

Year-end report January – December 2024



Nanexa AB (PUBL)

Significant events during the fourth quarter 2024

- In October, Nanexa announced that the dosing of the last patient was completed in the Phase I study with long-acting depot formulation of the GLP-1-analogue liraglutide with PharmaShell (NEX-22).
- Nanexa announced in early November that the company's Phase I study for NEX-22 in type 2-diabetes was completed for all patients.
- In late November, Nanexa announced positive results in the company's phase I study for NEX-22, long-acting GLP1, in type 2-diabetes. The study evaluates a depot formulation of the GLP-1 analogue liraglutide for once-monthly dosing.

Significant events after the end of the period

- In January, Nanexa announced that the company has decided to carry out a directed share issue, deviating from existing shareholders' preferential rights, of units amounting to 35 MSEK in two steps. Furthermore, it was announced that the company has taken loans totaling 20 MSEK.
- Nanexa AB announced in January that the company is calling shareholders to an Extraordinary General Meeting on February 13, 2025, in connection with the above-mentioned issue.
- In January Nanexa announced that the Phase I-study with NEX-22, the company's one-month formulation of liraglutide, will resume with further dose escalation with an estimated start in the first quarter of 2025. The study has now received regulatory approval for the administration of 30 mg liraglutide in an additional dose group.
- At the Extraordinary General Meeting on February 13, it was decided that the directed share issue would be completed.

Financial overview

1 October - 31 December 2024

- Turnover amounted to: TSEK 4,517 (6,816)
- Operating profit (EBIT) amounted to: TSEK -12,025 (-51,367)
- Profit after tax amounted to: TSEK -11,631 (-51,150)
- Earnings per share amounted to: SEK -0.09 (-0.52)
- Cash flow for the period amounted to: TSEK -18,718 (44,599)
- Cash and cash equivalents at end of period: TSEK 10,292 (65,168)

1 January - 31 December 2024

- Turnover amounted to: TSEK 24,361 (29,327)
- Operating profit (EBIT) amounted to: TSEK -26,062 (-76,625)
- Profit after tax amounted to: TSEK -24,905 (-76,398)
- Earnings per share amounted to: SEK -0.18 (-1.09)
- Cash flow for the period amounted to: TSEK -54,877 (-16,014)
- Cash and cash equivalents at end of period: TSEK 10,292 (65,168)
- The Board of Directors proposes that no dividend will be paid for the financial year 2024

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

CEO's comment

The fourth quarter provided a strong end to the year for us at Nanexa. Operationally, we are proud to have created the first depot formulation of a GLP-1 agonist with one month release. We look forward with confidence to a good development as we advance the NEX-22 project forward towards further value-enhancing clinical studies and licensing. In January 2025, a directed new share issue was carried out, securing the business going forward, which contributes to us looking forward with confidence to a very exciting 2025.



In addition to NEX-22, our major focus during 2024 has been the collaboration with Novo Nordisk and the evaluation they are conducting of our drug delivery system PharmaShell for one of their substances. In many ways, this project resembles our own NEX-22 project, which has created great synergy effects. The evaluation with Novo Nordisk continues at an undiminished pace and our assessment is that we now fulfil the profile set so far in the evaluation. We believe that this will allow us to finalize the evaluation with good results within the agreed timeframe. What this potentially will lead to is hard to speculate about at this point, but our goal is to move forward in the project and initiate a negotiation within the year.

During the period, we have demonstrated a one-month release profile in humans using the PharmaShell system. Additionally, we have made progress in developing a three-month depot formulation and now have preliminary preclinical data supporting this release profile. This development broadens the potential use of the PharmaShell system for both existing and new partners.

The NEX-22 project, a GLP-1 product for the treatment of type 2 diabetes administered once a month instead of daily, is developing according to plan, and during the fourth quarter, we have shown Proof of Concept in humans. The study results from the recently completed phase I study clearly show that NEX-22 achieves a one-month release profile, which was also the goal. It is also very positive that no side effects, such as nausea, vomiting, or diarrhea, were observed, not even in the highest dose group. This is worth noting as it is very common for patients to experience these side effects at the beginning of their treatment with GLP-1 products. The focus going forward in the project is now on securing a licensing deal while we take the next step in the project, which means that we will soon expand the study with a higher dose group and prepare for the next clinical study where we expect to reach full clinical dose. This in turn opens the possibility for the simplified registration pathway (so-called 505 (b)(2)) in the US.

