# SPAGO NANOMEDICAL AB



# Interim report

January- September 2023

# Tumorad<sup>®</sup> in clinic

## **JULY – SEPTEMBER IN BRIEF**

- Net sales for the quarter amounted to KSEK 271 (KSEK 397)
- The loss for the quarter amounted to KSEK –7,113 (KSEK -8,594)
- Operating expenses for the quarter amounted to KSEK -8,795 (KSEK -10,406)
- Earnings per share, before and after dilution, for the quarter amounted to SEK -0.08 (SEK -0.11)
- Cash and cash equivalents at the end of the quarter amounted to KSEK 25,974 (KSEK 71,234)

#### **JANUARY – SEPTEMBER IN BRIEF**

- Net sales for the year amounted to KSEK 472 (KSEK 912)
- The loss for the year amounted to KSEK -29,387 (KSEK -28,039)
- Operating expenses for the year amounted to KSEK -36,945 (KSEK -32,590)
- Earnings per share, before and after dilution, for the year amounted to SEK -0.32 (SEK -0.51)

#### SIGNIFICANT EVENTS AFTER THE QUARTER

- The company's application to start a clinical phase I/IIa study in Australia with the candidate drug in the radionuclide therapy program Tumorad, <sup>177</sup>Lu-SN201, has been approved. The study is conducted in patients with advanced cancer and the first patient is expected to be included shortly.
- Four new patent applications have been filed with the European Patent Office (EPO) to expand the patent protection for Tumorad. If granted, Tumorad will receive protection in all strategically key markets, including the EU, US and Japan, until at least 2042.
- The Board decided, with the support from the AGM, to carry out a fully secured rights issue of approximately MSEK 30.6 for the continued development of Tumorad, including, among other things, the inclusion of patients and obtaining initial results in the first clinical study with Tumorad in cancer patients. The subscription period in the rights issue is November 9-23. For each unit subscribed for in the rights issue, the shareholder receives a warrant (TO12) that entitles the holder to subscribe for one new share during the period May 17-30, 2024.

Unless otherwise stated, this Interim report refers to the group. Figures in parentheses refer to the parent company and to the corresponding period last year. No operations were conducted in the subsidiary during the financial year 2022, which is why comparative figures for the group are missing.

## **CEO STATEMENT**

After intensive preparations and anxious waiting, we now have received approval from the ethics review committee at St. Vincent's Hospital in Melbourne, and it has been registered with the Australian Therapeutic Goods Administration (TGA)" in Australia for starting our first clinical study within the Tumorad program, Tumorad-01. I am very happy to put this important milestone behind us and now focus on delivering results with the drug candidate <sup>177</sup>Lu-SN201 in patients with advanced cancer. With a clinically validated and patented platform technology, together with a clearly differentiated profile in radioisotope drugs and imaging, we can enable effective treatment of larger groups of patients with severe disease.

Following the positive results from our SpagoPix diagnostic program in breast cancer, which clearly demonstrate that our platform works well for targeting solid tumors, we are now further increasing our focus on cancer drug development by starting our first clinical study within the Tumorad program - Tumorad-01. The start of the study marks a very significant milestone for Spago Nanomedical, transforming the company to be strongly focused on clinical development of our programs. Radioisotope drugs, also referred to as radionuclide therapy, is an area that has received significantly increased attention in recent years as a result of clinical and commercial progress and several major completed transactions by global pharma companies. The interest in the field is steadily increasing from investors as well as other pharmaceutical companies.

Tumorad is our leading development program and we see great value in now advancing and accelerating the clinical development with the phase I/IIa study Tumorad-01. There is still a great medical need for more effective methods to treat metastatic and aggressive cancer. Therefore, the Board of Directors of Spago Nanomedical recently decided on a share issue with preferential rights for existing shareholders with the main purpose of financing the Tumorad-01 study until initial results can be generated.

