Interim report Q2, 2024

Nanexa AB (PUBL)

Significant events during the second quarter 2024

- Nanexa announced in April that additional supplements had been requested from the European Medicines Agency in the ongoing review process of the clinical trial application for the Phase I study with NEX-22.
- Nanexa announced in mid-May that the European Medicines Agency had approved the company's clinical trial application for the Phase I study with NEX-22, following review of the submitted complete data.
- At Nanexa's Annual General Meeting on May 15, it was resolved in accordance with the Board's proposal, among other things, to elect Hanna Tilus as a new Board member and to authorize the Board to decide on a rights issue and a directed issue.
- Nanexa announced in June that the company's Phase I study with NEX-22 for the treatment of type 2 diabetes had been initiated with dosing of the first patient.
- Nanexa announced that Cecilia Danckwardt-Lilliestrom will take over as Chief Financial Officer as of September 1, 2024, as the current CFO Björn Svanström has chosen to leave the company.

Significant events after the end of the period

- Nanexa announced that the company's Phase I study for type 2 diabetes continues dose escalation according to plan with its long-acting depot formulation of the GLP-1 analog liraglutide.

Financial overview

1 April - 30 June 2024

- Turnover amounted to: TSEK 5,657 (7,655)
- Operating profit (EBIT) amounted to: TSEK -6,124 (-10,067)
- Profit after tax amounted to: TSEK -6,012 (-9,951)
- Earnings per share amounted to: SEK -0.04 (-0.16)
- Cash flow for the period amounted to: TSEK -6,529 (-22,141)
- Cash and cash equivalents at end of period: TSEK 41,311 (38,358)

1 January - 30 June 2024

- Turnover amounted to: TSEK 13,411 (15,828)
- Operating profit (EBIT) amounted to: TSEK -9,487 (-18,770)
- Profit after tax amounted to: TSEK -8,835 (-18,553)
- Earnings per share amounted to: SEK -0.07 (-0.31)
- Cash flow for the period amounted to: TSEK -23,857 (-42,824)
- Cash and cash equivalents at end of period: TSEK 41,311 (38,358)

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

CEO’s comment

Q2 has been an eventful quarter for Nanexa, especially as we have initiated the first clinical study in our lead project NEX-22. This was made possible after the European Medicines Agency approved our trial application for the Phase I dose escalation study. We have also made progress on several fronts in our collaborative projects and, through renewed GMP certification, ensured that we can continue to produce clinical trial material in our own facility.

NEX-22

In the middle of the quarter, after submitting additional responses and supplements, we received approval from the European Medicines Agency for our clinical trial application. This allowed us to start our Phase I study with NEX-22 in collaboration with our CRO, Profil, in Germany in June.

The aim of the project is to develop a long-acting, one-month depot of the GLP-1 analog liraglutide for type 2 diabetes and ultimately obesity.

In the study, we are evaluating pharmacokinetics, safety and tolerability, with a particular focus on injection reactions. The first patient was dosed at the beginning of June and by the end of July we were able to conclude that both pharmacokinetics and tolerability at the injection site looked good for that group, allowing us to proceed with dose group two of the study.

Collaboration with Novo Nordisk

In our second priority area, the collaboration with Novo Nordisk where we are evaluating our PharmaShell system for their compounds, we have invested significant development resources during the quarter. The work is progressing according to plan with the aim of delivering formulations that can proceed to preclinical evaluation. A successful evaluation in this project could open up great commercial opportunities in the future.

Other partner projects

In other high-potential partner projects, we have also made progress. We are continuously generating new data in ongoing projects that form the basis for potentially expanded agreements and are seeing increasing interest from pharmaceutical companies to enter into new collaborations.

Areas of particular interest to our partners include intratumoral administration for high local efficacy in solid tumors with minimal systemic side effects. Here, our high drug load and small injection volumes come in handy. The formulation of monoclonal antibodies also continues to attract great interest, as do long-acting formulations of oligonucleotides based on PharmaShell. In the latter area, initial studies have now been conducted with a partner and we look forward to continued collaboration in this exciting area.

