

A photograph of two scientists in a laboratory. A woman in the foreground, wearing glasses and a white lab coat, is using a red bulb pipette to transfer liquid into a flask. A man in the background, also in a white lab coat and glasses, is looking at a document. The scene is brightly lit, suggesting a clean and professional environment.

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# **INTERIM REPORT JANUARY – MARCH 2022**

NANEXA AB (PUBL)

# Nanexa AB (PUBL)

## **Significant events during the first quarter 2022**

- Nanexa AB 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 occurred in the NEX-18 clinical study. With these results, Nanexa is expanding the preclinical programme to optimise the formulation of NEX-18 and the project is expected to go back into clinical studies next year.
- Nanexa made progress in the patent infringement lawsuit it is pursuing against the US company VitriVax, Inc. A US court denied VitriVax's motion to dismiss Nanexa's patent infringement claim and denied as moot VitriVax's motion to stay discovery. Nanexa's motion to compel the discovery process to continue was also successful.

## **Significant events after the end of the period**

- No significant events after the end of the period.

## **Summary of the reporting period 1 January – 31 March 2022**

- Turnover amounted to: TSEK 298 (536)
- Operating profit (EBIT) amounted to: TSEK -12,331 (-6,623)
- Profit after tax amounted to: TSEK -12,370 (-6,670)
- Earnings per share amounted to: SEK -0.24 (-0.29)
- Cash flow for the period amounted to: TSEK -17,934 (22,158)
- Cash and cash equivalents at end of period: TSEK 87,726 (34,849)

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

# The CEO's comments

*Nanexa took several important steps in its development during the first quarter of 2022. The NEX-18 and NEX-20 product projects are progressing with pre-clinical evaluation of formulations to take forward into clinical development and we have been granted a new patent in the US, as well as confirmation that the European Patent Office (EPO) intends to grant our EU patent in the spring. We also had a positive development in the patent infringement case in the US against VitriVax.*



## New plant soon in operation

Work on our new plant for scaling up the production process is now complete and we are starting to put it into operation. The plant, designed for the company's PharmaShell® process, is unique in its kind, both in terms of cleanroom production capability and scalability. We will be able to show that the process can be scaled up and that we can produce clinical trial material for all different phases of clinical development, including Phase III studies, which is a great advantage for us. This will make a big difference especially for our potential partners, as it shows that our technology has reached a new level of maturity.

The plant can also work with cytostatics (cancer drugs) and it is prepared for sterile/aseptic production, which opens up the possibility of working with biological drugs. This means that we will have a completely new breadth in our future offering. The production of trial materials will be carried out according to the plan we have developed with Applied Materials, which will provide some production staff in addition to equipment. We regard this as a great success for our cooperation.

## The development of NEX-20 is proceeding according to plan

The development of the NEX-20 project is progressing according to plan, with the evaluation of several formulations in various pre-clinical models. The aim is to select a formulation in the next quarter to take forward in the project to preliminary pre-clinical and toxicology studies and further into clinical development. Preparations for the first clinical study in healthy volunteers have already started and our plan is to complete the clinical trial application to the Medical Products Agency to start the study this year.

## Next steps in the development of NEX-18

Enrolment of patients in the Phase I clinical study of NEX-18 was halted in September 2021 due to moderate skin reactions at the injection site. Since October 2021, additional preclinical studies have been ongoing to clarify the cause. These indicate that it is not PharmaShell itself that is causing the skin reactions and we also believe we have a potential solution to the problem. We are now focusing on a reformulation of NEX-18 with the aim of moving the project forward with an optimised product. The reformulation will be further studied preclinically in 2022. Given continued positive results, the clinical phase of the project will then be resumed.