Tumorad-01 is initially conducted at clinics in Australia. The Phase I part is a dose escalation, first-in-human study, intended to be conducted in up to 30 patients with advanced cancer, with the primary objective of evaluating the safety, tolerability and dosimetry of the drug candidate <sup>177</sup>Lu-SN201. The study received approval from an ethical review committee in October and we expect the first patient to be dosed shortly. With a study design that enables continuous data reporting, we expect initial results on the drug's safety and biodistribution during the first half of next year. These data are of great importance as they can provide an early indication of the possibility to reach a favorable benefit-risk ratio.

The rapid start of the study immediately after approval was made possible by extensive preparatory work completed in the third quarter. Among other things, the large-scale GMP-classified production of trial materials was completed, as well as the process for isotope labeling and delivery of radiopharmaceuticals to the clinics. Through a good network of CROs, we have ensured the delivery of drugs and implementation of the study at clinics in Australia. The goal is to gradually broaden the study to include clinics in Europe, and the preparations for this are in full swing.

Our strong belief in Tumorad as an opportunity for a new promising treatment for several types of aggressive and metastatic cancer is based on previous research results, and the significant medical need for more effective treatments. With modern targeted drugs, radioisotopes can be delivered to certain types of tumors inside the body and thus treat more patients, including those with metastatic cancer or with tumors that cannot be treated with external radiation. This is also reflected in the strong, increasing interest in new radioisotope drugs from both big pharmaceutical companies and specialist investors.

We see several clinical advantages of our technology compared to other radioisotope drugs, both launched and in development. The vast majority of these are designed to reach only a certain tumor type expressing a specific target protein. This is where our drug candidate <sup>177</sup>Lu-SN201 differs, as its mechanism makes it possible to treat several different types of cancer, especially those where currently there are no targeted treatments.

In parallel with taking Tumorad into the clinic, development work has continued with the company's program for selective contrast agents, SpagoPix, where the product candidate SN132D has the potential to significantly improve the precision of magnetic resonance imaging (MRI). SN132D can provide visualization of tumors and other lesions with higher precision than what is possible with today's contrast agents, which increases the chances of successful treatment. Previous clinical results from patients with breast cancer demonstrate a selective accumulation of SN132D in breast tumors, as well as in the pancreas and liver. These data represent a clear first clinical validation that paves the way for broader use of the platform in both radioisotope drugs and additional imaging indications such as endometriosis.

The clinical phase IIa study SPAGOPIX-02, evaluating SN132D in patients with documented or suspected endometriosis, is now in the analysis phase and we expect topline data before year end. Endometriosis is a painful disease that affects up to 10% of all women of childbearing age and with a great need for improved diagnosis and treatment. If positive results in SPAGOPIX-02, we believe that this study will be key for the further development of the SpagoPix program and enable further discussions with potential license partners.

By means of the fully secured share issue of 30.6 MSEK with preferential rights for the company's existing shareholders and subscription period November 9-29, we potentiate delivery of meaningful results with Tumorad in cancer patients. I am very pleased by the major up-front support by several of our largest shareholders and I hope that both existing and new owners will join us on this exciting journey.

Thank you for your continued engagement in Spago Nanomedical, I look forward to keeping you updated as we progress.

Mats Hansen, CEO Spago Nanomedical AB

"With a study design that enables continuous data reporting, we expect initial results on the drug's safety and biodistribution during the first half of next year"



## **SPAGO NANOMEDICAL IN BRIEF**

Spago Nanomedical AB (publ) is a Swedish clinical phase company, developing products for treatment and diagnostics of cancer and other severe diseases. Spago Nanomedical's share is listed on Nasdaq First North Growth Market (ticker: SPAGO).

The company intends to develop pharmaceuticals and diagnostic products for diseases with a high medical need under its own auspices until clinical proof-of-concept. Subsequent development and future commercialization are intended to take place through strategic license or partnership agreements with established pharmaceutical companies with the necessary capacity and global reach in each project area.

