



YEAR-END REPORT 2023

NANEXA AB (PUBL)

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Significant events during the fourth quarter 2023

- Nanexa announced the completion of the phase I study NEX-20-01. In addition to previously communicated positive results from the pharmacokinetic evaluation, the company received final safety and tolerability data that also support the further development of the project.
- Nanexa announced the outcome of the company's rights issue of approximately SEK 121 million, which showed that 42,146,268 shares, corresponding to approximately 34.7 percent of the rights issue, had been subscribed with and without subscription rights. Hence, guarantee commitments of 32,853,732 shares, corresponding to approximately 27.1 percent of the offered shares, were utilized and the rights issue provided the company with SEK 75 million before deduction of transaction costs.
- Nanexa signed a so-called Material Transfer and Feasibility Study Agreement with one of the largest global pharmaceutical companies, for the evaluation of Nanexa's drug delivery system, PharmaShell®, in a depot formulation of a monoclonal antibody.
- Nanexa announced that the clinical trial application for the Phase I study of NEX-22 in patients with type 2 diabetes has been received and validated by the European Medicines Agency (EMA).
- Nanexa's Board of Directors decided to focus the business on three key areas. The decision entails tactical prioritization and cost savings with the aim that the current cash position and expected revenues from evaluation agreements will be sufficient until mid 2025 and enable significant value-creating progress in prioritized collaborations and the proprietary project NEX-22.

Significant events after the end of the period

- No significant event after the end of the period.

Summary of the reporting period 1 October – 31 December 2023

- Turnover amounted to: TSEK 6,816 (819)
- Operating profit (EBIT) amounted to: SEK -51,367 (-17,869)
- Profit after tax amounted to: TSEK -51,150 (-17,932)
- Earnings per share amounted to: SEK -0.52 (-0.35)
- Cash flow for the period amounted to: TSEK 44,599 (35,574)
- Cash and cash equivalents at end of period: TSEK 65,168 (81,182)

Summary of the reporting period 1 January – 31 December 2023

- Turnover amounted to: TSEK 29,327 (2,860)
- Operating profit (EBIT) amounted to: TSEK -76,625 (-57,981)
- Profit after tax amounted to: TSEK -76,398 (-58,571)
- Earnings per share amounted to: SEK -1.09 (-1.16)
- Cash flow for the period amounted to: TSEK -16,014 (-24,478)
- Cash and cash equivalents at end of period: TSEK 65,168 (81,182)
- The Board of Directors proposes that no dividend is paid for the fiscal year 2023.

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

The CEO's comment

The fourth quarter ends the year with the submission of a clinical trial application for our high-priority project NEX-22, a new evaluation agreement with one of the world's largest pharmaceutical companies and secured funding through 2024 and into 2025. Our focus areas have been clearly defined to enable value-creating progress in the short and long term. Our collaborations with Novo Nordisk and other global partners are also developing in the right direction, which together makes us confident that 2024 will be a good year for Nanexa.



It is very satisfying that NEX-22 now enters the clinical development phase after a fast and efficient work from Nanexa's team. We started the project in late fall 2022 and have now in the last quarter of 2023 submitted a clinical trial application to the German authorities for a first phase I PK study in type 2 diabetes patients. The authorities' review of the application is currently underway where we are answering a number of questions. The goal is to get a final approval during the first quarter, but we do not rule out that it can be delayed somewhat into the second quarter. NEX-22 represents a very interesting exposure to the type 2 diabetes and obesity markets and our assessment is that there are great commercial opportunities if we succeed. The goal is to create a product of a GLP-1 substance (liraglutide) for dosing only once a month compared to the current once a day or once a week.

In the NEX-20 project, we have taken major steps forward during the year and during the last quarter we completed the first clinical phase I study. The study confirmed the desired release profile obtained in various animal studies and that the injection site reactions were reversible during the study. These results support our belief in the potential of the product and the progress of our PharmaShell® drug delivery system. We look forward to taking this project forward as soon as priorities allow. The next step will be to optimize the product formulation to further reduce injection site reactions before entering a Phase Ib clinical trial.

Our collaboration with Novo Nordisk and the evaluation of PharmaShell in combination with their compound has developed well during the year and the last quarter. Good collaboration with the Novo Nordisk team and good results from our development make me confident about the future development of this project and our collaboration with Novo Nordisk in 2024.