Ensured production capacity

During the quarter, the Swedish Medical Products Agency conducted a scheduled inspection of our operations. They found that our quality systems and processes are of a high standard and our operations are in good order and were thus able to renew our GMP certification for the manufacture of clinical trial materials.

Streamlining of operations

We continue to streamline our operations and ensure that we have the right staffing to carry out our tasks. This has involved a reduction in staffing in line with the operational priorities we decided on at the end of last year. We have also improved some administrative procedures to maximize the use of our resources for value-adding R&D activities.

I look forward to an exciting fall where the goal is to finalize the important NEX-22 study and deliver successfully in our partner projects, especially in the collaboration with Novo Nordisk. I would also like to extend a special thanks to the staff for their good cooperation and loyalty during the period.

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.

Financial comments

Result and cash flow

Second quarter 2024

Sales for the quarter amounted to SEK 5,657 (7,655) thousand, of which SEK 1,123 (2,012) thousand relates to revenue within the framework of evaluation agreements entered into regarding 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 769 (0) thousand relates to the coating of sensors. Capitalized development costs amounted to SEK 5,080 (9,418) 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 -3,750 (-9,128) thousand, with costs related to NEX-22 accounting for the majority and the decrease relative to the previous year being attributable to cost reductions and other projects being temporarily de-prioritized. Other external costs amounted to SEK -4,943 (-7,190) thousand and have decreased by just over 30 percent, mainly through savings measures. Personnel costs in the second quarter amounted to SEK -5,680 (-7,311) thousand, where the decrease is mainly explained by lower provisions for variable remuneration. The impact of the savings program on staff costs will pay off in the coming quarters. Personnel costs for the quarter include a provision of SEK 439 thousand for temporarily reduced remuneration to management and the Board.

The result for the second quarter amounted to SEK -6,012 (-9,951) thousand.

Cash flow for the quarter amounted to SEK -6,529 (-22,141) thousand. The improvement is due to both a general reduction in costs and the change in working capital, which amounted to SEK 2,973 (-4,925) thousand, where both reduced current receivables and increased trade payables played a role. Cash flow from investing activities amounted to SEK -5,612 (-10,136) thousand, where investments in intangible assets, mainly capitalized development costs, were significantly lower than for the corresponding period last year. The negative cash flow from financing activities of SEK -551 (-551) thousand relates entirely to amortization of loans.

The period January-June 2024

Sales for the period amounted to SEK 13,411 (15,828) thousand, of which SEK 7,531 (11,286) thousand relates to the prepaid exclusivity fee from Novo Nordisk, SEK 4,347 (4,031) thousand relates to revenue from partner projects with Novo Nordisk and others, and SEK 1,533 (512) thousand relates to sensor coating. Capitalized development costs amounted to SEK 11,365 (14,712) thousand, of which about 70 percent relates to NEX-22 and the remainder to the PharmaShell system.

External project and development costs during the period amounted to SEK -8,122 (-15,581) thousand, a decrease mainly attributable to the focus of R&D activities on the NEX-22 project. Other external expenses amounted to SEK -10 202 (-13 466) thousand, where the decrease is explained by broad savings in administrative services and travel. Personnel costs amounted to SEK -11,156 (-13,385) thousand during the period and have decreased mainly due to lower provisions for variable remuneration compared to the previous year. Depreciation and amortization amounted to SEK -4,971 (-6,715) thousand, where the decrease is mainly explained by a lower level of capitalized development costs in the current year and the write-downs made in the paused NEX-18 and NEX-20 projects at the end of 2023.

The result for the period amounted to SEK -8,835 (-18,553) thousand.

Cash flow for the period January-June 2024 amounted to SEK -23,857 (-42,824) thousand. Also for the first half of the year, cost savings have had a positive effect on cash flow and the change in working capital amounted to SEK -4,135 (-13,250) thousand, where the difference between the years is largely explained by a lower rate of revenue recognition of deferred income from Novo Nordisk. Cash flow from investing activities amounted to SEK -14,609 (-16,515) thousand, where capitalized development costs decreased significantly while capitalized patent costs increased to a lesser extent and investments in property, plant and equipment were largely unchanged at a low level. Cash flow from financing activities amounted to SEK -1,066 (-1,161) thousand and consists primarily of amortization of loans.

