Nanexa AB
New facility important step in scaling up activity with eventful year ahead

Johan Widmark | 2022-06-13 08:00

New facility up and running

While the inauguration of Nanexa's new premises showed both the high class GMP classified facilities as well as a confident board and management, the event did not provide any news. The benefits of Nanexa's solution center around the improvements in patient compliance, comfort and cost reduction associated with long acting injectables, while to a varying extent relying on the original drugs' documentation on efficacy etc. While our view and valuation remains based on seeing the proprietary projects through to Proof-of-Concept in phase II, Nanexa is continuously looking at minimizing what Proof-of-Concept would actually need to include. This leaves room for a small chance of finding a license deal after safety, tolerability and PK profile in phase Ib, rather than going through a full phase II alone. This would reduce the financial upside somewhat but also shorten the lead time to de-risk the case which would be beneficial for shareholders.

An eventful year ahead

With the initiation of phase I with NEX-20 (a long acting injectable of lenalidomide for the treatment of multiple myeloma) in Q4'22, the announcement of a third proprietary project before year end 2022 (potentially a biological drug) and the restart of clinical trials of NEX-18 in 2023, we expect an eventful period ahead. While the new facility will increase costs going forward, we believe it will have a positive effect on the chances for a platform licensing deal for PharmaShell. This would moderate the need for additional financing while also providing an important reference point for the value of the platform, and most likely work as a positive trigger for the share.

Support for a fair value of SEK 6.3-7.7 per share

At the end of Q1'22 net cash amounted to SEK 85m, which is expected to finance the continued development into H1 2023. All in all, we see an accumulated probability for the company's two preclinical projects of 6.4% from pre-clinic to approval, which with a risk-adjusted NPV for NEX-18, NEX-20 and the platform PharmaShell (2.6 + 1.7 + 2.8 SEK per share) provides support for a fair value of SEK 6.3-7.7 per share. Furthermore, we see that a successful start of clinical studies for both NEX-18 and NEX-20 can be expected to justify a revaluation to SEK 9 per share.

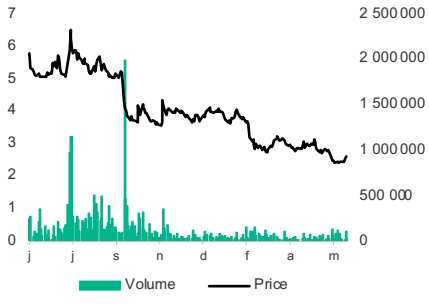
Sum-of-the-parts Nanexa

Project	LOA	Launch	NPV MSEK	per share SEK
NEX-18	6,4%	2026	130	2,6
NEX-20	6,4%	2027	84	1,7
NEX-21	-	-	-	0,0
PharmaShell Platform	20%	-	142	2,8
SOTP			**356**	**7,0**

Source: Emergers

Nanexa

Fair Value, SEK	**6,3 - 7,7**
Current Price, SEK	2,62
Number of Shares (M)	50,7
Mkt Cap (MSEK)	203
Net Debt (MSEK)	-85
Enterprise Value (MSEK)	117
Market	First North



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.

The company was listed on Spotlight (formerly Aktietorget) in 2015. Due to a number of capital acquisitions and delays in the projects, the share has been under significant pressure since then.

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 two of its own projects, NEX-18 and NEX-20, and is expected to select and present a third, NEX-21 in 2022.

- **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, the

partner projects are in areas outside oncology. Several partner projects have passed in vitro proof of concept and are now in animal studies.

Overview of valuation of NEX-18 and NEX-20

NEX-18 (all the way to market scenario)

Own development to market

		Annual Average		
	Assumptions	Clinical Phase 2023-2026	Sales Ramp-up 2027-2033	Maturity 2034-2040
Number of patients		**71 753**	**80 746**	**89 995**
	Peak mkt share			
Market share	10%	n.a.	5%	6%
Patients treated NEX-18				
	Price increase			
Treatment Price USD	1,0%			
Treatment Rev/y USD	9,0	0	37 473	40 374
Revenue		**0,0**	**165,5**	**194,7**
Cost				
Phase 1		-0,2	0,0	0,0
Phase 2		-0,8	0,0	0,0
Phase 3		-6,0	0,0	0,0
Approval		0,0	-0,1	0,0
COGS	15%	0,0	-24,8	-29,2
SG&A	20%	0,0	-33,1	-38,9
Total Cost		**-7,0**	**-58,0**	**-68,1**
CF pre tax		**0,0**	**107,5**	**126,5**
Tax paid	20%	0,0	-21,5	-25,3
CF post tax		**0,0**	**86,0**	**101,2**
Discount factor	12%	*0,807*	*0,395*	*0,167*
PV		0,0	28,3	18,9
NPV, MUSD	359			
NPV, MSEK	3229			
Investment	-315			
NPV, MSEK	2914			
rNPV, MSEK	188			

