

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 – SEPTEMBER 2022**

NANEXA AB (PUBL)

# **Nanexa AB (PUBL)**

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

- During the quarter, Nanexa announced the start of the product project NEX-22, addressing a very large market. In NEX-22, the company will develop a long-acting formulation of liraglutide with PharmaShell® for the treatment of type 2 diabetes. NEX-22 is the company's third proprietary product development project
- Nanexa expanded its collaboration agreement with Applied Materials, Inc., through an amendment regulating commercial arrangements, paving the way for potential future license agreements with customers in the pharmaceutical industry
- Nanexa received extended GMP certificate from the Swedish Medical Products Agency for production of clinical trial material in the new production plant in Uppsala
- Nanexa signed a Material Transfer and Feasibility Study Agreement with an option to license, with a Global Pharmaceutical Company, for evaluation of the PharmaShell® drug delivery system making a depot formulation of a specific compound for local release
- Nanexa AB and VitriVax, Inc. filed a notice with the Court requesting that Nanexa's patent infringement lawsuit pending in the District of Delaware be stayed while the parties work to finalize settlement terms to which they have agreed in principle.

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

- In October 2022, Nanexa signed a Material Transfer and Feasibility Study Agreement with a Speciality Pharma company, for evaluation of the PharmaShell drug delivery system making a depot formulation of a specific compound for intravitreal delivery.

## **Summary of the reporting period 1 July – 30 September 2022**

- Turnover amounted to: TSEK 1,531 (826)
- Operating profit (EBIT) amounted to: TSEK -11,927 (-7,857)
- Profit after tax amounted to: TSEK -12,045 (-7,904)
- Earnings per share amounted to: SEK -0.24 (-0.18)
- Cash flow for the period amounted to: TSEK -21,297 (91,203)
- Cash and cash equivalents at end of period: TSEK 45,608 (119,799)

## **Summary of the reporting period 1 January – 30 September 2022**

- Turnover amounted to: TSEK 2,040 (1,704)
- Operating profit (EBIT) amounted to: TSEK -40,112 (-22,776)
- Profit after tax amounted to: TSEK -40,639 (-22,912)
- Earnings per share amounted to: SEK -0.80 (-0.75)
- Cash flow for the period amounted to: TSEK -60,052 (107,108)
- Cash and cash equivalents at end of period: 45,608 (119,799)

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

# The CEO's comments



*The third quarter of 2022 has been eventful for Nanexa. The NEX-22 product development project, which addresses a huge market, was launched in September and will continue with preclinical development in the coming quarters. We also signed an agreement with a major global pharmaceutical company, obtained an extended GMP certificate for our new pilot plant, continued on schedule with product development projects and reached an agreement in all material respects with Vitrivax, Inc.*

## Kick-off for the NEX-22 product project

In September, we launched the NEX-22 product development project with the aim of developing a long-acting drug for type 2 diabetes. The decision to launch the project was taken after a thorough evaluation of the clinical needs, market potential and technical possibilities of the PharmaShell system. Thanks to Nanexa's unique PharmaShell system, it will be possible to offer a drug that provides patients with a one-month supply of the peptide liraglutide.

This is a major step in drug development for type 2 diabetes and after talking to a number of prominent experts and opinion leaders in the field of diabetes, we have a solid basis for both preclinical and clinical development of the drug. The NEX-22 will be our third in-house product project.

## Nanexa signs evaluation agreement with global pharmaceutical company

During the quarter, Nanexa signed an evaluation agreement with an option to license with one of the largest global pharmaceutical companies, relating to Nanexa's drug delivery system, PharmaShell®. The study concerns a specific commercial pharmaceutical product that, using the PharmaShell system, will result in a long-acting injectable product for local administration. We look forward to working with the pharmaceutical company to begin work with the goal of generating results that can be used as the basis for a more comprehensive development programme. The agreement includes details of what will be investigated, clarification of patent rights, a fixed fee to Nanexa for this evaluation and an option to license.

## Extended GMP certificate for pilot plant

Nanexa's 900 m<sup>2</sup> pilot facility in Uppsala Business Park is taking another step forward. We already have GMP certification for small-scale manufacture and release of clinical trial material, and now we also get a certificate for manufacturing in the new facility. The production facility is designed for more efficient and large-scale manufacturing, where also toxic and biological drugs will be possible to produce using the Atomic Layer Deposition technology. First in the production pipeline is our own project NEX-20, where production of investigational material has already been completed for a Phase 1 study planned to start in the fourth quarter of 2022.