During the year, the cost savings we have implemented have had the expected effect, and all resources have been focused on our prioritized projects. The Board of Directors and management have also worked actively to secure financing, and we are therefore very pleased with the directed issue we carried out in January 2025. It ensures that we can continue to pursue NEX-22 while we complete the work with Novo Nordisk with the goal set on further collaboration and, if possible, a licensing agreement. I want to thank all existing and new shareholders as well as the staff for your continued support and commitment to the development of Nanexa.

David Westberg, CEO

Financial comments

Result and cash flow

Fourth quarter 2024

Sales for the quarter amounted to SEK 4,517 (6,816) thousand, of which SEK 1,111 (1,729) thousand relates to revenue within the framework of evaluation agreements entered regarding the PharmaShell® technology, SEK 3,228 (5,017) thousand relates to accrual of prepaid revenue related to the exclusivity agreement entered with Novo Nordisk A/S and SEK 172 (0) thousand relates to the coating of sensors. The monthly accrued revenue from Novo Nordisk A/S has been adjusted downwards for the rest of the period due to a new assessment. Capitalized development costs amounted to SEK 6,284 (8,056) 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 -5,113 (-6,663) 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 -5,993 (-6,013) thousand and were almost unchanged. Personnel costs in the quarter amounted to SEK -8,742 (-3,958) thousand, where the increase is explained by retroactive bonus for 2023 and 2024. The outcome for 2024 is on the other hand also affected by the savings program on staff costs that reduced the costs with SEK 621 thousand.

The result for the fourth quarter amounted to SEK -11,631 (-51,150) thousand.

Cash flow for the quarter amounted to SEK -18,718 (44,599) thousand. The change in working capital amounted to SEK -2,813 (-7,153) thousand and comes mainly from the deferred income from the exclusivity agreement with Novo Nordisk. Cash flow from investing activities amounted to SEK -7,875 (-10,269) thousand, where investments in intangible assets, mainly capitalized development costs, were lower than for the corresponding period last year. The cash flow from financing activities amounts to SEK 1 290 (62 257) thousand, where no capital injections were carried out during the quarter. The cash flow from the financing activities thus relates entirely to a net amount from new loans and amortizations of loans.

The period January-December 2024

Sales for the year amounted to SEK 24,361 (29,327) thousand, of which SEK 14,524 (21,946) thousand relates to the prepaid exclusivity fee from Novo Nordisk, SEK 7,223 (6,696) thousand relates to revenue within the framework of evaluation agreements entered regarding the PharmaShell® technology, and SEK 2,592 (599) thousand relates to coating of sensors. The monthly accrued revenue from Novo Nordisk A/S has been adjusted downwards for the rest of the period due to a new assessment. Capitalized development costs amounted to SEK 22,331 (29,830) thousand and mainly relate to investments in NEX-22 and, to a lesser extent, the PharmaShell system.

External project and development costs during the period amounted to SEK -16,527 (-27,709) thousand, a decrease mainly attributable to the focus of R&D activities on the NEX-22 project. Other external expenses amounted to SEK -20,607 (-24,697) thousand, where the decrease is explained by savings in administrative services, consulting expenses and travel. Personnel costs amounted to SEK -25,077 (-23,415) thousand during the period where the increase is explained by retroactive bonus for 2023 and 2024. The outcome for 2024 is on the other hand also affected by the savings program on staff costs that reduced the costs with SEK 931 thousand.

Depreciation and amortization amounted to SEK -10,859 (-59,868) 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 year amounted to SEK -24,905 (-76,398) thousand.

Cash flow for the period January-December 2024 amounted to SEK -54,877 (-16,014) thousand. Cost savings have had a positive effect on cash flow and the change in working capital amounted to SEK -11,742 (-25,763) 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 -28,120 (-34,248) 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 -327 (60,892) thousand where no capital injections were carried out during the year. The cash flow from the financing activities thus relates entirely to a net amount from new loans and amortizations of loans.

