

A photograph of two scientists in a laboratory. A woman in the foreground, wearing glasses and a white lab coat, is using a red bulb pipette to transfer liquid into a flask. A man in the background, also in a lab coat and glasses, is looking at a document. The scene is brightly lit, suggesting a clean and professional environment.

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INTERIM REPORT JANUARI – MARCH 2023

NANEXA AB (PUBL)

Nanexa AB (PUBL)

Significant events during the first quarter 2023

- Nanexa AB announced positive outcome in the first preclinical study with NEX-22. In a one-month study in rats, single doses of two different PharmaShell® formulations were studied in different doses. The results show a controlled release of liraglutide, with plasma exposure over 28 days for NEX-22, compared to around 2 days for a formulation with liraglutide without the PharmaShell coating.

Significant events after the end of the period

- No significant events after the end of the quarter.

Summary of the reporting period 1 January – 31 March 2023

- Turnover amounted to: TSEK 8,173 (298)
- Operating profit (EBIT) amounted to: TSEK -8,703 (-12,331)
- Profit after tax amounted to: TSEK -8,603 (-12,370)
- Earnings per share amounted to: SEK -0.14 (-0.24)
- Cash flow for the period amounted to: TSEK -20,682 (-17,934)
- Cash and cash equivalents at end of period: TSEK 60,500 (87,726)

Figures in brackets refer to the corresponding period in the previous year.

The CEO's comments

During the first quarter of 2023, important advances were made in our projects as well as towards bringing PharmaShell to market. We obtained highly promising results from the preclinical study of NEX-22, where we extended the release of liraglutide from two days to a month's controlled release, a result that clearly shows opportunities going forward for both the NEX-22 project and our important collaboration with Novo Nordisk. The clinical study with NEX-20, a long-acting formulation of liraglutide for treatment of Multiple Myeloma, which commenced at the end of last year, has proceeded according to plan during the quarter, and is continuing during the second quarter.



The year started based on a very important agreement for the company

In December last year we signed an exclusivity- and evaluation agreement with Novo Nordisk, an important agreement that might represent a very interesting development for us. The agreement entails Novo Nordisk evaluating our PharmaShell® technology in order to improve dosage of one of their products that is currently on the market and develop a one-month depot, which will make the treatment simpler compared with today's product, creating a unique product in the market. It is highly gratifying that we started the work immediately after the turn of the year, and we have excellent conditions to deliver material to Novo Nordisk during the year to start its evaluation in preclinical studies. The goal is to sign a licence agreement for development and marketing if the evaluation is positive.

Important advances in the project portfolio

During March, we were able to present good news regarding the development of NEX-22, our latest project for treatment of the very major indication type 2-diabetes. The preclinical rat study displayed promising results, in which single doses of two different PharmaShell formulations with varying doses were tested. The study demonstrated a controlled release of liraglutide with plasma exposure that lasted for 28 days for NEX-22 compared with about 2 days for a solution of liraglutide (Victoza) without PharmaShell. I view this as a very promising result and am looking forward to taking the project further through optimisation of the PharmaShell formulation and tests in additional preclinical studies during the year, and onward into clinical development. The development of a one-month preparation of a GLP-1 substance such as liraglutide is considered to potentially have a major benefit in relation to today's products for treatment of type-2 diabetes and could take a significant market share in a very large and growing market.

This result also has a clear bearing on the collaborative project we have with Novo Nordisk and therefore gives us a very good start in the development work.

The clinical phase I-study in the NEX-20 project is proceeding, where we are studying different doses of PharmaShell-coated lenalidomide for treatment of multiple myeloma with a one-month depot preparation. We estimate that the study will be completed before the end of June and are looking forward to the results that the study will give us.

The successful preclinical study with NEX-22 and the progress in our ongoing clinical trials shows the strength and the potential in our product portfolio. Positive results from both preclinical and clinical studies are crucial in progressing our products through development stages and attracting partners. These advances are increasing our commitment to supply innovative and improved long-acting treatment for patients in need and strengthening our position in the market.

