



naneXa

Year-end report
2021

Nanexa AB (publ)

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“Nanexa AB is a nanotechnology drug delivery company focusing its operations on the development of PharmaShell®, a new and groundbreaking drug delivery system with great potential within a majority of substance types and indication area. Within the framework of PharmaShell®, Nanexa has partnership agreements with among others, AstraZeneca

Significant events during the fourth quarter 2021

- Nanexa received a decision from the Swedish Financial Supervisory Authority to pay a penalty of SEK 1,000,000 in relation to an incident that occurred in 2017.
- Nanexa signed an additional Material Transfer and Feasibility Study Agreement with one of its existing customers for the evaluation of the PharmaShell technology with a specific biological drug substance.
- Additional preclinical studies were initiated in October to investigate the cause of the moderate skin reactions seen in the company's Phase I study of NEX-18, a long acting formulation of azacitidine based on PharmaShell.

Significant events after the end of the period

- Nanexa was granted a patent in the US (US 11,214,865 B2) for an ALD reactor adapted for large-scale production of PharmaShell-coated drugs.
- Nanexa announced that the company's preclinical investigation indicates the cause of and a potential solution to the moderate skin reactions that arose in the clinical study with NEX-18. With these results, Nanexa is expanding its preclinical program to optimize the formulation of NEX-18, and the project is expected to re-enter clinical phase next year.

Summary of the reporting period 1 October - 31 December 2021

- Turnover amounted to: TSEK 670 (549)
- Operating profit (EBIT) amounted to: TSEK -13,045 (-7,768)
- Profit after tax amounted to: TSEK -13,087 (-7,814)
- Earnings per share amounted to: SEK -0.26 (-0.37)
- Cash flow for the period amounted to: TSEK -14,139 (-13,300)
- Cash and cash equivalents at end of period: TSEK 105,660 (12,691)

Summary of the reporting period 1 January - 31 December 2021

- Turnover amounted to: TSEK 2,374 (2,367)
- Operating profit (EBIT) amounted to: TSEK -35,821 (-21,489)
- Profit after tax amounted to: TSEK -35,999 (-21,736)
- Earnings per share amounted to: SEK -1.01 (-1.09)
- Cash flow for the period amounted to: 92 969 (1 313) TSEK
- Cash and cash equivalents at end of period: TSEK 105,660 (12,691)
- The Board of Directors proposes that no dividend is paid

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

The CEO's comments

An eventful year lays a solid foundation

2021 was an eventful year. We started the first clinical trial with a PharmaShell® formulated product, NEX-18. A formulation based on ALD technology had never been used in clinical trials before, so this was a very big step for the project and for Nanexa. We also started project number two, NEX-20, which showed very promising pre-clinical results in animal studies. During the year, we also generated positive results in various evaluation trials with partner companies. We deepened our cooperation with Applied Materials and installed the first equipment from them at our premises in Uppsala. Finally, we completed a major financing effort that will ensure the continued operation and development of the company.

Subsequent to the end of the fourth quarter, we announced that Nanexa is taking the next step in the development of NEX-18, a long-acting formulation of azacitidine based on PharmaShell technology, by expanding the preclinical programme to optimise the formulation of NEX-18. The additional preclinical studies with NEX-18 that started in October 2021 **have** provided us with a lot of new knowledge and positive results. They have so far shown that it is not PharmaShell itself, but rather the active ingredient, that is causing the moderate skin reactions seen in the first clinical trial. This is encouraging and important information for how we move the project forward. We believe we have a good solution for how to optimise the NEX-18 formulation to prevent similar skin reactions, a solution we will be able to benefit from in other projects going forward. We expect to re-enrol patients in a new clinical trial with NEX-18 in 2023.

The clinical trial initially showed that PharmaShell works as expected in creating a favourable pharmacokinetic profile. The fact that we saw convincing PK results in the patients included is consistent with the release profile we have seen in preclinical studies. We have learnt a great deal during the year, at an early stage, which we can draw on in the development of all our programmes in the future.

For our second project, NEX-20, a depot formulation of lenalidomide for the treatment of multiple myeloma, we have **completed the first** preclinical studies and the project is progressing according to plan to enter clinic trials by the end of this year. The phase 1 clinical trial is planned to be conducted in healthy volunteers, which will allow a faster implementation.

The evaluation of candidates for our third product project is also progressing well and we expect to make a decision on it in the second half of 2022.

Work is progressing on our new GMP-rated facility for scaling up the production process. The premises are now largely ready for occupation and we expect the final inspection to take place in March. The facility, which is unique in its kind, will then be ready for the installation of additional production equipment from Applied Materials. This will be done according to an agreed plan with Applied Materials, who will provide some production personnel in addition to equipment. The pilot plant will provide an opportunity to increase the efficiency of development and to produce clinical trial material on a large scale.