## NEX-18 is nearing resumption of clinical phase

NEX-18 and the development with an optimised product is proceeding according to plan. In-depth discussions with the scientific council that we have assembled for the project, have also helped us to realise that we can potentially achieve a superior effect with NEX-18 compared to Vidaza. As a result, we are adjusting our plans to demonstrate this preclinically before moving into clinical development. Such a product would potentially have a very good market position.

## NEX-20 clinical trial about to start

The preparations for the clinical trial in healthy volunteers are ongoing and the study is planned to start in the fourth quarter of this year. The clinical trial application has been submitted to the Medical Products Agency, the CRO we are working with is ready to start and the clinical trial material has been produced. Our assessment is that approval from the Medical Products Agency and the ethics committee and the release of trial material will take place in the near future, so that the trial can start as planned.

## Nanexa and Vitrivax, Inc. have reached an agreement

On September 27, Nanexa and Vitrivax, Inc. filed a notice requesting that Nanexa's patent infringement lawsuit in Delaware be stayed, pending the parties finalizing the terms of a settlement. The companies have already agreed on the main elements of the settlement.

## From one eventful quarter to another

I am very proud of what we at Nanexa have achieved this quarter. We have entered into several important partnerships, which is positive for the company. All our projects continue to progress very satisfactorily and we have launched our new product project, NEX-22, which aims to simplify the daily lives of type 2 diabetics, something we know is in demand both by patients and by pharmaceutical companies that are active in the indication. We are now looking ahead to an equally exciting quarter, where we will enter the clinical phase and continue our work to secure financing for continued long-term value creation.

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**

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, Q3 2022

## Comments on the result and the financial position

### Third quarter 2022

Turnover for the quarter amounted to TSEK 1,531 (826) and is mainly attributable to an evaluation agreement concluded and a customer order for sensor coating. Capitalised development costs amounted to TSEK 7,509 (2,827), attributable mainly to investments in the 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 TSEK -6,915 (-2,556), an increase mainly attributable to activities within NEX-20. Other external expenses amounted to TSEK -7,127 (-3,579), with the increase largely attributable to one-off costs of approximately TSEK -1,610 related to the patent litigation in the US and higher costs for the new production facility. Personnel costs amounted to TSEK -4,068 (-3,383) in the third quarter, an increase in line with the growth of the organisation and the business.

The result for the third quarter amounted to TSEK -12,045 (-7,904), while cash flow for the quarter amounted to TSEK -21,297 (91,203), of which investments accounted for TSEK -9,533 (-9,297), and mainly related to capitalised patent and development costs.

### The period January-September 2022

Turnover for the period amounted to TSEK 2,040 (1,704) and relates to previous and recent evaluation contracts and customer orders for sensor coating. Capitalised development costs amounted to TSEK 17,782 (12,012), attributable mainly to NEX-20, NEX-18 and the PharmaShell-system. External project and development costs in the period amounted to TSEK -17,473 (-9,670), mainly attributable to activities within NEX-20 and NEX-18 and to start-up and work on GMP certification of the new manufacturing facility. Other external expenses amounted to TSEK -20,832 (-10,489), with the increase largely explained by non-recurring costs of TSEK -5,067 related to the refurbishment of and moving to new premises, as well as the patent litigation in the US. Personnel costs amounted to TSEK -14,210 (-10,876) during the period and have increased with a growing organisation in line with the company's strategic plan.

The profit for the period amounted to TSEK -40,639 (-22,912).

Cash flow for the period amounted to TSEK -60,052 (107,108), of which investments amounted to TSEK -28,484 (-20,090), of which TSEK -7,768 (-6,358) relates to tangible fixed assets production plant, and other investments relate to capitalised patent and development costs.

Cash and cash equivalents as of 30 September 2022 amounted to TSEK 45,608 (119,799). The board of directors believes that the company does not have funding for the next 12 months, but sees good opportunities and is actively working on securing continued funding for the business under the current business plan.

## Employees

The number of employees at the end of the period was 19 (15), of which 7 (5) were women and 12 (10) were men. The average number of employees (FTE) was 18 (13) in the third quarter and 17 (12) for the period January-September 2022. In addition to employed staff, Nanexa regularly hires about ten consultants with specialist expertise.