## EU patent pending and patent granted in the US

During the quarter, Nanexa was granted a patent in the US for an ALD reactor adapted for large-scale production of PharmaShell-coated drugs. The patent is a good complement to Nanexa's product and process patents for the PharmaShell drug delivery system. In the process of filing our patent application for PharmaShell in the EU, we felt obliged to correct some changes in the patent text made by the examiner at the European Patent Office (EPO). Our corrections were accepted and we were recently notified that the EPO intends to grant the patent in the second quarter of 2022.

During the first quarter, success was achieved in Nanexa's patent infringement case in the US. The United States District Court for the District of Delaware has, inter alia, denied VitriVax's motion to dismiss Nanexa's patent infringement claim. Nanexa will continue to actively protect its valuable intellectual property rights related to its PharmaShell drug delivery system.

## Reinforced organisation and scaling up of activities

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. Kristine 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 looking forward to the coming year, when we will enter the clinical phase of NEX-20 and make progress in the NEX-18 project. We are also looking forward to getting back on track with partnering activities. For example, Nanexa has been invited as a speaker at the CRS (Controlled Release Society) 2022 Annual Meeting and Expo to be held in July in Montreal, Canada. It is a major international conference that brings together senior executives in drug development and business development from most major global pharmaceutical companies. But the first task ahead of us is the commissioning of our new pilot plant and ensuring the progress of our two projects.

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 drives the development of innovative drugs projects based on existing drug substances through the preclinical and clinical development, primarily up to and including Proof of Concept. The objective is subsequently to drive the projects further towards commercialization, through a licence partner or on our own behalf, depending on what it is deemed to create the most value for the company. In addition, the company will work actively to out-license the PharmaShell technology to pharmaceutical companies that want to create their own unique long-acting products with PharmaShell.

Nanexa's projects, NEX-18 and NEX-20, are being developed in order to produce improved versions of the drugs azacitidine for the treatment of myelodysplastic syndrome (MDS), and lenalidomide for the treatment of multiple myeloma, which are two forms of blood cancer. The properties of the PharmaShell system are used to improve these treatments by reducing the burden on patients and caregivers of, for example, the inconvenient and costly administration of azacitidine and by improving compliance/adherence to lenalidomide treatment. Nanexa also intends to start a further proprietary product project during 2022. The basis for selecting the project is that there must be a clear medical need, a long-term and strong market potential and good technical prerequisites.

Nanexa currently has a number of evaluation agreements with 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 and unique 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**

Nanexa is a pharmaceutical company with its own unique drug delivery-system, PharmaShell, focused on long-acting injectable drugs.

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, Q1 2022

## Comments on the result and the financial position

Sales in the first quarter of 2022 amounted to TSEK 298 (536) and derived from customer orders for sensor coating and delivery in one of the PharmaShell® evaluation agreements. Capitalised development costs during the quarter amounted to TSEK 4,929 (4,433) and is attributable mainly to investments in the NEX-18 and NEX-20 projects and the PharmaShell-system.

Project costs in the first quarter amounted to TSEK -5,089 (-3,431), an increase mainly attributable to NEX-20 and NEX-18 activities. Other external costs amounted to TSEK -5,668 (-2,902), with the increase largely explained by costs related to the refurbishment and fitting out of new premises, as well as the patent litigation in the US. Personnel costs amounted to TSEK -4,693 (-3,548), where the increase was a result of the significant strengthening of the organisation compared to the previous year.

The result for the first quarter amounted to TSEK -12,370 (-6,670) thousand.

Cash and cash equivalents amounted to TSEK 87,726 (34,849) as at 31 March 2022 and it is the board's assessment that the business is financed for the next 12 months.

The number of employees at the end of the period was 18 (12), of which 6 (4) were women and 12 (8) were men. The average number of employees during the first quarter of 2022 was 16 (12). In addition to employed staff, Nanexa regularly hires about ten consultants with specialist expertise.

## Related party transactions

During the first quarter, the company has purchased consultancy services from board members Otto Skolling through Pharmor AB for TSEK 405 (270) and Bengt Gustavsson through Sangus Jazz AB for TSEK 604 (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 March 2022, the number of shareholders in Nanexa amounted to 2,993.

