Interim report
January – September 2024

Nanexa AB (PUBL)

Significant events during the third quarter 2024

- Nanexa announced in August that the company´s Phase I study for type 2-diabetes within the NEX-22-project continues with increasing dose escalation according to plan with the company´s long-acting depot formulation of the GLP-1-analog liraglutid.
- Nanexa announced in September that the first patient in the third and final dose group of the company's Phase 1 study with its depot formulation of the GLP-1-analogue liraglutid has been dosed. The study was initiated in June 2024 and so far, two consecutive dose escalation groups have been studied.
- Nanexa announced that Cecilia Danckwardt-Lilliestrom has taken the position of Chief Financial Officer as of 1 September 2024.

Significant events after the end of the period

- Nanexa announced in October that the dosing of the last patient was completed according to plan in the Phase I study with the long-acting depot formulation of the GLP-1 analog liraglutide with PharmaShell (NEX-22).
- Nanexa AB announced in the beginning of November that the company´s Phase I study for the NEX-22 project in type 2 diabetes has been completed for all patients. The study evaluates a long-acting depot formulation of the GLP-1 analog liraglutide with Nanexa's patented PharmaShell® system.
- Recent press releases confirm the increasing importance of long acting GLP-1 agonists and, as expected, Novo Nordisk and other actors will continue to seek better treatment alternatives in this rapidly growing field

Financial overview

1 July - 30 September 2024

- Turnover amounted to: TSEK 6,434 (6,683)
- Operating profit (EBIT) amounted to: TSEK -4,450 (-6,488)
- Profit after tax amounted to: TSEK -4,438 (-6,694)
- Earnings per share amounted to: SEK -0.03 (-0.11)
- Cash flow for the period amounted to: TSEK -12,302 (-17,790)
- Cash and cash equivalents at end of period: TSEK 29,009 (20,569)

1 January - 30 September 2024

- Turnover amounted to: TSEK 19,844 (22,511)
- Operating profit (EBIT) amounted to: TSEK -14,037 (-25,258)
- Profit after tax amounted to: TSEK -13,273 (-25,247)
- Earnings per share amounted to: SEK -0.10 (-0.42)
- Cash flow for the period amounted to: TSEK -36,160 (-60,613)
- Cash and cash equivalents at end of period: TSEK 29,009 (20,569)

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

CEO’s comment

Over the past quarter, we have made significant progress on our prioritized development project, while implementing strategic savings in line with our business plan. The NEX-22 project and the evaluation of the PharmaShell system with Novo Nordisk remain top priorities and we see promising results in both of these areas.

I would particularly like to highlight the work on NEX-22, our one-month formulation of the GLP-1 substance liraglutide. Here we have reached an important milestone as we have recently enrolled all patients in our ongoing Phase I study in line with our original timeline. The study is a dose-escalation study in patients with type 2 diabetes, comprising three dose groups with three patients in each, where NEX-22 is administered subcutaneously and then continuously releases liraglutide. The preliminary results show a clear prolongation of release which is very encouraging. The safety profile has been positive, with only mild injection site reactions in a few patients and no reports of nausea, which is a common side effect of GLP-1-based treatment.

I look forward to presenting the full results to our potential partners later this year. We believe that NEX-22 has the potential to be the first one-month product in the GLP-1 category that can be taken forward for product development and regulatory evaluation. Upon approval, NEX-22 could compete with the weekly treatments that currently dominate the market. Even a smaller market share would mean significant revenues.

Regarding the evaluations of PharmaShell carried out by partner companies, we have a clear focus on optimizing shell formulation and analyzing and evaluating them internally. This is an important step before we manufacture material for the complementary studies that Novo Nordisk will conduct. In that project as well, we are making clear progress and believe that we will be able to deliver according to our common goal.

We have also started planning for upcoming partner conferences where we will present both NEX-22 and the PharmaShell system. I look forward to the opportunity to meet potential partners again and discuss further collaborations and out-licensing opportunities.

Our cost savings have yielded positive results and will continue to strengthen the company going forward. At the same time, business discussions are ongoing for further collaborations and evaluations. The issue of financing remains relevant, and we continuously evaluate various opportunities to secure long-term financing.

David Westberg, CEO Nanexa

Financial comments

Result and cash flow

Third quarter 2024

Sales for the quarter amounted to SEK 6,434 (6,683) thousand, of which SEK 912 (948) thousand relates to revenue within the framework of evaluation agreements entered regarding the PharmaShell® technology, SEK 3,766 (5,643) thousand relates to accrual of prepaid revenue related to the exclusivity agreement entered with Novo Nordisk A/S and SEK 1,750 (88) thousand relates to the coating of sensors. Capitalized development costs amounted to SEK 4,682 (7,062) 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 -3,292 (-5,465) 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 -4,412 (-5,219) thousand and have decreased by 20 percent, mainly through savings measures. Personnel costs in the third quarter amounted to SEK -5,180 (-6,072) thousand, where the decrease is mainly explained by the savings program on staff costs. Personnel costs for the quarter include a provision of SEK 436 (439) thousand for temporarily reduced remuneration to management and the Board.