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 in image diagnostics and treatment of cancer and other severe diseases. With the development programs Tumorad and SpagoPix, Spago Nanomedical aims to improve the conditions for effective healthcare for large groups of patients while meeting the need for stronger positioning and renewal of product portfolios of commercial pharmaceutical companies.

#### **Tumorad**®

The Tumorad development program aims to develop new radiopharmaceuticals for radionuclide therapy against aggressive cancer. Preclinical results show that the drug candidate in the program, <sup>177</sup>Lu-SN201, accumulates in tumors, delays growth and prolongs survival at clinical useful doses. This opens up for wide use of <sup>177</sup>Lu-SN201 for the treatment of various cancers where there are currently no opportunities for clinically effective treatment with radiopharmaceuticals, such as ovarian cancer and triple-negative breast cancer. A phase I/IIa clinical study in patients with advanced cancer will be initiated in the fourth quarter to evaluate safety, tolerability, biodistribution and initial efficacy of <sup>177</sup>Lu-SN20. See further under "Program - Tumorad".

#### **SpagoPix**

The SpagoPix development program aims to improve the precision of MRI scans for suspected cancer and other serious diseases by launching a selective contrast agent for more precise visualization of tumors and other lesions. Initial clinical results show that the product candidate within the program, SN132D, provides clinically relevant contrast in breast cancer tumors, in the liver and in the pancreas, while maintaining good safety. A phase IIa clinical study is currently investigating the possibility of increasing the precision in the diagnosis of endometriosis. See further under "Program -SpagoPix".



## **PROGRAM - TUMORAD**

#### **BACKGROUND AND MARKET**

Radiation therapy has long been used effectively in the fight against cancer. Along with surgery and chemotherapy, radiotherapy is a cornerstone in the treatment of several cancers. The development and approval of new generations of radioactive drugs, radiopharmaceuticals, for internal radiotherapy, known as radionuclide therapy (RNT), has led to a renaissance in the field. Radionuclide therapy has received increased attention in recent years, in line with clinical and commercial advances and a number of major deals completed in the field. In Tumorad, nanoparticles are loaded with radioactive isotopes that enables internal radiation therapy of aggressive cancer with high precision. Tumorad may therefore provide the opportunity to treat cancer that cannot be treated with other types of radiopharmaceuticals.

Despite important advances and new cancer therapies, long-term survival is however still unsatisfactory in many cases, especially in the treatment of spread (metastatic) cancer. Treatment resistance is a significant challenge in cancer care, and there is therefore a clear clinical need for new treatment options. Internal radiation therapy, is a valuable alternative or complement to existing treatment. Unlike the radionuclide therapies that are currently used clinically and which target specific cancers, Tumorad is designed for physiological and selective accumulation in tumors and other lesions via the "Enhanced Permeability and Retention (EPR) effect"<sup>1</sup>. The mechanism of action gives Tumorad the opportunity to treat different types of solid tumors and thus potentially has a significantly higher market value.

Interest in RNT is very high and is shown not least by a number of deals in recent years where large pharmaceutical companies have acquired or invested billions in RNT projects. Today there are just over a handful of approved RNT products and the market is expected to grow rapidly in steps with further market approvals, increased subsides, and a remaining large medical need. Tumorad is expected to be used both as a complement to surgery, chemotherapy, and immunotherapies, as well as first treatment options. This opens up opportunities for optimized development and for broad use in the market. Based on mortality data in a number of major cancer indications (colorectal, gastric, breast, pancreatic, and ovarian cancer) which based on clinical science can be expected to be candidates for treatment with <sup>177</sup>Lu-SN201 (indications with documented EPR effect), as well as prices of comparable existing pharmaceuticals, the company estimates the annual addressable market for Tumorad 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 programs with regards to the material's structure and production. SpagoPix has in the clinical studies SPAGOPIX-01 and SPAGOPIX-02 shown that the material is safe to give to patients and that the mechanism for selective accumulation of the nanoparticle in tumors via the EPR effect works. Furthermore, the radioactive isotope <sup>177</sup>Lu is already used clinically today and has been shown to have an effect on cancer tumors. This opens up for successful use of the Tumorad particles for the purpose of radionuclide treatment of cancer.