## Related party transactions

During the third quarter, the company has purchased consultancy services from board member Bengt Gustavsson through Sangus Jazz AB for TSEK 481 (404). During the period January-September 2022, the company has bought consultancy services from board members Otto Skolling through Pharmor AB for TSEK 810 (810) and Bengt Gustavsson through Sangus Jazz AB for TSEK 1,747 (493).

## 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 30 September 2022, the number of shareholders in Nanexa was 2,939.

## Earnings per share

Earnings per share before and after dilution amounted to SEK -0.24 (-0.18) for the third quarter of 2022 and to SEK -0.80 (-0.75) for the period January – September 2022.

## The number of shares

As of 30 September 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 average number of shares during the third quarter was 50,695,626 (43,532,114) and during the first nine months of 2022 it was 50,695,626 (30,557,579). Including full dilution of outstanding warrants, the average number of shares was 53,142,572 (48,153,339) during the third quarter and 52,512,091 (37,973,214) during the first nine months of 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.

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 25/10/2022

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, CEO Nanexa AB

## Income statement

Amount in TSEK	01/07/2022 – 30/09/2022	01/07/2021 – 30/09/2021	01/01/2022 – 30/09/2022	01/01/2021 – 30/09/2021	01/01/2021- 31/12/2021
<b>Operating revenue</b>					
Net sales	1,531	826	2,040	1,704	2,374
Capitalised work on own account	7,509	2,827	17,782	12,012	15,636
Other income	122	4	307	114	150
<b>Total operating revenue</b>	<b>9,161</b>	<b>3,657</b>	<b>20,128</b>	<b>13,830</b>	<b>18,160</b>
<b>Operating expenses</b>					
External project and development costs	-6,915	-2,556	-17,473	-9,670	-13,698
Other external expenses	-7,127	-3,579	-20,832	-10,489	-15,844
Personnel costs	-4,068	-3,383	-14,210	-10,876	-16,743
Depreciation on intangible and tangible fixed assets	-2,891	-1,930	-7,473	-5,409	-7,468
Other operating costs	-86	-66	-251	-162	-228
<b>Total costs</b>	<b>-21,089</b>	<b>-11,514</b>	<b>-60,241</b>	<b>-36,606</b>	<b>-53,981</b>
<b>Operating profit (EBIT)</b>	<b>-11,927</b>	<b>-7,857</b>	<b>-40,112</b>	<b>-22,776</b>	<b>-35,821</b>
<b>Profit/loss from financial items</b>					
Interest income and similar income statement items	0	0	0	0	0
Interest expenses and similar income statement items	-148	-49	-561	-142	-186
<b>Total profit/loss from financial items</b>	<b>-148</b>	<b>-49</b>	<b>-561</b>	<b>-142</b>	<b>-186</b>
<b>Taxes</b>					
Tax revenue	30	2	34	6	8
<b>Total taxes</b>	<b>30</b>	<b>2</b>	<b>34</b>	<b>6</b>	<b>8</b>
<b>Profit/loss for the period</b>	<b>-12,045</b>	<b>-7,904</b>	<b>-40,639</b>	<b>-22,912</b>	<b>-35,999</b>
<b>Earnings per share (SEK)</b>	<b>-0.24</b>	<b>-0.18</b>	<b>-0.80</b>	<b>-0.75</b>	<b>-1.01</b>

## Balance sheet

Amount in TSEK	30/09/2022	30/09/2021	31/12/2021
<b>Assets</b>			
<b>Fixed assets</b>			
Intangible fixed assets	60,602	43,049	45,708
Tangible fixed assets	15,833	8,769	2,834
Ongoing new facilities and advances regarding tangible fixed assets	34	0	6,915
Financial fixed assets	69	78	63
<b>Total fixed assets</b>	<b>76,536</b>	<b>51,896</b>	<b>55,520</b>
<b>Current assets</b>			
Stock	425	0	269
Current receivables	7,501	3,373	3,547
Cash and cash equivalents	45,608	119,799	105,660
<b>Total current assets</b>	<b>53,535</b>	<b>123,172</b>	<b>109,476</b>
<b>Total assets</b>	<b>130,070</b>	<b>175,068</b>	<b>164,996</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	6,561	6,561	6,561
Not registered share capital	0	0	0
Restricted equity	53,917	38,052	40,483
Share premium reserve	249,770	284,729	249,456
Profit and loss account reserve brought forward	-158,640	-142,049	-109,208
Loss for the period	-40,639	-22,912	-35,999
<b>Total equity</b>	<b>110,969</b>	<b>164,381</b>	<b>151,293</b>
<b>Non-current liabilities</b>			
Liabilities to credit institutions	4,554	2,888	2,573
<b>Total non-current liabilities</b>	<b>4,554</b>	<b>2,888</b>	<b>2,573</b>
<b>Current liabilities</b>			
Accounts payable	8,171	3,304	3,730
Other current liabilities	6,377	4,495	7,400
<b>Total current liabilities</b>	<b>14,548</b>	<b>7,799</b>	<b>11,130</b>
<b>Total equity and liabilities</b>	<b>130,070</b>	<b>175,068</b>	<b>164,996</b>



