Nanexa AB
Capital raise to pursue a broad set of opportunities in 2024 and 2025

Johan Widmark | 2023-09-22 08:00

As we had expected, Nanexa announced a SEK 121m rights issue, albeit at a slightly higher than expected both discount and amount. This will give Nanexa runway to start and complete phase I with NEX-22 for type 2 diabetes (in 2024), initiate phase Ib with NEX-20 for treatment of Multiple Myeloma, continue development of PharmaShell, and likely finance operations well into 2025. With participation from largest shareholder Novo Nordisk, Board and Management, totaling 20% of the issue, plus guarantors, some 62% of the issue is secured. In light of Novo Nordisk's renewed commitment and the heightened general interest in GLP-1 drugs, we have reviewed our model and see a 30% probability for a license deal with Novo Nordisk, which we expect would transform Nanexa into a billion SEK company.

SEK 107m injection secure broad set of activities in 2024

Of the net proceeds of SEK 107m after costs, around 30% will go to NEX-22, for treatment of type 2 diabetes, for the implementation of phase I, preparation and initiation of phase II and advisory meetings with FDA regarding continued clinical program. 15 % will go to NEX-20 for completion of the Phase Ia clinical study, and preparation and initiation of dose escalation study, Phase Ib, in patients with Multiple Myeloma. 20% will got to further development of PharmaShell to broaden the use in biological medicines, e.g. peptides and monoclonal antibodies while 10% will be allocated to business development aimed at broader development/licensing agreements. 10% will go to preclinical evaluation of NEX-18 and the rest to production and general admin.

Subscription price is set at SEK 1 per share which is a pretty steep discount compared to previous close. At 121,4m new shares this will mean a 67% dilution for non-participating shareholders.

Wide range of outcomes

Earlier in H2'23, Nanexa announced the initial positive PK data for NEX-20, showing a controlled release of lenalidomide. Now, Nanexa expects the full PK profile, safety and tolerability data later in H2'23. Primary focus however seems to be on NEX-22 where Nanexa expects to submit the clinical trial application later in H2'23 with initiation of phase I in early 2024. 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.

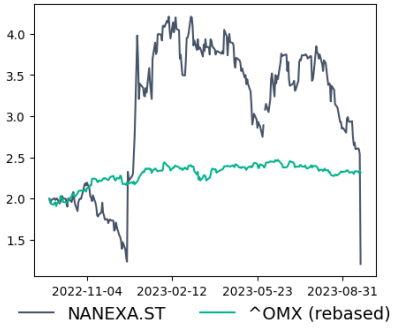
This runs in parallel with Nanexa's evaluation agreement with Novo Nordisk for an unspecified target. Our base-case assumption is that this is most likely to be other GLP-1 Semaglutide, now accounting for over 1/3 of Novo Nordisk's revenues, with very positive growth prospects. In Q2'23, 45% of Novo Nordisk's revenues were for some GLP-1 drug. We now see a 30% probability for a license deal with Novo Nordisk, estimating a 3% royalty fee in such a deal. A rough assumption the application of PharmaShell on 10%-40% of Novo Nordisk's portfolio corresponds to a SEK 250m -1bn NPV for the Novo Nordisk deal alone. But all estimates with regards to Novo's potential application of PharmaShell, pricing strategy and customer segmentation are highly uncertain.

Translating to a wide valuation range

The wide range of outcomes, especially with regards to potential applicability of PharmaShell on Novo Nordisk's products in the event of a license deal, means that it's near futile to try to pin down a single number in a valuation of

Nanexa

Fair Value, SEK	**3,3 - 8,7**
Current Price, SEK	1,23
Number of Shares (M)	60,7
Mkt Cap (MSEK)	74
Net Debt (MSEK)	-38
Enterprise Value (MSEK)	36
Market	First North



Nanexa. It is however worth noting that the standalone pursuit of NEX-22 is most likely mutually exclusive with a license deal with Novo Nordisk. In our Sum of the Parts valuation, this gives support for a valuation range anywhere between SEK 600m and 1.6bn, corresponding to SEK 3.3-8.7 per share post issue. This compares to our earlier fair value at SEK 6.4-7.7 per share which however was based on the expectation of a SEK 80m share issue at 25% discount.