Extensive development and optimization work has previously resulted in the candidate drug, <sup>177</sup>Lu-SN201 provides the desired exposure to radioactivity in tumors, while minimizing the impact on other organs. Furthermore, preclinical efficacy studies have shown that <sup>177</sup>Lu-SN201 inhibits tumor growth and prolongs survival in a model for aggressive breast cancer. The company has also shown that <sup>177</sup>Lu-SN201 reduces tumor growth and prolongs survival by 37 percent 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 SN201 on a larger scale for clinical studies is completed and in the fourth quarter a clinical phase I/IIa dose

<sup>&</sup>lt;sup>1</sup> Eriksson et al., 2014 & Mattisson et al., 2023

escalation and dose expansion, first-in-human study in patients with advanced cancer will be initiated. The primary objective of the study is to evaluate safety, biodistribution, tolerability and initial efficacy of <sup>177</sup>Lu-SN201. The Phase I part of the study will include up to 30 patients and the company expects to receive an indication of safety and efficacy in patients early in the study. The study will initially be conducted at a number of clinics in Australia and as the study progresses, clinics in other countries may also be included.

## **PROGRAM - SPAGOPIX**

#### BACKGROUND

SpagoPix is a tumor-selective contrast agent with extraordinary signal strength and potential to significantly improve cancer diagnostics based on magnetic resonance imaging (MRI). Through better and more precise visualization of soft tissue tumors and other lesions, the chances of successful treatment of patients are increased.

The product candidate within SpagoPix, SN132D, is as well as the candidate drug <sup>177</sup>Lu-SN201 designed for physiological and selective accumulation in tumors and other lesions via the scientifically well-established mechanism EPR effect. 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 selective mechanism of action and the high signal strength gives MRI images better contrast between cancer tissue and the healthy tissue, which creates the conditions for more optimally utilizing the potential of MRI. SN132D can provide the ability to detect tumors and other lesions with higher precision than is possible with today's contrast agents, thereby opening for earlier diagnostics, more efficient surgery, screening of high-risk patients, monitoring and follow-up of patients before and after surgery, and facilitating automated image analysis for example with AI-based systems. Improved methods for accurate visualization and diagnosis of tumors would increase the probability of a successful treatment and thus the patients' chance of better survival and quality of life. SN132D can also provide the opportunity for better imaging of other disease states where the EPR effect is pronounced, such as endometriosis, and thus open to earlier detection and more effective treatment even of this disease with a great medical need for improved imaging.

In addition to the good diagnostic properties, SN132D is also free of the metal gadolinium, which in some patients has been linked to side effects and accumulation in the body, for example in the brain. There are also increasing signs that gadolinium can pose an environmental problem when it ends up in waste water. The authorities in all major markets have introduced bans and restrictions on the use of certain types of gadolinium contrast agents. Overall, the shortcomings of the MRI contrast agents used today constitute an obstacle to the wider use of MRI. SN132D is instead based on manganese, a naturally occurring element that is essential for many functions in the human body.

In summary, these properties make SN132D a unique contrast agent with the potential to significantly improve the imaging of tumors and other lesions compared to conventional MRI contrast agents.

#### MARKET

In order to effectively demonstrate clinical proof of concept for the program and the company's platform technology, the development of the 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 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. It is estimated that more than 176 million women of reproductive age are affected worldwide and endometriosis accounts for societal healthcare costs of a similar order as diseases such as type 2 diabetes or rheumatoid

arthritis. Currently, the average time to diagnosis is 7 years and the clinical need for improved diagnostic technologies is high.

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.

#### **STATUS**

The clinical phase I study SPAGOPIX-01, conducted at two hospitals in Sweden, was concluded in the end of 2022. In total, 14 patients with confirmed breast cancer were included. The primary objective with the study was to study safety at different doses of SN132D. A secondary objective was to document how this new contrast agent can enhance MRI images of cancer tumors in breast and pancreas with suspicious spread to the liver.