I have previously mentioned that we have also made progress in other partner projects during the year and my assessment remains that one or more of these collaborations will be able to expand into more comprehensive development agreements.

We signed another evaluation agreement in the fourth quarter. The agreement concerns the very interesting area of long-acting monoclonal antibodies (mAbs). This is our second evaluation agreement for this type of substance and my assessment is that we will also be able to deliver interesting results here.

Despite challenging financial market conditions, we also completed a rights issue in the fourth quarter that secured funding for the company throughout 2024 and into 2025. This strengthens our position and allows us to focus on our business plan going forward. In connection with the financing, the company decided, until further notice, to focus its operations on three key areas, the NEX-22 project, the Novo Nordisk collaboration and additional prioritized partner projects. The decision entails cost savings with the goal that today's cash and expected revenues from evaluation agreements will cover operating costs by mid-year 2025. It is my firm assessment that this creates the best conditions for good value growth in both the short and long term.

Many thanks to our investors and partners for their continued support and commitment during this eventful quarter.

David Westberg, CEO Nanexa

About Nanexa

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

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

Addressing important medical needs and substantial markets

The company has taken important steps in the development in recent years, driving three drug candidates in as many very interesting areas. All three projects address important medical needs and substantial markets, where the recently launched project, NEX-22, targets treatment of type 2 diabetes, which is huge market with annual sales of USD 50 billion in 7MM (the seven major markets in the Western world).

The NEX-20 and NEX-18 projects are developed to create improved versions and depot formulations of the drugs azacytidine, for treatment of myelodysplastic syndrome (MDS), and lenalidomide, for treatment of multiple myeloma, two types of blood cancer. The properties of the PharmaShell system are utilised to improve these treatments, for example by reducing the burden on patients and caregivers of the inconvenient and costly administration of azacytidine, and by improving compliance to treatment of type 2 diabetes with liraglutide or multiple myeloma with lenalidomide.

The basis for selecting the projects is that there must be a clear medical need, a strong long-term market potential and good technical prerequisites. Nanexa product projects combine already marketed drugs with the company's drug delivery system PharmaShell, enabling formulation of unique long-acting products. The projects' development programs are based on comparison with already approved products, which provides for significantly shorter and less expensive development projects, with significantly lower risk compared to traditional product projects based on new drug substances.

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

A patented technology with large potential

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

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

Vision

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

Business concept

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

Nanexa focuses primarily on developing improved versions of existing drugs to achieve new and significantly improved properties that generate value for patients, healthcare and society in general. Thanks to PharmaShell, Nanexa is able to develop products with significant patent protection and high market value. Starting from well-tested pharmaceutical substances means that the biological risk is reduced and the development projects are less costly than for projects with new untested substances. It also makes the registration process easier and shortens the time to market.

Furthermore, the company will license the actual PharmaShell technology to pharmaceutical companies which intend to use it in their own development of unique long-acting drugs. These collaborations contribute revenue for Nanexa as early as the evaluation phase. They also help validate and increase Nanexa's knowledge of the possibilities of the company's technology. In the relatively short term, there are opportunities for extensive development agreements and, in the long run, licensing agreements where there is significant commercial potential.

Comments, Q4 2023

Result and cash flow

Fourth quarter 2023

Revenue for the quarter amounted to SEK 6,816 (819) thousand, of which SEK 1,729 (204) thousand relates to revenue within the framework of the evaluation agreements regarding the PharmaShell® technology and SEK 5,017 (608) thousand relates to the accrual of deferred revenue of USD 4 million related to the exclusivity agreement entered into with Novo Nordisk A/S in December 2022. The monthly accrued amount has, in connection with the year-end closing and updated assessment of duration within the framework of the exclusivity agreement, been adjusted downwards by SEK 626 thousand as from December 2023. Capitalized development costs amounted to SEK 8,056 (6,529) thousand and relates mainly to investments in NEX-22 and to a lesser extent NEX-20 and the PharmaShell system.

