# Nanexa AB: Clinical milestones align ahead of Phase Ib/II and licensing push

Johan Widmark | 2025-05-07 08:00

**Nanexa continues to strengthen the foundation for the upcoming Phase Ib/II study in the NEX-22 project, with preliminary PK data from the final dose cohort confirming a dose-dependent profile. Management now targets treatment of the first patient in Phase Ib/II before year-end. While the company has terminated its exclusive equipment deal with Applied Materials (AMAT), it receives a USD 750k one-time payment and gains future manufacturing flexibility. With SEK 49m in cash plus the payment from AMAT, securing funding into 2026, and positive clinical data paving the way for Phase Ib/II, we maintain our view of an rNPV for NEX-22 alone of SEK 730m (SEK 4.7 per share), or SEK 5.6–9.8 per share including pipeline potential.**

## Final dose group confirms tolerability, PK profile

Initial PK data from the highest 30 mg dose in the extended Phase I study of NEX-22 confirm a predictable and dose-dependent exposure, with continued good tolerability and absence of typical GLP-1 side effects such as nausea or vomiting. This supports Nanexa's aim to offer a once-monthly liraglutide formulation with fewer side effects, a highly attractive proposition for the large type 2 diabetes market. Final patient visits are being completed, with full results expected shortly.

In parallel, Nanexa has ended its long-standing collaboration with Applied Materials, gaining short-term cash while freeing itself from exclusivity in manufacturing equipment. However, Applied Materials' venture arm, Applied Ventures, still owns some 7 million shares in Nanexa, which it can now be expected to exit, potentially putting non-negligible pressure on the share. Additionally, Bridget Lacey has joined as Chief Business Officer, as the company reports rising interest in the PharmaShell technology and more active partnering discussions.

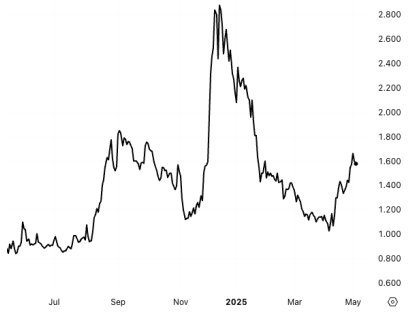
## Valuation and outlook

With a strengthened financial position following the raise in Q1'25 and promising Phase I results, we continue to expect treatment of the first patient in the next Phase Ib/II trial before year-end. 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 meeting 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. Based on this, we continue to find support for an rNPV of SEK 5.6–9.8 per share, driven primarily by NEX-22. However, with few near-term catalysts beyond potential partnering progress, we expect limited share price momentum over the next 6–9 months unless a license deal materialises.

**Nanexa**

| | |
|---|---|
| **Fair Value, SEK** | **6.6 - 9.8** |
| Current Price, SEK | 1.68 |
| Number of Shares (M) | 156.9 |
| Mkt Cap (MSEK) | 228 |
| Net Debt (MSEK) | -56 |
| Enterprise Value (MSEK) | 220 |
| 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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