Based on analysis of the second dose group, the interim results 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 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. Beyond 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. The interim results from the study were presented at the 2022 San Antonio Breast Cancer Symposium and further publications based on the final study report are planned.

At the end of 2022, the company initiated a phase IIa clinical study, SPAGOPIX-02, in patients with suspected endometriosis. The study evaluates the safety and MRI enhancing properties of SN132D in participants with suspected endometriosis. Comparisons are made with transvaginal ultrasound and non-contrast enhanced MRI to consider the diagnostic potential of SN132D in endometriosis. Preliminary analysis of data from SPAGOPIX-02 shows that SN132D has a good safety profile in patients with endometriosis. Further evaluation of the MRI contrast enhancing properties, particularly in lesions indicative of deep endometriosis, is ongoing. In total, 8 patients have been included in the study at Skåne University Hospital in Malmö, which is sufficient to provide for a meaningful assessment and recruitment has therefore completed.

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 after confirmed proof-of-concept. The process of evaluating potential licensees is ongoing and has so far resulted in valuable feedback. On the basis of this, together with promising interim data, which shows good contrast enhancement in tumors and target organs without background noise, the company is currently evaluating the positioning in cancer and other diseases to maximize the opportunity for partnership.

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.

## FINANCIAL DEVELOPMENT

#### RESULTS

Operating expenses amounted to KSEK -8,795 (KSEK -10,406) for the quarter and KSEK -36,945 (KSEK -32,590) for the year. The operating costs during the year are primarily related to the production of material for the planned clinical phase I/IIa study in the Tumorad program as well as other clinic preparatory activities such as compilation of material for the clinical trial application, consultation and advice with relevant regulatory agencies, and identification of suitable clinical sites for the study.

Total revenue amounted to KSEK 1,487 (KSEK 1,751) for the quarter and KSEK 6,876 (KSEK 4,452) for the year, and relates mainly to development expenses and patent expenses for the SpagoPix program that were capitalized in the balance sheet during the period as well as an accrued innovation support from the Australian authorities for the development activities that the company carried out during the year.

The operating result amounted to KSEK -7,308 (KSEK -8,655) for the quarter and KSEK -30,069 (KSEK -28,138) for the year. Earnings per share before and after dilution amounted to SEK -0.08 (SEK -0.11) for the quarter and SEK -0.32 (SEK -0.51) for the year.

#### **INVESTMENTS AND FINANCIAL POSITION**

At the end of the quarter, cash and cash equivalents amounted to KSEK 25,974 (KSEK 71,234).

Cash flow from operating activities amounted to KSEK -4,556 (KSEK -9,941) for the quarter and KSEK -32,387 (KSEK -30,663) for the year. The cash flow in the quarter relates to the ongoing clinic preparatory activities in the Tumorad program. Cash flow from investment activities amounted to KSEK -642 (KSEK -885) for the quarter and KSEK -3,519 (KSEK -2,370) for the year. The investments mainly consist of intangible assets, which are the development and patent expenses that were capitalized during the period. Cash flow from financing activities amounted to KSEK -221 (KSEK -221 (KSEK 52,647) for the quarter and KSEK -221 (KSEK 51,807) for the year.

At the end of the quarter, the company's equity amounted to KSEK 167,606 (KSEK 208,314) and the equity ratio to 96.7 percent (98.0 percent). Equity per share, before dilution, amounted to SEK 1.84 (SEK 2.29).

#### **SHARES AND SHARE CAPITAL**

The number of registered shares as of September 30, 2023 amounted to 90,943,723. Since 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. By the end of the quarter, the share's quota value amounted to SEK 0.10, whereby the share capital amounted to SEK 9,094,372.30. The number of shareholders at the end of the period were 2,780. The largest owners at the end of the period were Peter Lindell, with companies and related parties, Avanza Pension, Mikael Lönn, Eva Redhe and Tiel Ridderstad.

