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Interim report
1 January – 30 September 2021

Nanexa AB (publ)

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Nanexa AB is a nanotechnology drug delivery company focusing its activities on the development of PharmaShell®, a new and groundbreaking drug delivery system that is considered to have great potential in a number of medical indications. The PharmaShell technology is applied in Nanexa's own product projects and together with development partners such as large pharmaceutical companies and smaller biotech companies in both human and veterinary medicine, including AstraZeneca.

Significant events during the third quarter 2021

- In July, Nanexa completed the fully underwritten rights issue decided in June 2021, supported by the authorisation from the Annual General Meeting, which raised SEK 107 million after issue costs for the company.
- The European Patent Office (EPO) announced in July its intention to grant a European patent for Nanexa's PharmaShell® technology.
- Nanexa received two orders for the surface treatment of a large number of sensors for the detection of radioactive isotopes of the noble gas xenon, from two US customers for a total value of approximately SEK 1.7 million.
- Nanexa decided at the end of September to pause the inclusion of patients in the company's Phase I trial of NEX-18, a depot formulation of 5-azacitidine, due to moderate skin reactions at the injection site. An investigation into the cause was initiated with the clinics participating in the study.

Significant events after the end of the period

- 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 depot formulation of 5-azacitidine.

Summary of the reporting period 1 July – 30 September 2021

- Turnover amounted to: TSEK 826 (530)
- Operating profit (EBIT) amounted to: TSEK -7,857 (-3,814)
- Profit after tax amounted to: TSEK -7,904 (-3,894)
- Earnings per share amounted to: SEK -0.18 (-0.18)
- Cash flow for the period amounted to: TSEK 91,203 (-8,098)
- Cash and cash equivalents at end of period: TSEK 119,799 (25,990)

Summary of the reporting period 1 January – 30 September 2021

- Turnover amounted to: TSEK 1,704 (1,819)
- Operating profit (EBIT) amounted to: TSEK -22,776 (-13,713)
- Profit after tax amounted to: TSEK -22,912 (-13,914)
- Earnings per share amounted to: SEK -0.75 (-0.71)
- Cash flow for the period amounted to: TSEK 107,108 (14,612)
- Cash and cash equivalents at end of period: TSEK 119,799 (25,990)

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

The CEO's comments

The third quarter has been eventful and at times challenging given the pause of the NEX-18 trial which we had not anticipated. The evaluation agreement signed with an existing customer in October is a sign of strength for our technology and thanks to the rights issue completed in the third quarter, we are well funded to pursue our plans and to drive our projects to value-enhancing milestones.

The NEX-18 study, our first clinical trial with PharmaShell®, is a Phase I study to investigate pharmacokinetics, safety and tolerability. The goal of NEX-18, a depot formulation of azacitidine used to treat myelodysplastic syndrome (MDS), is to replace the current seven injections per month with just one, which would make life much easier for patients and offer significant cost savings. The study preliminarily shows that PharmaShell® works as expected pharmacokinetically, i.e. we obtained results showing a prolonged release of azacitidine in humans, which is in line with what has been previously shown in the preclinical studies.

Enrolment of patients in the NEX-18 trial, which started earlier in the year, was halted in the third quarter due to moderate skin reactions at the injection site and, together with the clinics in the trial, we initiated an investigation to clarify the cause. We have also initiated additional preclinical animal studies to obtain a deeper understanding of the observed skin reactions and to ensure that we move forward in the development of NEX-18 in the most optimal way. These additional studies are expected to be completed in the first quarter of 2022.

While the investigation and preclinical studies of NEX-18 are ongoing, we will prioritise NEX-20, a depot formulation of lenalidomide in multiple myeloma, where preclinical studies are now being conducted. We plan to start the first clinical study of NEX-20 in the second half of 2022.

In terms of selecting the next drug candidate for NEX-21, we will go a little further in the evaluation of a number of compounds before finally selecting the indication and compound to pursue as our next project. We estimate that this selection will take place in the first half of 2022.

