Nanexa AB: NEX-22 Progress, Revaluation and Financing

Johan Widmark | 2024-08-28 08:00

After initiating dosing of the first patient in June with Nanexa's long-acting depot formulation of the GLP-1 analog liraglutide, NEX-22 for the treatment of type 2 diabetes, phase I is now progressing with the second cohort, according to plan. We now look forward to the outcome from subsequent cohorts and the full Phase I in 2024, and Ib in late 2025, as well as the partner project with Novo Nordisk and other advanced evaluation projects. Since the dip following the CMD in May, the stock has undergone a remarkable revaluation and tripled in value. We continue to find support for a fair value of SEK 2.6-9.9 per share, not factoring in a rights issue, which is the likely scenario if a license deal fails to materialize within the next 6-9 months.

More news on progress with NEX-22 in H2'24

After confirming good pharmacokinetics and tolerability at the injection site, the Phase I study for NEX-22 has now progressed to dose escalation. This confirms that Nanexa is able to handle skin reactions at the injection site (without needing to employ the combination with an anti-inflammatory drug as detailed at the CMD). The timeline for NEX-22 is to complete Phase 1b and have a Pre-IND meeting with the FDA by the end of 2025, in the best-case scenario. Here it is worth keeping in mind that the 505b-path (for new or modified versions of previously approved drugs) to approval can roughly be compared to Phase III for a New Chemical Entity.

For NEX-22, we anticipate that a successful Phase I and Ib/II trial would pave the way for out-licensing opportunities, potentially unlocking a total deal value estimated between USD 300 million (Xplico estimate, with the majority coming from upfront payments and milestones) and USD 800 million (the high end of our estimate, where royalties would constitute a larger part). This could justify an upfront payment of USD 40 million, assuming a 5% peak market share. While NEX-22 is the most interesting and promising opportunity in Nanexa, it is of course closely interlinked with the partner project with Novo Nordisk (that is also Nanexa's largest shareholder at just shy of 20% of shares). That project is ongoing and scheduled to be concluded in 2025.

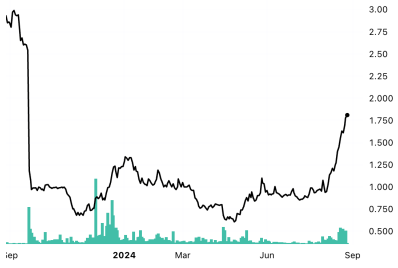
License deal needed in 6-9 months to avoid rights issue

Additionally, partner project portfolio consists of monoclonal antibody projects (around half), peptides and small molecule projects. A review of the partner projects at the CMD showed that PharmaShell, in the finalized projects, have produced successful results, but that the projects were either under review or had been deprioritized for reasons outside Nanexa's control.

With a moderate cash draw during Q2'24 of SEK 6.5m, we now expect expenses to increase as phase I with NEX-22 progresses. Cash at the end of Q2'24 amounted to SEK 41m and Nanexa now has less than 12 months of runway. Based on our SOTP for NEX-22, the Novo Nordisk project and the PharmaShell evaluation deals, we continue to find support for an rNPV of SEK 2.6-9.9 per share. This wide range reflects the wide range of potential outcomes for the company's various projects and partnerships. But this does not factor in a rights issue, which is the likely scenario if a licence deal does not materialize within the next 6-9 months. We now look forward to the outcome of Phase I with NEX-22 and more positive news flow from the partner projects.

Nanexa

Fair Value, SEK	**2,6 - 9,9**
Current Price, SEK	1.80
Number of Shares (M)	135.7
Mkt Cap (MSEK)	244
Net Debt (MSEK)	-41
Enterprise Value (MSEK)	202
Market	First North



Sum-of-the-parts Nanexa

Project	Likelihood	Launch	NPV MSEK	SEK per share
NEX-22	15,0%	2029	205	1,5
Novo Nordisk	15% | 30%	-	250 - 990	1,8 - 7,3
Other PharmaShell	20,0%	-	142	1,0
SOTP (NEX-22, other PharmaShell)			**347**	**2,6**
SOTP (Novo Nordisk, other PharmaShell)			**590 - 1340**	**4,4 - 9,9**

Source: Emergers

About Nanexa

Nanexa is a drug delivery company focused on long-acting injectable drugs based on the company's patented PharmaShell ALD technology which combined with traditional drug development enables the company to develop Long Acting Injectibles (LAI) on theoretically any drug, both small molecule and biomedical. This is expected to enable drugs with improved efficacy, reduced side effects, improved availability and increased adherence to the treatment plan from patients.

