



INTERIM REPORT JANUARY- SEPTEMBER 2023

NANEXA AB (PUBL)

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Significant events during the third quarter 2023

- Nanexa AB received pharmacokinetic data from the Phase 1 study NEX-20-01 confirming a release profile of lenalidomide in different doses up to 21 days and announced that final data on safety and tolerability will be announced later in the autumn.
- Nanexa received results from a preclinical study of NEX-22 in minipigs confirming a long release profile of liraglutide, which was previously seen in rats. The data show that a release profile of NEX-22 can be obtained for at least 28 days, which was the duration of the pharmacokinetic study and the goal of the study.
- Nanexa was granted a patent in India relating to its PharmaShell® technology. The patent covers the relevant manufacturing method, coated drug particles that result therefrom, and pharmaceutical composition containing those particles. The PharmaShell patent was already granted in the US, Japan, Korea, China, Canada and in European countries, and with the approval in India, Nanexa now has patents in all countries where it applied for patent protection.
- On September 21, Nanexa announced that the company is conducting a rights issue of approximately SEK 121 million, which was secured by subscription commitments and guarantee commitments totaling SEK 75 million. The company also decided, as a result of the rights issue, to postpone the publication of the company's interim report for the period January - September 2023 to November 20, 2023.

Significant events after the end of the period

- In October, Nanexa announced that the phase I study NEX-20-01 has been completed with the last follow-up visits for the last of the three dose levels studied. In addition to previously communicated positive results from the pharmacokinetic evaluation, the company has now also received final safety and tolerability data that also support the further development of the project.
- On October 11, Nanexa published an EU growth prospectus in connection with the previously announced rights issue.
- Nanexa announced on October 20 that the company has received additional subscription commitment of approximately SEK 4.7 million in the ongoing rights issue from one of the company's largest shareholders, Applied Materials Europe B.V., a company in the same group as Applied Ventures, LLC.
- On October 30, Nanexa announced the outcome of the company's rights issue of approximately SEK 121 million, for which the subscription period ended on October 26. The outcome showed that 42,146,268 shares, corresponding to approximately 34.7 percent of the rights issue, had been subscribed with and without subscription rights. Thus, guarantee commitments of 32,853,732 shares, corresponding to approximately 27.1 percent of the offered shares, were utilized and the rights issue provides the company with SEK 75 million before transaction costs.

Summary of the reporting period 1 July – 30 September 2023

- Turnover amounted to: TSEK 6,683 (1,531)
- Operating profit (EBIT) amounted to: SEK -6,488 (-11,927)
- Profit after tax amounted to: TSEK -6,694 (-12,045)
- Earnings per share amounted to: SEK -0.11 (-0.24)
- Cash flow for the period amounted to: TSEK -17,790 (-21,297)
- Cash and cash equivalents at end of period: TSEK 20,569 (45,608)

Summary of the reporting period 1 January – 30 September 2023

- Turnover amounted to: TSEK 22,511 (2,040)
- Operating profit (EBIT) amounted to: TSEK -25,258 (-40,112)
- Profit after tax amounted to: TSEK -25,247 (-40,639)
- Earnings per share amounted to: SEK -0.42 (-0.80)
- Cash flow for the period amounted to: TSEK -60,613 (-60,052)
- Cash and cash equivalents at end of period: TSEK 20,569 (45,608)

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

The CEO's comment

During the third quarter, we have shown strength with both secured financing and positive results from clinical and preclinical studies. Our pioneering drug delivery technology, PharmaShell®, continues to attract great interest in the industry and the collaborations with Novo Nordisk and other partners are progressing. We look forward to an exciting period of intense and even more focused work on our projects.



Secured funding in an uncertain market

We have always been advocates of medical innovation. For many years, with the support of loyal investors, we have focused on developing long-acting injectable drugs with our innovative PharmaShell® drug delivery system. The system has the potential to change the way drugs are developed and to improve and streamline treatment in a variety of disease areas. We are determined to take full advantage of the commercial potential through both our own and partner-driven projects. A rights issue was therefore announced during the quarter to secure financing for this work.

