



naneXa

YEAR-END REPORT 2022

NANEXA AB (PUBL)

Nanexa AB (PUBL)

Significant events during the fourth quarter 2022

- During the quarter, Nanexa signed an exclusivity and evaluation agreement, a so-called Material Transfer and Feasibility Study Agreement with leading global pharmaceutical company Novo Nordisk A/S ("Novo Nordisk") for the evaluation of Nanexa's drug delivery system PharmaShell® with Novo Nordisk products within a certain substance class. As part of the agreement, Nanexa receives payments of approximately SEK 46.1 million for providing Novo Nordisk a time-limited exclusivity and work performed during the evaluation period. In connection with the agreement, a directed issue of shares to Novo Nordisk was also carried out, which brought SEK 17.2 million before issue costs to Nanexa and made Novo Nordisk the largest shareholder, with 16.5 percent of the shares and votes in the company.
- Nanexa started, according to plan, the Phase 1 study with NEX-20, a long-acting formulation of lenalidomide for treatment of multiple myeloma. The study is carried out in healthy volunteers with the aim to study the pharmacokinetic profile, safety and tolerability of the drug.
- Nanexa AB and VitriVax, Inc. jointly announce that they have resolved the patent infringement lawsuit filed by Nanexa AB against VitriVax, Inc. in the United States District Court for the District of Delaware.
- Nanexa signed a Material Transfer and Feasibility Study Agreement with a Specialty Pharma company, for evaluation of the PharmaShell drug delivery system making a depot formulation of specific compounds for intravitreal delivery.
- During the quarter, a Nomination Committee was appointed in Nanexa AB (publ) for the Annual General Meeting 2023, in accordance with the principles adopted by Nanexa's Annual General Meeting on 9 June 2022, consisting of Philip Norin, Hanno Lindroth (appointed by Mårten Rooth), Christian Östberg (appointed by Anders Johansson) and Göran Ando (Chairman of the Board, adjunct).

Significant events after the end of the period

- No significant events after the end of the period

Summary of the reporting period 1 October – 31 December 2022

- Turnover amounted to: TSEK 819 (670)
- Operating profit (EBIT) amounted to: TSEK -17,869 (-13,045)
- Profit after tax amounted to: TSEK: -17,932 (-13,087)
- Earnings per share amounted to: SEK -0.35 (-0.26)
- Cash flow for the period amounted to: TSEK 35,574 (-14,139)
- Cash and cash equivalents at end of period: TSEK 81,182 (105,660)

Summary of the reporting period 1 January – 31 December 2022

- Turnover amounted to: TSEK 2,860 (2,374)
- Operating profit (EBIT) amounted to: TSEK -57,981 (-35,821)
- Profit after tax amounted to: TSEK -58,571 (-35,999)
- Earnings per share amounted to: SEK -1.16 (-1.01)
- Cash flow for the period amounted to: TSEK -24,478 (92,969)
- Cash and cash equivalents at end of period: TSEK 81,182 (105,660)
- The Board of Directors proposes that no dividend is paid for the fiscal year 2022.

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

The CEO's comments

The fourth quarter of 2022 was a period of intensive activity and we took several large, important steps on our commercialisation journey. The biggest event was undoubtedly the exclusivity and evaluation agreement, worth 46.1 MSEK, and the directed issue of 17.2 MSEK carried out with Novo Nordisk, which thus became Nanexa's largest shareholder. But it is also pleasing that we started the phase 1 study with NEX-20, achieved a final solution to the patent dispute with VitriVax, Inc. and signed a further two evaluation agreements, including one with a pharmaceutical company specialising in the ophthalmic field.



The agreement and directed issue to Novo Nordisk

Our agreement and the directed issue to Novo Nordisk meant that the fourth quarter of 2022 was a very special quarter. Novo Nordisk is a leading global pharmaceutical company engaged in the research, development, manufacture and commercialisation of pharmaceutical products and related equipment for the treatment of a range of illnesses including diabetes and obesity. By combining their products with our PharmaShell® technology, we will develop new formulations that will then be evaluated by Novo Nordisk in preclinical studies. The collaboration strengthens Nanexa's portfolio of partner projects and provides a solid foundation for it to be developed into a more comprehensive development programme and long-term license agreement.