In order to strengthen the organisation and place an even stronger focus on our product development projects, we have hired Kristine Bäck as senior project manager and member of the management team in the first quarter of 2022 to take overall responsibility for the progress of the projects. Kristine Bäck has over 20 years of experience in drug development from major companies such as AstraZeneca, Amgen, Sobi and Oncopeptides and is a very important addition to our organisation. I am also pleased to announce that Joel Hellrup, PhD in pharmaceutical sciences and employed at Nanexa since 2016, has assumed the position as head of pharmaceutical development.

During the quarter we signed a further Material Transfer and Feasibility Study Agreement with one of our existing customers for an in-depth evaluation of the PharmaShell technology with a specific biological drug substance. It is a drug compound that we have worked with in the past with good results and this agreement is a continuation of that collaboration. If the project continues to generate good results, we hope to sign an even deeper, long-term product development agreement.

Naturally, I am disappointed that we had to stop the NEX-18 study, but I am glad that we now see a way forward for this important project. Otherwise, I am very pleased with our strong team of employees and everything we have achieved during the year and I look forward to continuing to develop the company in the coming years. Our new GMP-rated facility for scaling up the production process will be completed in 2022. This will be a capacity that we will find very interesting to communicate to our market. We are continuing the development of our two ongoing product projects and are deciding on the direction of the third project. The past year has been challenging for us, as it has been for many others, given the pandemic we have had to cope with. I am therefore looking forward to a day without restrictions, where among other things, we can meet and make important contacts with more potential partner companies and gradually move closer to more comprehensive development agreements. I look forward to getting back to you during the year.

David Westberg, CEO Nanexa

Comments on the result and the financial position

Turnover for the fourth quarter of 2021 amounted to TSEK 670 (530) and for the period January-December 2021 it amounted to TSEK 2,374 (2,367). Both the quarterly and annual revenues are mainly related to customer orders for sensor coating, and to some extent to PharmaShell® evaluation contracts. Capitalised development costs amounted to TSEK 3,624 (5,184) in the fourth quarter and to SEK 15,636 (18,492) in January-December 2021 and mainly relates to investments in the NEX-18 and NEX-20 projects and the PharmaShell platform.

Other external costs in the fourth quarter amounted to TSEK -9,382 (-7,457) and during the period January-December to TSEK -29,542 (-24,445), an increase mainly attributable to the above-mentioned development projects and, to a lesser extent, also to increased costs for consultants and administration. Personnel costs amounted to TSEK -5,868 (-4,400) in the fourth quarter and to TSEK -16,743 (-12,553) for the full year 2021, where the increase resulted from the significant strengthening of the R&D organisation during the year.

The result for the fourth quarter amounted to TSEK -13,087 (-7,814) and for the period January-December 2021 it amounted to TSEK -35,999 (-21,736).

Cash and cash equivalents as of 31 December 2021 amounted to TSEK 105,660 (12,691). During the period January-December, the company raised a total of approximately SEK 144 million after issuance costs, of which SEK 12.3 million was through a directed issue to Applied Ventures, LLC, of shares and warrants that were subsequently partially exercised, SEK 24.5 million through the redemption of warrants of series TO2, and SEK 107 million through a rights issue at the beginning of the third quarter of 2021. Overall, the board's assessment is that operations are funded for the next 12 months.

The number of employees at the end of the period was 16 (10), of which 4 (3) were women and 12 (7) were men. The average number of employees during 2021 was 13 (10). In addition to employed staff, Nanexa regularly hires about ten consultants with specialist expertise.

Related party transactions

During the year, the company has purchased consultancy services from board members Otto Skolling through Pharmor AB for TSEK 1 235 (709) and Bengt Gustavsson through Sanguis Jazz AB for TSEK 1 144 (0).

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 2021, the number of shareholders in Nanexa amounted to 3,107.

Earnings per share

The result per share before and after dilution for the fourth quarter of 2021 amounted to TSEK -0.26 (-0.37) and for the period January-December 2021 to SEK -1.01 (-1.09).

The number of shares

As of 31 December 2021, 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 52,191,626.

The average number of shares in the fourth quarter was 50,695,626 (21,223,854) and for the period January-December 2021 it was 35,633,470 (19,914,967). Including full dilution of outstanding warrants, the average number of shares in the fourth quarter was 54,232,075 (25,371,832) and for the period January-December it was 42,071,338 (22,655,354).

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.

20 April 2022	Annual Report 2021
20 April 2022	Interim report January-March 2022
21 July 2022	Interim report January-June 2022
25 October 2022	Interim report January-September 2022
16 February 2023	Year-end report 2022

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

Annual General Meeting 2022

The annual general meeting of Nanexa AB (publ) will be held in Uppsala on 9 June 2022. The notice of the annual general meeting will be available on the Nanexa website, www.nanexa.se, as of 11 May 2022.