Financial position

As of December 31, 2024, cash and cash equivalents and short-term investments amounted to SEK 10,292 (65,168) thousand and equity amounted to SEK 70,925 (95,830) thousand.

The company decided already in the fourth quarter of 2023 on tactical priorities, whereby operations were focused on three key areas and significant cost savings have been realized. The Board of Directors believes that the company's current working capital and cash, including the injection of external capital during 2025, are sufficient to finance the business for the next 12 months from the submission of this report.

Employees

The number of employees as of December 31, 2024, was 13 (19), of which 4 (8) women and 9 (11) men. The average number of employees (FTE) amounted to 14 (19) in the fourth quarter and 17 (19) in the period January-December 2024. In addition to employed staff, Nanexa continuously hires consultants with specialist expertise.

Related party transactions

The company has not had any related party transactions either in the fourth quarter or in the period January-December 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, 2024, the number of shareholders in Nanexa was 6,187.

Earnings per share

Earnings per share, before and after dilution, amounted to SEK -0.09 (-0.52) for the fourth quarter of 2024 and SEK -0.18 (-1,09) for the period January-December 2024.

Number of shares

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

The average number of shares for the fourth quarter amounted to 135,695,626 (98,195,626), and for the period January-December 2024, amounted to 135,695,626 (70,147,681). Including full dilution of outstanding warrants, the average number of shares for the fourth quarter amounted to 135,695,626 (100,903,626), and for the period January-December 2024, 135,695,626 (72,738,358).

The outstanding programs for warrants by December 31, 2024, were:

TO6 (2022/2025) that can be used to subscribe for shares between June 15 to July 31, 2025. The number of outstanding warrants in program TO6 are 983,000, corresponding to a dilution of 0,72%. The strike price is set to 4,95 SEK.

TO7 (2023/2026) that can be used to subscribe for shares between July 1 to August 31, 2026. The number of outstanding warrants in program TO7 are 1,345,000, of which the number of subscribed warrants amounts to 425,000, corresponding to a dilution of 0,31%. The strike price is set to 5,31 SEK.

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.

April 10, 2025	Annual Report 2024
May 6, 2025	Interim report January-March 2025
May 15, 2025	Annual general meeting 2024

Annual general meeting 2025

The Annual General Meeting of Nanexa AB (publ) will be held in Uppsala on May 15, 2025, and the notice will be available on Nanexa´s website, www.nanexa.com.

Dividend

The Board of Directors proposes that no dividend will be paid for the financial year 2024.

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

Uppsala 02/19/2025

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	01/10/2024 – 31/12/2024	01/10/2023 – 31/12/2023	01/01/2024 – 31/12/2024	01/01/2023 – 31/12/2023
Operating revenue				
Turnover	4,517	6,816	24,361	29,327
Capitalised development costs	6,284	8,056	22,331	29,830
Other income	272	85	597	328
Total revenue	11,073	14,957	47,289	59,486
Operating expenses				
External project and development costs	-5,113	-6,663	-16,527	-27,709
Other external expenses	-5,993	-6,013	-20,607	-24,697
Personnel costs	-8,742	-3,958	-25,077	-23,415
Depreciation on intangible and tangible fixed assets	-3,179	-49,502	-10,859	-59,868
Other operating costs	-73	-189	-281	-421
Total costs	-23,099	-66,323	-73,351	-136,110
Operating profit (EBIT)	-12,025	-51,367	-26,062	-76,625
Profit/loss from financial items				
Interest income and similar income statement items	490	570	1,510	602
Interest expenses and similar income statement items	-122	-379	-461	-487
Total profit/loss from financial items	369	191	1,049	115
Taxes				
Tax revenue	25	25	108	112
Total taxes	25	25	108	112
Profit/loss for the period	-11,631	-51,150	-24,905	-76,398
Earnings per share (SEK)	-0.09	-0.52	-0.18	-1.09