Own control over development

One year ago, we were en route to putting our new plant into operation and now, one year later, we are pleased and proud that it is in operation and furthermore certified by the Medical Products Agency. The plant is also ready for installation of more equipment from Applied Materials, which will increase our capacity. This state-of-the-art plant is unique of its kind in that it enables work with cytostatics as well as biological drugs, and is a key factor in Nanexa's future operation. Having our own plant gives us independence and control over our manufacturing, which is crucial to both drive the development of our own projects and those of partners as effectively as possible, and to be able to scale up our production process over time. We are convinced that our unique plant will open up new opportunities and contribute to us continuing to drive development of innovative drugs for patients in need.

Increased interest throughout the world

There is substantial interest in Nanexa, PharmaShell and our projects, and it is continuing to grow, which has resulted in a number of invitations to meetings and conferences throughout the world. During the quarter we have had the opportunity to present our PharmaShell technology and our projects in several highly relevant contexts, for both potential partners and investors.

In February this year, Nanexa was invited to, and participated in, the fourth annual "Beyond Medicines' Barriers" meeting, which was arranged by the Myeloma Foundation (IMF) in Lugano, Switzerland, together with a number of the large global

pharmaceutical companies, which gave us the opportunity to discuss patients' challenges with today's treatment and the possibilities to improve patients' adherence to treatment with NEX-20.

Participation in this important event gave us the opportunity to demonstrate our expertise both within the indication area and in relation to long-acting injectables based on our patented PharmaShell technology. Attending events such as this both strengthens our reputation within the pharmaceutical industry and increases interest from potential partners and other actors.

Strong start to the year

All in all, we have started the year strongly, with the focus on a number of important deliveries after an eventful last year, not least NEX-22 and the collaboration with Novo Nordisk. I am looking forward to a new year with continued advances in both our own projects and partner projects, and participation in different activities where we can demonstrate the importance of PharmaShell and the possibilities of our depot drugs for both the patient and health care.

We entered 2023 with increased confidence, new and important collaborative partners and an injection of capital. Our agreements with large global pharmaceuticals companies have shown that the development of our projects and our technology is moving in entirely the right direction.

We work continuously to secure long-term financing and based on recent developments, where we also added Novo Nordisk as the largest shareholder, we see good opportunities for that.

David Westberg, CEO Nanexa

About Nanexa

Nanexa is developing PharmaShell® – a drug delivery-system with major potential

Nanexa is a pharmaceutical company developing injectable drug products based on the proprietary and innovative drug delivery system PharmaShell®, the high drug load delivery system enabling the next-generation, long-acting injectables atomic layer precision.

The company has taken important steps in the development in recent years, now driving three drug candidates in as many very interesting areas. All three projects address important medical needs and substantial markets, where the recently launched project, NEX-22, targets treatment of type 2 diabetes, which is huge market with annual sales of USD 50 billion in 7MM (the seven major markets in the Western world). The NEX-18 and NEX-20 projects are developed to create improved versions and depot formulations of the drugs azacytidine, for treatment of myelodysplastic syndrome (MDS), and lenalidomide, for treatment of multiple myeloma, two types of blood cancer. The properties of the PharmaShell system are utilised to improve these treatments, for example by reducing the burden on patients and caregivers of the inconvenient and costly administration of azacytidine, and by improving compliance to treatment of type 2 diabetes with liraglutide or multiple myeloma with lenalidomide. The basis for selecting the projects is that there must be a clear medical need, a strong long-term market potential and good technical prerequisites.

Nanexa product projects combine already marketed drugs with the company's drug delivery system PharmaShell, enabling formulation of unique long-acting products. The projects' development programs are based on comparison with already approved products, which provides for significantly shorter and less expensive development projects, with significantly lower risk compared to traditional product projects based on new drug substances.

In addition to the own product projects, Nanexa works actively to out-license the PharmaShell technology to pharmaceutical companies that want to create their own unique long-acting products. The company currently has a number of evaluation agreements with other pharmaceutical companies, where the aim of the evaluation work is to establish a basis for further collaboration and out-licensing of the PharmaShell technology for the development of specific new products for the partner companies.

PharmaShell is based on the Atomic Layer Deposition (ALD) coating technology, which has long been an established technology in the semiconductor industry. The PharmaShell system has a wide range of applications and can be applied to both small-molecule drugs and to biological molecules such as peptides and proteins.

