Interim report Q1, 2024

Nanexa AB (PUBL)

Significant events during the first quarter 2024

- No significant events during the quarter

Significant events after the end of the period

- Nanexa announced that in the ongoing review process of the clinical trial application for the phase I study with NEX-22, additional supplements have been requested from the German Medicines Agency, which in the new European regulatory process takes more time than expected. The company estimates that it can obtain approval and start the study towards the end of the second quarter of 2024.

Financial overview

1 January - 31 March 2024

- Turnover amounted to: TSEK 7,754 (8,173)
- Operating profit (EBIT) amounted to: TSEK -3,363 (-8,703)
- Profit after tax amounted to: TSEK -2,823 (-8,603)
- Earnings per share amounted to: SEK -0.02 (-0.14)
- Cash flow for the period amounted to: TSEK -17,328 (-20,682)
- Cash and cash equivalents at end of period: TSEK 47,839 (60,500)

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

CEO’s comment

2024 has started at a high pace based on the strategic decision made at the end of last year to focus on three key areas where we see opportunities for significant contracts and revenues during 2024-2025. These areas are as previously communicated:

- Our own project NEX-22, a one-month product of liraglutide (GLP-1 analog) for improved type-2 diabetes treatment
- The collaboration with Novo Nordisk, a one-month product of one of their compounds
- Priority collaborations with other global pharmaceutical companies.

At the beginning of the year, we have also implemented a savings program to enable as long a runway as possible with available funds. Among other things, this means that the NEX-18 and NEX-20 projects are temporarily postponed.

NEX-22

As communicated late last year, we have submitted a clinical trial application for our first clinical study in the NEX-22 project. It is a phase I study in type 2 diabetes patients where we will evaluate different doses of our PharmaShell coated GLP-1 compound liraglutide. Our hope was to get approval of the application to be able to start the study during Q1 this year. The application was also essentially approved while some additions needed to be made, which we handled quickly in the middle of the quarter. However, due to administrative reasons related to the European Medicines Agency's review system, the application had to be resubmitted, delaying the process. As we now received a number of new questions, the timeline for approval is pushed further forward, although we do not see any difficulties in answering the questions. At present, we estimate that it is possible to get the approval during the latter part of Q2. Otherwise, all preparations are ready to start the study together with our CRO Profile. Despite this delay, we see the opportunity to run the study so that we obtain relevant data during the year that shows the possibility of creating a one-month product of liraglutide - both in terms of release profile and safety, mainly related to injection site reactions.

Collaboration with Novo Nordisk

Our collaboration with Novo Nordisk is progressing well. The results generated make us feel a strong optimism for the continued collaboration on formulations based on PharmaShell and one of their substances. It is our goal that this will lead to a commercially very attractive long-acting product. If we succeed with the first evaluation steps, my assessment is that we have good conditions for a favorable license agreement with them.

Other partner projects

As we communicated in the fall, progress has also been made in other partner projects. Both in vitro results and, above all, data from various animal studies where we see that the release profile of the drugs achieves the desired profile - and where effect data has also been studied and given satisfactory results. Our assessment is therefore still that there are good opportunities for significantly broader development agreements here. Above all, we have hopes for one of the collaborations, but at the same time we are aware that decision-making processes and negotiations with the major pharmaceutical companies can take time.

With a continued high pace and good momentum in our business, I look forward to driving the business forward with full force in all our priority areas for the rest of the year and beyond.

David Westberg, CEO Nanexa

About Nanexa

Nanexa develops PharmaShell® – a drug delivery-system with great potential

Nanexa is a pharmaceutical company that develops long-acting injectable drugs based on PharmaShell® – a proprietary patented drug-delivery system for controlled release of various types of active pharmaceutical substances. Based on PharmaShell, Nanexa both develops its own drugs and collaborates with other pharmaceutical companies, including Novo Nordisk and AstraZeneca, to develop products with their active substances.

Addresses important disease areas and markets

Nanexa focuses its own development projects on disease areas with high medical need where the market is large and growing. Today, the company focuses primarily on the NEX-22 project with the goal of developing a one-month depot formulation of the GLP-1 substance liraglutide for the treatment of type 2 diabetes. The company also has two oncology projects for the indications myelodysplastic syndrome (MDS) and multiple myeloma, which are two forms of blood cancer.

In Nanexa's own projects, the company starts from existing and proven drug substances where the patent protection has expired. In this way, Nanexa minimizes the biological risk, reduces development time and facilitates the approval process. At the same time, Nanexa can use its technology to create new patent protection and thus create great value, both in its own product projects and for products in partner-driven projects.