The agreement also provides us with significant payment, partly for providing Novo Nordisk with fixed-term exclusivity for the use of PharmaShell within a certain substance class and partly for the work carried out by Nanexa during the evaluation. In combination with the directed share issue, the company receives approximately 63.3 MSEK, which puts us in a better position to develop Nanexa into a world-leading pharmaceutical company in long-acting injectable drug products. The agreement is of course a major milestone and we are extremely proud of it. We are also very pleased to have Novo Nordisk as a strong, long-term shareholder of Nanexa.

New important step for NEX-20

According to plan, we started a Phase 1 study with NEX-20 during the fourth quarter. The study is carried out on healthy volunteers who receive a single injection of NEX-20 and are then monitored to establish the pharmacokinetic profile, safety and tolerability of the drug. The results of the study are expected to give a good idea of the adjustments that need to be made to the formulation in the future development of the project. NEX-20 is a long-acting formulation of lenalidomide, based on Nanexa's drug delivery system PharmaShell, and is aimed at the very large market for the treatment of the multiple myeloma blood cancer. NEX-20 provides significant advantages for the patients compared to current treatment methods. Instead of taking lenalidomide in the form of an oral capsule once a day for 21–28 days per monthly treatment cycle, the patient is given a single injection per month, which ensures that patients receive their correct dosage throughout the treatment. The patient's everyday life is simplified considerably and it is also cost-effective for healthcare. We are very pleased to have taken the next step in the project into clinical development.

Resolution of the patent infringement lawsuit and two new evaluation agreements

In November, we were able to announce that an agreement has been reached in the patent infringement lawsuit against VitriVax, Inc. In a confidential settlement agreement which includes a conditional licensing mechanism, VitriVax, Inc. has guaranteed that the company is not infringing and will not infringe our patents. It is important for Nanexa to defend our patents and the lawsuit confirms that we have strong protection for PharmaShell. We are pleased that the dispute has been concluded with a positive outcome for us and we will now focus on continuing to develop our technology and patent portfolio and on generating business based on them.

Besides the Novo Nordisk agreement, we signed a further two evaluation agreements during the quarter, referred to as Material Transfer and Feasibility Study Agreements. For contractual reasons, we are unable to describe one of the agreements in detail but the other is with a pharmaceutical company in the ophthalmic field. That agreement relates to the evaluation of PharmaShell in a depot formulation of a specific commercial pharmaceutical product for intravitreal administration. The high drug load we are able to achieve in a project like this is a key advantage and there are several possible advantages to a local, targeted release of the active substance in the eye. It is also very exciting for Nanexa to enter into a collaboration with a pharmaceutical company in the ophthalmic field, where we have identified tremendous potential.

A positive end to an eventful year

Overall, we have had a strong end to an eventful year. During the year, Nanexa entered into several important cooperation agreements with large global pharmaceutical companies, including Novo Nordisk. We have also started a new product project in the form of NEX-22 and have launched our unique, state-of-the-art production facility. We have also successfully defended our patents. I am extremely proud of the steps we have taken as a company and look forward to a new year in which we will carry out further work on the three product projects we now have, maintain the trust of our new large shareholder Novo Nordisk and continue to work according to our cooperation agreements. I thank the entire team at Nanexa for an exciting year full of milestones.

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.

The company has taken important steps in the development in recent years, now 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-18 and NEX-20 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.

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.

The proprietary product projects are primarily focused on development of so called "super generics", new drugs based on existing substances where the patent has expired, and which are reformulated using the PharmaShell technology in order to achieve new and significantly improved properties for both patients and healthcare providers. The combination with PharmaShell also creates a product with significant patent protection. Being based on proven drugs, the development projects are significantly less costly, with a simpler registration process, shorter time to market and significantly lower risk than projects with drugs based on completely new substances.

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.