Unless otherwise stated, this Interim report refers to the Group. Figures in parentheses refer to the parent company and to the corresponding period last year. No operations were conducted in the subsidiary during the financial year 2022, which is why comparative figures for the group are missing.

## **INCOME STATEMENT**

	Group	Parent	Group	Parent	Parent
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Amounts in KSEK	2023	2022	2023	2022	2022
Income					
Net sales	271	397	472	912	1 054
Internal work capitalized	72	134	208	389	441
External work capitalized	570	751	3 210	1 848	3 254
Other operating income	574	469	2 986	1 303	1 711
Total income	1 487	1 751	6 876	4 452	6 460
Operating costs					
Project costs	-3 136	-4 423	-18 256	-13 331	-20 353
Other external costs	-1 762	-1 730	-6 221	-6 125	-8 071
Personnel costs	-3 387	-4 051	-11 786	-12 523	-16 765
Depreciation/amortization of fixed assets	-70	-92	-205	-274	-356
Other operating costs	-441	-111	-476	-337	-380
Total operating costs	-8 795	-10 406	-36 945	-32 590	-45 925
OPERATING RESULT	-7 308	-8 655	-30 069	-28 138	-39 465
Financial items					
Interest income and similar items	195	61	681	99	268
Total financial items	195	61	681	99	268
RESULT AFTER FINANCIAL ITEMS	-7 113	-8 594	-29 387	-28 039	-39 197
PROFIT/LOSS FOR THE PERIOD	-7 113	-8 594	-29 387	-28 039	-39 197

## **BALANCE SHEET**

	Group	Parent	Parent
Amounts in KSEK	30 Sep 2023	30 Sep 2022	31 Dec 2022
ASSETS			
NON-CURRENT ASSETS			
Intangible assets			
Capitalized expenditure for development	134 864	130 466	131 744
Patents	8 412	7 933	8 113
Tangible assets			
Equipment, tools, fixtures and fittings	747	934	853
Financial assets			
Other long-term receivables	96	0	0
Total non-current assets	144 118	139 333	140 710
CURRENT ASSETS			
Accounts receivables	0	0	49
Other current assets	615	520	662
Prepaid expenses and accrued income	2 568	1 511	2 431
Cash and cash equivalents	25 974	71 234	62 101
Total current assets	29 157	73 264	65 243
TOTAL ASSETS	173 275	212 597	205 953
EQUITY AND LIABILITIES			
Equity			
Equity	167 606	208 314	197 156
Total eqiuty	167 606	208 314	197 156
Provisions			
Provisions for pensions	96	0	0
Other provision	23	0	0
Total provisions	119	0	0
Current liabilities			
Accounts payables	2 826	1 242	4 725
Other current liabilities	462	454	494
Accrued expenses and deferred income	2 263	2 587	3 577
Total current liabilities	5 551	4 283	8 797
TOTAL EQUITY AND LIABILITIES	173 275	212 597	205 953

## **STATEMENT OF CHANGES IN EQUITY**

Amounts in KSEK	Share capital	Dev. fund	Other contributed capital	Translation difference	Other equity incl. profit/loss	Total equity
Opening balance Jan 1, 2022	41 182	84 418	255 366	0	-196 155	184 812
Capitalization of development expenses		2 237			-2 237	0
Share issue	49 761		9 952			59 713
Issuance costs			-8 172			-8 172
Profit/loss					-28 039	-28 039
Closing balance Sep 30, 2022	90 944	86 655	257 146	0	-226 430	208 314
Opening balance, Oct 1, 2022	90 944	86 655	257 146	0	-226 430	208 314
Capitalization of development expenses		1 458			-1 458	0
Profit/loss					-11 158	-11 158
Closing balance Dec 31, 2022	90 944	88 113	257 146	0	-239 047	197 156
Opening balance, Jan 1, 2023	90 944	88 113	257 146	0	-239 047	197 156
Reduction of share capital	-81 849				81 849	0
Capitalization of development expenses		3 418			-3 418	0
Issuance costs			-221			-221
Translation difference				58		58
Profit/loss					-29 387	-29 387
Closing balance Sep 30, 2023	9 094	91 532	256 925	58	-190 003	167 606