In 2020, Nanexa entered into a collaboration agreement with the world's largest ALD equipment supplier, Applied Materials, Inc., which will facilitate the scale-up of the company's manufacturing of pharmaceuticals based on the PharmaShell system. The first equipment developed by Applied Materials was installed in 2021 and more equipment will be installed in the new pilot plant that Nanexa has designed and built in Uppsala. The pilot plant provides the company with unique capacity for pharmaceutical manufacturing, as it is adapted to meet strict requirements for handling cytostatics and other highly toxic drugs, as well as for so-called aseptic manufacturing, which is critical for the production of depot drugs from biological substances, such as monoclonal antibodies.

Vision

Nanexa will become a world-leading drug development company for long-acting injectables, developing a new generation of innovative drug products enabled by our unique PharmaShell technology.

Business concept

The company will drive the development of innovative drugs from discovery phase through preclinical and clinical development, primarily up to and including completed clinical Proof of Concept in phase II. The objective is subsequently to drive the projects further towards commercialization, together with licence partners or on our own behalf, depending on what is deemed to create the most value for the company.

The proprietary product projects are primarily focused on development of so called "super generics", new drugs based on existing substances where the patent has expired, and which are reformulated using the PharmaShell technology in order to achieve new and significantly improved properties for both patients and healthcare providers. The combination with PharmaShell also creates a product with significant patent protection. Being based on proven drugs, the development projects are significantly less costly, with a simpler registration process, shorter time to market and significantly lower risk than projects with drugs based on completely new substances.

Furthermore, the company will license the actual PharmaShell technology to pharmaceutical companies which intend to use it in their own development of unique long-acting drugs.

Comments, Q1 2023

Comments on the result and the financial position

Turnover and earnings

Net sales for the quarter amounted to TSEK 8,173 (298), of which TSEK 2,011 is attributable mainly to income generated within the framework of evaluation agreements entered into in respect of PharmaShell, including with Novo Nordisk, TSEK 512 concerns surface coating of sensors and TSEK 5,643 concerns allocation of prepaid fee of 4 million dollars related to the exclusivity agreement that was concluded with Novo Nordisk A/S in December 2022. Capitalised development costs amounted to TSEK 5,294 (4,929), attributable mainly to investments in NEX-20 and NEX-22, and to a lesser extent NEX-18 and the PharmaShell® system.

External project and development costs during the quarter amounted to TSEK -6,453 (-5,089), with the increase relative to last year mainly attributable to the recently commenced NEX-22 project. Other external costs amounted to TSEK -6,276 (-5,668), with the increase primarily explained by higher costs for the new facility for R&D and production, which was put into operation during the second quarter of 2022. Personnel costs amounted to TSEK -6,074 (-4,693) in the first quarter, where the increase is due partly to an increase in the number of employees and partly to higher variable remuneration compared with the previous year.

The loss for the first quarter amounted to TSEK -8,603 (-12,370).

Cash flow and investments

Cash flow for the quarter amounted to TSEK -20,682 (-17,934). Change in working capital amounted to TSEK -8,324 (611), which is principally explained by a decrease in prepaid income from Novo Nordisk, as well as, to a lesser extent, an increase in accounts receivable and prepaid expenses for preclinical studies. Cash flow from investing activities, primarily concerning development costs and patents, amounted to TSEK -6,379 (-8,121). Amortisation of loans amounted to TSEK -551 (-315).

Financial position

Cash and cash equivalents and current investments as of 31/03/2023 amounted to TSEK 60,500 (87,726).

The company works continuously to secure the long-term financing and based on recent developments, including agreements with and addition of Novo Nordisk to the shareholder list, the board and management see good opportunities to secure continued financing.

The Board considers that the company's current working capital and cash and cash equivalents are sufficient to finance the operations according to the current business plan until the end of 2023, but not for the next 12 months from the submission of this report. To ensure working capital, the company may postpone planned investments and activities, whereby current funds could be sufficient until end of the first quarter of 2024, but may also be financed by raising capital or agreements on licenses and/or exclusivity regarding the PharmaShell technology.

If financing cannot be obtained, there is a material uncertainty factor that could lead to a negative impact on the company's business plan and ability to pursue development at the planned pace, and lead to doubts about the company's ability to continue its operations.