External project and development costs in the fourth quarter amounted to SEK -6,663 (-6,295) thousand, where half relates to NEX-22, a smaller part to NEX-20 and the remainder relates to other projects and general costs for R&D and production. Other external costs amounted to SEK -6,013 (-7,984) thousand, where the largest decrease is attributable to the patent dispute in the US that was concluded at the end of 2022. The quarter's personnel costs amounted to SEK -3,958 (-8,562) thousand, where the decrease is explained by differences in provisions for variable remuneration between the years. In connection with the decision on tactical priorities in the project portfolio, where the development of NEX-18 and NEX-20 is paused until sufficient funds are provided to the company, it was decided to write down the book value of capitalized development costs related to these projects. This increased depreciation for the quarter and had a negative effect on earnings totaling SEK -45,563 thousand.

The result for the fourth quarter amounted to SEK -51,150 (-17,932) thousand.

Cash flow for the quarter amounted to SEK 44,599 (35,574) thousand. The change in working capital amounted to SEK -5,385 (41,897) thousand, where the high amount in the fourth quarter of 2022 stems from deferred income from the exclusivity agreement that was then entered into with Novo Nordisk, which has then partly been recognized as income during 2023. Cash flow from investing activities amounted to SEK -10,269 (-6,938) thousand, where mainly capitalized development costs and investments in property, plant and equipment were higher than in the corresponding period in 2022. Cash flow from financing activities amounted to SEK 62,257 (15,545) thousand, where new issue of shares gave net proceeds of SEK 62,844 (16,060) thousand, while amortization of loans amounted to SEK -587 (-515) thousand.

The period January-December 2023

Net sales for the year amounted to SEK 29,327 (2,860) thousand, of which SEK 21,946 (608) thousand relates to the prepaid exclusivity fee from Novo Nordisk, SEK 6,696 (1,208) thousand relates to income from partner projects with Novo Nordisk, among others, and SEK 599 (1,023) thousand relates to coating of sensors. Capitalized development costs amounted to SEK 29,830 (24,311) thousand, of which about 50 percent relates to NEX-22, about 25 percent to NEX-20 and the remaining parts to the PharmaShell system and NEX-18.

External project and development costs during the year amounted to SEK -27,709 (-23,769) thousand, an increase mainly attributable to the NEX-22 project and to a lesser extent PharmaShell development. Other external costs amounted to SEK -24,697 (-28,816) thousand, a decrease explained by non-recurring costs in 2022, mainly the patent dispute in the US and also the preparation of new premises, which more than offset increased costs for, among other things, rent and maintenance of the new pilot plant and financial services in 2023. Personnel costs amounted to SEK -23,415 (-22,773) thousand in 2023 and have increased with a slightly higher average number of employees, while the provision for variable remuneration was lower for 2023. Depreciation amounted to -59,868 (-10,504), where the increase is mainly explained by write-downs of capitalized development costs for NEX-18 and NEX-20 totaling SEK 45,563 thousand, which is due to the projects being paused in connection with decisions on short-term tactical prioritization of NEX-22 and certain partner projects.

The result for the year amounted to SEK -76 398 (-58 571) thousand.

Cash flow for the period January-December 2023 amounted to SEK -16 014 (-24 478) thousand. The change in working capital amounted to SEK -23,995 (40,259) thousand, where the large decrease is explained by the fact that prepaid income from Novo Nordisk of approximately SEK 44 million was booked at the end of 2022, which has then partly been recognized as income during 2023. Cash flow from investing activities amounted to SEK -34,248 (-35,422) thousand, where capitalized development costs increased while capitalized patent costs decreased, which also applies to investments in tangible fixed assets that were significantly higher in 2022 in connection with the move to new premises. Cash flow from financing activities amounted to SEK 60,892 (18,814) thousand, where new issues of shares and warrants provided net proceeds of SEK 63,132 (16,375) thousand, while the net of new and amortized loans amounted to SEK -2,240 (2,441) thousand.

Financial position

As of December 31, 2023, cash and short-term investments amounted to SEK 65,168 (81,182) thousand and equity amounted to SEK 95,830 (109,096) thousand.

In November 2023, the company completed a rights issue of SEK 121 million, which was covered by subscription commitments from existing owners, board and management, and guarantee commitments from external investors, totaling SEK 75 million. The outcome of the issue showed that shares corresponding to SEK 42.1 million were subscribed with and without subscription

rights and SEK 32.9 million were covered by guarantee commitments. The company thus received approximately SEK 63 million after deduction of transaction costs.