## **CASHFLOW STATEMENT IN SUMMARY**

	Group	Parent	Group	Parent	Parent
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Amounts in KSEK	2023	2022	2023	2022	2022
Cash flow from operating activities and before changes					
in working capital	-7 203	-8 563	-29 827	-27 864	-38 841
Changes in working capital	2 647	-1 378	-2 561	-2 799	654
Cash flow from operating activities	-4 556	-9 941	-32 387	-30 663	-38 187
Cash flow from investing activities	-642	-885	-3 519	-2 370	-3 829
Cash flow from financing activities	-221	52 647	-221	51 807	51 657
Cash flow for the period	-5 418	41 820	-36 127	18 773	9 641
Cash and cash equivalents at the beginning of the period	31 392	29 414	62 101	52 460	52 460
CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD	25 974	71 234	25 974	71 234	62 101

DATA PER SHARE	Group	Parent	Group	Parent	Parent
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
	2023	2022	2023	2022	2022
Earnings per share, before and after dilution,					
SEK	-0.08	-0.11	-0.32	-0.51	-0.61
Equity per share, before dilution, SEK	1.84	2.29	1.84	2.29	2.17
Average number of shares before dilution	90 943 723	81 196 060	90 943 723	54 666 782	63 810 559
Average number of shares after dilution	90 943 723	81 425 550	90 943 723	55 137 328	64 173 887
Number of shares at the end of the period	90 943 723	90 943 723	90 943 723	90 943 723	90 943 723

<b>OTHER KEY FIGURES</b>	Group	Parent	Group	Parent	Parent
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
	2023	2022	2023	2022	2022
Average number of employees	12	15	13	15	15
Equity ratio, %	96.7	98.0	96.7	98.0	95.7

## **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 2022.

## **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 Annual Report and consolidated statements (K3). The company's accounting principles are described in Note 1 in the company's annual report for 2022.

Consolidated accounts include the parent company Spago Nanomedical AB (publ) and the companies over which the parent company directly or indirectly has controlling interest (subsidiaries). Control means a right to shape another company's financial and operational strategies in order to obtain financial benefits. When assessing whether a controlling interest exists, account is taken of holdings of financial instruments that are capital instruments. Consideration is also given to whether the company has the opportunity to control the business through an agent. Controlling influence normally exists when the parent company directly or indirectly holds shares that represent more than 50% of the votes. A subsidiary's income and expenses are included in the consolidated accounts from and including the time of the acquisition/start-up up to and including the time when the parent company no longer has a controlling interest over the subsidiary. The accounting principles for the subsidiary are consistent with the group's accounting principles. All intra-group transactions, transactions and unrealized profits and losses attributable to intra-group transactions have been eliminated when preparing the consolidated accounts. The consolidated accounts are prepared according to the acquisition method, which means that the subsidiaries' taxed and untaxed equity is included in the group's equity only to the extent it was earned after the acquisition. The conversion of foreign companies takes place according to the current rate method (see also valuation in foreign currency in note 1 in the company's annual report for 2022).

Unless otherwise stated, this Interim report refers to the Group. Figures in parentheses refer to the parent company and to the corresponding period last year. The amounts are expressed in KSEK, which in this report refers to thousands of Swedish kronor.

## **TRANSACTIONS WITH RELATED PARTIES**

Chairman of the board, Hans Arwidsson, has during the quarter provided consulting services to the company within business development. Transactions with related parties have been made according to agreement based on market terms.

## **INVESTOR RELATIONS**

This report can be downloaded from the website <u>www.spagonanomedical.se</u>

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.

## 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 3, 2023

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

Hans Arwidsson Chairman of the board Kari Grønås

**Alan Raffensperger** 

**Nicklas Westerholm** 

**Mats Hansen** CEO