Nanexa was listed on Spotlight (formerly Aktietorget) in 2015 and is listed on Nasdaq First North since 2020.

PharmaShell ALD

ALD technology is used in a number of other areas outside the pharmaceutical industry. PharmaShell's ALD technology means that Nanexa can coat each individual particle with an extremely thin layer (10-50 nm) of inorganic oxides. The thickness and properties of this layer in turn control how the drug is released into the body.

PharmaShell has several benefits

- Makes it possible to tailor the length of the deposition in the body, to weekly, monthly or even longer. This means that you can reduce the number of treatment opportunities, which in turn can
    - benefit the patient's compliance with the treatment plan
    - reduce the perceived discomfort
    - reduce the cost of providing the treatment.
- Check the initial release of the drug in the body (initial burst), which also reduces the side effects.
- Adds very little to the volume (10-20%), which enables a high load capacity (up to 80% compared to other solutions of 30-50%).
    - This reduces the volume injected
    - Enables the use of less potent active substances
    - Longer depots
- Opportunity to apply to a wide range of different drugs
    - Small molecule
    - Biological, peptides and proteins etc.

All this, in turn, is expected to enable a more patient-centered treatment, with the possibility of developing treatments for "unmet clinical needs" and ultimately a better treatment effect and thus opening up a giant market.

Two-part strategy for realizing value in technology

Nanexa has two main strategic orientations for developing and realizing the potential of PharmaShell.

- **Own product portfolio** which involves developing own long-acting injectable formulations of existing drugs where the patents have expired. The goal is to take these own projects to proof of concept and then license them out or possibly take them further under their own auspices. So far, the company has presented three of its own projects, NEX-18, NEX-20 and NEX-22.

- **Partner projects** where PharmaShell is licensed in product-exclusive licenses to other pharmaceutical companies. The company has about 10 such pilot projects in pre-clinical development or pilot stage. In addition to AstraZeneca, which is a partner, Nanexa is so far silent about who these partners are and what these projects are focused on. While the own projects so far are in oncology and type 2 diabetes, the partner projects are covering a wider range of

indication areas. Several partner projects have passed in vitro proof of concept and also shown positive results in animal studies.

Licensing deal Novo Nordisk

Licensing scenario

			Annual Average		
			Clinical Phase	Sales Ramp-up	Maturity
		Assumptions	2023-2028	2029-2033	2034-2042
Novo Nordisk Revenue	DKKm		224 177	312 644	393 838
Share of revenue applicable w PharmaShell		10%	-	31 264	39 384
Royalty	DKKm	3%	-	842	1 182
Upfront	DKKm		1 249	-	-
Milestone	DKKm	Ph I	1 708	-	-
Milestone	DKKm	Ph II	2 180	-	-
Milestone	DKKm	Ph III	2 678	-	-
Milestone	DKKm	Appr.	3 746	-	-
Total Revenue	**DKKm**		**1 302**	**842**	**1 182**
Tax loss (opening)			-	10076,0	17081,1
Tax loss (utilized/generated)			-	967,0	1198,4
Tax loss (closing)			10,0	11042,9	18279,5
Tax paid	20,0%		-260,5	-168,4	-236,3
CF post tax, Risk adj.			**1042,0**	**673,8**	**945,2**
rNPV					
Discount factor		15%	*0,725*	*0,333*	*0,131*
PV	DKKm		712,3	214,3	120,6
LOA	%		-	-	-
Accumulated LOA	%		16,8%	5,0%	5,0%
rNPV	**DKKm**		**73,7**	**10,7**	**6,0**
SUM rNPV	DKKm	549,9			
SUM rNPV	SEKm	824,9			
rNPV per share	SEK	6,1			

Probability of license deal		at 10%	at 40%
Total rPNV	30%	247,5	989,8
rNPV per share	30%	1,8	7,3

Source: Emergers

Risks

In addition to the above-mentioned risks of failure in clinical development, which can have a strong negative impact on the company's value and constitute an inherent operational risk in all companies that develop drugs, there are additional risks to note.

