



nanexa

INTERIM REPORT JANUARY – JUNE 2022

NANEXA AB (PUBL)

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Significant events during the first quarter 2022

- The European Patent Office (EPO) granted the Nanexa's patent application relating to the drug delivery system PharmaShell®. The patent protection covers the manufacturing method of PharmaShell and products produced using the method.
- Nanexa was granted funding under the VINNOVA project "Verification in Test Center, Part III" for a maximum amount of SEK 290,000, for an internal research project with the aim of coating monoclonal antibodies (mAbs) with PharmaShell®.
- Nanexa completed its new facilities with offices, R&D laboratory and production pilot plant at Uppsala Business Park and an inauguration ceremony was held in June.
- The Swedish Medical Products Agency made an inspection of Nanexa's new pilot plant in order to issue a certificate for production and release of clinical trial material. The inspection was made without any major remarks.
- At Nanexa's Annual General Meeting on June 9, it was decided, among other things, to elect Richard Davis as new board member, on authorizations for the Board to decide on rights issue and directed issue, and to establish a warrant-based incentive program for employees. A total of 983,000 warrants were thereafter subscribed for, corresponding to a maximum dilution of 1.9%.

Significant events after the end of the period

- 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 and release of clinical trial material in the new pilot plant in Uppsala, based on the inspection made during the second quarter.

Summary of the reporting period 1 April – 30 June 2022

- Turnover amounted to: TSEK 211 (342)
- Operating profit (EBIT) amounted to: TSEK -15,854 (-8,296)
- Profit after tax amounted to: TSEK -16,224 (-8,339)
- Earnings per share amounted to: SEK -0.32 (-0.33)
- Cash flow for the period amounted to: TSEK -20,822 (-6,253)
- Cash and cash equivalents at end of period: TSEK 66,904 (28,596)

Summary of the reporting period 1 January – 30 June 2022

- Turnover amounted to: TSEK 509 (878)
- Operating profit (EBIT) amounted to: TSEK -28,185 (-14,919)
- Profit after tax amounted to: TSEK -28,594 (-15,008)
- Earnings per share amounted to: SEK -0.56 (-0.64)
- Cash flow for the period amounted to: TSEK -38,756 (15,905)
- Cash and cash equivalents at end of period: TSEK 66,904 (28,596)

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

The CEO's comments

During the second quarter of 2022, the NEX-18 and NEX-20 projects continued to develop according to plan and Nanexa received the PharmaShell® patent approval from the European Patent Office (EPO). We completed our new pilot plant in Uppsala, which was celebrated with a very well-attended and successful inauguration. The Medical Products Agency also conducted an inspection and Nanexa received certification after the end of the quarter for production of clinical trial materials at the facility. We also developed our first PharmaShell formulations with monoclonal antibodies, funded by a grant from VINNOVA.



The EPO approved Nanexa's PharmaShell patent

During the quarter, the European Patent Office (EPO) announced that Nanexa's patent application for PharmaShell had been approved. The patent protection covers the method of manufacturing PharmaShell and the products made by the method. The patent approval means that we are in an even more interesting position in discussions with potential partners.

Nanexa's new pilot plant in Uppsala inaugurated

In June, we inaugurated our new venture in Uppsala Business Park – a 900 square metre facility that houses offices, an R&D lab and a pilot plant. The new facility offers great opportunities for Nanexa and will already be used this year for the production of clinical trial materials for NEX-20. Newly developed equipment from Applied Materials and the ability to produce in clean rooms will allow us to scale up the process and to handle all types of pharmaceutical substances, both toxic and biological. The facility will enable drugs based on the PharmaShell drug delivery system to be brought all the way to market.

After the end of the period, we were also pleased to announce that we have expanded our collaboration agreement with Applied Materials, Inc. This is through a supplementary agreement that regulates commercial issues and paves the way for potential future licensing agreements with customers in the pharmaceutical industry.

At the Annual General Meeting in June, the Board of Directors was strengthened by the election of Richard Davis as a new member of the board. Richard has a PhD in pharmacology and many years' experience as both an investor and manager in drug development companies. Richard is based in London and currently works as Chief Business Officer at the Swiss oncology company Nouscom AG. With his previous experience from roles such as Global Oncology Venture and Transaction Lead at Johnson and Johnson Innovation, this further complements our already competent and experienced board.

The patent infringement litigation we are pursuing against the US company Vitrivax Inc. is progressing. In the first quarter, a US court rejected, among other things, Vitrivax's request to dismiss Nanexa's patent infringement claim.

The Medical Products Agency's inspection of the pilot plant resulted in an approval

During the quarter, the Swedish Medical Products Agency conducted an inspection of the new pilot plant for issuing a certificate for production of clinical trial materials. The inspection was carried out without any major remarks and Nanexa received final approval and GMP certification for the facility after the end of the period.

Nanexa developed a PharmaShell formulation with monoclonal antibodies

During the quarter, Nanexa developed a first PharmaShell formulation with monoclonal antibodies. This is a very interesting area for us and we know that there is a demand from the major pharmaceutical companies. The development was financed with funds within the framework of the VINNOVA project "Verification in Test Centre, part III" up to a maximum amount of SEK 290,000.