Balance Sheet

Amounts in TSEK	31/12/2024	31/12/2023
Assets		
Fixed assets		
Intangible fixed assets	59,397	40,476
Tangible fixed assets	12,583	14,278
Financial fixed assets	316	208
Total fixed assets	72,296	54,961
Current assets		
Stock	495	1,911
Current receivables	8,738	10,217
Short-term deposits	0	50,000
Cash and cash equivalents	10,292	15,168
Total current assets	19,525	77,296
Total assets	91,821	132,257
Equity and liabilities		
Equity		
Share capital	17,562	17,562
Restricted equity	51,318	34,282
Share premium reserve	317,961	317,961
Profit and loss account reserve brought forward	-291,011	-197,577
Loss for the period	-24,905	-76,398
Total equity	70,925	95,830
Non-current liabilities		
Liabilities to credit institutions	2,197	2,087
Other liabilities	0	3,766
Total non-current liabilities	2,197	5,852
Current liabilities		
Accounts payable	2,289	7,827
Other current liabilities	16,409	22,747
Total current liabilities	18,698	30,574
Total equity and liabilities	91,821	132,257
Pledged assets	7,015	7,015
Assets with retention of title	7,353	5,941

Cash flow analysis

Amounts in TSEK	01/10/2024 – 31/12/2024	01/10/2023 – 31/12/2023	01/01/2024 – 31/12/2024	01/01/2023 – 31/12/2023
Current activities				
Operating result	-12,025	-51,367	-26,062	-76,625
Adjustments for items not included in cash flow	2,337	51,193	10,452	60,080
Interest received	490	317	1,316	588
Interest paid	-122	-379	-396	-937
Cash flow from operating activities before change in working capital	-9,320	-235	-14,689	-16,895
Cash flow from change in working capital				
Change in inventories and work in progress	-379	-1,757	1,415	-1,424
Changes in accounts receivable - trade	-19	-2,100	230	-1,296
Change in receivables	-1,979	169	1,878	-1,112
Change in accounts payable - trade	-2,057	2,511	-5,538	3,167
Change in other liabilities	1,621	-5,977	-9,728	-25,098
Total from change in working capital	-2,813	-7,153	-11,742	-25,763
Cash flow from current activities	-12,133	-7,388	-26,430	-42,658
Investing activities				
Investments in intangible fixed assets	-6,691	-8,578	-26,784	-32,270
Investments in tangible fixed assets	-1,185	-1,691	-1,336	-1,979
Investments in financial fixed assets	0	0	0	0
Cash flow from investment activities	-7,875	-10,269	-28,120	-34,248
Financing activities				
New share issue	0	75,000	0	75,387
Issue costs	0	-12,156	0	-12,255
Borrowings	2,422	0	2,422	0
Amortisation of loans	-1,132	-587	-2,749	-2,240
Cash flow from financing activities	1,290	62,257	-327	60,892
Cash-flow for the period	-18,718	44,599	-54,877	-16,014
Cash and cash equivalents at the beginning of the period	29,009	20,569	65,168	81,182
Cash and cash equivalents at the end of the period	10,292	65,168	10,292	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			22,331		-22,331		0
Depreciation on capitalised development costs for the period			-5,295		5,295		0
Profit/loss for the period						-24,905	-24,905
Amount as of 31/12/2024	17,562	0	51,318	317,961	-291,011	-24,905	70,925

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

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

Assets with retention of title

	31/12/2024	31/12/2023
Assets with retention of title	7,353	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
 - o Makes depot formulation of high potency substances possible
 - o Enables high doses in depot preparations
- Very high drug load (up to 80 per cent)
 - o Minimizes injection volumes
 - o Enables depot preparation of less potent drugs
 - o Enables longer depot preparations
- Flexible, can be used for many different drugs
 - o Small molecules
 - o Biological substances such as peptides and proteins
 - o Substances with high and low solubility
- Prevents breakdown of the drug after injection into the body
 - o The PharmaShell coating protects the substances from being broken down while they are in depots
- Numerous applications
 - o Subcutaneous or intramuscular administration for systemic exposure
 - o Local administration in the case of tumors 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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