The result for the third quarter amounted to SEK -4,438 (-6,694) thousand.

Cash flow for the quarter amounted to SEK -12,302 (-17,790) thousand. The improvement is due to both a general reduction in costs and the change in working capital, which amounted to SEK -4,793 (-5,360) thousand. Cash flow from investing activities amounted to SEK -5,637 (-7,464) thousand, where investments in intangible assets, mainly capitalized development costs, were lower than for the corresponding period last year. The negative cash flow from financing activities of SEK -551 (-204) thousand relates entirely to amortization of loans.

The period January-September 2024

Sales for the period amounted to SEK 19,844 (22,511) thousand, of which SEK 11,297 (16,929) thousand relates to the prepaid exclusivity fee from Novo Nordisk, SEK 5,939 (4,967) thousand relates to revenue from partner projects with Novo Nordisk and others, and SEK 2,592 (599) thousand relates to sensor coating. Capitalized development costs amounted to SEK 16,047 (21,774) thousand, of which about 65 percent relates to NEX-22 and the remainder to the PharmaShell system.

External project and development costs during the period amounted to SEK -11,414 (-21,047) thousand, a decrease mainly attributable to the focus of R&D activities on the NEX-22 project. Other external expenses amounted to SEK -14,614 (-18,685) thousand, where the decrease is explained by broad savings in administrative services, consulting expenses and travel. Personnel costs amounted to SEK -16,335 (-19,458) thousand during the period and have decreased mainly due to the savings program on staff costs. Depreciation and amortization amounted to SEK -2,709 (-3,651) 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 -13,273 (-25,247) thousand.

Cash flow for the period January-September 2024 amounted to SEK -36,160 (-60,613) thousand. Also, for the first nine months of the year, cost savings have had a positive effect on cash flow and the change in working capital amounted to SEK -8,928 (-18,610) 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 -20,246 (-23,979) thousand, where capitalized development costs decreased significantly while capitalized patent costs increased and investments in property, plant and equipment were largely unchanged at a very low level. Cash flow from financing activities amounted to SEK -1,617 (-1,365) thousand and consists of amortization of loans.

Financial position

As of September 30, 2024, cash and cash equivalents and short-term investments amounted to SEK 29,009 (20,569) thousand and equity amounted to SEK 82,557 (84,137) 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 agreements with partners and possible injection of external capital if the need arises.

Employees

The number of employees as of September 30, 2024, was 16 (19), of which 6 (8) women and 10 (11) men. The average number of employees (FTE) amounted to 17 (20) in the third quarter of 2024 and 18 (19) in the period January-September 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 third quarter or in the period January-September 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 September 30, 2024, the number of shareholders in Nanexa was 3,591.

Earnings per share

Earnings per share, before and after dilution, amounted to SEK -0.03 (-0.11) for the third quarter of 2024 and SEK -0.10 (-0.42) for the period January-September 2024.

Number of shares

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

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 07/11/2024

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	01/07/2024 – 30/09/2024	01/07/2023 – 30/09/2023	01/01/2024 – 30/09/2024	01/01/2023 – 30/09/2023	01/01/2023 – 31/12/2023
Operating revenue					
Turnover	6,434	6,683	19,844	22,511	29,327
Capitalised development costs	4,682	7,062	16,047	21,774	29,830
Other income	87	-642	325	244	328
Total revenue	**11,203**	**13,103**	**36,216**	**44,529**	**59,486**
Operating expenses					
External project and development costs	-3,292	-5,465	-11,414	-21,047	-27,709
Other external expenses	-4,412	-5,219	-14,614	-18,685	-24,697
Personnel costs	-5,180	-6,072	-16,335	-19,458	-23,415
Depreciation on intangible and tangible fixed assets	-2,709	-3,651	-7,681	-10,366	-59,868
Other operating costs	-160	817	-209	-232	-421
Total costs	**-15,753**	**-19,591**	**-50,253**	**-69,787**	**-136,110**
Operating profit (EBIT)	**-4,550**	**-6,488**	**-14,037**	**-25,258**	**-76,625**
Profit/loss from financial items					
Interest income and similar income statement items	196	114	1,020	482	602
Interest expenses and similar income statement items	-113	-347	-339	-559	-487
Total profit/loss from financial items	**84**	**-234**	**681**	**-76**	**115**
Taxes					
Tax revenue	28	28	83	87	112
Total taxes	**28**	**28**	**83**	**87**	**112**
Profit/loss for the period	**-4,438**	**-6,694**	**-13,273**	**-25,247**	**-76,398**
Earnings per share (SEK)	**-0.03**	**-0.11**	**-0.10**	**-0.42**	**-1.09**