After the end of the quarter, we signed another Material Transfer and Feasibility Study Agreement with one of our existing customers, a global pharmaceutical company that will evaluate the PharmaShell® technology with a specific biological drug substance. We see the extended collaboration as a sign of strength for the PharmaShell® technology.

Our collaboration with Applied Materials progressed well during the quarter. We are looking forward to the installation of production equipment that will streamline our development and create opportunities for scaling up, both for our own projects and our partner projects.

I am looking forward to the future with great confidence. We are well financed as a result of the rights issue that closed in July. We will obtain further preclinical results from NEX-18 and NEX-20 and move forward in their clinical development. We will also decide on the indication for our third project. In addition, we also expect further development of the collaborations that we have with existing and new partner companies for licensing out the technology, and not least progress in our collaboration with Applied Materials. We have an exciting time ahead of us and I look forward to keeping you updated.

David Westberg

CEO Nanexa

Financial overview

Turnover for the third quarter of 2021 amounted to TSEK 826 (530) and for the period January-September 2021 it amounted to TSEK 1,704 (1,819). The quarter's turnover is mainly due to a customer order for surface-coating of sensors. Other external costs amounted to TSEK -6,135 (-6,406) in the third quarter and TSEK -20,159 (-16,980) in the period January-September, an increase mainly attributable to the work on the proprietary product projects NEX-18 and NEX-20 and the development of the PharmaShell® platform. Personnel costs amounted to TSEK -3,383 (-2,425) in the third quarter and TSEK -10,876 (-8,153) since the beginning of the year, mainly as a result of the significant growth of the organisation. Capitalised development costs amounted to TSEK 2,827 (5,838) in the third quarter and to SEK 12,012 (13,307) in January-September 2021 and mainly relates to investments in the NEX-18 and NEX-20 projects and the PharmaShell platform. The result for the third quarter amounted to TSEK -7,904 (-3,894) and for the period January-September 2021 it amounted to TSEK -22,912 (-13,914).

Cash and cash equivalents as of 30 September 2021 amounted to TSEK 119,799 (25,990). During the period January-September, the company raised a total of approximately SEK 144 million after issuance costs, of which SEK 12.3 million was from Applied Ventures, LLC, through a directed issue 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 the rights issue that was completed at the beginning of the third quarter of 2021. Applied Ventures holds approximately 3.1 million additional (non-transferable) warrants to subscribe for shares at a 10% discount to the current share price in connection with a subscription period in December 2021.

The number of employees at the end of the period was 15 (11), of which 5 (3) were women and 10 (8) were men. The average number of employees in the third quarter was 13 (10) and in the period January-September 2021 it was 12 (10).

The share

Nanexa AB (publ) was listed on Nasdaq First North Growth Market on 29 May 2020. The share was previously listed on the Spotlight Stock Market since 17 June 2015.

Earnings per share

The result per share before and after dilution for the third quarter of 2021 amounted to TSEK -0.18 (-0.18) and for the period January-September 2021 to SEK -0.75 (-0.71).

The number of shares

As of 30 September 2021, Nanexa AB (publ) had 50,695,626 outstanding shares with a quota value of SEK 0.13. The number of shares at full dilution of outstanding warrants was 55,269,025.

The average number of shares in the third quarter of 2021 was 43,532,114 and in January-September it was 30,557,579. Including full dilution of outstanding warrants, the average number of shares in the third quarter was 48,153,339 and for the period January-September it was 37,973,214.

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.