A patented drug delivery-system

PharmaShell enables the development and production of a completely new generation of long-acting injectable drugs. With PharmaShell, Nanexa coats small particles of an active pharmaceutical substance with an extremely thin, dense coating of an inorganic material, like the shell of an egg. The coating process takes place using Atomic Layer Deposition (ALD) technology, which allows the thickness and composition of the coating material to be adjusted. In this way, it is possible to control the dissolution time of the coating and thus the release of the pharmaceutical substance from the depot into the body.

Nanexa's products consist of injectable drug formulations that are placed as a depot under the skin or locally, for example in a cancerous tumour. This depot continuously releases active drug substances over a long period of time without the patient having to frequently keep track of their medication or come to the clinic for treatment. This streamlines treatments, makes everyday life easier for the patient and frees up resources for healthcare providers. Nanexa's proprietary and patented PharmaShell drug delivery system allows the company to customize and control the rate of release of both biological and small molecule drug substances.

The benefits of depot formulations

For patients

- Depot drugs make it easier for the patient. Instead of needing to monitor daily medication or visiting the clinic to get treatment, depot drugs are released over a long period.
- Depot drugs can deliver a more even, continuous dose, which can reduce certain side-effects associated with other modes of administration.

For the healthcare sector

- Depot drugs produce greater adherence in the treatment as there is no need for the patient to monitor tablets or injections.
- Greater adherence in turn leads to greater efficacy for the treatment.

For the payers

- Fewer patient visits to clinics and hospitals save money for society.
- Greater adherence produces more cost-effective treatment.

For pharmaceutical companies

- Increases revenue streams as long-acting and injectable products offer great opportunities to improve treatments in many indications and allow for product differentiation.
- Improves existing products and provide better product life cycles.
- Extends patent protection via new dosage forms on existing products.

Sustainability

- Depot drugs provide greater control over pharmaceutical substances and reduce the risk of them being handled incorrectly.
- Patients avoid handling the drug, which reduces the risk, for example, of it being flushed down the toilet or thrown into the rubbish.
- Depot medicines reduce the number of plastic syringes and other components, thus reducing the impact on the environment.

PharmaShell® – unique features

- Possibility of controlling the depot length in order to optimise treatment. Everything from one week to one month or several months
- Possible to control the initial release after administration in the body, which is a common problem for most competing depot preparation systems
    - Makes depot formulation of high potency substances possible
    - Enables high doses in depot preparations
- Very high drug load (up to 80 per cent)
    - Minimises injection volumes
    - Enables depot preparation of less potent drugs
    - Enables longer depot preparations
- Flexible, can be used for many different drugs
    - Small molecules
    - Biological substances such as peptides and proteins
    - Substances with high and low solubility
- Prevents breakdown of the drug after injection into the body
    - The PharmaShell coating protects the substances from being broken down while they are in depots
- Numerous applications
    - Subcutaneous or intramuscular administration for systemic exposure
    - Local administration in the case of tumours or other tissue for local effect

Nanexa's business model

Nanexa has a two-part business model where the company develops its own products and enters into licensing agreements for PharmaShell®. In its own product projects, Nanexa takes them through the preclinical and clinical phases, mainly until proof of concept (phase I or II). Then an assessment is made of how the commercialization should take place - either in-house or in collaboration with a licensing partner. A license agreement usually includes an initial payment, known as a signing fee, and milestone payments when defined development goals are achieved. A milestone payment is also made in connection with market approval of the drug, after which sales-based royalties are paid. Desirable partners are, for example, global pharmaceutical companies with strong market positions in the relevant area. Another possibility is license deals with one or more operators with a strong market presence in important regions. Decisions are made based on what is considered to create the most value for the company.

At the same time, Nanexa works actively to out-license its technology to other pharmaceutical companies that want to develop long-acting drugs. Nanexa currently has a number of evaluation agreements in place with the aim of creating a basis for further collaborations and out-licensing agreements. These include a very interesting project with Novo Nordisk and evaluations with several of the world's largest pharmaceutical companies.

Although the revenues from the company's product projects are expected to be significantly higher than the revenues from out-licensing agreements regarding PharmaShell, the company sees significant opportunities for attractive license agreements also from several of the evaluation projects. In addition, the technology licenses can be more numerous, closer in time and make a significant contribution to the total revenues.

Comments, Q1 2024

Result and cash flow

Revenue for the quarter amounted to SEK 7,754 (8,173) thousand, of which SEK 3,223 (1,576) thousand relates to revenue within the framework of evaluation agreements entered into for the PharmaShell® technology, SEK 3,766 (5,643) thousand relates to accrual of prepaid revenue related to the exclusivity agreement entered into with Novo Nordisk A/S and SEK 764 (512) thousand relates to coating of sensors. Capitalized development costs amounted to SEK 6,285 (5,294) thousand and mainly relate to investments in NEX-22 and to a lesser extent the PharmaShell system.

