
- Earnings per share, before and after dilution, for the half-year period amounted to SEK -0.47 (SEK -0.47).

SIGNIFICANT EVENTS DURING THE QUARTER

- Extended patent protection for SpagoPix in Japan and in USA until at least 2038.
- Spago Nanomedical raised approximately SEK 58.4 million before transaction costs in the Rights Issue, which was subscribed to a total of 94.6 percent. The Rights Issue aims to accelerate development and initiate clinical studies in cancer patients with the radionuclide therapy Tumorad® (¹⁷⁷Lu-SN201).

SIGNIFICANT EVENTS AFTER THE QUARTER

- The board resolved to issue 1,079,161 new shares in a directed issue to the guarantors in the Rights Issue who chose to receive remuneration in the form of newly issued shares in the company.

CEO STATEMENT

The favorable and intense start to the year continued in the second quarter with sustained good development for both of our projects, SpagoPix (SN132D) and Tumorad (^{177}Lu -SN201). During the period, we were also able to secure funding for the continuous development of our radionuclide therapy project, Tumorad.

In the light of previous successful preclinical results showing that ^{177}Lu -SN201 significantly delays tumor growth and prolongs survival in both an aggressive breast cancer and a colorectal cancer model, our primary focus is now to initiate clinical studies of ^{177}Lu -SN201 in cancer patients. Parallel to the clinical preparations, preclinical activities are ongoing to broaden the scope of Tumorad to further potential indications with major medical needs, both as monotherapy and in combination with other drugs. This is important work to position the project and lay the foundation for the clinical and regulatory strategy.

Another prioritized area for us is to complete the ongoing phase I clinical trial SPAGOPIX-01 with the MRI contrast agent SN132D. The study has already shown that SN132D clearly accumulates in cancer tumors and provide images that with both high precision and positive contrast show breast cancer tumors without background noise. In addition to the positive results in breast cancer, the study also shows that SN132D provides good contrast in the liver and pancreas. The medical need for better diagnostic imaging for patients with pancreatic cancer is very high. We have therefore opened the ongoing study also to this patient group in order to cost-effectively demonstrate a broader potential for SN132D. We are also evaluating the potential for SN132D in other indications with a high clinical need for improved imaging diagnostics. With these positive results and prospects, we continue the dialogue with potential development partners.

At the end of June, we were able to report the outcome of our rights issue, which brought the company roughly SEK 58 million before deduction of issue costs. I am very happy for the trust that existing and new owners show us. Both of our projects have delivered promising results, and it is important to keep up the pace of the continued development. The capital raise gives us the conditions to focus fully on continuing to build future value, for both patients and shareholders. Not least, we see great potential shareholder value in advancing and accelerating the development of our drug candidate in the Tumorad project, given its unique treatment principle, a significant market potential and a great interest in radionuclide therapy among both pharmaceutical companies and investors.

During the period, we were also able to extend the patent protection for SpagoPix in both the US and Japan until at least 2038. The approved patent, entitled "Chemical Compounds for Coating of Nanostructures", covers the surface material ("coating") of our unique nanoparticles. The patent has already been approved in Europe, and further approvals are expected in more countries. The strengthened patent protection is central to us being able to maximize the value of our project portfolio in the best possible way.

Strengthened by both the funding and the positive development in the projects, I look forward to updating you on upcoming milestones.

Mats Hansen, CEO Spago Nanomedical AB

"The capital raise gives us the conditions to focus fully on continuing to build future value, for both patients and shareholders."



SPAGO NANOMEDICAL IN BRIEF

Spago Nanomedical AB is a Swedish nanomedicines company in clinical development phase, developing products for diagnostics and treatment of life-threatening diseases.

The company's operations are based on a patented material for the design of functional nanoparticles that accumulate physiologically in tumors, thus enabling higher precision and improved cancer patient care. The current pipeline projects have the potential to facilitate diagnostics and improve the treatment of cancer indications with urgent medical needs.