Source: Emergers

NEX-18 (licensing scenario)

Licensing after phase II

		Annual Average		
	Assumptions	Clinical Phase 2021-2025	Sales Ramp-up 2026-2030	Maturity 2031-2041
Cost phase I		-1,0	0,0	0,0
Upfront	10 MUSD	3,3	0,0	0,0
Milstone phase II	20 MUSD	6,7	0,0	0,0
Milstone phase III	48 MUSD	48,0	0,0	0,0
First Sale	12 MUSD	0,0	1,5	0,0
Royalties	15%	0,0	24,8	29,2
Total CF pre tax		**15,4**	**26,3**	**29,2**
Tax paid	20,6%	-3,2	-5,4	-6,0
CF post tax, Risk adj.		**12,2**	**20,9**	**23,2**
Discount factor	12%	*0,807*	*0,395*	*0,167*
rPV		8,4	7,2	4,3
rNPV, MUSD	130			
rNPV, MSEK	1168			
Investment	-45			
NPV, MSEK	1123			
rNPV, MSEK	72			
Value midpoint, MSEK	130			
Value midpoint, SEK per share	2,6			

Source: Emergers

NEX-20

Own development to market

		Annual Average		
	Assumptions	Clinical Phase 2021-2026	Sales Ramp-up 2027-2031	Maturity 2032-2041
Number of patients		**67 318**	**72 661**	**80 695**
Immunomodulary	Market share	65%	9%	9%
Immunomodulary	Market value BUSD	9 230	1 400	1 400
Patients treated with lenalidomid		45 580	40 000	40 000
	Peak mkt share			
Market share	10%	n.a.	3%	7%
Patients treated w NEX-20				
Treatmet cycles per patient	10			
	Price increase			
Treatment Price USD	1,0%	118 792	35 707	38 486
Revenue		**0,0**	**68,8**	**210,9**
Cost				
Phase 1		-0,2	0,0	0,0
Phase 2		-0,7	0,0	0,0
Phase 3		-5,0	0,0	0,0
Approval		0,0	-0,2	0,0
COGS	15%	0,0	-10,3	-31,6
SG&A	20%	0,0	-13,8	-42,2
Total Cost		**-5,8**	**-24,3**	**-73,8**
CF pre tax		**-5,8**	**44,5**	**137,1**
Tax paid	20,0%	0,0	-7,6	-27,4
CF post tax		**-5,8**	**36,9**	**109,7**
Discount factor	12%	*0,767*	*0,409*	*0,182*
PV		-3,7	13,7	20,4
NPV, MUSD	250			
NPV, MSEK	2252			
Investment	-315			
NPV, MSEK	1937			
rNPV, MSEK	125			

Source: Emergers

NEX-20

Licensing after phase II

		Annual Average		
	Assumptions	Clinical Phase 2021-2026	Sales Ramp-up 2027-2031	Maturity 2032-2041
Cost phase I		-0,5	0,0	0,0
Upfront	10 MUSD	2,5	0,0	0,0
Milstone phase II	14 MUSD	4,6	0,0	0,0
Milstone phase III	33 MUSD	16,7	0,0	0,0
First Sale	8 MUSD	0,0	1,7	0,0
Royalties	15%	0,0	10,3	31,6
Total CF pre tax		**9,4**	**12,0**	**31,6**
Tax paid	20%	-1,9	-2,4	-6,3
CF post tax, Risk adj.		**7,5**	**9,6**	**25,3**
Discount factor	12%	*0,767*	*0,409*	*0,182*
PV		4,7	3,7	4,7
NPV, MUSD	79			
NPV, MSEK	708			
Investment	-45			
NPV, MSEK	663			
rNPV, MSEK	43			
Valuation Midpoint, MSEK	84			
Valuation Midpoint, SEK per share	1,7			

Source: Emergers

Clincal success rate & Likelihood of Approval

Based on statistics for "off-patent"

	Basis	Likelihood off-patent	Accumulated off-patent	Likelihood oncology	Accumulated oncology	Est. LOA NEX-18/20	Est. Acc NEX-18/20
Pre-clinical	Estimate	70,0%	10,3%	70,0%	3,7%	70,0%	6,4%
Phase 1	Statistical	60,4%	14,7%	48,8%	5,3%	54,6%	9,2%
Phase 2	Statistical	37,6%	24,3%	24,6%	10,8%	31,1%	16,9%
Phase 3	Statistical	70,3%	64,6%	47,7%	43,9%	59,0%	54,3%
Approval	Statistical	91,9%	91,9%	92,0%	92,0%	92,0%	92,0%

Source: Biotechnology Innovation Organization, 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 Luhrs** experience from a number of leading positions at companies such as Pfizer, Actelion and Celgene, Head of Pharmaceutical R&D, **Jonas Fransson**'s long experience in product development and commercialization of pharmaceuticals. at Pharmacia, Pfizer and SOBI, 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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