17 February 2022 Year-end report 2021

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

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

Uppsala 10/11/2021

The board of directors, Nanexa AB

Göran Ando (chairman)

Bengt Gustavsson (member)

Eva Nilsagård (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	01/07/2021- 30/09/2021	01/07/2020- 30/09/2020	01/01/2021- 30/09/2021	01/01/2020- 30/09/2020	01/01/2020- 31/12/2020
Operating revenue					
Net sales	826	530	1,704	1,819	2,367
Capitalised work on own account	2,827	5,838	12,012	13,307	18,492
Other income	4	39	114	112	119
Total operating revenue	3,657	6,407	13,830	15,238	20,978
Operating expenses					
Other external expenses	-6,135	-6,406	-20,159	-16,980	-24,445
Personnel costs	-3,383	-2,425	-10,876	-8,153	-12,553
Depreciation	-1,930	-1,361	-5,409	-3,670	-5,205
Other operating expenses	-66	-29	-162	-148	-264
Total costs	-11,514	-10,221	-36,606	-28,951	-42,467
Operating profit (EBIT)	-7,857	-3,814	-22,776	-13,713	-21,489
Profit/loss from financial items					
Interest income and similar income statement items	0	0	0	0	0
Interest expenses and similar income statement items	-49	-82	-142	-207	-255
Total profit/loss from financial items	-49	-82	-142	-207	-255
Taxes					
Tax revenue	2	2	6	6	8
Profit/loss for the period	-7,904	-3,894	-22,912	-13,914	-21,736
Earnings per share (SEK)	-0.18	-0.18	-0.75	-0.71	-1.09

Balance sheet

Amount in TSEK	30/09/2021	30/09/2020	31/12/2020
Assets			
Fixed assets			
Intangible fixed assets	43,049	29,027	33,542
Tangible fixed assets	8,769	3,915	3,595
Financial fixed assets	78	21	123
Total fixed assets	51,896	32,963	37,260
Current assets			
Stock	0	0	62
Current receivables	3,373	2,998	3,678
Cash and cash equivalent	119,799	25,990	12,691
Total current assets	123,172	28,988	16,431
Total assets	175,068	61,951	53,691
Equity and liabilities			
Equity			
Share capital	6,561	2,747	2,747
Restricted equity	38,052	24,725	29,105
Profit and loss account reserve brought forward	142,680	37,614	33,235
Loss for the period	-22,912	-13,914	-21,736
Total equity	164,381	51,172	43,351
Non-current liabilities			
Liabilities to credit institutions	2,888	3,109	2,850
Total non-current liabilities	2,888	3,109	2,850
Current liabilities			
Accounts payable	3,304	2,987	2,177
Other current liabilities	4,495	4,683	5,313
Total current liabilities	7,799	7,670	7,490
Total equity and liabilities	175,068	61,951	53,691

Cash flow analysis in summary

Amount in TSEK	01/07/2021– 30/09/2021	01/07/2020– 30/09/2020	01/01/2021– 30/09/2021	01/01/2020– 30/09/2020	01/01/2020 01/12/2020
Cash flow from operating activities.	-7,222	-1,448	-17,156	-10,477	-16,827
Cash flow from investment activities.	-9,297	-6,375	-20,090	-15,071	-20,801
Cash flow from financing activities.	107,722	-275	144,354	40,160	38,940
Cash flow for the period	91,203	-8,098	-107,108	14,612	1,313
Cash and cash equivalents at start of period	28,596	34,089	12,691	11,378	11,378
Cash and cash equivalents at end of period	119,799	25,990	119,799	25,990	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		160,355		164,169
Subscription warrants			156		156
Issue expenses			-20,383		-20,383
The period's capitalised development costs		12,012		-12,012	0
Depreciation for the period on Capitalized development costs		-3,065		3,065	0
Profit/loss for the period				-22,912	-22,912
Amount as of 30/09/2021	6,561	38,052	249,457	-129,689	164,381

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	1962	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

	30/09/2021	30/09/2020	31/12/2020
Corporate mortgages	7,015	6,300	6,300

Contingent liabilities

	30/09/2021	30/09/2020	31/12/2020
Other contingent liabilities	250	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.
The information was submitted, through the above contact persons, for publication on 10 November 2021 at 08:00 CEST.*

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