NEX-18 moves towards further clinical development

We are continuing to work on the development of NEX-18 with the aim of moving forward with an optimised product. We have obtained good results from the studies conducted so far and we will continue with preclinical development in 2022. Given continued positive results, the clinical phase of the project will then be resumed.

NEX-20 continues to go according to plan

The NEX-20 project is progressing according to plan with formulation development and evaluation in pre-clinical studies. Preparations for the first clinical trial in healthy volunteers are ongoing and our plan is still to start the clinical trial in Q4.

Nanexa participated in several important conferences

It is great that the conference activities have now commenced with physical meetings. In June, Nanexa attended the BIO International Convention in San Diego, USA, and in mid-July we participated in the CRS (Controlled Release Society) 2022 Annual Meeting and Expo held in Montreal, Canada, where we were invited as a speaker with three presentations and posters. Both conferences are major international conference that bring together senior executives in drug development and business development from most of the major global pharmaceutical companies.

I am very pleased that we have deepened our collaboration with Applied Materials during the quarter and that we have our pilot plant up and running and ready for operation. The board and management will continue to work on the long-term strategic development of the company in the coming quarters, including the selection of the next project. I look forward to a quarter where we continue to deliver on our NEX-18 and NEX-20 development projects as well as our partner projects, and to creating more business opportunities with existing and new partners.

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, Q2 2022

Comments on the result and the financial position

Sales for the second quarter of 2022 amounted to TSEK 211 (342) and for the period January-June 2022 to TSEK 509 (878), resulting from customer orders for coating of sensors and partial deliveries in one of the PharmaShell® evaluation agreements. Capitalised development costs amounted to TSEK 5,344 (4,752) in the quarter and to TSEK 10,273 (9,185) in January-June 2022. This mainly relates to investments in NEX-20 and to a lesser extent in NEX-18 and the PharmaShell system.

External project and development costs amounted to TSEK -5,469 (-3,684) in the second quarter and TSEK -10,558 (-7,114) in the first half of 2022, an increase mainly attributable to activities within NEX-20 and NEX-18 and to commissioning and work on GMP certification of the new pilot plant. Other external expenses amounted to TSEK -8 036 (-4 008) for the second quarter and TSEK -13 704 (-6 910) for the period January-June 2022, where the increase is to partly explained by one-off costs of TSEK 2,196 in the quarter and TSEK 3,507 in the first half of 2022, for rebuilding and moving to new premises and the patent litigation in the USA. Personnel costs amounted to TSEK -5,450 (-3,944) in the second quarter and TSEK -10,143 (-7,492) for January-June 2022. The increase resulted from the growth of the organisation in line with the company's strategic plan.

The result for the second quarter amounted to TSEK -16,224 (-8,339) and for the period January-June 2022 it amounted to TSEK -28,594 (-15,008).

The cash flow for the second quarter amounted to TSEK -20,822 (-6,253) and for the period January-June 2022 to TSEK -38,756 (15,905). Investments amounted to TSEK -10,830 (-5,475) in the second quarter and TSEK -18,951 (-10,794) in the first half of the year, of which TSEK -4,668 and TSEK -7,242 respectively relate to property, plant and equipment in the new pilot plant and other investments relate to capitalised patent and development costs. During the quarter, credit financing was utilised related to investments in production equipment from Nordea and the remainder of a previously approved loan from Almi totalling TSEK 5,873.

Cash and cash equivalents as of 30 June 2022 amounted to TSEK 66,904 (28,596).

The number of employees at the end of the period was 19 (13), of which 7 (4) were women and 12 (9) were men. The average number of employees was 18 (12) in the second quarter and 17 (12) for the period January-June 2022. In addition to employed staff, Nanexa regularly hires about ten consultants with specialist expertise.

Related party transactions

During the second 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 662 (88). The corresponding amounts for the period January-June 2022 were TSEK 810 (540) and TSEK 1,266 (88) respectively.

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 2,942.

Earnings per share

Earnings per share before and after dilution amounted to SEK -0.32 (-0.33) for the second quarter of 2022 and to SEK -0.56 (-0.64) for the period January-June 2022.

The number of shares

As of 30 June 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 second quarter was 50,695,626 (25,178,713) and during the first half of 2022 it was 50,695,626 (23,962,788). Including full dilution of outstanding warrants, the average number of shares was 52,191,626 (29,546,267) during the second quarter and 52,191,626 (29,170,481) during the first half 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.