Financing risk
As mentioned above, we believe that Nanexa is dependent on additional financing to be able to realize the potential in its project portfolio. Should the company fail to finance its continued operations on attractive terms and levels, there is a significant risk that the value of the company will be negatively affected.

Delays
Delays in clinical trials are more the rule than the exception and as many as 86% of projects do not meet their recruitment targets within the specified time frame, which means additional costs and delays.

Competing treatments
Of the USD 186 billion spent on global drug development in 2019, it is estimated that as much as 40% went to development projects in oncology and progress is being made all the time. It is therefore difficult to determine with certainty the long-term demand and competitiveness of an individual treatment.

Corporate Governance

Nanexa has an exceptionally experienced team in terms of board, management and advisors, with heavy positions from Swedish and international pharmaceutical companies behind it. Even though not everyone is a full-time employee but closely linked to the company, it is an impressive line-up, not least in light of the company's still modest size.

Chairman **Göran Ando** has over 30 years of experience from the pharmaceutical industry, with roles as medical director of Pfizer AB, VP at Bristol-Myers, research and development manager for Glaxo Group Research, CEO of Celltech Group PLC in the UK, and not least chairman of Novo Nordisk. A / S between 2013 and 2018. Göran Ando was also Vice President and Head of Research and Development at Pharmacia, where he was also responsible for manufacturing and business development. During his eight years as head of research and development at Pharmacia, 17 new drugs were approved by the FDA, prior to Pfizer's acquisition of Pharmacia.

In addition to the board's already heavy academic and practical competence and experience with, among others, **Eva Nilsagård** and **Birgit Stattin Norinder**. Eva Nilsagård has over 30 years of experience in senior positions, primarily in the automotive and medical / biotechnology industries, including as CFO for Vitrolife, Plastal Industri and OptiGroup, as well as senior positions within AstraZeneca and AB Volvo. Birgit Stattin Norinder has extensive experience from pharmaceutical and biotech companies in Sweden, the USA and the United Kingdom. She has led several research and development departments and been behind a number of new and approved drugs. She has been CEO and Chairman of Prolifix Ltd, Senior Vice Precident Worldwide Development at Pharmacia & Upjohn and Director International Regulatory Affairs at Glaxo Group Research Ltd. Birgit has also held a number of positions as a board member and chairman of European biotechnology companies. She is also a board member of AddLife AB, Hansa Biopharma AB and Oasmia Pharmaceutical AB.

CEO **David Westberg** has previous experience from Pharmacia, Pharmacia-UpJohn and Orexo, where he was responsible for two of Orexo's drug projects (Edluar and Zubsolv) from the early development phase, through formulation development and clinical studies to registration for market approval with the FDA in the USA.

In addition to the CEO, the rest of the management team has extensive experience with, among others, Chief Medical Officer, **Owe Luhr's** experience from a number of leading positions at companies such as Pfizer, Actelion and Celgene, Head of Pharmaceutical R&D, **Joel Hellrup** that has had a key role in the development of PharmaShell® and has several published scientific articles in the field, and **Marie Gårdmark**'s leading positions within the Medical Products Agency and experience from advisory meetings with the FDA and EMA. In addition, Nanexa has additional advisors attached to the company, which possesses cutting-edge expertise in, among other things, hematological cancer, with Professor **Axel Glasmacher** as Head of Global Clinical Research and Development in Hematology and Oncology at Celgene, and Dr **Karthik Ramasamy** as Associate Professor of Haematology & Consultant Haematologist.

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