***SpagoPix** is developing a gadolinium-free contrast agent for MRI with better precision in images of tumors and metastases. Imaging with improved precision increases the possibilities for successful treatment and survival.*

***Tumorad** is focused on the development of a completely form of radionuclide therapy for tumor-selective radiation treatment of cancer. The need for new radionuclide therapies for the treatment of difficult-to-threat, spread or aggressive tumors is great.*

*Spago Nanomedical's **vision** is to engage in competitive and successful development of products that increase the survival and quality of life for patients and thereby create long-term profitability for the company and its owners.*

*Spago Nanomedical's **objective** is to become a leading company within the development of diagnostics and therapy based on nanomedicine through the development of products that benefit patients and provide good health economics.*

*Spago Nanomedical's overall **strategy** is to conduct development of medical projects based on the company's proprietary and patented nanomaterial. The business strategy builds on commercializing the company's development projects through collaborations and outlicensing to industrial partners that have the resources to bring the product to market and clinical use. This reduces the need of capital and the time before revenue is received, and increases the potential for successful market penetration.*

Spago Nanomedical's share is listed on Nasdaq First North Growth Market (ticker: SPAGO).

PROJECT - SPAGOPIX

BACKGROUND

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

The product candidate within SpagoPix, SN132D, is designed for physiological and selective accumulation in tumors via the scientifically well-established mechanism "Enhanced Permeability and Retention (EPR) effect"¹. Furthermore, the contrast agent has a significantly better ability to amplify the signal measured in MRI examinations (relaxivity) compared to current contrast agents.

The combination of the tumor-selective mechanism of action and the high signal strength gives MRI images better contrast between cancer tissue and the surrounding tissue, which creates better opportunities to detect small and aggressive tumors with high specificity, and provides a more accurate and clearer image of the tumor. This reduces the risk that the surgeon will have to perform another operation if it turns out that the margins for healthy tissue have been too small. It also reduces the risk of the tumor being missed completely, which can have devastating consequences for the patient as the tumor can grow in the meantime and reach the advanced stage, and as such significantly worsen the prognosis for successful treatment. In addition, SN132D can help reduce the risk of false positive findings that often lead to additional biopsies and diagnostic procedures, and a great deal of suffering and anxiety for the patient.

In addition to the good diagnostic properties, SN132D is also free of gadolinium, an element that is found in all clinically used MRI contrast agents at present. Gadolinium has been shown to, among other things, accumulate in the brain², 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, 13 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 subsidies, 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 to 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 ¹⁷⁷Lu-SN201 inhibits tumor growth and prolongs survival in a model for aggressive breast cancer. The company has also shown that ¹⁷⁷Lu-SN201 reduces tumor growth and prolongs survival by 39% in a preclinical model for colorectal cancer compared to the control group. The material has shown a good safety profile in regulatory preclinical toxicology studies, as well as favorable distribution in the body (biodistribution) in preclinical dosimetry studies. Production of SN102 on a larger scale for clinical studies is ongoing. The goal is to initiate a clinical phase I/II trial in the latter part of 2022.

FINANCIAL DEVELOPMENT

RESULTS

Operating expenses amounted to KSEK -11,084 (KSEK -13,450) for the quarter and KSEK -22,184 (KSEK -20,889) for the half-year period. The higher operating costs during the half-year period are primarily related to the production of material for the planned clinical phase I/II study in the Tumorad-project as well as other clinic preparatory activities such as the design of the clinical study protocol and compilation of material for the clinical trial application, consultation and advice with relevant regulatory agencies, and identification of suitable clinical sites for the study. The increased costs are also related to business development of SpagoPix.

Total revenue amounted to KSEK 1,502 (KSEK 1,804) for the quarter and KSEK 2,701 (KSEK 3,155) for the half-year period, and relates to development expenses and patent expenses for the SpagoPix project that were capitalized in the balance sheet during the period.