The company decided during the fourth quarter on tactical priorities, whereby the business is 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 December 31, 2023, was 19 (19), of which 8 (7) were women and 11 (12) were men. The average number of employees (FTE) was 19 (18) in the fourth quarter and 19 (17) during the period January-December 2023. In addition to employed staff, Nanexa regularly hires about ten consultants with specialist expertise.

Related party transactions

During the fourth quarter of 2023, the company purchased consulting services from former board member Bengt Gustavsson through Sangus Jazz AB for SEK 0 (586) thousand. For the period January-December 2023, the corresponding amount was SEK 1,163 (2,334) thousand. Bengt Gustavsson left the board in connection with the annual general meeting on June 9, 2023. The consultancy services were clearly separated from the assignment as a board member of the company.

The share

Nanexa AB (publ) was listed on the Nasdaq First North Growth Market on 29 May 2020. The share was previously listed on the Spotlight Stock Market since 17 June 2015. As of December 31, 2023, the number of shareholders in Nanexa was 3,298.

Earnings per share

Earnings per share before and after dilution amounted to SEK -0.52 (-0.35) for the fourth quarter of 2023 and SEK -1.09 (-1.16) for the period January-December 2023.

Number of shares

The number of outstanding shares in Nanexa AB as of December 31, 2023 was 135,695,626 (50,695,626), with a quota value of SEK 0.13 per share. The number of shares at full dilution of outstanding warrants was 138,403,626 (53,174,626).

The average number of shares for the fourth quarter 2023 amounted to 98,195,626 (50,695,626) and for the period January-December 2023 to 70,147,681 (50,695,626). Including full dilution of outstanding warrants, the average number of shares for the fourth quarter 2023 amounted to 100,903,626 (53,174,626) and for the period January-December 2023 to 72,814,796 (52,679,086).

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.

March 27, 2024	Annual Report 2023
May 3, 2024	Interim report January-March 2024
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.

Annual general meeting 2024

The Annual General Meeting of Nanexa AB (publ) will be held in Uppsala on May 15, 2024 and the notice will be available on Nanexa's website, www.nanexa.com.

Dividend

The Board of Directors proposes that no dividend be paid for the financial year 2023.

Nomination committee

A nomination committee has been appointed in Nanexa AB (publ) for the Annual General Meeting 2024 in accordance with the principles adopted by Nanexa's Annual General Meeting on June 9, 2023. The Nomination Committee's task is to propose for the AGM 2024, among other things, board members, chairman of the board and auditor as well as fees for board members and auditor. The Nomination Committee is appointed by the three largest shareholders in the company in terms of votes, who have expressed their wish to participate in the work of the Nomination Committee. In addition, the Nomination Committee shall consist of Nanexa's Chairman of the Board.

The Nomination Committee consists of the following representatives: Marlon Värnik (appointed by Exelity AB), Christian Östberg (appointed by Gerhard Dal) and Göran Ando (Nanexa's Chairman of the Board, co-opted). Christian Östberg is appointed Chairman of the Nomination Committee.

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

Uppsala 21/02/2024

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	01/10/2023 – 31/12/2023	01/10/2022 – 31/12/2022	01/01/2023 – 31/12/2023	01/01/2022 – 31/12/2022
Operating revenue				
Turnover	6,816	819	29,327	2,860
Capitalised development costs	8,056	6,529	29,830	24,311
Other income	85	698	328	1,004
Total revenue	14,957	8,046	59,486	28,175
Operating expenses				
External project and development costs	-6,663	-6,295	-27,709	-23,769
Other external expenses	-6,013	-7,984	-24,697	-28,816
Personnel costs	-3,958	-8,562	-23,415	-22,773
Depreciation on intangible and tangible fixed assets	-49,502	-3,031	-59,868	-10,504
Other operating costs	-189	-42	-421	-294
Total operating expenses	66,323	-25,915	-136,110	-86,156
Operating profit (EBIT)	-51,367	-17,869	-76,625	-57,981
Profit/loss from financial items				
Interest income and similar income statement items	570	11	1,053	11
Interest expenses and similar income statement items	-379	-105	-937	-666
Total profit/loss from financial items	191	-93	115	-654
Taxes				
Tax revenue	25	30	112	64
Total taxes	25	30	112	64
Profit/loss for the period	-51,150	-17,932	-76,398	-58,571
Earnings per share (SEK)	-0.52	-0.35	-1.09	-1.16