Despite the shaky financial market, we are pleased to have successfully completed a significant rights issue that provides a capital injection of SEK 75 million before transaction costs. It is a confirmation of continued confidence from investors and partners in our business and our future potential. The capital injection enables us to reach several value-creating milestones going forward, focusing on NEX-22, our long-acting formulation of liraglutide for type 2 diabetes, and our exciting collaborations with Novo Nordisk, among others.

Positive results in several projects

One of the most significant advances in the third quarter was the completion of the first clinical study for NEX-20. The results from this study have been very encouraging and show a good pharmacokinetic profile for our formulation. The results also show a good correlation between the preclinical profile in different animal species and in humans.

Our work in the NEX-22 project continues according to plan and we are now compiling data from the preclinical development. We are working with our CRO, Profil, to finalize the clinical trial application for the first clinical study with the PharmaShell formulation of liraglutide. This phase I study will be conducted in patients suffering from type 2 diabetes and is expected to generate valuable data supporting the possibility of a one-month depot preparation of a GLP-1 product, a very expansive and highly valued market.

The future of PharmaShell

We have also made progress in our partner projects. The results from partner-driven evaluations of PharmaShell have been very promising and confirm our position as a leader in drug delivery technology in the pharmaceutical industry. The collaboration with Novo Nordisk continues to develop positively and it is also gratifying for this quarter that we have seen very interesting results in partner-driven evaluations with other world-leading pharmaceutical companies.

I want to emphasize that the interest in PharmaShell as a drug delivery system continues to grow. This is especially true in the area of formulation of biological drugs, such as peptides and monoclonal antibodies. At the latest global drug delivery conference, PODD, in Boston, where we recently participated and presented, PharmaShell was highlighted by independent stakeholders as one of the three most interesting technologies. We anticipate that even more evaluations will be initiated in this area, among others. This gives us several opportunities to move on from initial evaluations to larger development and license agreements that generate significant revenues.

Intensified and focused work ahead of us

I look to the future with great optimism. We are now ready to intensify our work on the NEX-22 project and to deliver results in our collaboration with Novo Nordisk and in other partner projects. In business development, we see increasing opportunities for more extensive agreements and with NEX-20 we continue to optimize the formulation to enter the next phase of clinical trials.

In summary, we have created the conditions for a very exciting journey and we thank all our investors and partners for their continued confidence.

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.

Addressing important medical needs and substantial markets

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-20 and NEX-18 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.

A patented technology with large potential

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

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.

Nanexa focuses primarily on developing improved versions of existing drugs to achieve new and significantly improved properties that generate value for patients, healthcare and society in general. Thanks to PharmaShell, Nanexa is able to develop products with significant patent protection and high market value. Starting from well-tested pharmaceutical substances means that the biological risk is reduced and the development projects are less costly than for projects with new untested substances. It also makes the registration process easier and shortens the time to market.

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. These collaborations contribute revenue for Nanexa as early as the evaluation phase. They also help validate and increase Nanexa's knowledge of the possibilities of the company's technology. In the relatively short term, there are opportunities for extensive development agreements and, in the long run, licensing agreements where there is significant commercial potential.

Comments, Q3 2023

Result and cash flow

Third quarter 2023

Turnover for the quarter amounted to SEK 6,683 (1,531) thousand, of which SEK 948 (804) thousand relates to revenue under evaluation agreements entered into for the PharmaShell® technology and SEK 5,643 (0) thousand relates to accrual of deferred revenue of USD 4 million related to the exclusivity agreement entered into with Novo Nordisk A/S in December 2022.

Capitalized development costs amounted to SEK 7,062 (7,509) thousand and relates mainly to investments in NEX-22 and to a lesser extent NEX-20, the PharmaShell system and NEX-18.

External project and development costs during the quarter amounted to SEK -5,465 (-6,915) thousand, where costs related to NEX-22 account for the majority and the decrease relative to the previous year is mainly attributable to lower costs in NEX-20. Other external expenses amounted to SEK -5,219 (-7,127) thousand, where the decrease is mainly explained by the patent dispute in the US that was concluded at the end of 2022. Personnel costs in the third quarter amounted to SEK -6,072 (-4,068) thousand, where the increase is partly due to a slightly higher number of employees and partly to a difference in the accrual of variable remuneration between the years, which will not have any effect on a full-year basis.