Employees

The number of employees as of March 31, 2023 was 18 (18), of which 7 (6) were women and 11 (12) were men, and the average number of employees (FTE) was 18 (16) in the first quarter of 2023. In addition to employed staff, Nanexa regularly hires about ten consultants with specialist expertise.

Related party transactions

During the fourth quarter, the company has purchased consultancy services from board member Bengt Gustavsson through Sangus Jazz AB for TSEK 606 (604). The consulting services are clearly separated from assignment as a member of the Board of Directors of the company.

The share

Nanexa AB (publ) was listed on the Nasdaq First North Growth Market on 29 May 2020. The share was previously listed on the Spotlight Stock Market since 17 June 2015. As of March 31, 2023, the number of shareholders in Nanexa was 3,060.

Earnings per share

Earnings per share before and after dilution amounted to SEK -0.14 (-0.24) for the first quarter of 2023.

Number of shares

As of 31 March 2023, Nanexa AB (publ) had 60,695,626 (50,695,626) outstanding shares with a quotient value of SEK 0.13. The number of shares at full dilution of outstanding warrants was 63,174,626 (52,191,626).

The average number of shares during the first quarter of 2023 was 60,695,626 (50,695,626) and including full dilution of outstanding warrants, the average number of shares was 63,174,626 (52,191,626).

Principles for preparing the report

The interim report has been prepared in accordance with the same accounting principles as in the company's most recent annual report, i.e., in accordance with the Annual Accounts Act and the Swedish Accounting Standards Board's general recommendations BFNAR 2012:1 Annual Report and Consolidated Accounts (K3).

Upcoming reporting

Nanexa AB provides recurring financial information according to the following plan.

August 23, 2023	Interim report January-June 2023
October 27, 2023	Interim report January-September 2023
February 20, 2024	Year-end report 2023

The company's financial year is 1 January - 31 December.

This interim report has not been subject to a comprehensive audit by the company's auditors.

Uppsala 04/05/2023

The board of directors, Nanexa AB

Göran Ando (chairman)

Richard Davis (member)

Bengt Gustavsson (member)

Eva Nilsagård (member)

Urban Paulsson (member)

Birgit Stattin Norinder (member)

Magnus Westgren (member)

David Westberg, CEO Nanexa AB

Income statement

Amount in TSEK	01/01/2023 – 31/03/2023	01/01/2022 – 31/03/2022	01/01/2022 – 31/12/2022
Operating revenue			
Net sales	8,173	298	2,860
Capitalised work on own account	5,294	4,929	24,311
Other income	806	93	1,004
Total operating revenue	14,272	5,320	28,175
Operating expenses			
External project and development costs	-6,453	-5,089	-23,769
Other external expenses	-6,276	-5,668	-28,816
Personnel costs	-6,074	-4,693	-22,773
Depreciation on intangible and tangible fixed assets	-3,264	-2,151	-10,504
Other operating costs	-908	-50	-294
Total costs	-22,975	-17,651	-86,156
Operating profit (EBIT)	-8,703	-12,331	-57,981
Profit/loss from financial items			
Interest income and similar income statement items	176	0	11
Interest expenses and similar income statement items	-105	-41	-666
Total profit/loss from financial items	70	-41	-655
Taxes			
Tax revenue	30	2	64
Total taxes	30	2	64
Profit/loss for the period	-8,603	-12,370	-58,571
Earnings per share (SEK)	-0.14	-0.24	-1.16

Balance Sheet

Amount in TSEK	31/03/2023	31/03/2022	31/12/2022
Assets			
Fixed assets			
Intangible fixed assets	68,997	49,489	65,248
Tangible fixed assets	14,459	8,481	15,093
Ongoing new facilities and advances regarding tangible fixed assets	33	3,457	33
Financial fixed assets	125	48	97
Total fixed assets	83,614	61,475	80,471
Current assets			
Stock	168	0	487
Current receivables	11,286	4,315	8,055
Short-term deposits	20,000	0	0
Cash and cash equivalents	40,500	87,726	81,182
Total current assets	71,954	92,041	89,724
Total assets	155,568	153,516	170,195
Equity and liabilities			
Equity			
Share capital	7,855	6,561	6,561
Not registered share capital	0	0	1,294
Restricted equity	62,018	44,108	58,649
Share premium reserve	264,477	249,456	264,536
Profit and loss account reserve brought forward	-225,314	-148,832	-163,373
Loss for the period	-8,603	-12,370	-58,571
Total equity	100,434	138,923	109,096
Non-current liabilities			
Liabilities to credit institutions	3,517	2,307	4,068
Other liabilities	12,577	0	18,220
Total non-current liabilities	16,094	2,307	22,288
Current liabilities			
Accounts payable	5,076	6 326	4,661
Other current liabilities	33,964	5,960	34,150
Total current liabilities	39,040	12,286	38,811
Total equity and liabilities	155,568	153,516	170,195
Pledged assets	7,015	7,015	7,015
Assets with retention of title	6,500	203	6 686
Contingent liabilities	0	250	0