Nominations committee

The 2021 annual general meeting of Nanexa resolved to establish a nominations committee with the task of proposing to the 2022 annual general meeting, 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 nominations 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 nominations committee. In addition, the nominations committee shall consist of the chairman of the board of Nanexa.

The nominations 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 of Nanexa, adjunct).

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

Uppsala 17/02/2022

The board of directors, Nanexa AB

Göran Ando (chairman)	Bengt Gustavsson (member)	Urban Paulsson (member)
Urban Paulsson (member)	Mårten Rooth (member)	Otto Skolling (member)
Birgit Stattin Norinder (member)	Magnus Westgren (member)	

David Westberg, CEO Nanexa AB

Income statement

Amount in TSEK	01/10/2021- 31/12/2021	01/10/2020- 31/12/2020	01/01/2021- 31/12/2021	01/01/2020- 31/12/2020
Operating revenue				
Net sales	670	549	2,374	2,367
Capitalised work on own account	3,624	5,184	15,636	18,492
Other income	36	7	150	119
Total operating revenue	4,330	5,740	18,160	20,978
Operating expenses				
Other external expenses	-9,382	-7,457	-29,542	-24,445
Personnel costs	-5,868	-4,400	-16,743	-12,553
Depreciation	-2,059	-1,535	-7,468	-5,205
Other operating expenses	-66	-116	-228	-264
Total costs	-17,376	-13,508	-53,981	-42,467
Operating profit (EBIT)	-13,045	-7,768	-35,821	-21,489
Profit/loss from financial items				
Interest income and similar income statement items	0	0	0	0
Interest expenses and similar income statement items	-44	-48	-186	-255
Total profit/loss from financial items	-44	-48	-186	-255
Taxes				
Tax revenue	2	2	8	8
Profit/loss for the period	-13,087	-7,814	-35,999	-21,736
Earnings per share (SEK)	-0.26	-0.37	-1.01	-1.09

Balance sheet

Amount in TSEK	31/12/2021	31/12/2020
Assets		
Fixed assets		
Intangible fixed assets	45,708	33,542
Tangible fixed assets	2,834	3,595
Ongoing new facilities and advances regarding tangible fixed assets	6,915	0
Financial fixed assets	63	123
Total fixed assets	55,520	37,260
Current assets		
Stock	269	62
Current receivables	3,547	3,678
Cash and cash equivalent	105,660	12,691
Total current assets	109,476	16,431
Total assets	164,996	53,691
Equity and liabilities		
Equity		
Share capital	6,561	2,747
Restricted equity	40,483	29,105
Share premium reserve	249,456	109,329
Profit and loss account reserve brought forward	-109 208	-76 094
Loss for the period	-35,999	-21,736
Total equity	151,293	43,351
Non-current liabilities		
Liabilities to credit institutions	2,573	2,850
Total non-current liabilities	2,573	2,850
Current liabilities		
Accounts payable	3,730	2,177
Other current liabilities	7,400	5,313
Total current liabilities	11,130	7,490
Total equity and liabilities	164,996	53,691

Cash flow analysis in summary

Amount in TSEK	01/10/2021 - 31/12/2021	01/10/2020 - 31/12/2020	01/01/2021 - 31/12/2021	01/01/2020 -31/12/2020
Cash flow from operating activities.	-7,973	-7,300	-25,128	-16,827
Cash flow from investment activities.	-5,698	-5,730	-25,789	-20,801
Cash flow from financing activities.	-468	-270	143,886	38,940
Cash flow for the period	-14,139	-13,300	92,969	1,313
Cash and cash equivalents at start of period	119,799	25,990	12,691	11,378
Cash and cash equivalents at end of period	105,660	12,691	105,660	12,691

Changes in equity

Amount in TSEK	Share capital	Fund for development work	Share premium reserve	Profit brought forward (including profit for the period)	Total equity
Amount as of 01/01/2021	2,747	29,105	109,329	-97,830	43,351
New share issue	3,814		160,354		164,168
Subscription warrants			156		156
Issue expenses			-20,383		-20,383
The period's capitalised development costs		15,636		-15,636	0
Depreciation for the period on Capitalized development costs		-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	-144,591	151,293

Amount in TSEK	Share capital	Fund for development work	Share premium reserve	Profit brought forward (including profit for the period)	Total equity
Amount as of 01/01/2020	1,962	13,016	69,905	-60,005	24,878
New share issue	785		44,695		45,480
Subscription warrants			1,283		1,283
Issue expenses			-6,554		-6,554
The period's capitalised development costs		18,492		-18,492	0
Depreciation for the period on Capitalized development costs		-2,403		2,403	0
Profit/loss for the period				-21,736	-21,736
Amount as of 31/12/2020	2,747	29,105	109,329	-97,830	43,351

Pledged assets

	31/12/2021	30/12/2020
Corporate mortgages	7,015	6,300

Contingent liabilities

	31/12/2021	31/12/2020
Other contingent liabilities	250	250

Contact

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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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