Nanexa AB
Progress with NEX-20 & NEX-22 Amid Rising GLP-1 Interest

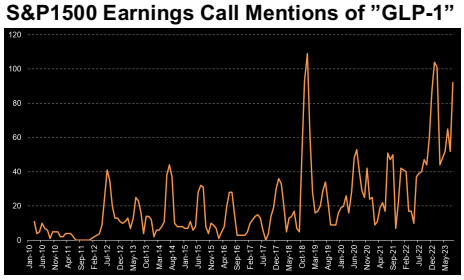
Johan Widmark | 2023-08-24 08:00

Nanexa's Q2'23 advancements with NEX-20 and NEX-22 underscore the company's forward momentum. NEX-20 is set to provide a more detailed release in October, while NEX-22 has shown promising results in minipigs, consistent with earlier rat studies. The rising general interest for the GLP-1 sector emphasizes the potential in Nanexa's partnership with Novo Nordisk. However, with cash just enough for the rest of the year, we expect a raise later in H2'23. Our updated rNPV model, taking a raise of another year's runway into account, supports a fair value of SEK 6.4-7.7 (6.6-7.2) per share, with further upside as the company continues to de-risk the portfolio with progress in clinical development.

Solid progress with NEX-20 and NEX-22 in Q2'23

For NEX-20 (a long-acting injectable of lenalidomide for treatment of multiple myeloma), Nanexa just released initial positive PK data from the healthy volunteers, showing a controlled release of lenalidomide. Now, Nanexa expects the full PK profile, safety and tolerability data in October. The company's primary focus in Q2'23 however, was on NEX-22 with a new study on minipigs confirming a long release profile of liraglutide. This conformed earlier studies in rats, with a controlled release of liraglutide for 28 days, compared to 2 days for a formulation without the PharmaShell coating. Now Nanexa expects to submit the clinical trial application later in H2'23 with initiation of phase I in early 2024 (a slight postponement compared to our earlier estimated timeline) for which it has signed the renowned CRO Profil.

S&P1500 Earnings Call Mentions of "GLP-1"



Source: Bloomberg

GLP-1 angle heating up

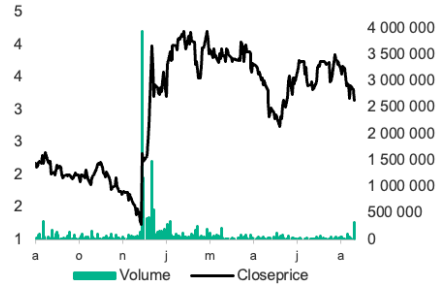
Surprisingly, the Nanexa share has not benefitted from the recent surge in interest in GLP-1. According to Bloomberg data, references to "GLP-1" in earnings call transcripts this quarter have more than doubled since the same period a year ago, driven by these drugs' capacity for weight loss, in addition to diabetes treatment. This newfound interest in GLP-1 has also caused share prices of Novo Nordisk and Eli Lilly to soar. NEX-22 is a long-acting depot formulation of GLP-1 agonist liraglutide. Liraglutide is currently available as a once-daily injection, but NEX-22 is designed to be injected once a month, meaning a significant improvement in convenience for patients, and adherence.

This is also positive for Nanexa's evaluation agreement with Novo Nordisk. While the primary target for that collaboration has not been specified, it could likely be other GLP-1 Semaglutide, now accounting for over 1/3 of Novo Nordisk's revenues, with very positive growth prospects. In Q2'23, 45% of Novo Nordisk's revenues were for some GLP-1 drug.

In light of recent development, we have raised our assessment of the probability for a future license deal with Novo Nordisk from 20% to 30%, while lowered the royalty assumption from 5% to 3%. As the target application drug is still not specified, our NPV model makes a rough assumption of an application of PharmaShell on 10% to Novo Nordisk's portfolio long term. This corresponds to an rNPV of SEK 4.1

Nanexa

Fair Value, SEK	**6,4 - 7,7**
Current Price, SEK	3,13
Number of Shares (M)	60,7
Mkt Cap (MSEK)	190
Net Debt (MSEK)	-38
Enterprise Value (MSEK)	152
Market	First North



per share. However, should PharmaShell be applied to all GLP-1 drugs in Novo's portfolio, the potential rNPV impact would be 4-5x that. But all estimates with regards to Novo's potential application of PharmaShell, pricing strategy and customer segmentation are highly uncertain.

Eventful 12 months ahead

Revenue in Q2'23 amounted to SEK 7.7m, driven by periodization of the prepaid fee from Novo Nordisk and other evaluation agreements for PharmaShell. With OPEX at SEK 27m the cash position of SEK 38.4m gives the Company runway to the end of 2023, but not much more. This highlights the need to secure additional funding, most likely in the form of a rights issue. But with a strategic industry giant such as Novo Nordisk as Nanexa's largest shareholder, chances to secure continued financing should be good.

With the progress in pre-clinical trials with NEX-22, the forthcoming completion of phase I with NEX-20, updates to our estimates for the evaluation agreement with Novo Nordisk, and an estimated rights issue of SEK 80m at an estimated 25% discount, we now find support for a fair value of SEK 6.4-7.7 (6.6-7.2) per share. After the results of phase I with NEX-20 later in H2'23, we look forward to initiation of Phase I with NEX-22 and NEX-18 (long-acting injectable azacitidine for myelodysplastic syndrome) in 2024.

Sum-of-the-parts Nanexa

Project	LOA	Launch	NPV MSEK	per share SEK	post estimated issue SEK
NEX-18	6,4%	2029	107	1,8	1,1
NEX-20	9,2%	2028	213	3,5	2,3
NEX-22	7,5%	2029	134	2,2	1,4
Novo Nordisk	25,0%	-	247	4,1	2,7
Other PharmaShell	20,0%	-	142	2,3	1,5
SOTP (NEX-18, NEX-20, NEX-22, other PharmaShe			**595**	**9,8**	**6,4**
SOTP (NEX-18, NEX-20, Novo Nordisk, other Phar			**709**	**11,7**	**7,7**

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.

License deal with Novo Nordisk

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)			#DIVISION/0!	10076,0	17081,1
Tax loss (utilized/generated)			#DIVISION/0!	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	13,6			
Probability of license deal					
Total rPNV	30%	247,5			
rNPV per share	30%	4,1			

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, **Bengt Gustafsson**'s background as Nordic Medical Director at Novartis Oncology and Celgene, and Professor **Magnus Westgren**'s over 300 scientific publications, **Eva Nilsagård** and **Birgit Stattin Norinder** were elected as new members at the Annual General Meeting. 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.

CFO **Björn Svanström** comes from previous roles in finance at SEB Enskilda, Teleca AB, CEO of Praktikerinvest and CFO of development companies in life science, including Dilafor AB.

In addition to the CEO and CFO, 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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