The operating result amounted to KSEK -9,581 (KSEK -11,646) for the quarter and KSEK -19,483 (KSEK -17,734) for the half-year period. Earnings per share before and after dilution amounted to SEK -0.23 (SEK -0.28) for the quarter and KSEK -0.47 (KSEK -0.47) for the half-year period.

INVESTMENTS AND FINANCIAL POSITION

At the end of the quarter, cash and cash equivalents amounted to KSEK 29,414 (KSEK 76,873). The net proceeds from the Rights Issue were received after the end of the quarter. The part of the issue proceeds paid by the end of the quarter to the assigned issuing institution are reported as Other current assets. The rest of the issue proceeds are reported as Subscribed but not paid-in capital.

Cash flow from operating activities amounted to KSEK -9,809 (KSEK -7,171) for the quarter and KSEK -20,760 (KSEK -13,675) for the half-year period. 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 -945 (KSEK -1,126) for the quarter and KSEK -1,485 (KSEK -2,109) for the half-year period. 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 -824 (KSEK -55) for the quarter and KSEK -802 (KSEK 64,208) for the half-year period. The cash flow from last year relates to the net proceeds received in the rights issue including the over-allotment issue, that was carried out. The net proceeds from the Right Issue, in which the subscription period expired on June 28, 2022, were received after the end of the quarter.

At the end of the quarter, the company's equity amounted to KSEK 215,947 (KSEK 206,208) and the equity ratio to 94.4 percent (96.7 percent). A total of 48,682,275 new shares were issued in the Rights Issue, which were registered with the Swedish Companies Registration Office after the end of the quarter. Equity per share, before dilution, amounted to SEK 2,40 (SEK 5.01).

SHARES AND SHARE CAPITAL

The number of registered shares as of June 30, 2022 amounted to 41,182,287. Since March 26, 2021 the share has been traded on the Nasdaq First North Growth Market, with the ticker SPAGO. The company then changed trading venue from Spotlight Stock Market, where it has been listed since the end of 2012. The share's quota value amounts to SEK 1, whereby the share capital is equal to the number of shares. The number of shareholders at the end of the period were 2,775. 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 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

<i>Amounts in KSEK</i>	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Jan-Dec 2021
Income					
Net sales	304	267	515	367	660
Internal work capitalized	91	409	255	748	1 376
External work capitalized	721	718	1 097	1 277	2 879
Other operating income	387	411	834	764	1 617
Total income	1 502	1 804	2 701	3 155	6 532
Operating costs					
Project costs	-4 335	-6 667	-8 908	-8 061	-21 691
Other external costs	-2 359	-1 939	-4 395	-4 090	-7 542
Personnel costs	-4 264	-4 719	-8 472	-8 500	-15 990
Depreciation/amortization of fixed assets	-93	-101	-182	-205	-376
Other operating costs	-32	-25	-226	-33	-125
Total operating costs	-11 084	-13 450	-22 184	-20 889	-45 723
OPERATING RESULT	-9 581	-11 646	-19 483	-17 734	-39 192
Financial items					
Interest income and similar items	17	39	38	58	120
Total financial items	17	39	38	58	120
RESULT AFTER FINANCIAL ITEMS	-9 565	-11 607	-19 445	-17 675	-39 071
PROFIT/LOSS FOR THE PERIOD	-9 565	-11 607	-19 445	-17 675	-39 071

BALANCE SHEET

ASSETS

<i>Amounts in KSEK</i>	Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
Subscribed but not paid-up capital	21 193	0	0
Non-current assets			
Intangible			
Capitalized expenditure for development work	129 743	126 936	128 848
Patents	7 770	6 997	7 314
Materiella anläggningstillgångar			
Equipment, tools, fixtures and fittings	1 027	957	1 075
Total non-current assets	138 540	134 890	137 237
Current assets			
Accounts receivables	0	0	38
Other current assets	38 290	443	856
Prepaid expenses and accrued income	1 401	1 076	1 033
Cash and cash equivalents	29 414	76 873	52 460
Total current assets	69 105	78 393	54 387
TOTAL ASSETS	228 838	213 282	191 624