Balance Sheet

Amounts in TSEK	30/09/2024	30/09/2023	31/12/2024
Assets			
Fixed assets			
Intangible fixed assets	54,951	80,644	40,476
Tangible fixed assets	12,333	13,309	14,245
Ongoing new facilities and advances regarding tangible fixed assets	33	1,724	33
Financial fixed assets	291	183	208
Total fixed assets	**67,608**	**95,860**	**54,961**
Current assets			
Stock	117	154	1,911
Current receivables	6,740	8,534	10,217
Short-term deposits	10,000	0	50,000
Cash and cash equivalents	19,009	20,569	15,168
Total current assets	**35,866**	**29,257**	**77,296**
Total assets	**103,474**	**125,118**	**132,257**
Equity and liabilities			
Equity			
Share capital	17,562	7,855	17,562
Not registered share capital	0	0	0
Restricted equity	46,567	74,038	34,282
Share premium reserve	317,961	264,824	317,961
Profit and loss account reserve brought forward	-286,260	-237,334	-197,577
Loss for the period	-13,273	-25,247	-76,398
Total equity	**82,557**	**84,137**	**95,830**
Provisions			
Other provisions	875	0	0
Total provisions	**875**	**0**	**0**
Non-current liabilities			
Liabilities to credit institutions	1,247	2,415	2,087
Other liabilities	0	1,291	3,766
Total non-current liabilities	**1,247**	**3,706**	**5,852**
Current liabilities			
Accounts payable	4,346	5,317	7,827
Other current liabilities	14,449	31,958	22,747
Total current liabilities	**18,795**	**37,275**	**30,574**
Total equity and liabilities	**103,474**	**125,118**	**132,257**
Pledged assets	**7,015**	**7,015**	**7,015**
Assets with retention of title	**5,383**	**6,127**	**5,941**

Cash flow analysis

Amounts in TSEK	01/07/2024 – 30/09/2024	01/07/2023 – 30/09/2023	01/01/2024 – 30/09/2024	01/01/2023 – 30/09/2023	01/01/2023 – 31/12/2023
Current activities					
Operating result	-4,550	-6,488	-14,037	-25,258	-76,625
Adjustments for items not included in cash flow	3,145	1,960	8,116	8,887	60,080
Interest received	257	114	826	271	588
Interest paid	-173	-347	-274	-559	-937
Cash flow from operating activities before change in working capital	**-1,321**	**-4,761**	**-5,369**	**-16,659**	**-16,895**
Cash flow from change in working capital					
Change in inventories and work in progress	2	2,366	1,794	333	-1,424
Changes in accounts receivable - trade	721	460	249	803	-1,296
Change in receivables	903	628	3,857	-1,281	-1,112
Change in accounts payable - trade	-2,202	-2,788	-3,481	656	3,167
Change in other liabilities	-4,217	-6,027	-11,347	-19,121	-25,098
Total from change in working capital	**-4,793**	**-5,360**	**-8,928**	**-18,610**	**-25,763**
Cash flow from current activities	**-6,114**	**-10,122**	**-14,297**	**-35,269**	**-42,658**
Investing activities					
Investments in intangible fixed assets	-5,637	-7,363	-20,094	-23,692	-32,270
Investments in tangible fixed assets	0	-102	-152	-288	-1,979
Investments in financial fixed assets	0	0	0	0	0
Cash flow from investment activities	**-5,637**	**-7,464**	**-20,246**	**-23,979**	**-34,248**
Financing activities					
New share issue	0	387	0	387	75,387
Issue costs	0	-39	0	-99	-12,255
Borrowings	0	0	0	0	0
Amortisation of loans	-551	-551	-1,617	-1,653	-2,240
Cash flow from financing activities	**-551**	**-204**	**-1,617**	**-1,365**	**60,892**
Cash-flow for the period	**-12,302**	**-17,790**	**-36,160**	**-60,613**	**-16,014**
Cash and cash equivalents at the beginning of the period	41,311	38,358	65,168	81,182	81,182
Cash and cash equivalents at the end of the period	**29,009**	**20,569**	**29,009**	**20,569**	**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			16,047		-16,047		**0**
Depreciation on capitalised development costs for the period			-3,762		3,762		**0**
Profit/loss for the period						-13,273	-13,273
Amount as of 30/09/2024	**17,562**	**0**	**46,567**	**317,961**	**-286,260**	**-13,273**	**82,557**

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

	30/09/2024	30/09/2023	31/12/2023
Corporate mortgages	7,015	7,015	7,015

Assets with retention of title

	30/09/2024	30/09/2023	31/12/2023
Assets with retention of title	5,383	6,127	5,941

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 tumor. 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 optimize 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)
    - Minimizes 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.

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