Nanexa AB: Targeting treatment of first patient in phase Ib/II with NEX-22 before year-end

Johan Widmark | 2025-02-20 08:00

Nanexa's Q4 report did not reveal much new, although the conference call provided welcome clarity on the rationale behind the extension of phase I with a higher dose (as dosing in the original phase I caused suspiciously few side effects). Management now targets the treatment of the first patient in phase Ib/II before year-end. Following the recent directed issue of units plus loan, raising a total of SEK 55m before costs, Nanexa is now less focused on achieving a regional license deal in Asia and is instead aiming to secure a global co-development deal for the continued development of NEX-22. With near-term financing secured into 2026, the recent positive results in the Phase I study for NEX-22, and adjusting for the dilution from the directed unit issue (excluding the warrants), we now find support for an rNPV for NEX-22 alone of SEK 730m or SEK 4.7 per share. All in all, this means that we now find support for an rNPV of SEK 5.6-9.8 per share. However, we also note that, apart from securing a co-development license deal, there are few catalysts for the share in the next 6-9 months.

Now targeting start of phase Ib/II before year-end

At the Q4 call, management stated that the extension of phase I for NEX-22, a once-monthly depot formulation of the GLP-1 analog liraglutide for type 2 diabetes, will not delay the development timeline, but that it will run alongside the other development efforts. Nonetheless, it now seems that the current target is to treat the first patient in the next phase Ib/II trial before year-end (as opposed to our previous expectation, in Q3'25). This trial will be a direct pharmacokinetic comparison of NEX-22 to Victoza, where Nanexa will focus on similarity in order to build on Victoza's original documentation. If successful, a Pre-IND with the FDA could be held by the end of 2025. After completing Phase III with some 300-400 patients, an application for NEX-22 could realistically be submitted in 2028, with a product on the market by 2029, some three years ahead of any competing long-acting Semaglutide drug. This timeline presents a highly attractive opportunity for potential licensees of NEX-22.

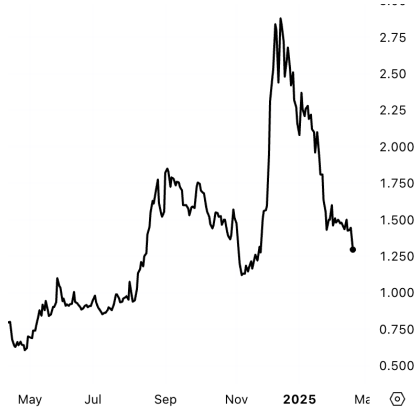
Funding secured

With the directed issue of units in January amounting to SEK 35m, supplemented by SEK 20m in loans, Nanexa has now secured funding for its continued development activities into 2026. The loan includes an arrangement fee of 3% and carries an interest rate of 1% per month, while the directed issue resulted in a dilution of 13.5%, with an additional 15.9% dilution if the warrants are exercised (set at a subscription price of SEK 2.00 per share).

The recent positive results in the Phase I study have significantly improved Nanexa's chances of securing a license deal, and Nanexa will now focus on the continued development of NEX-22 and the development project with Novo Nordisk, for which the company reports very promising progress. Adjusting for the dilution from the directed unit issue (but excluding the warrants), we now find support for an rNPV for NEX-22 alone of SEK 730m or SEK 4.7 per share. All in all, this means that we now find support for an rNPV of SEK 5.6-9.8 per share. However, we also note that, apart from securing a co-development license deal, there are not many catalysts for the share in the next 6-9 months.

Nanexa

Fair Value, SEK	**6.6 - 9.8**
Current Price, SEK	1.27
Number of Shares (M)	156.9
Mkt Cap (MSEK)	172
Net Debt (MSEK)	-63
Enterprise Value (MSEK)	164
Market	First North



Sum-of-the-parts Nanexa

Project	Launch	NPV MSEK	SEK per share
NEX-22	2029	731	4.7
Novo Nordisk	-	160 - 660	1.1 - 4.2
Other PharmaShell	-	142	0.9
SOTP (NEX-22, other PharmaShell)		**873**	**5.6**
SOTP (Novo Nordisk, other PharmaShell		**1040 - 1530**	**6.6 - 9.8**

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.

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, 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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