Financial position

As of June 30, 2024, cash and cash equivalents and short-term investments amounted to SEK 41,311 (38,358) thousand and equity amounted to SEK 86,995 (90,438) thousand.

The company decided in Q4 2023 on tactical priorities, whereby operations are focused on three key areas and significant cost savings are also realized. However, the Board of Directors believes that the company's current working capital and cash are not sufficient to finance the business for the next 12 months from the submission of this report, but at the same time sees good opportunities for additional financing through significant agreements with partners and possible injection of external capital if the need arises.

Employees

The number of employees as of June 30, 2024 was 19 (21), of which 8 (8) women and 11 (13) men. The average number of employees (FTE) amounted to 19 (20) in the second quarter of 2024 and 19 (19) in the period January-June 2024. 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 either in the second quarter or in the period January-June 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 June 30, 2023, the number of shareholders in Nanexa was 3,218.

Earnings per share

Earnings per share, before and after dilution, amounted to SEK -0.04 (-0.16) for the first quarter of 2024 and SEK -0.07 (-0.31) for the period January-June 2024.

Number of shares

The number of outstanding shares in Nanexa AB as of June 30, 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 second quarter, and for the period January-June 2024, amounted to 135,695,626 (60,695,626). Including full dilution of outstanding warrants, the average number of shares for the second quarter, and for the period January-June 2024, was 138,403,626 (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.

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 27/08/2024

The board of directors, Nanexa AB

Göran Ando (chairman)

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

Birgit Stattin Norinder (member) Hanna Tilus (member)

David Westberg, CEO Nanexa AB

Income statement

Amounts in TSEK	01/04/2024 – 30/06/2024	01/04/2023 – 30/06/2023	01/01/2024 – 30/06/2024	01/01/2023 – 30/06/2023	01/01/2023 – 31/12/2023
Operating revenue					
Turnover	5,657	7,655	13,411	15,828	29,327
Capitalised development costs	5,080	9,418	11,365	14,712	29,830
Other income	85	80	238	886	328
Total revenue	**10,822**	**17,154**	**25,013**	**31,426**	**59,486**
Operating expenses					
External project and development costs	-3,750	-9,128	-8,122	-15,581	-27,709
Other external expenses	-4,943	-7,190	-10,202	-13,466	-24,697
Personnel costs	-5,680	-7,311	-11,156	-13,385	-23,415
Depreciation on intangible and tangible fixed assets	-2,545	-3,451	-4,971	-6,715	-59,868
Other operating costs	-28	-141	-50	-1,049	-421
Total costs	**-16,946**	**-27,221**	**-34,501**	**-50,196**	**-136,110**
Operating profit (EBIT)	**-6,124**	**-10,067**	**-9,487**	**-18,770**	**-76,625**
Profit/loss from financial items					
Interest income and similar income statement items	192	193	823	369	602
Interest expenses and similar income statement items	-108	-106	-226	-211	-487
Total profit/loss from financial items	**84**	**87**	**597**	**157**	**115**
Taxes					
Tax revenue	28	30	55	60	112
Total taxes	**28**	**30**	**55**	**60**	**112**
Profit/loss for the period	**-6,012**	**-9,951**	**-8,835**	**-18,553**	**-76,398**
Earnings per share (SEK)	**-0.04**	**-0.16**	**-0.07**	**-0.31**	**-1.09**