Comments, Q4 2022

Comments on the result and the financial position

Fourth quarter 2022

Net sales for the quarter amounted to 819 (670) TSEK and are mainly attributable to the exclusivity and evaluation agreement entered into with Novo Nordisk A/S and work carried out in an evaluation agreement previously entered into with another partner. The exclusivity fee of a total of 4 million dollars is distributed over the exclusivity period. Capitalised development costs amounted to 6,529 (3,624) TSEK, attributable mainly to investments in NEX-20 and to a lesser extent in NEX-18, NEX-22 and the PharmaShell®-system. External project and development costs during the quarter amounted to -6,295 (-4,028) TSEK, an increase mainly attributable to activities within NEX-20. Other external costs amounted to -7,984 (-5,354) TSEK, with the increase largely attributable to one-off costs of approximately -1,212 TSEK relating to the patent litigation in the US and higher costs for the new production facility. Personnel costs amounted to -8,562 (-5,868) TSEK in the fourth quarter. The increase is due partly to an increase in the number of employees and partly to higher variable remuneration compared with the previous year.

The loss for the fourth quarter amounted to -17,932 (-13,087) TSEK, while cash flow for the quarter amounted to 35,574 (-14,139) TSEK, of which the exclusivity fee and net issue amount from Novo Nordisk amounted to 57,441 (0) TSEK, investments (mainly patent and development costs) amounted to -6,938 (-5,698) TSEK and other cash flow from operating activities amounted to -14,414 (-7,973) TSEK.

The period January-December 2022

Total sales for the year amounted to 2,860 (2,374) TSEK and related mainly to previous and recent evaluation and exclusivity agreements and orders for sensor coating. Capitalised development costs amounted to 24,311 (15,636) TSEK, attributable mainly to NEX-20 and to a lesser extent NEX-18, NEX-22 and the PharmaShell-system. External project and development costs in the period amounted to -23,769 (-13,698) TSEK, with the increase being mainly attributable to activities within NEX-20 and to start-up and work on GMP certification of the new manufacturing facility. Other external costs amounted to -28,816 (-15,844) TSEK, with the increase being largely attributable to one-off costs of a total of approximately -6,279 TSEK relating mainly to the patent litigation in the US and also moving and fitting out new premises and higher costs for premises for the new production facility. Personnel costs amounted to -22,773 (-16,743) TSEK during the year and have increased due to a growing organisation in line with the company's strategic plan and higher variable remuneration for 2022.

The loss for the year amounted to -58,571 (-35,999) TSEK.

The cash flow for the period amounted to -24,478 (92,969) TSEK. The exclusivity fee of 41,381 TSEK paid by Novo Nordisk has been recognised as revenue to a lesser extent during the period and most of it has been distributed over time, which mainly explains the increase in current- and non-current liabilities. Other cash flow from operating activities amounted to -49,252 (-25,182) TSEK and investments amounted to -35,422 (-25,789) TSEK, of which -7,768 (-7,764) TSEK related to tangible fixed assets in the production facility and other investments related to capitalised development costs and patents. Net proceeds from new issues of shares and warrants during the period amounted to 16,374 (143,941) TSEK and new loan financing, linked to investments in production equipment among other things, amounted to 5,985 (1,000) TSEK, while amortisation of these loans and loans raised previously amounted to -3,544 (-1,055) TSEK.

Cash and cash equivalents as of 31/12/2022 amounted to 81,182 (105,660) TSEK. The Board of Directors considers that the company has sufficient financing for the next 12 months.

Employees

The number of employees at the end of the period was 19 (17), of which 7 (5) were women and 12 (12) were men. The average number of employees (FTE) was 18 (14) in the fourth quarter and 17 (13) for the period January-December 2022. In addition to employed staff, Nanexa regularly hires about ten consultants with specialist expertise.

Related party transactions

During the fourth quarter, the company has purchased consultancy services from board member Bengt Gustavsson through Sangus Jazz AB for TSEK 586 (651). During the period January-December 2022, the company has bought consultancy services from board members Otto Skolling through Pharmor AB for TSEK 810 (1,235) and Bengt Gustavsson through Sangus Jazz AB for TSEK 2,334 (1,144). Otto Skolling resigned from the Board of Directors at the time of the 2022 Annual General Meeting. The consulting services are clearly separated from assignments as a member of the Board of Directors 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 31 December 2022, the number of shareholders in Nanexa was 3,060.

