Nanexa AB
Charging to enter triple clinical trials in the coming year

Johan Widmark | 2022-10-26 08:00

Besides starting its third proprietary development project in Q2 (NEX-22, a long-acting formulation of liraglutide for treatment of type 2 diabetes), Nanexa has also picked up pace in signing new PharmaShell platform evaluation agreements, with two new deals in the last couple of months. With the start of phase I with NEX-20 in Q4'22 (a long-acting injectable of lenalidomide for treatment of multiple myeloma), and phase I with NEX-22 and NEX-18 (long-acting injectable azacitidine for myelodysplastic syndrome) in 2023, we expect an eventful year ahead. We now find support for fair value of SEK 6.6-8.1 per share, before adjustment for a likely capital raise which is drawing closer.

NEX-22 third proprietary development project

The most noteworthy event during Q3 was the announcement of Nanexa's third proprietary development project, NEX-22, a long-acting formulation of liraglutide for treatment of type 2 diabetes. Liraglutide is a so-called GLP-1 (Glucagon-like Peptide-1) analogue and today, diabetes treatments are a USD 50 bn market, where GLP-1 analogues account for about USD 15 billion. Today patients on liraglutide take a daily injection of the drug, which Nanexa hopes to replace with a monthly long-acting injectable. One study shows that only 50% of patients suffering from T2D is taking their prescribed injections, which means that improving patient adherence could have significant positive effects on treatment efficacy and cost for the healthcare system. We estimate an rNPV for NEX-22 of around SEK 80m or SEK 1.6 per share. See details in our report New project NEX-22 to add significant daily benefits for 50m patient market.

Two Material Transfer and Feasibility Study Agreements

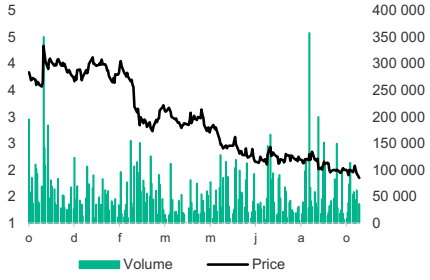
In Q2, Nanexa also expanded its collaboration agreement with Applied Materials, and received an extended GMP certification for its new production facilities in Uppsala. Importantly, Nanexa has also signed two Material Transfer and Feasibility Study Agreements in the past months, one with a leading global pharma company and another with a specialty pharma company for a depot formulation of a specific compound for intravitreal delivery (into the eye).

Fair value of SEK 6.6-8.1 could be cut in potential issue

With the initiation of phase I with NEX-20 before year end and the restart of clinical trials of NEX-18 and phase I with NEX-22 in 2023, we expect an eventful period ahead. At present, cash position amounts to SEK 45.6m which means that Nanexa is financed for continued development into H1 2023 and that we're likely to see a capital raise soon. All in all, our estimated risk-adjusted NPV for NEX-18, NEX-20, NEX-22 and the platform PharmaShell (1.9 + 1.1 + 1.6 + 2.8 SEK per share) provide support for a fair value of SEK 6.6-8.1 per share, which a potential issue at SEK 1.50 per share could cut to SEK 3.6, still providing a significant upside with plenty of milestones ahead.

Nanexa

Fair Value, SEK	**6,6 - 8,1**
Current Price, SEK	2,00
Number of Shares (M)	50,7
Mkt Cap (MSEK)	101
Net Debt (MSEK)	-46
Enterprise Value (MSEK)	56
Market	First North



Sum-of-the-parts Nanexa

Project	LOA	Launch	NPV MSEK	per share SEK	post estimated issue SEK
NEX-18	6,4%	2028	96	1,9	0,9
NEX-20	6,4%	2028	57	1,1	0,5
NEX-22	5,0%	2029	79	1,6	0,8
PharmaShell Platform	20%	-	142	2,8	1,4
SOTP			**295**	**7,4**	**3,6**

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.

The company was listed on Spotlight (formerly Aktietorget) in 2015 and is listed on Nasdaq First North since 2020. Due to a number of capital injections 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 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.