External project and development costs during the quarter amounted to SEK -4,372 (-6,453) thousand, where costs related to NEX-22 account for the majority and the decrease relative to the previous year is attributable to cost reductions and other projects being temporarily de-prioritized. Other external costs amounted to SEK -5,259 (-6,276) thousand and have decreased slightly due to savings measures. Personnel costs during the first quarter amounted to SEK -5,476 (-6,074) thousand, where the decrease is explained by lower provisions for variable remuneration.

The result for the first quarter amounted to SEK -2,823 (-8,603) thousand.

Cash flow for the quarter amounted to SEK -17,328 (-20,682) thousand. Change in working capital amounted to SEK -7,108 (-8,324) thousand and cash flow from investing activities amounted to SEK -8,845 (-6,294) thousand, where investments in intangible assets, both capitalized development and patent costs were higher than the corresponding period last year. The negative cash flow from financing activities of SEK -515 (-551) thousand relates entirely to amortization of loans.

Financial position

As of March 31, 2024, cash and short-term investments amounted to SEK 47,839 (60,500) thousand and equity amounted to SEK 93,007 (100,434) thousand.

In the fourth quarter, the company decided on tactical priorities, whereby operations are focused on three key areas and significant cost savings can also be realized. Overall, the Board therefore assesses that the company's current working capital and cash and cash equivalents are sufficient to finance operations for the next 12 months from the submission of this report.

Employees

The number of employees as of March 31, 2024 was 19 (18), of which 8 (7) women and 11 (11) men. The average number of employees (FTE) during the first quarter of 2024 amounted to 19 (18). In addition to employed staff, Nanexa continuously hires about ten consultants with specialist expertise.

Related party transactions

The company has not had any related party transactions in the first quarter of 2024.

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 December 31, 2023, the number of shareholders in Nanexa was 3,258.

Earnings per share

Earnings per share before and after dilution amounted to SEK -0.02 (-0.14) for the first quarter of 2024.

Number of shares

The number of outstanding shares in Nanexa AB as of March 31, 2024 was 135,695,626 (60,695,626), with a quota value of SEK 0.13 per share. The number of shares at full dilution of outstanding warrants was 138,403,626 (63,174,626).

The average number of shares for the fourth quarter 2023 amounted to 135,695,626 (60,695,626) and including full dilution of outstanding warrants, the average number of shares was138,403,626 (63,174,626).

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 27, 2024	Interim report January-June 2024
November 7, 2024	Interim report January-September 2024
February 19, 2025	Year-end report 2024

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 03/05/2024

The board of directors, Nanexa AB

Göran Ando (chairman)

Richard Davis (member) Jakob Dynnes Hansen (member) Eva Nilsagård (member)

Birgit Stattin Norinder (member) Magnus Westgren (member)

David Westberg, CEO Nanexa AB

Income statement

Amounts in TSEK	01/01/2024 – 31/03/2024	01/01/2023 – 31/03/2023	01/01/2023 – 31/12/2023
Operating revenue			
Turnover	7,754	8,173	29,327
Capitalised development costs	6,285	5,294	29,830
Other income	153	806	328
Total revenue	**14,192**	**14,272**	**59,486**
Operating expenses			
External project and development costs	-4,372	-6,453	-27,709
Other external expenses	-5,259	-6,276	-24,697
Personnel costs	-5,476	-6,074	-23,415
Depreciation on intangible and tangible fixed assets	-2,427	-3,264	-59,868
Other operating costs	-21	-908	-421
Total costs	**-17,555**	**-22,975**	**-136,110**
Operating profit (EBIT)	**-3,363**	**-8,703**	**-76,625**
Profit/loss from financial items			
Interest income and similar income statement items	632	176	602
Interest expenses and similar income statement items	-119	-105	-487
Total profit/loss from financial items	**513**	**70**	**115**
Taxes			
Tax revenue	28	30	112
Total taxes	**28**	**30**	**112**
Profit/loss for the period	**-2,823**	**-8,603**	**-76,398**
Earnings per share before dilution (SEK)	-0.02	-0.14	-1.09
Earnings per share after dilution (SEK)	*-0.02*	*-0.14*	*-1.05*