Balance Sheet

Amounts in TSEK	31/12/2023	31/12/2022
Assets		
Fixed assets		
Intangible fixed assets	40,476	65,248
Tangible fixed assets	14,245	15,093
Ongoing new facilities and advances regarding tangible fixed assets	33	33
Financial fixed assets	208	97
Total fixed assets	54,961	80,471
Current assets		
Stock	1,911	487
Current receivables	10,718	8,055
Short-term deposits	50,000	0
Cash and cash equivalents	15,168	81,182
Total current assets	77,797	89,724
Total assets	132,758	170,195
Equity and liabilities		
Equity		
Share capital	17,562	6,561
Not registered share capital	0	1,294
Restricted equity	34,282	58,649
Share premium reserve	317,961	264,536
Profit and loss account reserve brought forward	-197,577	-163,373
Loss for the period	-76,398	-58,571
Total equity	95,830	109,096
Non-current liabilities		
Liabilities to credit institutions	2,087	4,068
Other liabilities	3,766	18,220
Total non-current liabilities	5,852	22,288
Current liabilities		
Accounts payable	7,827	4,661
Other current liabilities	23,248	34,150
Total current liabilities	31,075	38,811
Total equity and liabilities	132,758	170,195
Pledged assets	7,015	7,015
Assets with retention of title	5,941	6,686

Cash flow analysis

Amounts in TSEK	01/10/2023 – 31/12/2023	01/10/2022 – 31/12/2022	01/01/2023 – 31/12/2023	01/01/2022 – 31/12/2022
Current activities				
Operating result	-51,367	-17,869	-76,625	-57,981
Adjustments for items not included in cash flow	51,193	3,032	60,080	10,505
Interest received	317	11	588	11
Interest paid	-379	-105	-937	-665
Cash flow from operating activities before change in working capital	-235	-14,930	-16,895	-48,130
Cash flow from change in working capital				
Change in inventories and work in progress	-1,757	-62	-1,424	-218
Changes in accounts receivable - trade	-2,100	401	-1,296	-902
Change in receivables	169	-954	-1,112	-3,577
Change in accounts payable - trade	2,511	-3,511	3,167	931
Change in other liabilities	-5,977	46,022	-25,098	44,025
Total from change in working capital	-7,153	41,897	-25,763	40,259
Cash flow from current activities	-7,388	26,967	-42,658	-7,871
Investing activities				
Investments in intangible fixed assets	-8,578	-6,938	-32,270	-27,654
Investments in tangible fixed assets	-1,691	0	-1,979	-7,768
Investments in financial fixed assets	0	0	0	0
Cash flow from investment activities	-10,269	-6,938	-34,248	-35,422
Financing activities				
New share issue	75,000	17,200	75,387	17,515
Issue costs	-12,156	-1,140	-12,255	-1,140
Borrowings	0	0	0	5,985
Amortisation of loans	-587	-515	-2,240	-3,544
Cash flow from financing activities	62,257	15,545	60,892	18,814
Cash-flow for the period	44,599	35,574	-16,014	-24,478
Cash and cash equivalents at the beginning of the period	20,569	45,608	81,182	105,660
Cash and cash equivalents at the end of the period	65,168	81,182	65,168	81,182

Changes in equity

Amounts in TSEK	Share capital	Fund for development work	Share premium reserve	Share premium reserve	Profit/Loss brought forward	Profit/Loss for the period	Total equity
Amount as of 01/01/2023	6,561	1,294	58,649	264,536	-163,373	-58,571	109,096
Previous year's result					-58,571	58,571	0
New share issue	11,001			65,294			76,295
Ongoing new issue		-1,294					-1,294
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 31/12/2023	17,562	0	34,282	317,961	-197,577	-76,398	95,830

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

Pledged assets

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

Assets with retention of title

	31/12/2023	31/12/2022
Assets with retention of title	5,941	6,686

Contact

David Westberg
CEO
+46 709-42 83 03
david.westberg@nanexa.se

Nanexa AB

Virdings Allé 2, SE-754 50 Uppsala, Sweden
Phone: +46 (0) 18 100 300
Org nr. 556833-0285
info@nanexa.se