Cash flow analysis

Amounts in TSEK	01/01/2023 – 31/03/2023	01/01/2022 – 31/03/2022	01/01/2022 – 31/12/2022
Current activities			
Operating result	-8,703	-12,331	-57,982
Adjustments for items not included in cash flow	3,349	2,151	10,505
Interest received	90	0	11
Interest paid	-105	-41	-665
Cash flow from operating activities before change in working capital	-5,369	-10,221	-48,130
Cash flow from change in working capital			
Change in inventories and work in progress	319	269	-218
Changes in accounts receivable - trade	749	-599	-902
Change in receivables	-3,979	-153	-3,577
Change in accounts payable - trade	415	2,596	931
Change in other liabilities	-5,829	-1,502	44,025
Total from change in working capital	-8,324	611	40,259
Cash flow from current activities	-13,693	-9,610	-7,871
Investing activities			
Investments in intangible fixed assets	-6,294	-5,547	-27,654
Investments in tangible fixed assets	-86	-2,574	-7,768
Investments in financial fixed assets	0	0	0
Cash flow from investment activities	-6,379	-8,121	-35,422
Financing activities			
New share issue	0	0	17,515
Issue costs	-59	0	-1,140
Borrowings	0	112	5,985
Amortisation of loans	-551	-315	-3,544
Cash flow from financing activities	-610	-203	18,814
Cash-flow for the period	-20,682	-17,934	-24,478
Cash and cash equivalents at the beginning of the period	81,182	105,660	105,660
Cash and cash equivalents at the end of the period	60,500	87,726	81,182

Changes in equity

Amounts in TSEK	Share capital	Fund for development work	Share premium reserve	Share premium reserve	Profit/Loss brought forward	Profit/Loss for the period	Total equity
Amount as of 01/01/2023	6,561	1,294	58,649	264,536	-163,373	-58,571	109,096
Previous year's result					-58,571	58,571	0
New share issue							0
Ongoing new issue	1,294	-1,294					0
Subscription warrants							0
Issue expenses				-59			-59
Capitalized development costs for the period			5,294		-5,294		0
Depreciation on capitalised development costs for the period			-1,925		1,925		0
Profit/loss for the period						-8,603	-8,603
Amount as of 31/03/2023	7,855	0	62,018	264,477	-225,314	-8,603	100,434

Amounts in TSEK	Share capital	Fund for development work	Share premium reserve	Share premium reserve	Profit/Loss brought forward	Profit/Loss for the period	Total equity
Amount as of 01/01/2022	6,561		40,483	249,456	-109,208	-35,999	151,293
Previous year's result					-35,999	35,999	0
New share issue							0
Ongoing new issue		1,294		15,906			17,200
Subscription warrants				314			314
Issue expenses				-1,140			-1,140
Capitalized development costs for the period			24,311		-24,311		0
Depreciation on capitalised development costs for the period			-6,145		6,145		0
Profit/loss for the period						-58,571	-58,571
Amount as of 31/12/2022	6,561	1,294	58,649	264,536	-163,373	-58,571	109,096

Pledged assets

	31/03/2023	31/03/2022	31/12/2022
Corporate mortgages	7,015	7,015	7,015

Assets with retention of title

	31/03/2023	31/03/2022	31/12/2022
Assets with retention of title	6,500	0	6,686

Contingent liabilities

	31/03/2023	31/03/2022	31/12/2022
Other contingent liabilities	0	250	0

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*This information is such that Nanexa is obliged to publish in accordance with the EU Market Abuse Regulation.
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