Nanexa AB: Progress for rival at Novo illustrates the significant value potential in Nanexa

Johan Widmark | 2024-11-08 08:00

NEX-22 is progressing as expected, with the last patient in Phase I treated, results anticipated later in November, and Phase IIb scheduled for Q3'25. On the business side, however, Danish, US-listed Ascendis Pharma has signed a $285m license agreement with Novo Nordisk for Ascendis' TransCon technology for a once-monthly GLP-1 drug. While it was known and expected that Novo Nordisk would consider multiple candidates for advancing its GLP-1 drugs to less frequent dosing, it is naturally disappointing that Nanexa was not first in line. However, this doesn't eliminate the possibility of a future deal between Nanexa and Novo. Moreover, the deal establishes a compelling value benchmark for other potential licensees of a long-acting GLP-1 drug, of which there are likely to be many. 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 likely if a license deal fails to materialize in the next 6 months.

Second place is not first loser

On Nov 4th, Novo Nordisk and Ascendis Pharma signed an agreement to develop a once-monthly GLP-1 receptor agonist (GLP-1RA) for obesity and type 2 diabetes. Novo Nordisk will hold exclusive rights to expand the new therapies into other areas. Ascendis will license its TransCon technology to Novo Nordisk, with Ascendis eligible for up to $285m in upfront, milestones, and royalties, and $77.5m for each additional asset. This is exactly the kind of deal that shareholders would have hoped for Nanexa, and while it a) does not affect the current collaboration with Novo, b) does not rule out any future licensing deal with Nanexa, and c) is natural and expected that Novo explores several long-acting alternatives simultaneously, it is of course disappointing that Nanexa is not Novo's first licensing choice in this field.

On the bright side, the Ascendis deal illustrates how the heat is turning up in the long-acting niche of the superhot GLP-1 market. It also gives a reference point on the level of licensing money involved, with an upfront close to 20x Nanexa's Mkt Cap. We still expect several Big and Mid-size pharma companies to be on the lookout for an angle on how to take up competition with Eli Lilly and Novo Nordisk, that are so far holding the most interesting pharma breakthrough in decades for themselves.

NEX-22 an attractive proposal for new entrants into GLP-1

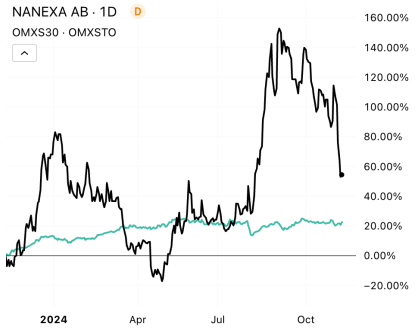
With all patients treated in the Phase I study, we now look forward to results to be announced later in November. With safety profile looking good, we expect smoot sailing towards initiating Phase IIb in Q3'25. With a Pre-IND with FDA by end of 2025 and a subsequent Phase III with some 400 patients, an application for NEX-22 could realistically be submitted in 2028 and with a product on the market by 2029, some three years ahead of a competing long-acting Semaglutide drug. This should be a highly attractive proposal for a potential licensee of NEX-22. Furthermore, 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.

License deal needed in 6 months to avoid rights issue

However, financing is a constantly pressing issue, with SEK 29m in cash at the end of Q3'24 giving Nanexa 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 months.

Nanexa

Fair Value, SEK	**2,6 - 9,9**
Current Price, SEK	1.15
Number of Shares (M)	135.7
Mkt Cap (MSEK)	156
Net Debt (MSEK)	-29
Enterprise Value (MSEK)	127
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.

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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