## Earnings per share

Earnings per share before and after dilution for the first quarter of 2022 amounted to SEK -0.24 (-0.29).

## The number of shares

As of 31 March 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 52,191,626.

The average number of shares during the first quarter was 50,695,626 (22,733,354) and, including full dilution of outstanding warrants, the average number of shares was 52,191,626 (28,790,520).

## 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
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.

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

Uppsala 20/04/2022

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	01/01/2022- 31/03/2022	01/01/2021- 31/03/2021	01/01/2021- 31/12/2021
<b>Operating revenue</b>			
Net sales	298	536	2,374
Capitalised work on own account	4,929	4,433	15,636
Other income	93	82	150
<b>Total operating revenue</b>	<b>5,320</b>	<b>5,051</b>	<b>18,160</b>
<b>Operating expenses</b>			
Project costs	-5,089	-3,431	-13,698
Other external expenses	-5,668	-2,902	-15,844
Personnel costs	-4,693	-3,548	-16,743
Depreciation	-2,151	-1,704	-7,468
Other operating expenses	-50	-90	-228
<b>Total costs</b>	<b>-17,651</b>	<b>-11,674</b>	<b>-53,981</b>
<b>Operating profit (EBIT)</b>	<b>-12,331</b>	<b>-6,623</b>	<b>-35,821</b>
<b>Profit/loss from financial items</b>			
Interest income and similar income statement items	0	0	0
Interest expenses and similar income statement items	-41	-49	-186
<b>Total profit/loss from financial items</b>	<b>-41</b>	<b>-49</b>	<b>-186</b>
<b>Taxes</b>			
Tax revenue	2	2	8
<b>Profit/loss for the period</b>	<b>-12,370</b>	<b>-6,670</b>	<b>-35,999</b>
<b>Earnings per share (SEK)</b>	<b>-0.24</b>	<b>-0.29</b>	<b>-1.01</b>

## Balance sheet

Amount in TSEK	31/03/2022	31/03/2021	31/12/2021
<b>Assets</b>			
<b>Fixed assets</b>			
Intangible fixed assets	49,489	37,368	45,708
Tangible fixed assets	8,481	3,383	2,834
Ongoing new facilities and advances regarding tangible fixed assets	3,457	0	6,915
Financial fixed assets	48	108	63
<b>Total fixed assets</b>	<b>61,475</b>	<b>40,859</b>	<b>55,520</b>
<b>Current assets</b>			
Stock	0	0	269
Current receivables	4,315	3,083	3,547
Cash and cash equivalents	87,726	34,849	105,660
<b>Total current assets</b>	<b>92,041</b>	<b>37,932</b>	<b>109,476</b>
<b>Total assets</b>	<b>153,516</b>	<b>78,791</b>	<b>164,996</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	6,561	3,218	6,561
Restricted equity	44,108	31,622	40,483
Share premium reserve	249,456	141,302	249,456
Profit and loss account reserve brought forward	-148,832	-101,347	-109,208
Loss for the period	-12,370	-6,670	-35,999
<b>Total equity</b>	<b>138,923</b>	<b>69,125</b>	<b>151,293</b>
<b>Non-current liabilities</b>			
Liabilities to credit institutions	2,307	2,591	2,573
<b>Total non-current liabilities</b>	<b>2,307</b>	<b>2,591</b>	<b>2,573</b>
<b>Current liabilities</b>			
Accounts payable	6,326	2,539	3,730
Bank overdraft facilities	0	0	0
Other current liabilities	5,960	4,536	7,400
<b>Total current liabilities</b>	<b>12,286</b>	<b>7,075</b>	<b>11,130</b>
<b>Total equity and liabilities</b>	<b>153,516</b>	<b>78,791</b>	<b>164,996</b>