Earnings per share

Earnings per share before and after dilution amounted to SEK -0.35 (-0.26) for the fourth quarter of 2022 and to SEK -1.16 (-1.01) for the period January-December 2022.

Number of shares

As of 31 December 2022, Nanexa AB (publ) had 50,695,626 outstanding shares with a quotient value of SEK 0.13. The number of shares at full dilution of outstanding warrants was 53,174,626. The directed issue of 10,000,000 shares to Novo Nordisk was registered on 2 January 2023.

The average number of shares during the fourth quarter was 50,695,626 (50,695,626) and during the period January-December 2022 it was 50,695,626 (35 633 470). Including full dilution of outstanding warrants, the average number of shares was 53,174,626 (54,232,075) during the fourth quarter and 52,679,086 (42,071,338) during the period January-December 2022.

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 5, 2023	Annual Report 2022
May 4, 2023	Interim report January-March 2023
August 23, 2023	Interim report January-June 2023
October 27, 2023	Interim report January-September 2023
February 20, 2024	Year-end report 2023

The company's financial year is 1 January - 31 December.

Annual General Meeting 2023

The annual general meeting of Nanexa AB (publ) will be held in Uppsala on 29 May 2023. The notice of the annual general meeting will be available on the Nanexa website, www.nanexa.se, as of 25 April 2023.

Dividend

The Board of Directors proposes that no dividend is paid for the fiscal year 2022.

Nomination Committee

A nomination committee has been appointed in Nanexa AB (publ) for the Annual General Meeting 2023, in accordance with the principles adopted by Nanexa's Annual General Meeting on 9 June 2022. The task of the nomination committee is to propose, among other things, the members of the board of directors, the chairman of the board of directors and the auditor, as well as the remuneration of the members of the board of directors and the auditor. The nomination committee is appointed by the three largest shareholders of the company in terms of voting rights, who upon request have expressed their wish to participate in the work of the nomination committee. In addition, the nomination committee shall consist of the chairman of the board of Nanexa.

The nomination committee consists of the following representatives: Philip Norin, Hanno Lindroth (appointed by Mårten Rooth), Christian Östberg (appointed by Anders Johansson) and Göran Ando (Chairman of the Board, adjunct).

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

Uppsala 16/02/2023

The board of directors, Nanexa AB

Göran Ando (chairman)

Bengt Gustavsson (member)

Richard Davis (member)

Eva Nilsagård (member)

Urban Paulsson (member)

Birgit Stattin Norinder (member)

Magnus Westgren (member)

David Westberg, VD Nanexa AB

Income statement

Amount in TSEK	01/10/2022 – 31/12/2022	01/10/2021 – 31/12/2021	01/01/2022 – 31/12/2022	01/01/2021 – 31/12/2021
Operating revenue				
Net sales	819	670	2,860	2,374
Capitalised work on own account	6,529	3,624	24,311	15,636
Other income	698	36	1,004	150
Total operating revenue	8,046	4,330	28,175	18,160
Operating expenses				
Project costs	-6,295	-4,028	-23,769	-13,698
Other external expenses	-7,984	-5,354	-28,816	-15,844
Personnel costs	-8,562	-5,868	-22,773	-16,743
Depreciation on intangible and tangible fixed assets	-3,031	-2,059	-10,504	-7,468
Other operating expenses	-42	-66	-294	-228
Total costs	-25,915	-17,376	-85,156	-53,981
Operating profit (EBIT)	-17,869	-13,045	-57,981	-35,821
Profit/loss from financial items				
Interest income and similar income statement items	11	0	11	0
Interest expenses and similar income statement items	-105	-44	-666	-186
Total profit/loss from financial items	-93	-44	-654	-186
Taxes				
Tax revenue	30	2	64	8
Total taxes	30	2	64	8
Profit/loss for the period	-17,932	-13,087	-58,571	-35,999
Earnings per share (SEK)	-0.35	-0.26	-1.16	-1.01