## Cash flow analysis

Amount in TSEK	01/07/2022 – 30/09/2022	01/07/2021 – 30/09/2021	01/01/2022 – 30/09/2022	01/01/2021 – 30/09/2021	01/01/2021- 31/12/2021
<b>Current activities</b>					
Operating result	-11,927	-7,859	-40,112	-22,780	-35,826
Adjustments for items not included in cash flow	2,891	1,930	7,473	5,409	7,468
Interest paid	-148	-46	-561	-138	-181
<b>Cash flow from operating activities before change in working capital</b>	<b>-9,184</b>	<b>-5,975</b>	<b>-33,200</b>	<b>-17,509</b>	<b>-28,539</b>
<b>Cash flow from change in working capital</b>					
Change in inventories and work in progress	410	0	-156	62	-207
Changes in accounts receivable - trade	-1,454	-475	-1,304	268	544
Change in receivables	3,058	408	-2,623	88	-344
Change in accounts payable - trade	-1,314	-219	4,443	929	1,552
Change in other liabilities	-1,195	-961	-1,997	-994	1,866
<b>Total from change in working capital</b>	<b>-495</b>	<b>-1 247</b>	<b>-1 638</b>	<b>353</b>	<b>3 411</b>
<b>Cash flow from current activities</b>	<b>-9,680</b>	<b>-7,222</b>	<b>-34,837</b>	<b>-17,156</b>	<b>-25,128</b>
<b>Investing activities</b>					
Investments in intangible fixed assets	-9,008	-3,117	-20,717	-13,732	-18,025
Investments in tangible fixed assets	-526	-6,180	-7,768	-6,358	-7,764
Investments in financial fixed assets	0	0	0	0	0
<b>Cash flow from investment activities</b>	<b>-9,533</b>	<b>-9,297</b>	<b>-28,484</b>	<b>-20,090</b>	<b>-25,789</b>
<b>Financing activities</b>					
New share issue	315	107,981	315	144,131	143,941
Borrowings	0	0	5,985	1,000	1,000
Amortisation of loans	-2,398	-259	-3,031	-777	-1,055
<b>Cash flow from financing activities</b>	<b>-2,084</b>	<b>107,722</b>	<b>3,269</b>	<b>144,354</b>	<b>143,886</b>
<b>Cash-flow for the period</b>	<b>-21,297</b>	<b>91,203</b>	<b>-60,052</b>	<b>107,108</b>	<b>92,969</b>
Cash and cash equivalents at the beginning of the period	66,904	28,596	105,660	12,691	12,691
Cash and cash equivalents at the end of the period	45,608	119,799	45,608	119,799	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>-109,207</b>	<b>-35,999</b>	<b>151,294</b>
Previous year's result				-35,999	35,999	0
New share issue						0
Ongoing new issue						0
Subscription warrants			314			314
Issue expenses						0
Capitalized development costs for the period		17,782		-17,782		0
Depreciation on capitalised development costs for the period		-4,348		4,348		0
Profit/loss for the period					-40,639	-40,639
<b>Amount as of 30/09/2022</b>	<b>6,561</b>	<b>53,917</b>	<b>249,770</b>	<b>-158,640</b>	<b>-40,639</b>	<b>110,969</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

	30/09/2022	30/09/2021	31/12/2021
Corporate mortgages	7,015	6,300	7,015

## Assets with retention of title

	30/09/2022	30/09/2021	31/12/2021
Assets with retention of title	6,872	0	0

## Contingent liabilities

	30/09/2022	30/09/2021	31/12/2021
Other contingent liabilities	0	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 25 October 2022 at 08:00 CEST.*

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