Nanexa AB
Novo Nordisk deal offers both scientific validation and investor-friendly financing

Johan Widmark | 2022-12-23 09:00

The combination of an exclusive evaluation agreement and directed share issue to Novo Nordisk, global leader in diabetes treatment, provides both a significant validation of PharmaShell and a 63 MSEK capital injection that secures runway into 2024, thereby eliminating the risk of a previously impending rights issue.

Based on rough assumptions of 20% probability for a licensing deal with Novo Nordisk, an application of PharmaShell on 10% of Novo's portfolio long-term and a 5% royalty rate, this motivates a new fair value of 6.3-7.9 (6.6-8.1) SEK per share, after adjusting for 17% dilution and a mutual exclusivity between a Novo Nordisk license and NEX-22. After a +80% surge in the share price after the news, this leaves a significant revaluation potential, where we find support from a broad pipeline of activities moving into 2023.

First exclusive evaluation agreement

As a Christmas gift to its tested shareholders, Nanexa has signed a Material Transfer and Feasibility Study Agreement with Novo Nordisk for the evaluation of PharmaShell on Novo Nordisk products. For this, Nanexa will receive payment of 42 MSEK in an upfront for the exclusivity and another 4.4 MSEK for work performed. The exclusivity is limited to an unspecified substance class that is narrow enough not to affect or restrict Nanexa in relation to other evaluation agreements in any meaningful way.

The deal also lets Nanexa continue the development of the proprietary project NEX-22, a long-acting formulation of liraglutide for the treatment of type 2 diabetes, which is in competition with Novo Nordisk's own portfolio. However, should Nanexa reach a license agreement with Novo Nordisk sometime in the future, NEX-22 would most likely be either included in the deal or shut down, although that is not clear at the moment. See details in our report New project NEX-22 to add significant daily benefits for 50m patient market.

Capital injection alleviates risk of near-term rights issue

In addition, Nanexa also carries out a directed share issue to Novo Nordisk of 10m shares at a price of 1.72 SEK per share, making Novo Nordisk Nanexa's largest shareholder at 16%. Combined with the exclusivity Nanexa will receive 59 + 4 MSEK, which along with existing cash at the end of Q3'22 at 46 MSEK, will finance all activities through 2023. Interestingly, the price at 1.72 SEK per share means a hefty 33% premium compared to the previous close at 1.23 SEK but a more balanced premium of 10% compared to 20-day VWAP.

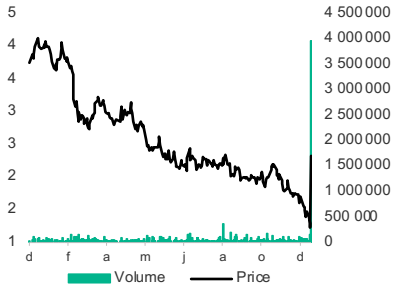
Potential Novo license deal > current Market Cap

The deal provides a renowned, strategically important and financially strong shareholder that can bring valuable industry and sector knowledge. This means a significant validation of Nanexa's scientific thesis and investment case.

Based on rough assumptions of 20% probability for a future license deal with Novo Nordisk, an applicability of PharmaShell on 10% to Novo

Nanexa

Fair Value, SEK	**6,3 - 7,9**
Current Price, SEK	2,33
Number of Shares (M)	60,7
Mkt Cap (MSEK)	141
Net Debt (MSEK)	-105
Enterprise Value (MSEK)	37
Market	First North



Nordisk's portfolio long term, a 5% royalty with upfront and milestones attached, and similar clinical development LOA as in the case of NEX-22, and a 15% discount rate, this corresponds to an rNPV of 187 MSEK or 3.1 SEK per share.

It is worth noting however that a potential license deal with Novo Nordisk and a continued development of NEX-22 on a stand-alone basis are most likely mutually exclusive. But it's hard to make a meaningful scenario analysis of how that might pan out at this point, which is why our valuation range is made up of each scenario's SOTP value.

All in all, we now find support for a fair value of SEK 6.3-7.9 per share, and with the recent start of phase I with NEX-20 (a long-acting injectable of lenalidomide for the treatment of multiple myeloma), and phase I with NEX-22 in 2023 and NEX-18 (long-acting injectable azacitidine for myelodysplastic syndrome) in 2023 or 2024, we expect an eventful year ahead.

Sum-of-the-parts Nanexa

Project	LOA	Launch	NPV MSEK	per share SEK
NEX-18	6,4%	2028	96	1,6
NEX-20	6,4%	2028	57	0,9
NEX-22	5,0%	2029	89	1,5
Novo Nordisk	20,0%	-	187	3,1
Other PharmaShell	20,0%	-	142	2,3
SOTP (NEX-18, NEX-20, NEX-22, other PharmaShell)			**384**	**6,3**
SOTP (NEX-18, NEX-20, Novo Nordisk, other PharmaShell)			**482**	**7,9**

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. Due to a number of capital injections and delays in the projects, the share has been under significant pressure since.

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		
		Assumptions	Clinical Phase 2023-2028	Sales Ramp-up 2029-2033	Maturity 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	5%	-	1 404	1 969
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**	**1 404**	**1 969**
Tax paid	20,0%		-260,5	-280,7	-393,8
CF post tax, Risk adj.			**1042,0**	**1122,9**	**1575,4**
rNPV					
Discount factor		15%	*0,725*	*0,333*	*0,131*
PV	DKKm		712,3	357,2	200,9
LOA	%		-	-	-
Accumulated LOA	%		16,8%	5,0%	5,0%
rNPV	**DKKm**		**73,7**	**17,8**	**10,0**
SUM rNPV	DKKm	621,7			
SUM rNPV	SEKm	932,6			
rNPV per share	SEK	15,4			
Probability of license deal					
Total rPNV	20%	186,5			
rNPV per share	20%	3,1			

Source: Emergers

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

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 2023-2026	Sales Ramp-up 2027-2033	Maturity 2034-2040
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	1,6			

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	0,9			

Source: Emergers

NEX-22

Licensing scenario after phase II

		Annual Average		
		Clinical Phase 2023-2028	Sales Ramp-up 2029-2033	Maturity 2034-2041
	Assumptions			
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 loss (opening)		2,4	88,2	911,1
Tax loss (utilized/generated)		6,1	71,2	113,0
Tax loss (closing)		8,6	159,3	1024,1
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	0,0	0,7	0,6
Total rNPV	USDm	8,3		
Total rNPV	SEKm	89,3		
rNPV per share	SEK	1,5		

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.

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. Emerger's standard fees are SEK 240 000 pay 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