So, after the right issue set to be completed in October and 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	pre issue SEK per share	post issue SEK per share
NEX-18	6,4%	2029	107	1,8	0,6
NEX-20	9,2%	2028	213	3,5	1,2
NEX-22	7,5%	2029	134	2,2	0,7
Novo Nordisk	25,0%	-	250 - 990	4,1 - 16,3	1,4 - 5,4
Other PharmaShell	20,0%	-	142	2,3	0,8
SOTP (NEX-18, NEX-20, NEX-22, other PharmaShell)			**595**	**9,8**	**3,3**
SOTP (NEX-18, NEX-20, Novo Nordisk, other Pharma			**840 - 1590**	**13,9 - 26,1**	**4,6 - 8,7**

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.

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	13,6			

Probability of license deal		at 10%	at 40%
Total rPNV	30%	247,5	989,8
rNPV per share	30%	4,1	16,3

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, **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.

Disclaimer

General disclaimer and copyright
This material is not intended to be financial advice. This material has been commissioned by the Company in question and prepared and issued by Emergers, in consideration of a fee payable by the Company. Emergers charges a standard fee for the production and broad dissemination of a detailed note followed by regular update notes. Fees are paid upfront in cash without recourse. Emergers may seek additional fees for the provision of roadshows and related IR services for the client but do not get remunerated for any investment banking services. We never take payment in stock, options or warrants for any of our services.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however, we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained herein represent those of the research analyst at Emergers at the time of publication. The company has been allowed to influence factual statements before publication, but forecasts, conclusions and valuation reasoning are Emergers' own. Forward-looking information or statements contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of Liability: To the fullest extent allowed by law, Emergers shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained in this material.

No personalised advice: The information that we provide should not be construed in any manner whatsoever as, personalised advice. Also, the information provided by us should not be construed by any subscriber or prospective subscriber as Emergers's solicitation to effect, or attempt to effect, any transaction in a security. The securities described in this material may not be eligible for sale in all jurisdictions or to certain categories of investors. Investors are encouraged to seek additional information as well as consult a financial advisor before any investment decision.

Investment in securities mentioned: Emergers has a restrictive policy relating to personal dealing and conflicts of interest. Emergers does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Emergers may have a position in any or related securities mentioned in this report, subject to Emergers' policies on personal dealing and conflicts of interest.

United Kingdom
This document is prepared and provided by Emergers for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research.

This Communication is being distributed in the United Kingdom and is directed only at (i) persons having professional experience in matters relating to investments, i.e. investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "FPO") (ii) high net-worth companies, unincorporated associations or other bodies within the meaning of Article 49 of the FPO and (iii) persons to whom it is otherwise lawful to distribute it. The investment or investment activity to which this document relates is available only to such persons. It is not intended that this document be distributed or passed on, directly or indirectly, to any other class of persons and in any event and under no circumstances should persons of any other description rely on or act upon the contents of this document.

This Communication is being supplied to you solely for your information and may not be reproduced by, further distributed to or published in whole or in part by, any other person.

United States
Emergers relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. This report is a bona fide publication of general and regular circulation offering impersonal investment-related advice, not tailored to a specific investment portfolio or the needs of current and/or prospective subscribers. As such, Emergers does not offer or provide personal advice and the research provided is for informational purposes only. No mention of a particular security in this report constitutes a recommendation to buy, sell or hold that or any security, or that any particular security, portfolio of securities, transaction or investment strategy is suitable for any specific person.

Johan Widmark | Tel: 0739196641 | Mail: johan@emergers.se

Emergers
Incirrata AB
Enbacken 16
187 44 Täby
Sweden

Phone: 0739 – 19 66 41
Email: johan@emergers.se
Corp reg no: 556815-7837