EQUITY AND LIABILITIES

<i>Amounts in KSEK</i>	Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
Equity			
Equity	215 947	206 208	184 812
Total equity	215 947	206 208	184 812
Current liabilities			
Accounts payables	2 593	4 349	3 860
Other current liabilities	388	457	407
Accrued expenses and deferred income	9 910	2 268	2 545
Total current liabilities	12 891	7 074	6 812
TOTAL EQUITY AND LIABILITIES	228 838	213 282	191 624

CHANGES IN EQUITY

<i>Amounts in KSEK</i>	Share capital	Not reg. share capital	Dev. fund	Share prem. reserve	Retained earnings	Profit/loss	Total equity
Opening balance Jan 1, 2021	31 545	0	80 164	200 795	-133 902	-18 928	159 674
Appropriations of net results according to the AGM's resolution					-18 928	18 928	0
Share issue	9 638			62 646			72 284
Issuance costs				-8 075			-8 075
Capitalization of development expenses			2 025		-2 025		0
Profit/loss						-17 675	-17 675
Closing balance Jun 30, 2021	41 182	0	82 189	255 366	-154 855	-17 675	206 208
Opening balance Jul 1, 2021	41 182	0	82 189	255 366	-154 855	-17 675	206 208
Capitalization of development expenses			2 229		-2 229		0
Profit/loss						-21 396	-21 396
Closing balance Dec 31, 2021	41 182	0	84 418	255 366	-157 083	-39 071	184 812
Opening balance, Jan 1, 2022	41 182	0	84 418	255 366	-157 083	-39 071	184 812
Appropriations of net results according to the AGM's resolution					-39 071	39 071	0
Ongoing share issue		48 682		9 736			58 419
Issuance costs				-7 838			-7 838
Capitalization of development expenses			1 351		-1 351		0
Profit/loss						-19 445	-19 445
Closing balance Jun 30, 2022	41 182	48 682	85 770	257 264	-197 506	-19 445	215 947

CASHFLOW STATEMENT IN SUMMARY

<i>Amounts in KSEK</i>	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Jan-Dec 2021
Cash flow from operating activities and before changes in working capital	-9 488	-11 665	-19 301	-17 838	-38 695
Changes in working capital	-321	4 495	-1 459	4 163	3 126
Cash flow from operating activities	-9 809	-7 171	-20 760	-13 675	-35 569
Cash flow from investing activities	-945	-1 126	-1 485	-2 109	-4 627
Cash flow from financing activities	-824	-55	-802	64 208	64 208
Cash flow for the period	-11 578	-8 352	-23 046	48 425	24 012
Cash and cash equivalents at the beginning of the period	40 992	85 225	52 460	28 448	28 448
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	29 414	76 873	29 414	76 873	52 460

DATA PER SHARE

	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Jan-Dec 2021
Earnings per share, before and after dilution, SEK*	-0.23	-0.28	-0.47	-0.47	-0.99
Equity per share, before dilution, SEK*	2.40	5.01	2.40	5.01	4.49
Average number of shares before dilution*	42 252 227	41 182 287	41 720 213	37 610 093	39 410 870
Average number of shares after dilution*	42 631 778	41 744 839	42 190 759	38 172 645	39 973 422
Number of shares at the end of the period*	89 864 562	41 182 287	89 864 562	41 182 287	41 182 287

* Subscribed but not registered shares are included.

OTHER KEY FIGURES

	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Jan-Dec 2021
Average number of employees	15	17	15	16	16
Equity ratio, %	94.4	96.7	94.4	96.7	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.

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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, 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