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 26/08/2022

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	01/04/2022 – 30/06/2022	01/04/2021 – 30/06/2021	01/01/2022 – 30/06/2022	01/01/2021 – 30/06/2021	01/01/2021- 31/12/2021
Operating revenue					
Net sales	211	342	509	878	2,374
Capitalised work on own account	5,344	4,752	10,273	9,185	15,636
Other income	92	27	185	110	150
Total operating revenue	5,647	5,121	10,967	10,173	18,160
Operating expenses					
Project costs	-5,469	-3,684	-10,558	-7,114	-13,698
Other external expenses	-8,036	-4,008	-13,704	-6,910	-15,844
Personnel costs	-5,450	-3,944	-10,143	-7,492	-16,743
Depreciation on intangible and tangible fixed assets	-2,431	-1,775	-4,582	-3,479	-7,468
Other operating expenses	-115	-6	-165	-97	-228
Total costs	-21,501	-13,417	-39,152	-25,092	-53,981
Operating profit (EBIT)	-15,854	-8,296	-28,185	-14,919	-35,821
Profit/loss from financial items					
Interest income and similar income statement items	0	0	0	0	0
Interest expenses and similar income statement items	-372	-45	-413	-93	-186
Total profit/loss from financial items	-372	-45	-413	-93	-186
Taxes					
Tax revenue	2	2	4	4	8
Total taxes	2	2	4	4	8
Profit/loss for the period	-16,224	-8,339	-28,594	-15,008	-35,999
Earnings per share (SEK)	-0.32	-0.33	-0.56	-0.64	-1.01

Balance sheet

Amount in TSEK	30/06/2022	30/06/2021	31/12/2021
Assets			
Subscribed but unpaid capital	0	126,895	0
Fixed assets			
Intangible fixed assets	53,744	41,462	45,708
Tangible fixed assets	10,620	2,989	2,834
Ongoing new facilities and advances regarding tangible fixed assets	5,461	0	6,915
Financial fixed assets	42	93	63
Total fixed assets	69,867	44,544	55,520
Current assets			
Stock	835	0	269
Current receivables	9,103	3,289	3,547
Cash and cash equivalents	66,904	28,596	105,660
Total current assets	76,842	31,885	109,476
Total assets	146,709	203,324	164,996
Equity and liabilities			
Equity			
Share capital	6,561	3,281	6,561
Not registered share capital	0	3,281	0
Restricted equity	48,021	36,342	40,483
Share premium reserve	249,456	249,656	249,456
Profit and loss account reserve brought forward	-152,744	-105,068	-109,208
Loss for the period	-28,594	-15,008	-35,999
Total equity	122,700	172,484	151,293
Non-current liabilities			
Liabilities to credit institutions	5,667	3,332	2,573
Total non-current liabilities	5,667	3,332	2,573
Current liabilities			
Accounts payable	9,485	3,680	3,730
Other current liabilities	8,857	23,828	7,400
Total current liabilities	18,342	27,508	11,130
Total equity and liabilities	146,709	203,324	164,996

Cash flow analysis

Amount in TSEK	01/04/2022 – 30/06/2022	01/04/2021 – 30/06/2021	01/01/2022 – 30/06/2022	01/01/2021 – 30/06/2021	01/01/2021- 31/12/2021
Current activities					
Operating result	-15,854	-8,297	-28,185	-14,920	-35,826
Adjustments for items not included in cash flow	2,431	1,775	4,582	3,479	7,468
Interest paid	-372	-44	-413	-92	-181
Cash flow from operating activities before change in working capital	-13,795	-6,566	-24,016	-11,533	-28,539
Cash flow from change in working capital					
Change in inventories and work in progress	-835	0	-566	62	-207
Changes in accounts receivable - trade	749	-132	150	744	544
Change in receivables	-5,527	-56	-5,680	-321	-344
Change in accounts payable - trade	3,160	786	5,756	1,148	1,552
Change in other liabilities	700	826	-802	-33	1,866
Total from change in working capital	-1,753	1,424	-1,142	1,600	3,411
Cash flow from current activities	-15,548	-5,142	-25,158	-9,933	-25,128
Investing activities					
Investments in intangible fixed assets	-6,162	-5,475	-11,709	-10,616	-18,025
Investments in tangible fixed assets	-4,668	0	-7,242	-178	-7,764
Investments in financial fixed assets	0	0	0	0	0
Cash flow from investment activities	-10,830	-5,475	-18,951	-10,794	-25,789
Financing activities					
New share issue	0	3,623	0	36,150	143,941
Borrowings	5,873	1,000	5,985	1,000	1,000
Amortisation of loans	-317	-259	-632	-518	-1,055
Cash flow from financing activities	5,556	4,364	5,353	36,632	143,886
Cash-flow for the period	-20,822	-6,253	-38,756	15,905	92,969
Cash and cash equivalents at the beginning of the period	87,726	34,849	105,660	12,691	12,691
Cash and cash equivalents at the end of the period	66,904	28,596	66,904	28,596	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
Amount as of 01/01/2022	6,561	40,483	249,456	-109,207	-35,999	151,294
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		10,273		-10,273		0
Depreciation on capitalised development costs for the period		-2,735		2,735		0
Profit/loss for the period					-28,594	-28,594
Amount as of 30/06/2022	6,561	48,021	249,456	-152,744	-28,594	122,700

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

	30/06/2022	30/06/2021	31/12/2021
Corporate mortgages	7,015	6,300	7,015

Assets with retention of title

	30/06/2022	30/06/2021	31/12/2021
Assets with retention of title	7,058	0	0

Contingent liabilities

	30/06/2022	30/06/2021	31/12/2021
Other contingent liabilities	0	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 26 August 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