Balance sheet

Amount in TSEK	31/12/2022	31/12/2021
Assets		
Fixed assets		
Intangible fixed assets	65,248	45,708
Tangible fixed assets	15,093	2,834
Ongoing new facilities and advances regarding tangible fixed assets	33	6,915
Financial fixed assets	97	63
Total fixed assets	80,471	55,520
Current assets		
Stock	487	269
Current receivables	8,055	3,547
Cash and cash equivalents	81,182	105,660
Total current assets	89,724	109,476
Total assets	170,195	164,996
Equity and liabilities		
Equity		
Share capital	6,561	6,561
Not registered share capital	1,294	0
Restricted equity	58,649	40,483
Share premium reserve	264,536	249,456
Profit and loss account reserve brought forward	-163,373	-109,208
Loss for the period	-58,571	-35,999
Total equity	109,096	151,293
Non-current liabilities		
Liabilities to credit institutions	4,068	2,573
Other non-current liabilities	18,220	0
Total non-current liabilities	22,288	2,573
Current liabilities		
Accounts payable	4,661	3,730
Other current liabilities	34,150	7,400
Total current liabilities	38,811	11,130
Total equity and liabilities	170,195	164,996
Pledged assets	7,015	7,015
Assets with retention of title	6,686	0
Contingent liabilities	0	250

Cash flow analysis

Amount in TSEK	01/10/2022 – 31/12/2022	01/10/2021 – 31/12/2021	01/01/2022 – 31/12/2022	01/01/2021 – 31/12/2021
Current activities				
Operating result	-17,869	-13,046	-57,982	-35,826
Adjustments for items not included in cash flow	3,032	2,059	10,505	7,468
Interest received	11	0	11	0
Interest paid	-105	-43	-665	-181
Cash flow from operating activities before change in working capital	-14,930	-11,030	-48,130	-28,539
Cash flow from change in working capital				
Change in inventories and work in progress	-62	-269	-218	-207
Changes in accounts receivable - trade	401	0	-902	544
Change in receivables	-954	-157	-3,577	-344
Change in accounts payable - trade	-3,511	624	931	1,552
Change in other liabilities	46,022	2,859	44,025	1,866
Total from change in working capital	41,897	3,057	40,259	3,411
Cash flow from current activities	26,967	-7,973	-7,871	-25,128
Investing activities				
Investments in intangible fixed assets	-6,938	-4,292	-27,654	-18,025
Investments in tangible fixed assets	0	-1,406	-7,768	-7,764
Investments in financial fixed assets	0	0	0	0
Cash flow from investment activities	-6,938	-5,698	-35,422	-25,789
Financing activities				
New share issue	17,200	-190	17,515	143,941
Issue costs	-1,140		-1,140	
Borrowings	0	0	5,985	1,000
Amortisation of loans	-515	-278	-3,544	-1,055
Cash flow from financing activities	15,545	-468	18,814	143,886
Cash-flow for the period	35,574	-14,139	-24,478	92,969
Cash and cash equivalents at the beginning of the period	45,608	119,799	105,660	12,691
Cash and cash equivalents at the end of the period	81,182	105,660	81,182	105,660

Changes in equity

Amount 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 01/01/2022	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			0
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

Amount in TSEK	Share capital	Fund for development work	Share premium reserve	Profit/loss brought forward	Profit/loss for the period	Total equity
Amount as of 01/01/2021	2,747	29,105	109,329	-76,094	-21,736	43,351
New share issue	3,814		160,354			164,168
Ongoing new issue			0			0
Appropriation according to this year's AGM decision				-21,736	21,736	0
Subscription warrants			156			156
Issue expenses			-20,383			-20,383
Capitalized development costs for the period		15,636		-15,636		0
Depreciation on capitalised development costs for the period		-4,258		4,258		0
Profit/loss for the period					-35,999	-35,999
Amount as of 31/12/2021	6,561	40,483	249,456	-109,208	-35,999	151,293

Pledged assets

	31/12/2022	31/12/2021
Corporate mortgages	7,015	7,015

Assets with retention of title

	31/12/2022	31/12/2021
Assets with retention of title	6,686	0

Contingent liabilities

	31/12/2022	31/12/2021
Other contingent liabilities	0	250

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*This information is such that Nanexa is obliged to publish in accordance with the EU Market Abuse Regulation.
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