## Cash flow analysis

Amount in TSEK	01/01/2022- 31/03/2022	01/01/2021- 31/03/2021	01/01/2021- 31/12/2021
<b>Current activities</b>			
Operating result	-12,331	-6,623	-35,826
Adjustments for items not included in cash flow	2,151	1,704	7,468
Interest paid	-41	-49	-181
<b>Cash flow from operating activities before change in working capital</b>	<b>-10,221</b>	<b>-4,968</b>	<b>-28,539</b>
<b>Cash flow from change in working capital</b>			
Change in inventories and work in progress	269	62	-207
Changes in accounts receivable - trade	-599	876	544
Change in receivables	-153	-265	-344
Change in accounts payable - trade	2,596	362	1,552
Change in other liabilities	-1,502	-859	1,866
<b>Total from change in working capital</b>	<b>611</b>	<b>176</b>	<b>3,411</b>
<b>Cash flow from current activities</b>	<b>-9,610</b>	<b>-4,792</b>	<b>-25,128</b>
<b>Investing activities</b>			
Investments in intangible fixed assets	-5,547	-5,140	-18,025
Investments in tangible fixed assets	-2,574	-178	-7,764
Investments in financial fixed assets	0	0	0
<b>Cash flow from investment activities</b>	<b>-8,121</b>	<b>-5,318</b>	<b>-25,789</b>
<b>Financing activities</b>			
New share issue	0	32,527	143,941
Borrowings	112	0	1,000
Amortisation of loans	-315	-259	-1,055
<b>Cash flow from financing activities</b>	<b>-203</b>	<b>32,268</b>	<b>143,886</b>
<b>Cash-flow for the period</b>	<b>-17,934</b>	<b>22,158</b>	<b>92,969</b>
Cash and cash equivalents at the beginning of the period	105,660	12,691	12,691
Cash and cash equivalents at the end of the period	87,726	34,849	105,660

## Changes in equity

Amount in TSEK	Share capital	Fund for development work	Share premium reserve	Profit/loss brought forward	Profit/loss for the period	Total equity
<b>Amount as of 01/01/2022</b>	<b>6,561</b>	<b>40,483</b>	<b>249,456</b>	<b>-109,208</b>	<b>-35,999</b>	<b>151,293</b>
Previous year's result				-35,999	35,999	0
New share issue						0
Ongoing new issue						0
Subscription warrants						0
Issue expenses						0
Capitalized development costs for the period		4,929		-4,929		0
Depreciation on capitalised development costs for the period		-1,304		1,304		0
Profit/loss for the period					-12,370	-12,370
<b>Amount as of 31/03/2022</b>	<b>6,561</b>	<b>44,108</b>	<b>249,456</b>	<b>-148,832</b>	<b>-12,370</b>	<b>138,923</b>

Amount in TSEK	Share capital	Fund for development work	Share premium reserve	Profit/loss brought forward	Profit/loss for the period	Total equity
<b>Amount as of 01/01/2021</b>	<b>2,747</b>	<b>29,105</b>	<b>109,329</b>	<b>-76,094</b>	<b>-21,736</b>	<b>43,351</b>
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
<b>Amount as of 31/12/2021</b>	<b>6,561</b>	<b>40,483</b>	<b>249,456</b>	<b>-109,208</b>	<b>-35,999</b>	<b>151,293</b>

## Pledged assets

	31/03/2022	31/03/2021	31/12/2021
Corporate mortgages	7,015	6,300	7,015

## Contingent liabilities

	31/03/2022	31/03/2021	31/12/2021
Other contingent liabilities	250	250	250

## Contact

**David Westberg**  
CEO  
0709-42 83 03  
david.westberg@nanexa.se

*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 20 April 2022 at 08:00 CEST.*

## Nanexa AB

Virdings Allé 32B, SE-754 50 Uppsala, Sweden  
Phone: +46 (0) 18 100 300  
Org. no. 556833-0285  
info@nanexa.se