The loss for the third quarter amounted to SEK -6,694 (-12,045) thousand.

Cash flow for the quarter amounted to SEK -17,790 (-21,297) thousand. Change in working capital amounted to SEK -5,360 (-495) thousand, a decrease that corresponds to reduced deferred income from Novo Nordisk. Cash flow from investing activities amounted to SEK -7,464 (-9,533) thousand, where investments in both intangible fixed assets, capitalized development as well as patent costs, and investments in tangible fixed assets were lower than in the corresponding period in 2022. Cash flow from financing activities amounted to SEK -204 (-2,084) thousand, where the issue of warrants to employees contributed positively with SEK 387 (315) thousand, while amortization of loans amounted to SEK -551 (-2,398) thousand.

The period January-September 2023

Turnover for the period amounted to SEK 22,511 (2,040) thousand, of which SEK 16,929 (0) thousand relates to the prepaid exclusivity fee from Novo Nordisk, SEK 4,967 (1,004) thousand relates to income from partner projects with Novo Nordisk, among others, and SEK 599 (1,023) thousand relates to coating of sensors. Capitalized development costs amounted to SEK 21,774 (17,782) thousand, of which 50 percent relates to NEX-22, just over 25 percent to NEX-20 and the remaining parts to the PharmaShell system and NEX-18.

External project and development costs during the period totalled SEK -21,047 (-17,473) thousand, an increase mainly attributable to preclinical and clinical development within NEX-22 and NEX-20. Other external costs amounted to SEK -18,685 (-20,832) thousand, a decrease that is explained by non-recurring costs in 2022, mainly the patent dispute in the US and also the preparation of new premises, which more than offset increased costs for, among other things, rent and maintenance of the new pilot facility and financial services in 2023. Personnel costs amounted to SEK -19,458 (-14,210) thousand during the period and have increased with a slightly higher number of employees and a higher salary increase in 2023, as well as a difference in the accrual of variable remuneration between the years.

The loss for the period amounted to SEK -25,247 (-40,639) thousand.

Cash flow for the period January-September 2023 amounted to SEK -60,613 (-60,052) thousand. Change in working capital amounted to SEK -18,610 (-1,638) thousand, where the decrease is entirely explained by the fact that deferred income decreases as income from the exclusivity agreement with Novo Nordisk is recognized. Cash flow from investing activities amounted to SEK -23,979 (-28,484) thousand, where investments in intangible fixed assets increased while investments in tangible fixed assets were significantly higher in 2022 in connection with the move to new premises. Cash flow from financing activities amounted to SEK -1 365 (3,269) thousand, where the net of loans raised and amortization of loans amounted to SEK -1,653 (2,954) thousand.

Financial position

As of September 30, 2023, cash and cash equivalents and short-term investments amounted to kSEK 20,569 (45,608) and equity amounted to kSEK 84,137 (110,969).

In September 2023, the company announced a rights issue of SEK 121 million, which was covered by subscription commitments from existing owners, board and management, and guarantee commitments from external investors, totaling SEK 75 million. The outcome of the issue showed that shares corresponding to SEK 42.1 million were subscribed with and without subscription rights and SEK 32.9 million were covered by guarantee commitments. The company is thus expected to raise a total of approximately SEK [63] million after deduction of transaction costs. The board of directors thus assesses that the company's current working capital and cash and cash equivalents are sufficient to finance the operations for the next 12 months from the submission of this report.

Employees

The number of employees as of September 30, 2023 was 19 (19), of which 8 (7) were women and 11 (12) were men, and the average number of employees (FTE) was 20 (18) in the third quarter of 2023 and 19 (17) during the period January-September 2023. In addition to employed staff, Nanexa regularly hires about ten consultants with specialist expertise.

Related party transactions

During the second quarter 2023, the company has purchased consultancy services from board member Bengt Gustavsson through Sangus Jazz AB for SEK (481) thousand. For the period January-September 2023, the corresponding amount was SEK 989 (1,747). The consulting services are clearly separated from assignment as a member of the Board of Directors of the company.