Valuation overview of NEX-22, NEX-18 and NEX-20

NEX-22

Licensing scenario after phase II

		Annual Average		
		Clinical Phase 2022-2028	**Sales Ramp-up 2029-2033**	**Maturity 2034-2041**
GLP-1 treatments	USDbn	22,363	35,534	44,028
Market Share	%	0,0%	1,9%	2,6%
Revenue	USDm	-	712	1130
Upfront	USDm	10	-	-
Milestone Phase III	USDm	33	-	-
Milestone Approval	USDm	10	-	-
Royalty	10%	-	71,2	113,0
Total revenue		7,6	71,2	113,0
Cost	USDm	-2,0	-	-
EBIT	USDm	6,1	71,2	113,0
Tax paid	20,0%	-1,5	-14,2	-22,6
CF post tax, Risk adj.		**4,7**	**56,9**	**90,4**
rNPV				
Discount factor	15%	*0,683*	*0,290*	*0,121*
PV	USDm	2,0	13,5	12,5
LOA	%	-	-	-
Accumulated LOA	%	21,0%	5,0%	5,0%
rNPV	USDm	-0,1	0,7	0,6
Total rNPV	USDm	7,3		
Total rNPV	SEKm	78,6		
rNPV per share	SEK	1,6		

Source: Emergers

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	15%	*0,771*	*0,321*	*0,111*
PV		0,0	22,0	12,8
NPV, MUSD	266			
NPV, MSEK	2394			
Investment	-315			
NPV, MSEK	2079			
rNPV, MSEK	134			

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
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	15%	*0,771*	*0,321*	*0,111*
rPV		7,8	5,6	2,9
rNPV, MUSD	104			
rNPV, MSEK	940			
Investment	-45			
NPV, MSEK	895			
rNPV, MSEK	58			
Value midpoint, MSEK	96			
Value midpoint, SEK per share	1,9			

Source: Emergers

NEX-20

Own development to market

	Assumptions	Annual Average 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	15%	*0,725*	*0,333*	*0,124*
PV		-3,3	10,9	13,9
NPV, MUSD	174			
NPV, MSEK	1567			
Investment	-315			
NPV, MSEK	1252			
rNPV, MSEK	81			

Source: Emergers

NEX-20

Licensing after phase II

	Assumptions	Annual Average 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	13 MUSD	4,4	0,0	0,0
Milstone phase III	31 MUSD	15,7	0,0	0,0
First Sale	8 MUSD	0,0	1,6	0,0
Royalties	15%	0,0	10,3	31,6
Total CF pre tax		**8,9**	**11,9**	**31,6**
Tax paid	20%	-1,8	-2,4	-6,3
CF post tax, Risk adj.		**7,1**	**9,5**	**25,3**
Discount factor	15%	*0,725*	*0,333*	*0,124*
PV		4,0	3,0	3,2
NPV, MUSD	61			
NPV, MSEK	553			
Investment	-45			
NPV, MSEK	508			
rNPV, MSEK	33			
Valuation Midpoint, MSEK	57			
Valuation Midpoint, SEK per share	1,1			

Source: Emergers

Clincal success rate & Likelihood of Approval

Based on statistics for "off-patent" and oncology

	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

Clincal success rate & Likelihood of Approval

Based on statistics for "off-patent", Autoimmune and Chronic High prevalence

Likelihood	Pre-clin Estimate	Phase I Statistical	Phase 2 Statistical	Phase 3 Statistical	Approval Statistical
Chronic, high prevalence disease		46,0%	23,1%	59,5%	92,6%
Off-patent		60,4%	37,6%	70,3%	91,9%
Autoimmune		55,2%	31,4%	65,3%	94,1%
Likelihood	**50,0%**	**53,9%**	**30,7%**	**65,0%**	**92,9%**

Accumulated Likelihood	Pre-clin Estimate	Phase I Statistical	Phase 2 Statistical	Phase 3 Statistical	Approval Statistical
Chronic, high prevalence disease		5,9%	12,7%	55,1%	92,6%
Off-patent		14,7%	24,3%	64,6%	91,9%
Autoimmune		10,7%	19,3%	61,4%	94,1%
Acc. LOA	**5,0%**	**10,0%**	**18,5%**	**60,4%**	**92,9%**

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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