Balance Sheet

Amounts in TSEK	30/06/2024	30/06/2023	31/12/2024
Assets			
Fixed assets			
Intangible fixed assets	51,376	76,265	40,476
Tangible fixed assets	12,982	13,875	14,245
Ongoing new facilities and advances regarding tangible fixed assets	33	33	33
Financial fixed assets	263	155	208
Total fixed assets	**64,654**	**90,329**	**54,961**
Current assets			
Stock	118	2,520	1,911
Current receivables	8,364	9,623	10,217
Short-term deposits	15,000	20,010	50,000
Cash and cash equivalents	26,311	18,348	15,168
Total current assets	**49,793**	**50,501**	**77,296**
Total assets	**114,447**	**140,830**	**132,257**
Equity and liabilities			
Equity			
Share capital	17,562	7,855	17,562
Not registered share capital	0	0	0
Restricted equity	43,264	69,308	34,282
Share premium reserve	317,961	264,477	317,961
Profit and loss account reserve brought forward	-282,958	-232,604	-197,577
Loss for the period	-8,835	-18,553	-76,398
Total equity	**86,995**	**90,483**	**95,830**
Provisions			
Other provisions	439	0	0
Total provisions	**430**	**0**	**0**
Non-current liabilities			
Liabilities to credit institutions	1,539	2,966	2,087
Other liabilities	0	6,934	3,766
Total non-current liabilities	**1,539**	**9,900**	**5,852**
Current liabilities			
Accounts payable	6,548	8,105	7,827
Other current liabilities	18,926	32,342	22,747
Total current liabilities	**25,474**	**40,446**	**30,574**
Total equity and liabilities	**114,447**	**140,830**	**132,257**
Pledged assets	**7,015**	**7,015**	**7,015**
Assets with retention of title	**5,569**	**6,240**	**5,941**

Cash flow analysis

Amounts in TSEK	01/04/2024 – 30/06/2024	01/04/2023 – 30/06/2023	01/01/2024 – 30/06/2024	01/01/2023 – 30/06/2023	01/01/2023 – 31/12/2023
Current activities					
Operating result	-6,124	-10,067	-9,487	-18,770	-76,625
Adjustments for items not included in cash flow	2,545	3,577	4,971	6,926	60,080
Interest received	413	67	569	157	588
Interest paid	-173	-106	-101	-211	-937
Cash flow from operating activities before change in working capital	**-3,339**	**-6,529**	**-4,048**	**-11,898**	**-16,895**
Cash flow from change in working capital					
Change in inventories and work in progress	141	-2,352	1,792	-2,033	-1,424
Changes in accounts receivable - trade	780	-405	-472	343	-1,296
Change in receivables	4,948	2,069	2,954	-1,910	-1,112
Change in accounts payable - trade	1,738	3,029	-1,279	3,444	3,167
Change in other liabilities	-4,634	-7,265	-7,130	-13,094	-25,098
Total from change in working capital	**2,973**	**-4,925**	**-4,135**	**-13,250**	**-25,763**
Cash flow from current activities	**-366**	**-11,455**	**-8,183**	**-25,148**	**-42,658**
Investing activities					
Investments in intangible fixed assets	-5,612	-10,035	-14,457	-16,329	-32,270
Investments in tangible fixed assets	0	-100	-152	-186	-1,979
Investments in financial fixed assets	0	0	0	0	0
Cash flow from investment activities	**-5,612**	**-10,136**	**-14,609**	**-16,515**	**-34,248**
Financing activities					
New share issue	0	0	0	0	75,387
Issue costs	0	0	0	-59	-12,255
Borrowings	0	0	0	0	0
Amortisation of loans	-551	-551	-1,066	-1,102	-2,240
Cash flow from financing activities	**-551**	**-551**	**-1,066**	**-1,161**	**60,892**
Cash-flow for the period	**-6,529**	**- 22,141**	**-23,857**	**-42,824**	**-16,014**
Cash and cash equivalents at the beginning of the period	47,839	60,500	65,168	81,182	81,182
Cash and cash equivalents at the end of the period	**41,311**	**38,358**	**41,311**	**38,358**	**65,168**

Change in equity

Amounts in TSEK	Share capital	Not registered share capital	Fund for development work	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			11,365		-11,365		**0**
Depreciation on capitalised development costs for the period			-2,383		2,383		**0**
Profit/loss for the period						-8,835	**-8,835**
Amount as of 30/06/2024	**17,562**	**0**	**43,264**	**317,961**	**-282,958**	**-8,835**	**86,995**

Amounts in TSEK	Share capital	Not registered share capital	Fund for development work	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

	30/06/2024	30/06/2023	31/12/2023
Corporate mortgages	7,015	7,015	7,015

Assets with retention of title

	30/06/2024	30/06/2023	31/12/2023
Assets with retention of title	5,569	6,240	5,941

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