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 June 30, 2023, the number of shareholders in Nanexa was 3,011.

Earnings per share

Earnings per share before and after dilution amounted to SEK -0.11 (-0.24) for the third quarter of 2023 and SEK -0.42 (-0.80) for the period January-September 2023.

Number of shares

As of September 30, 2023, Nanexa AB (publ) had 60,695,626 (50,695,626) outstanding shares with a quotient value of SEK 0.13. The number of shares at full dilution of outstanding warrants was 63,174,626 (53,174,626).

The average number of shares during the third quarter of 2023 was 60,695,626 (50,695,626) and 60,695,626 (50,695,626) for the period January-September 2023. Including full dilution of outstanding warrants, the average number of shares for the third quarter was 63,174,626 (52,191,626) and 63,174,626 (52,512,091) for the period January-September 2023.

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.

February 20, 2024 Year-end report 2023

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 23/08/2023

The board of directors, Nanexa AB

Göran Ando (chairman)

Richard Davis (member)

Jakob Dynnes Hansen (member)

Eva Nilsagård (member)

Birgit Stattin Norinder (member)

Magnus Westgren (member)

David Westberg, CEO Nanexa AB

Income statement

Amounts in TSEK	01/07/2023 – 30/09/2023	01/07/2022 – 30/09/2022	01/01/2023 – 30/09/2023	01/01/2022 – 30/09/2022	01/01/2022 – 31/12/2022
Operating revenue					
Turnover	6,683	1,531	22,511	2 040	2,860
Capitalised development costs	7,062	7,509	21,774	17 782	24,311
Other income	-642	122	244	307	1,004
Total revenue	13,103	9,161	44,529	20 128	28,175
Operating expenses					
External project and development costs	-5,465	-6,915	-21,047	-17,473	-23,769
Other external expenses	-5,219	-7,127	-18,685	-20,832	-28,816
Personnel costs	-6,072	-4,068	-19,458	-14,210	-22,773
Depreciation on intangible and tangible fixed assets	-3,651	-2,891	-10,366	-7,473	-10,504
Other operating costs	817	-86	-232	-251	-294
Total costs	-19,591	-21,087	-69,787	-60,241	-86,156
Operating profit (EBIT)	-6,488	-11,927	-25,258	-40,112	-57,981
Profit/loss from financial items					
Interest income and similar income statement items	114	0	482	0	11
Interest expenses and similar income statement items	-347	-148	-559	-561	-666
Total profit/loss from financial items	-234	-148	-76	-561	-655
Taxes					
Tax revenue	28	30	87	34	64
Total taxes	28	30	87	34	64
Profit/loss for the period	-6,694	-12,045	-25,247	-40,639	-58,571
Earnings per share before and after dilution (SEK)	-0.11	-0.24	-0.42	-0.80	-1.16

Balance Sheet

Amounts in TSEK	30/09/2023	30/09/2022	31/12/2022
Assets			
Fixed assets			
Intangible fixed assets	80,644	60,602	65,248
Tangible fixed assets	13,309	15,833	15,093
Ongoing new facilities and advances regarding tangible fixed assets	1,724	34	33
Financial fixed assets	183	69	97
Total fixed assets	95,860	76,536	80,471
Current assets			
Stock	154	425	487
Current receivables	8,534	7,501	8,055
Short-term deposits	0	0	0
Cash and cash equivalents	20,569	45,608	81,182
Total current assets	29,257	53,535	89,724
Total assets	125,118	130,070	170,195
Equity and liabilities			
Equity			
Share capital	7,855	6,561	6,561
Not registered share capital	0	0	1,294
Restricted equity	74,038	53,917	58,649
Share premium reserve	264,824	249,770	264,536
Profit and loss account reserve brought forward	-237,334	-158,640	-163,373
Loss for the period	-25,247	-40,639	-58,571
Total equity	84,137	110,969	109,096
Non-current liabilities			
Liabilities to credit institutions	2,415	4,554	4,068
Other liabilities	1,291	0	18,220
Total non-current liabilities	3,706	4,554	22,288
Current liabilities			
Accounts payable	5,317	8,171	4,661
Other current liabilities	31,958	6,377	34,150
Total current liabilities	37,275	14,548	38,811
Total equity and liabilities	125,118	130,070	170,195
Pledged assets	7,015	7,015	7,015
Assets with retention of title	6,127	6,872	6,686
Contingent liabilities	0	0	0