Balance Sheet

Amounts in TSEK	31/03/2024	31/03/2023	31/12/2024
Assets			
Fixed assets			
Intangible fixed assets	47,649	68,997	40,476
Tangible fixed assets	13,641	14,459	14,245
Ongoing new facilities and advances regarding tangible fixed assets	33	33	33
Financial fixed assets	235	125	208
Total fixed assets	**61,559**	**83,614**	**54,961**
Current assets			
Stock	259	168	1911
Current receivables	14,250	11,286	10,217
Short-term deposits	35,000	20,000	50,000
Cash and cash equivalents	12,839	40,500	15,168
Total current assets	**62,348**	**71,954**	**77,296**
Total assets	**123,907**	**155,568**	**132,257**
Equity and liabilities			
Equity			
Share capital	17,562	7,855	17,562
Not registered share capital	0	0	0
Restricted equity	39,444	62,018	34,282
Share premium reserve	317,961	264,477	317,961
Profit and loss account reserve brought forward	-279,138	-225,314	-197,577
Loss for the period	-2,823	-8,603	-76,398
Total equity	**93,007**	**100,434**	**95,830**
Non-current liabilities			
Liabilities to credit institutions	1,831	3,517	2,087
Other liabilities	0	12,577	3,766
Total non-current liabilities	**1,831**	**16,094**	**5,852**
Current liabilities			
Accounts payable	4,810	5,076	7,827
Other current liabilities	24,258	33,964	22,747
Total current liabilities	**29,068**	**39,040**	**30,574**
Total equity and liabilities	123,907	155,568	132,257
Pledged assets	**7,015**	**7,015**	**7,015**
Assets with retention of title	**5,755**	**6,500**	**5,941**

Cash flow analysis

Amounts in TSEK	01/01/2024 – 31/03/2024	01/01/2023 – 31/03/2023	01/01/2023 – 31/12/2023
Current activities			
Operating result	-3,363	-8,703	-76,625
Adjustments for items not included in cash flow	2,427	3,349	60,080
Interest received	156	90	588
Interest paid	71	-105	-937
Cash flow from operating activities before change in working capital	**-709**	**-5,369**	**-16,895**
Cash flow from change in working capital			
Change in inventories and work in progress	1,652	319	-1,424
Changes in accounts receivable - trade	-1,252	749	-1,296
Change in receivables	-1,994	-3,979	-1,112
Change in accounts payable - trade	-3,017	415	3,167
Change in other liabilities	-2,496	-5,829	-25,098
Total from change in working capital	**-7,108**	**-8,324**	**-25,763**
Cash flow from current activities	**-7,817**	**-13,693**	**-42,658**
Investing activities			
Investments in intangible fixed assets	-8,845	-6,294	-32,270
Investments in tangible fixed assets	-152	-86	-1,979
Investments in financial fixed assets	0	0	0
Cash flow from investment activities	**-8,997**	**-6,379**	**-34,248**
Financing activities			
New share issue	0	0	75,387
Issue costs	0	-59	-12,255
Borrowings	0	0	0
Amortisation of loans	-515	-551	-2,240
Cash flow from financing activities	**-515**	**-610**	**60,892**
Cash-flow for the period	**-17,328**	**-20,682**	**-16,014**
Cash and cash equivalents at the beginning of the period	65,168	81,182	81,182
Cash and cash equivalents at the end of the period	**47,839**	**60,500**	**65,168**

Förändring av eget kapital

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 01/01/2024	**17,562**	**0**	**34,282**	**317,961**	**-197,577**	**-76,398**	**95,830**
Previous year's result					-76,398	76,398	**0**
New share issue							**0**
Ongoing new issue							**0**
Subscription warrants							**0**
Issue expenses							**0**
Capitalized development costs for the period			6,285		-6,285		**0**
Depreciation on capitalised development costs for the period			-1,123		1,123		**0**
Profit/loss for the period						-2,823	**-2,823**
Amount as of 31/03/2024	**17,562**	**0**	**39,444**	**317,961**	**-279,138**	**-2,823**	**93,007**

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	11,000	-1,294		65,293			**75,000**
Ongoing new issue							**0**
Subscription warrants				387			**387**
Issue expenses				-12,255			**-12,255**
Capitalized development costs for the period			29,830		-29,830		**0**
Depreciation on capitalised development costs for the period			-54,197		54,197		**0**
Profit/loss for the period						-76,398	**-76,398**
Amount as of 31/12/2024	**17,562**	**0**	**34,282**	**317,961**	**-197,577**	**-76,398**	**95,830**

Pledged assets

	31/03/2024	31/03/2023	31/12/2023
Corporate mortgages	7,015	7,015	7,015

Assets with retention of title

	31/03/2024	31/03/2023	31/12/2023
Assets with retention of title	5,755	6,500	5,941

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