Cash flow analysis

Amounts in TSEK	01/07/2023 – 30/09/2023	01/07/2022 – 30/09/2022	01/01/2023 – 30/09/2023	01/01/2022 – 30/09/2022	01/01/2022 – 31/12/2022
Current activities					
Operating result	-6,488	-11,927	-25,258	-40,112	-57,981
Adjustments for items not included in cash flow	1,960	2,891	8,887	7,473	10,505
Interest received	114	0	271	0	11
Interest paid	-347	-148	-559	-561	-665
Cash flow from operating activities before change in working capital	-4,761	-9,184	-16,659	-33,200	-48,130
Cash flow from change in working capital					
Change in inventories and work in progress	2,366	410	333	-156	-218
Changes in accounts receivable - trade	460	-1,454	803	-1,304	-902
Change in receivables	628	3,058	-1,281	-2,623	-3,577
Change in accounts payable - trade	-2,788	-1,314	656	4,443	931
Change in other liabilities	-6,027	-1,195	-19,121	-1,997	44,025
Total from change in working capital	-5,360	-495	-18,610	-1,638	40,259
Cash flow from current activities	-10,122	-9,680	-35,269	-34,837	-7,871
Investing activities					
Investments in intangible fixed assets	-7,363	-9,008	-23,692	-20,717	-27,654
Investments in tangible fixed assets	-102	-526	-288	-7,768	-7,768
Investments in financial fixed assets	0	0	0	0	0
Cash flow from investment activities	-7,464	-9,533	-23,979	-28,484	-35,422
Financing activities					
New share issue	387	315	387	315	17,515
Issue costs	-39	0	-99	0	-1,140
Borrowings	0	0	0	5,985	5,985
Amortisation of loans	-551	-2,398	-1,653	-3,031	-3,544
Cash flow from financing activities	-204	-2,084	-1,365	3,269	18,814
Cash-flow for the period	-17,790	-21,297	-60,613	-60,052	-24,478
Cash and cash equivalents at the beginning of the period	38,358	66,904	81,182	105,660	105,660
Cash and cash equivalents at the end of the period	20,569	45,608	20,569	45,608	81,182

Changes in equity

Amounts in TSEK	Share capital	Fund for development work	Share premium reserve	Share premium reserve	Profit/Loss brought forward	Profit/Loss for the period	Total equity
Amount as of 01/01/2023	6,561	1,294	58,649	264,536	-163,373	-58,571	109,096
Previous year's result					-58,571	58,571	0
New share issue							0
Ongoing new issue	1,294	-1,294					0
Subscription warrants				387			387
Issue expenses				-99			-99
Capitalized development costs for the period			21,774		-21,774		0
Depreciation on capitalised development costs for the period			-6,385		6,385		0
Profit/loss for the period						-25,247	-25 247
Amount as of 30/09/2023	7,855	0	74,038	264,824	-237,334	-25,247	84 137

Amounts in TSEK	Share capital	Fund for development work	Share premium reserve	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	-109,208	-35,999	151,293
Previous year's result					-35,999	35,999	0
New share issue							0
Ongoing new issue		1,294		15,906			17,200
Subscription warrants				314			314
Issue expenses				-1,140			-1,140
Capitalized development costs for the period			24,311		-24,311		0
Depreciation on capitalised development costs for the period			-6,145		6,145		0
Profit/loss for the period						-58,571	-58,571
Amount as of 31/12/2022	6,561	1,294	58,649	264,536	-163,373	-58,571	109,096

Pledged assets

	30/09/2023	30/09/2022	31/12/2022
Corporate mortgages	7,015	7,015	7,015

Assets with retention of title

	30/09/2023	30/09/2022	31/12/2022
Assets with retention of title	6,127	6,872	6,686

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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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